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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report

Commission File Number 001-38974

BIOPHYTIS S.A.

(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

FRANCE
(Jurisdiction of incorporation or organization)

Biophytis S.A.
Sorbonne University—BC 9, Bâtiment A 4ème étage
4 pace Jussieu
75005 Paris, France
(Address of principal executive offices)

Stanislas Veillet
Chief Executive Officer
Biophytis S.A.
Tel: +33 1 44 27 23 00
(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 10 ordinary shares, €0.20 nominal value per share	BPTS	The Nasdaq Capital Market
Ordinary shares, €0.20 nominal value per share*	*	The Nasdaq Capital Market*

**Not for trading, but only in connection with the registration of the American Depositary Shares.*

Securities registered or to be registered pursuant to Section 12(g) of the Act. None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary shares: 100,757,097 shares outstanding as of December 31, 2020**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒	Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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INTRODUCTION

Unless otherwise indicated, "BIOPHYTIS," "the Company," "our company," "we," "us" and "our" refer to BIOPHYTIS S.A. and its consolidated subsidiaries.

This annual report may contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this annual report, including logos, artwork and other visual displays, may appear without the ® or ^{TM} symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

Our audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our financial statements included in this annual report are presented in euros and, unless otherwise specified, all monetary amounts are in euros. All references in this annual report to "$," "US$," "U.S.$," "U.S. dollars," "dollars" and "USD" mean U.S. dollars and all references to "€" and "euros," mean euros, unless otherwise noted. Throughout this report, references to ADSs mean American Depositary Shares, or ADSs, or ordinary shares represented by such ADSs, as the case may be.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F, or annual report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this annual report, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this annual report, the words "anticipate," "believe," "can," "could," "estimate," "expect," "intend," "is designed to," "may," "might," "plan," "potential," "predict," "objective," "should," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the timing, progress and results of clinical trials for our drug candidates, including statements regarding the timing of initiation and completion of clinical trials, dosing of subjects and the period during which the results of the clinical trials will become available;
- the potential impact of COVID-19 on our clinical trials and our operations generally;
- the timing, scope or likelihood of regulatory filings and approvals for our drug candidates;
- our ability to successfully commercialize our drug candidates;
- potential benefits of the clinical development and commercial experience of our management team;
- our ability to effectively market any drug candidates that receive regulatory approval on our own or through third parties;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectation regarding the safety and efficacy of our drug candidates;
- the potential clinical utility and benefits of our drug candidates;
- our ability to advance our drug candidates through various stages of development, especially through pivotal safety and efficacy trials;
- our estimates regarding the potential market opportunity for our drug candidates;
- developments and projections relating to our competitors or our industry;
- our ability to become profitable;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our ability to secure additional financing when needed on acceptable terms;
- the impact of government laws and regulations in the United States, France and foreign countries;
- the implementation of our business model, strategic plans for our business, drug candidates and technology;
- our intellectual property position;
- our ability to rely on orphan drug designation for market exclusivity;
- our ability to attract or retain key employees, advisors or consultants; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

You should refer to the section of this annual report titled "Item 3.D—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits to this annual report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This annual report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this annual report is generally reliable, such information is inherently imprecise.

PART I

Item 1. Identity of Director, Senior Management and Advisers.

Not applicable.

Item 2. Offer Statistics and Expected Timetable.

Not applicable.

Item 3. Key Information.

A. Selected Financial Data

Not applicable.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business is subject to a number of risks and uncertainties that may adversely affect our business, financial condition, results of operations, cash flows, and prospects. These risks are discussed more fully below and include, but are not limited to:

- Risks Related to Our Limited Operating History, Financial Condition, and Capital Requirements
    - Health pandemics or epidemics, including the current outbreak of COVID-19.
    - History of losses.
    - Our need for substantial additional financing to achieve our goals.
    - Limited resources and difficulties related to prioritizing drug candidate development.
    - Indebtedness could restrict our operations and make us more vulnerable to adverse economic conditions.
    - Our debt agreements contain restrictions that limit our flexibility in operating our business.
- Risks Related to Our Business
    - We are in the early stages of development.
    - Our ability to obtain regulatory approval for our drug candidates.
    - Our ability to enroll patients in our clinical trials.
    - Undesirable side effects that related to any of our drug candidates.
    - Failure to achieve physician acceptance and patient adoption.
    - Reliance on third parties for raw materials and to conduct our preclinical studies and clinical trials.
    - Competition.
    - Government restrictions on pricing and reimbursement.
    - Our ability to establish or secure sales capabilities.
    - Attracting and retaining senior management and key scientific personnel.
    - Product liability lawsuits.
    - The success of our existing and future collaborations.

- Significant disruptions to our information technology systems or breaches of data security and/or misconduct by our employees or independence contractors.
- Ability to comply with environmental laws and regulations.

- Risks Related to Intellectual Property
  - Our ability to protect our intellectual property and proprietary rights.
  - Our ability to resolve disputes concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others.
- Risks Related to Government Regulation
  - The status of the COVID-19 pandemic and availability of vaccines.
  - Competition (including from generic drugs).
  - Our ability to obtain orphan drug designation, if we pursue it.
  - The impact of healthcare legislation on our business.
  - Our relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers.
  - The impact of U.S. and foreign anti-corruption and anti-money laundering laws on our business.
  - Our failure to maintain certain tax benefits applicable to French technology companies.
  - The impact of U.S. tax laws and regulations on our business.
- Risks Related to the Ownership of the ADSs and Ordinary Shares and Our Status as a Non-U.S. Company with Foreign Private Issuer Status
  - The requirements of being a U.S. public company.
  - The Public Company Accounting Oversight Board, or PCAOB, is currently unable to inspect the audit work and practices of auditors operating in France, including our auditor.
  - An active trading market may not develop for our ADSs.
  - The market price of our equity securities may be volatile.
  - Foreign exchange risk.
  - Possible increased risk of securities class action litigation following our U.S. initial public offering.
  - Coverage of our company and business by securities or industry analysts.
  - No current intention to pay dividends.
  - Dilution to investors as a result of a significant number of outstanding warrants and convertible debt instruments.
  - The possibility of future sales of a substantial number of our securities could adversely affect the price of our securities.
  - U.S. investors may have difficulty enforcing civil liabilities against our company and directors and senior management and the experts named in this annual report.
  - ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement.
  - Our governing documents and French corporate law may delay or discourage a takeover attempt.
  - The ability of ADS holders to exercise voting rights, participate in any future preferential subscription rights, receive dividends, or transfer their ADSs.
  - Our status as a foreign private issuer and an “emerging growth company”.
  - Risks associated with being characterized a passive foreign investment company.
  - Our ability to maintain effective internal control over financial reporting.

Risks Related to Our Limited Operating History, Financial Condition, and Capital Requirements

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the current outbreak of COVID-19 and future coronavirus outbreaks, and in particular in regions where we or third parties on which we rely have significant manufacturing facilties, concentrations of clinical trial sites or other business operations.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the current outbreak of COVID-19, which the World Health Organization, or WHO, declared a global pandemic and which has prompted severe lifestyle and commercial restrictions aimed at reducing the spread of the disease. Since March 2020, the U.S. federal and state and non-U.S. governments have implemented restricted travel and shelter-in-place orders, which, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. As a result of these developments, we implemented work-from-home policies for most of our employees. We also implemented social distancing and sanitary measures. Some of our clinical study sites had to be closed, and we had to revise the protocols and obtain IRB review and approval to continue our clinical trials. With the second wave of COVID-19, governments have imposed and may impose further quarantines or other restrictions, which may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions, the potential impact of changing government orders in response to the spread of COVID-19 cases and other limitations on our ability to conduct our business in the ordinary course. Although we do not anticipate any impacts to our clinical programs, these and similar, and perhaps more severe, disruptions in our operations could negatively impact our business operating results and financial condition in the future.

Quarantines, shutdowns and shelter-in-place and similar government orders related to COVID-19 or other infectious diseases, or the perception that such events, orders or other restrictions on the conduct of business operations could occur, could impact personnel at third-party supplier, manufacturing or packaging facilities in the United States and other countries, or the availability or costs of materials, which could disrupt our supply chain. Although we do not anticipate any clinical supply issues or concerns for our planned clinical trials, restrictions resulting from the COVID-19 outbreak may disrupt our supply chain in the future and delay or limit our ability to obtain sufficient materials for our drug candidates.

In addition, our current clinical trial and planned clinical trials may be affected by the ongoing COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, and sites conducting potential patient enrollment may not be able or willing to comply with clinical trial protocols whether due to quarantines impeding patient movement or interrupting healthcare services, or due to potential patient concerns regarding interactions with medical facilities or staff. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be delayed or disrupted, which may adversely impact our clinical trial operations. Furthermore, when the primary endpoint of one of our studies is a site-based assessment, there is a risk that participants will not be able to or want to undergo this required in person assessment for safety reasons, resulting in a delay to our studies and potentially compromising the timing and results of our study. COVID-19 may also lead to increased costs, due to a prolonged study timeframe, resulting in the need to add study staff and the need to utilize additional technological tools, such as remote monitoring, remote source-data verification and remote audits.

Regulatory authorities may also experience a significantly increased workload, with requirements and demands for short review timelines for COVID-19 studies on the one hand and the need to amend study protocols to address COVID-19-related limitations in study conduct on the other hand. This can prolong review timelines and reduce the availability to run expedited programs which put a high demand on regulatory staff. There is also a risk that the changes to protocols of ongoing clinical trials (other than for COVID-19 indications) that were made to address restrictions imposed in the context of the coronavirus pandemic will negatively impact the review conducted by the relevant regulatory agencies. In which case, such agencies may consider the data to be insufficient to support acceptance of the data and the statistical plan. For example, changing in-office and in-person checks and visits to phone contacts may not be sufficient for regulatory review. We will not know until we complete our ongoing studies, complete analysis, and submit such data what, if any, limitations and effects could result.

In addition, the global COVID-19 pandemic has adversely affected, and any future significant outbreak of contagious diseases could similarly adversely affect, the economics and financial markets of many countries, including the United States, resulting in an economic downturn that could reduce our ability to access capital, which could negatively affect our liquidity and ability to process our clinical trials and business operations and suppress demand for our future products. Any of these events could have a material adverse effect on our business, financial condition, results of operations or cash flow. In addition, a recession, down-turn or market correction resulting from the COVID-19 pandemic could materially adversely affect the value of our ADSs and ordinary shares.

We are a clinical-stage biotechnology company with no products approved for commercial sale. We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Biotechnology product development is a highly speculative undertaking because it entails substantial upfront capital expenditures and significant risk that any potential drug candidate will not demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval or become commercially viable. We have incurred significant losses since our inception in 2006, and we anticipate that we will continue to incur losses for the foreseeable future, which, together with our limited operating history, may make it difficult to assess our future viability.

We incurred losses of €14.0 million, €17.8 million and €17.1 million ($20.9 million) for the years ended December 31, 2018, 2019 and 2020, respectively. Substantially all of our losses have resulted from expenses incurred in connection with our preclinical and clinical programs and other research and development activities and from general and administrative costs associated with our operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our drug candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' equity and working capital.

We will require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources on our preclinical studies and clinical trials and other research and development activities. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the preclinical and clinical development of our current drug candidates and the discovery and development of any other drug candidates we may choose to pursue. These expenditures will include costs associated with conducting preclinical studies and clinical trials and obtaining regulatory approvals, and any expenses associated with commercializing, marketing and selling products approved for sale that we elect to commercialize ourselves. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development of our current drug candidates or any future drug candidates we may choose to pursue.

As of December 31, 2020, we had capital resources consisting of cash, cash equivalents, and other current financial assets of €18.7 million ($22.9 million) (translated solely for convenience into dollars at an exchange rate of €1.00=$1.223, the noon buying rate of the Federal Reserve Bank of New York on December 31, 2020). Since December 31, 2020, we have received approximately €13.49 million ($16.35 million, using the exchange rate of €1.00 = $1.212 on February 12, 2021, the closing date) in net proceeds from our U.S. initial public offering of ADSs, which closed on February 12, 2021. We have also issued an aggregate of 377,210 ordinary shares upon the conversion of share subscription warrants and founders' warrants for a total consideration of €101.8 thousand. We also repaid €567 thousand of the carrying amount of the Kreos loan.

We expect our existing capital resources, including our ability to draw down on our credit facility with ATLAS (as described in further detail in "Item 5, Operating and Financial Review and Prospects" of this annual report), will be enough to fund our planned operating expenses for the next 12 months. However, our current operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds even sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the scope, progress, data and costs of researching and developing our current drug candidates and any other drug candidates we may choose to pursue in the future, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our current drug candidates or any future drug candidates we may choose to pursue;
- the number and characteristics of any additional drug candidates we develop or acquire;
- any costs associated with manufacturing our current drug candidates and any future drug candidates;
- the cost of sourcing purified extracts and a supply chain in sufficient quantity and quality to meet our needs;
- the cost of commercialization activities associated with any of our current drug candidates or any future drug candidates that are approved for sale and that we choose to commercialize ourselves, including marketing, sales and distribution costs;

- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to any current or future drug candidates that are approved for sale;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs that become required as a result of modified or revised clinical protocols for our clinical trials;
- the costs that become required due to necessity of having to perform additional clinical trials;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products, if any.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis on terms acceptable to us, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our current drug candidates or any future drug candidate;
- seek corporate partners for our drug candidates when we would otherwise develop our drug candidates on our own, or at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate any efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our current drug candidates or any future drug candidates.

We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, unless and until our drug candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of debt and equity securities, as well as public aid for innovation and reimbursement of the French research tax credit, described elsewhere in this annual report. We will need to seek additional funding in the future and currently intend to do so through collaborations, public or private equity offerings or debt financings, credit or loan facilities, public funding, or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we enter into arrangements with collaborators or others, we may be required to relinquish rights to some of our drug candidates that we would otherwise pursue on our own. If we raise additional funds by issuing equity securities, our shareholders will suffer dilution and the terms of any financing may adversely affect the rights of our shareholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing shareholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

We have benefited from certain reimbursable financial advances and non-reimbursable subsidies from the French government that if terminated or reduced may restrict our ability to successfully develop, manufacture and commercialize our drug candidates.

We have benefited from certain reimbursable advances and non-reimbursable subsidies from the French government and intend to continue to seek advances and/or subsidies from these agencies in the future in order to accelerate the development of our drug candidates. There is no assurance that these benefits will continue to be available to us in the future. If such benefits and programs were to be terminated or reduced, it could have an adverse effect on our business, operating results and financial condition and could deprive us of financial resources necessary for research and development of our drug candidates. Furthermore, the advances and subsidies are generally subject to contractual conditions, including our compliance with agreed upon preliminary budgets and scientific programs, informing the lender of any deviations from such agreed upon budgets and programs, and our compliance with certain financial ratios to ensure our solvency. In the event that we do not comply with the contractual conditions of the subsidies, we may be required to reimburse the French government for any outstanding payments (€832 thousand as of December 31, 2020) on an accelerated basis and could be liable for any damages incurred by such agencies resulting from the breach of contract.

Due to the significant resources required for the development of our drug candidates, we must prioritize development of certain drug candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We plan to develop a pipeline of drug candidates to treat age-related diseases and diseases whose progression and symptoms are similar to those associated with aging. Due to the significant resources required for the development of drug candidates, we must focus our attention and resources on specific diseases and disease pathways and decide which drug candidates to pursue and the amount of resources to allocate to each.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular drug candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties in respect of certain programs may subsequently prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or drug candidates or misread trends in the aging or healthspan, or biotechnolgy industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other drug candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such drug candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

Our operating results may fluctuate significantly, which may make our future operating results difficult to predict.

Our operating results may fluctuate significantly, which may make it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, any commercialization activities relating to our drug candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our drug candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional drug candidates;
- the timing and amount of any future milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our drug candidates and/or redesign, delays and/or change of scope of our preclinical or clinical trials;
- the timing of receipt of approvals for our drug candidates from regulatory authorities in the United States and internationally;
- the timing and success of competing drug candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- coverage and reimbursement policies with respect to our drug candidates, if approved; and
- the level of demand for our products, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our ordinary shares and ADSs could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

Our indebtedness could restrict our operations and make us more vulnerable to adverse economic conditions.

On September 10, 2018, we entered into a Venture Loan Agreement and Bonds Issue Agreement with Kreos Capital V (UK) Ltd., or Kreos, which provides for up to €10 million in financing to us. Pursuant to the terms of the agreements, Kreos agreed to subscribe for up to €10 million in non-convertible bonds, to be issued by us in up to four tranches of €2.5 million each. The first two tranches were issued in September 2018, a third tranche was issued in December 2018, and the final tranche was issued on March 1, 2019. Each tranche bears a 10% annual interest rate and must be repaid in 36 monthly installments, with monthly payments of €320,004 commencing in April 2019. In connection with the first tranche, we issued a warrant to Kreos giving them the right to purchase 442,477 new ordinary shares at an exercise price of €2.67 per share over a 7-year period from the issue date.

If we are unable to make the required payments, we may need to refinance all or a portion of our indebtedness, sell assets, delay capital expenditures or seek additional equity. The terms of our existing or future debt agreements may also restrict us from affecting any of these alternatives. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. Further, changes in the credit and capital markets, including market disruptions and interest rate fluctuations, may increase the cost of financing, make it more difficult to obtain favorable terms, or restrict our access to these sources of future liquidity. In addition, any failure to make scheduled payments of interest and principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness on commercially reasonable terms or at all. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, could have a material adverse effect on our business, financial condition and results of operations, as well as on our ability to satisfy our obligations in respect of our indebtedness.

Pursuant to the terms of the agreements, we have the right, at any time but with no less than 30 days prior notice to Kreos, to prepay or purchase the bonds, exclusively in full. The prepayment will be equal to (i) the principal amount outstanding, plus (ii) the sum of all interest repayments which would have been paid throughout the remainder of the term of the relevant tranche discounted by 10% per annum.

Our debt agreements contain restrictions that limit our flexibility in operating our business.

Our Venture Loan Agreement and Bonds Issue Agreement with Kreos and our convertible notes agreement with ATLAS Special Opportunities LLC, or ATLAS, impose certain operating and financial restrictions. These covenants may limit our ability and the ability of our subsidiaries, under certain circumstances, to, among other things:

- incur additional indebtedness;
- create or incur liens;
- sell or transfer assets; and
- pay dividends and distributions.

These agreements also contain certain customary affirmative covenants and events of default, including a change of control.

As a result of the covenants and restrictions contained in our existing debt agreements, we are limited in how we conduct our business, and we may be unable to raise additional debt to compete effectively or to take advantage of new business opportunities. The terms of any future indebtedness we may incur could include more restrictive covenants. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from Kreos and ATLAS, and/or amend the covenants.

Our failure to comply with the restrictive covenants described above as well as others contained in our future debt instruments from time to time could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their maturity dates. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments. If we are unable to repay, refinance or restructure our indebtedness under our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. If we are forced to refinance these borrowings on less favorable terms or if we are unable to repay, refinance or restructure such indebtedness, our financial condition and results of operations could be adversely affected.

Risks Related to Our Business

Our business is dependent on the successful development, regulatory approval, manufacture and commercialization of our drug candidates, both of which are in the early stages of development.

We have no products approved for sale. Our lead drug candidate, Sarconeos (BIO101), is in clinical development and our second drug candidate, Macuneos (BIO201) is still in the preclinical phase. Our life-cycle extension drug candidates, BIO103 and BIO203, are still in the preclinical development phase. To secure marketing approval for our lead drug candidates, we will need to meet endpoints satisfactory to the U.S. Food and Drug Administration, or FDA, and European Medicines Agency, or EMA, in larger confirmatory clinical trials. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of drug candidates. However, given our early stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a drug candidate sufficient to warrant approval for commercialization.

In the future, we may also become dependent on other drug candidates that we may develop or acquire. The clinical and commercial success of our current drug candidates and any future drug candidates will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete Investigational New Drug, or IND-enabling studies and successfully submit IND or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA, EMA or similar regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our drug candidates or any future drug candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our drug candidates by the FDA, the EMA and similar regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA, EMA and similar regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our drug candidates or any future drug candidates;
- our ability to perform clinical trials according to modified clinical trial protocols and to adapt to work environments that are changing due to the COVID-19 pandemic (*e.g.,* a significant number of our employees who are working from home);
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our drug candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA, EMA and similar regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our drug candidates or any future drug candidates or approved products, if any;
- the ability of any third parties with whom we contract to manufacture adequate clinical trial and commercial supplies, if approved, of our current drug candidates or any future drug candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with applicable requirements including current good manufacturing practices, ("cGMP");
- with respect to any approved drug candidates that we elect to commercialize ourselves, our ability to successfully develop a commercial strategy and thereafter commercialize such drug candidates, whether alone or in collaboration with others;
- the convenience of our treatment or dosing regimen;
- our sourcing of purified extracts and a supply chain in sufficient quantity and quality to meet product needs for clinical development and commercialization;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our drug candidates or any future drug candidates, if approved, including relative to alternative and competing treatments;
- patient demand for our drug candidates, if approved;

- our ability to maintain adequate drug diversion controls for Sarconeos (BIO101), which has a potential for misuse/abuse among body builders and other sportsmen as a result of its intended anabolic effect;
- lifestyle and commercial restrictions as a result of the current outbreak of COVID-19;
- the potential impact of changing government orders in response to upticks in COVID-19 cases and other limitations on our ability to conduct our business in the ordinary course;
- prioritization of hospital resources toward the COVID-19 pandemic which would otherwise be used for clinical studies;
- the ability of our participants to safely follow clinical trial protocols because of quarantines impeding patient movement or interrupting healthcare services, or due to potential patient concerns regarding interactions with medical facilities or staff as a result of the COVID-19 pandemic;
- our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be delayed or disrupted, which may be adversely impact our clinical trial operations;
- delays due to the COVID-19 pandemic, including due to reduced workforce productivity as a result of our implementation of a temporary work-from-home policy or illness among personnel, or due to delays at our third-party contract research organizations throughout the world for similar reasons or due to restirctions imposed by applicable governmental authorities;
- the impact, if any on the data from ongoing studies that have been impacted by the initial and subsequent waves of the coronavirus pandemic effect, and whether changes that were made to accommodate the pandemic will allow regulatory acceptance of the resulting data or whether the data will be sufficient for regulatory review—the effect of such changes will not be known until we complete ongoing studies, data analysis, and submit the data for regulatory review;
- our ability to establish and enforce intellectual property rights in and to our current drug candidates and any future drug candidates we may develop;
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims; and
- risks related to COVID-19, the status of the ongoing pandemic, availability of vaccines, and pattern of spread (which may depend on persistence, or lack thereof, of antibodies which, as of the date of this annual report, is suspected to be no longer than six to 12 months).

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize or license our drug candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize or license any of our drug candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our drug candidates or any future drug candidates we may develop to continue our business or achieve profitability.

We may not be able to obtain regulatory approval for our drug candidates under applicable regulatory requirements. The denial, delay or imposed limitations of or on any such approval would preclude, delay or limit the commercialization of our drug candidates and adversely impact our potential to generate revenue and/or raise financing, our business and our results of operations.

To gain approval to market our drug candidates, we must provide the FDA, EMA and other foreign regulatory authorities with clinical data that adequately demonstrate the safety and efficacy of the drug candidate for the intended indication applied for in the applicable regulatory filing. It is not currently known what effect, if any, modification of ongoing non-COVID-19 related studies resulting from the COVID-19 pandemic, will have on the acceptability of data from such revised studies. Product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical development programs. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after promising data in preclinical studies or earlier phase clinical trials. These setbacks have been caused by, among other things, new preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early phase clinical trials does not ensure that later phase clinical trials will be successful, and the results of clinical trials conducted by other parties may not be indicative of the results in trials we may conduct.

The research, testing, manufacturing, packaging, labeling, approval, sale, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA, EMA and other foreign regulatory authorities, and such regulations differ from country to country. We are not permitted to market our investigational drug candidates in the EU, the United States or any other country until they receive the requisite approval from the applicable regulatory authorities of such jurisdictions.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory actitivty that can occur within a given geographic area, ranging from mission-critical inspections to resumption of all regulatory activities. With the second wave of COVID-19, if global health concerns prevent the FDA, EMA and other foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, EMA or other foreign regulatory authorities to timely review and process regulatory submissions, which could have a material adverse effect on our business.

The FDA, EMA or any foreign regulatory authorities can delay, limit or deny approval of our drug candidates for many reasons, including:

- our inability to demonstrate to the satisfaction of the agency that a drug candidate is safe and effective for the requested indication;
- the agency's disagreement with, or questions on, our trial protocol or the interpretation of data from preclinical studies or clinical trials, including studies impacted by the coronavirus pandemic;
- the agency's refusal to accept the data that is produced from modified protocols (*e.g.,* data collected from phone contacts instead of in-office and in-person checks and visits may not be sufficient for regulatory approval or clearance);
- our inability to demonstrate that the clinical and other benefits of a drug candidate outweigh any safety or other perceived risks;
- the agency's requirement for additional preclinical studies or clinical trials;
- the agency's non-approval of the formulation, labeling or specifications of a drug candidate;
- the agency's failure to approve the manufacturing processes or facilities of third-party manufacturers upon which we rely;
- our inability to demonstrate to the satisfaction of the agency the sourcing of purified extracts and that our supply chain is in sufficient quantity and quality to meet product specifications; or
- the potential for approval policies or regulations of the FDA, EMA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

In addition, the legal and regulatory basis for expedited and emergency programs related to COVID-19 may be revoked and withdrawn if the public health assessment warrants the removal of the pandemic and emergency status.

Of the large number of biotechnology and pharmaceutical products in development, only a small percentage successfully complete the applicable regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA, EMA or applicable foreign authorities for any of our drug candidates, the applicable agency may grant approval contingent on the performance of costly additional clinical trials, which may be required after approval. The FDA, EMA or the applicable foreign regulatory agency also may approve our drug candidates for a more limited indication or a narrower patient population than we originally requested, and the applicable agency, may not approve our drug candidates with the labeling that we believe is necessary or desirable for the successful commercialization of such drug candidates.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of our drug candidates and would materially adversely impact our business and prospects.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the different phases, or stages, of the clinical trial process. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology, biopharmaceutical and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or earlier phase clinical trials. These setbacks have been caused by, among other things, new preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. The results of our preclinical studies or *in vivo* and *in vitro* studies provide very limited data in diseases whose physiopathology is not well understood and may not be predictive of the results of study outcomes in human clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and early phase clinical trials. Notwithstanding any promising results in earlier studies, we cannot be certain that we will not face setbacks and receive less promising results in later studies. Even if we are able to initiate and complete clinical trials, including studies underway during the initial coronavirus pandemic, the safety and efficacy data may not be sufficient to obtain regulatory approval for our drug candidates.

We may experience delays in obtaining the necessary regulatory authorization for our MYODA and COVA clinical program of Sarconeos (BIO101) and/or our MACA clinical trial program for Macuneos (BIO201), completing our SARA-INT Phase 2 clinical trial of Sarconeos (BIO101), and initiating other planned studies and trials. Additionally, we cannot be certain that studies or trials for our drug candidates will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA, EMA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly from one country to another, notably among different CROs and trial sites;
- institutional review boards, ethics committee or IRB approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- inability to access sites for initiation and patient monitoring and enrollment due to travel or quarantine restrictions imposed by national, federal, state or local governance;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites;
- sourcing of purified extracts and a supply chain in sufficient quantity and quality to meet product needs;
- safety issues that are discovered in preclinical studies that will be conducted concurrently with the COVA clinical trial;
- supply chain and sourcing may be slow or significantly delayed as the result of COVID-19 restrictions on movement suspensions of service, and temporary global border closings; or
- obtaining sufficient product supply of drug candidate for use in preclinical studies, clinical trials, or during industrial scale up from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- patient screening, new patient enrollment, monitoring and data collection may be affected or delayed as a result of restrictions imposed by national, federal, state or local governments due to COVID-19;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to source or provide us with sufficient purified extracts for product supply to conduct and complete preclinical studies or clinical trials of our drug candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our drug candidates for various reasons, including non-compliance with regulatory requirements, inability to comply with applicable study protocol as a result of COVID-19 restrictions, a finding that our drug candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;

- limitations occurring as a result of public health emergencies, such as COVID-19;
- the impact, if any on the data from ongoing studies that have been impacted by the initial and subsequent waves of the coronavirus pandemic effect and whether changes to accommodate the pandemic will impact regulatory acceptance of the data or whether it will be sufficient for regulatory review, the effect of which will not be known until we complete ongoing studies, data analysis and submit the data for regulatory review;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the quality of our drug candidates or other materials necessary to conduct preclinical studies or clinical trials of our drug candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our drug candidates, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our drug candidates or, in due course, not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the treatment removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA, EMA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries, including foreign countries' enforcement of COVID-19 restrictions on movement and lifestyle.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future drug candidates.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our drug candidates, the commercial prospects of our drug candidates may be harmed, and our ability to generate revenues from any of these drug candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commercialize our products and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. If one or more of our drug candidates prove to be ineffective, unsafe or commercially unviable, our entire platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the ability of patients to be assessed in study sites, given potential lock-downs due to the COVID-19 pandemic;
- the design of the trial;
- patient enrollment may be delayed due to quarantines impeding patient movement or patient concerns regarding interaction and monitoring with medical facilities and staff;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

Our drug candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, EMA or comparable foreign regulatory authorities. For example, one of our drug products, Sarconeos (BIO101), has been identified as having potential for misuse/abuse of the intended anabolic effect by body builders and sportsmen. Participants in clinical studies with Sarconeos (BIO101) are advised not to allow anyone access to the trial medication and the investigators specifically instruct subjects not to share their medicine. This risk is likely to become more significant after marketing authorization is granted, and the label for the drug, if it becomes approved, may have warnings and restrictions on the use and distribution of the product.

If unacceptable side effects arise in the development of our drug candidates, we, the FDA, EMA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA, EMA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our drug candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. Failure to recognize or manage the potential side effects of our drug candidates could result in patient injury. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our drug candidates are used in combination with other drugs or treatments, they may interact negatively with those other drugs or treatments. We plan to conduct studies in order to assess the risks of interactions of our drug candidates with other drugs and treatments taken together. However, there can be no guarantee that our drug candidates will not interact negatively with other drugs or treatments not covered by our studies or that such interactions will not be revealed until after the products have been commercialized. These interactions could have adverse, unacceptable or undetected side effects, or could reduce or destroy the effectiveness of our drug candidates, which could diminish the commercial potential of our drug candidates, slow their development and consequently, have a material adverse effect on our business, financial condition and prospects.

Even if we successfully advance any of our drug candidates into and through clinical trials, such trials will likely only include a limited number of subjects and limited duration of exposure to our drug candidates. As a result, we cannot be assured that adverse effects of our drug candidates will not be uncovered when a significantly larger number of patients are exposed to the drug candidate. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of taking our drug candidates over a multi-year period. Certain clinical trial protocols that are revised because of the current COVID-19 pandemic may also make it more difficult to identify potential safety concerns early on.

If any of our drug candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or other warnings, including a potential for abuse warning;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the sales of our product may decrease significantly and the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our drug candidates prove to be unsafe, our entire platform and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if our current drug candidates or any future drug candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

Even if one or more of our drug candidates receives the necessary regulatory approvals, the commercial success of any of our current or future drug candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our drug candidates may not be commercially successful. For a variety of reasons, including among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future drug candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the feasabilty of adhering to heightened drug diversion protocols for drug product Sarconeos (BIO101) which has the potential for misuse/abuse by body builders and other sportsmen;
- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our drug candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- public misperception regarding the use of our therapies, or public bias against “anti-aging” companies;

- patient satisfaction with the administration and effectiveness of our drug candidates and overall treatment experience, including, for example, the convenience of any dosing regimen and storage method;
- the cost of treatment with our drug candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payers, physicians and patients;
- the timing of market introduction of the drug candidate as well as competitive products;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the approved labeling for our products;
- any regulatory agency's requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- COVID-19 may be substantially eradicated prior to our development of a successful therapy in the COVA clinical program by one or more of the vaccines that have been or may in the future be authorized for use, or the therapy produced by the COVA clinical program may not be effective against other or future coronaviruses, reducing or eliminating the need for this therapy to treat the disease;
- the SARS-CoV-2 virus could develop resistance to our treatment developed in the COVA clinical program, which could affect any long-term demand or sales potential for our potential therapies;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future drug candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our drug candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

We rely on third parties to provide the raw materials necessary for our drug candidates and to manufacture preclinical and clinical supplies of our drug candidates and we intend to rely on third parties to produce commercial supplies of any approved drug candidate. The loss of these suppliers or manufacturers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not have nor do we plan to build or acquire the infrastructure or capability internally to source the raw materials necessary to produce our drug candidates and/or to manufacture our drug candidates on a preclinical, clinical or commercial scale.

Sarconeos (BIO101) is a pharmaceutical-grade purification of 20-hydroxyecdysone, which is derived from the *Cyamnotis* sp or *Stemmacantha* sp, a plant cultivated in China and used for medicinal purposes in traditional Chinese medicine. There are a limited number of growers of this plant and suppliers of the plant material and we must account for the lead time required to grow sufficient quantities of the plant to meet our needs. At this time we rely on one supplier for the plant quantities we require for our clinical trials. We have not entered into a long-term supply agreement with this supplier. We have already obtained good manufacturing practices, or GMP, batches/GMP-compliant batches/batches produced in compliance with GMP of Sarconeos (BIO101) for our ongoing SARA-INT Phase 2 and COVA Phase 2/3 clinical trials and we believe we can secure sufficient quantities for our SARA, COVA and MYODA clinical programs through our current supply chain up to regulatory approval and/or marketing authorization. If our current supplier is unable to provide sufficient quantities of the plant to produce Sarconeos (BIO101) for future clinical trials, our ability to obtain regulatory approval for Sarconeos (BIO101) would be affected. If we receive regulatory approval, we will likely need substantial quantities of plants to produce Sarconeos (BIO101) for commercial development. If our current supplier is unable to provide sufficient quantities of the plant to produce Sarconeos (BIO101) and if we are unable to find an alternative source, our ability to commercialize Sarconeos (BIO101) would be impaired. In order to address this issue, we are evaluating alternative methods for producing 20-hydroxyecdysone in order to optimize the supply chain to support our projected commercial needs.

Macuneos (BIO201) is a pharmaceutical-grade purification of norbixin, which is derived from seeds of *Bixa orellana L.*, a plant traditionally used for medicinal purposes in the Amazon and currently used for producing a food color in many countries. Although this plant is more widely available, there are a limited number of suppliers of the plant material that could meet our requirement for quality. At this time we rely on one supplier for the plant quantities we will require for our MACA clinical program. We have not entered into a long-term supply agreement with this supplier. If our current supplier is unable to provide sufficient supply to produce Macuneos (BIO201) for future clinical trials, our ability to obtain regulatory approval Macuneos (BIO201) would be affected. If we receive regulatory approval, we will likely need substantial quantities of plants to produce Macuneos (BIO201) for commercial development. If our current supplier is unable to provide sufficient quantities of the plant to produce Macuneos (BIO201) and if we are unable to find an alternative source, our ability to commercialize Macuneos (BIO201) would be impaired. In order to address this issue, we are evaluating alternative methods for producing norbixin in order to optimize the supply chain to support our projected commercial needs.

Our contract manufacturing partner for both Sarconeos (BIO101) and Macuneos (BIO201) is Patheon, a part of Thermo Fisher Scientific, located in Germany. We have not entered into a long-term manufacturing agreement with Patheon or any other contract manufacturer.

The facilities used by our contract manufacturer to manufacture our drug candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA, EMA or other regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partner for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturer cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our drug candidates. In addition, we have limited control over the ability of our contract manufacturer to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our drug candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates. Any significant delay in, or quality control problems with respect to, the supply of a drug candidate, or the raw material components thereof, for an ongoing study or trial could considerably delay completion of our preclinical studies or future clinical trials, product testing and potential regulatory approval of our drug candidates. Moreover, quarantines, shutdowns, shelter-in-place and other restrictions related to COVID-19 or other infectious diseases, or the perception that such events, orders or other restrictions on the conduct of business operations could occur, could impact personnel at manufacturing facilities which could disrupt our supply chain.

If any of our drug candidates is approved by the FDA, EMA and/or comparable foreign regulatory authorities and we choose to independently commercialize such drug candidate, we will need to engage manufacturers for the commercial supply of such drug candidates. However, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our drug candidates, we will have no other means of producing our drug candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our drug candidates on a timely basis.

In addition, to manufacture our drug candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and, in some cases, we could be required to secure alternative sources of commercial supply, which could involve significant challenges and could require additional regulatory approvals. COVID-19 restrictions create a risk that we may not be able to develop or scale up manufacturing capacity on a timely basis or have access to logistics or supply channels. In addition, the development of commercial-scale manufacturing capabilities could require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our drug candidates on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the commercial launch of our drug candidates or any future drug candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such drug candidates, if approved.

We rely on third parties in the conduct of all of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of all of our future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our drug candidates.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. The FDA, EMA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our drug candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical studies play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. In addition, third parties may have proprietary COVID-19 policies that may create delays or service disruptions, including a temporary work-from-home policy that leads to reduced workforce productivity. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We face significant competition in an environment of rapid technological and scientific change, and our drug candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. A number of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

The biotechnology and pharmaceutical industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for drug candidates and other resources than we do. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the biotechnology and pharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, certain of our drug candidates, if approved, may compete with other products that treat age-related diseases, including over-the-counter, or OTC, treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We are aware of other companies seeking to develop treatments to prevent or treat aging-related diseases through various biological pathways. For sarcopenia, Sarconeos (BIO101) is currently the most advanced in clinical development given the recent failures of myostatin inhibitors (the last of these is bimagrumab, which was developed by Novartis and has failed in Phase 2 clinical studies). Indeed, the main challenge is to be able to identify the optimal target population given the dynamics in diagnostic criteria. The recent failures, combined with these dynamics, can deter major pharmaceutical companies from re-entering this space. While there are numerous clinical studies with new drug candidates to treat COVID-19, we believe Sarconeos (BIO101) is the most advanced drug candidate for the treatment of respiratory failure associated with COVID-19, specifically targeting the RAS imbalanced by SARS-CoV-2.

For DMD, our current focus on non-ambulatory patients with evidence of respiratory deterioration, puts us in a position to become one of the more advanced companies that develop medications for this population. Santhera Therapeutics, which was developing idebenone for this indication, has recently stopped their Phase 2/3 study and are no longer investing in this area. For dry AMD, we believe that we will compete with a number of companies that are developing drugs to treat this disease, for example, Allegro Ophthalmics, Apellis Pharmaceuticals, Astellas, Hemera Biosciences, Ionis Pharmaceuticals, Sarepta Therapeutics, Ophthotech Corporation and Roche and Stealth Biotherapeutics.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for treatment of age-related diseases generally, which could give such products significant regulatory and market timing advantages over any of our drug candidates. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA or EMA for indications our drug candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. Newly developed systemic or non-systemic treatments that replace existing therapies that are currently only utilized in patients suffering from severe disease may also have lessened side effects or reduced prices compared to current therapies, which make them more attractive for patients suffering from mild to moderate disease. Even if a generic product or an OTC product is less effective than our drug candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing drug candidates based upon cost or convenience. For additional information regarding our competition, see the section of this annual report titled “Business—Competition.”

In addition, another party may be successful in producing a more efficacious therapy for COVID-19 or a therapy with a more convenient or preferred route of administration or in producing a therapy in a more timely manner, which may lead to the diversion of funding away from us and toward other companies or lead to decreased demand for our potential therapies. Further, other therapies that are more affordable than our potential therapies may be used to treat COVID-19, including existing generic drugs, which could also hurt the funding of and demand for our potential therapies.

Several public and private entities have been working to develop a therapy or vaccine for COVID-19 including: BioNTech SE (together with Pfizer Inc.), Johnson & Johnson and Moderna, Inc., whose COVID-19 vaccines have been authorized for emergency use, and Alexion Pharmaceuticals, Inc., Incyte Corporation, Sanofi S.A., Regeneron Pharmaceuticals, Inc., Amgen Inc. (together with Adaptive Biotechnologies Corporation), Abcellera Biologics, Inc. (together with Eli Lilly and Company), Vir Biotenchonogy, Inc. (together with GSK, Biogen Inc. and WuXi Biologics Ltd.), Altimmune, Inc., AstraZeneca PLC (together with Oxford University), GlaxoSmithKline (GSK) (together with Sanofi S.A.), Hear Biologics, Inc., Inovio Pharmaceuticals, Inc., Novavax, Inc. and Vaxart, Inc., among others, who are still in the development stage. These entities may be more successful at developing, manufacturing or commercializing a therapy for COVID-19, especially given that several of these other organizations are much larger than we are and have access to larger pools of capital, including U.S. government funding, and broader manufacturing infrastructure. The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our development and manufacturing efforts or to ultimately commercialize a therapy for COVID-19, if approved.

Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues and become profitable even if we obtain regulatory approval to market a product.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes, and are challenging the prices charged for medical products.

In the United States, federal programs impose penalties on drug manufacturers in the form of mandatory additional rebates and/or discounts if commercial prices increase at a rate greater than the Consumer Price Index-Urban, and these rebates and/or discounts, which can be substantial, may impact our ability to raise commercial prices. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In the European Union, or EU, coverage and reimbursement possibilities for drug products differ from one Member State to another. Each Member State has the ability to set the prices and restrict the range of medicinal products for which their national health insurance systems provide reimbursement. Factors contributing to price changes between Member States depend on different regulatory approaches and instruments used by each Member State to govern the supply and demand of medicinal products. For example, in France, a pharmaceutical company may freely set a price of a drug after obtaining the National MA. However, in order for the product to be reimbursed under the French Social Security scheme, the pharmaceutical company must follow a specific process and submit an application to the French High Authority for Health, or HAS. The opinion issued by the HAS is then transmitted to the French Economic Committee for Health Products, or CEPS—with which the pharmaceutical company has to negotiate the price of the product. The final decision on reimbursement is issued by the French Minister of Health and can be revised afterwards depending on the cost/benefit balance of the medicinal product over time. Other EU countries may adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In view of these differences from one Member State to another, there is still a risk that some EU countries do not allow favorable reimbursements and pricing arrangements.

The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare costs to contain or reduce costs of healthcare may negatively affect our commercialization prospects, including:

- our ability to set a price we believe is fair for our products, if approved;
- our ability to obtain and maintain market acceptance by the medical community and patients;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

We cannot be sure that coverage and reimbursement will be available for any potential drug candidate that we may commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any drug candidate for which we obtain marketing approval.

We expect that additional U.S. state and federal healthcare reform measures, as well as similar measures by non-U.S. governments, will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in additional pricing pressure or reduced demand for any drug candidate we develop. For example, it is possible that additional governmental action (both in the United States and abroad) will be taken to address the COVID-19 pandemic, which could impact our business in an as-yet unknown manner.

In the event we elect to commercialize any of our drug candidates that receive regulatory approval, we will need to establish sales capabilities on our own or through third parties. If we are unsuccessful in our efforts, we may not be able to market and sell our drug candidates effectively in the United States, EU and/or other foreign jurisdictions, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize our drug candidates in the United States and foreign jurisdictions, we would need to establish marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our drug candidates receive regulatory approval and we elect to independently commercialize such drug candidates, we would expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such drug candidate, which would be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. Alternatively, we may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our drug candidates. If we are not successful in commercializing our drug candidates or any future drug candidates, either on our own or through arrangements with one or more third parties, and are not otherwise able to license these products to third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of the date of this annual report, we have 25 full-time employees, 20 of whom are engaged in research and development activities and four of whom are engaged in general and administrative activities. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our drug candidates or any future drug candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to and/or relations with third parties including regulatory agencies and market authorities;
- continue to improve our operational, financial and management controls, reports systems and procedures; and
- manage our information technology systems and data security.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our drug candidates or any future drug candidates, conduct our clinical trials and commercialize our current or any future drug candidates.

We are dependent upon the services of our senior management and the loss of any of these individuals could harm our business. The loss of services of any of our key executive officers or other members of our senior management team, may be disruptive to, or cause uncertainty in, our business and could have a negative impact on our ability to manage and grow our business effectively. Such disruption could have a material adverse impact on our financial performance, financial condition, and the market price of our ordinary shares.

Our success also depends on our ability to continue to attract, retain and motivate highly qualified clinical and scientific personnel. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future drug candidates.

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue; and
- the inability to commercialize our current or any future drug candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our current or any future drug candidates we develop. We currently carry product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our drug candidates, we intend to expand our insurance coverage to include the sale of such drug candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

Our existing collaborations as well as additional collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our drug candidates.

We utilize external collaborations and currently maintain several active early-stage research and discovery focused collaborations. We may seek to partner with pharmaceutical laboratories to conduct clinical trials of our drug candidates. We may also seek additional collaboration arrangements for the commercialization, or potentially for the development, of certain of our drug candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. To the extent that we decide to enter into additional collaboration agreements in the future, we may face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to prudently manage our existing collaborations or to enter new ones should we choose to do so. The terms of new collaborations or other arrangements that we may establish may not be favorable to us.

The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future drug candidates;

- collaborators may own or co-own intellectual property covering products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;

- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and

- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged.

In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws.

Under the data protection laws in the EU, and notably the General Data Protection Regulation, or GDPR, No. 2016/679, which entered into force on May 25, 2018 and is applicable personal data that we process in relation to our presence in the EU, the offering of products or services to individuals in the EU or the monitoring of the behavior of individuals in the EU, we have also a legal responsibility to report personal data breaches to the competent supervisory authority. The GDPR includes a broad definition and a short deadline for the notification of personal data breaches, which may be difficult to implement in practice and requires that we implement robust internal processes. Under the GDPR, we have to report personal data breaches to the competent supervisory authority within 72 hours of the time we become aware of a breach "unless the personal data breach is unlikely to result in a risk to the right and freedoms of natural persons" (Article 33 of the GDPR). In addition, the GDPR requires that we communicate the breach to the data subject if the breach is "likely to result in a high risk to the rights and freedoms of natural persons" (Article 34 of the GDPR). In order to fulfil these requirements, we have to implement specific internal processes to be followed in case of a personal data breach, which will allow us to (a) contain and recover the breach, (b) assess the risk to the data subjects, (c) notify, and possibly communicate the breach to the data subjects, (d) investigate and respond to the breach. The performance of these processes involve substantial costs in resources and time.

Finally, as a consequence of the decision by the European Court of Justice issued on July 16, 2020 (known as the "Schrems II decision"), which invalidated the privacy shield for data transfers between the EU and the United States, a reassessment of both data transfers to and storage of EU data by our U.S. entities or other U.S. companies will be required. To the extent that the U.S. legal system is not considered as providing an adequate level of protection by the European authorities, and that the other safeguards provided by applicable regulation (*e.g.*, Standard Contractual Clause, or SCCs, in their current form) are not deemed to fully address such inadequacies, additional protective measures will have to be assessed on a case-by-case basis, and implemented in order to ensure the compliance of such transfers, based on the new SCCs currently under discussion, prior to adoption.

Moreover, as we may rely on third parties that will also process as processor the data for which we are a data controller—for example, in the context of the manufacturing of our drug candidates or for the conduct of clinical trials, we must contractually ensure that strict security measures, as well as appropriate obligations including an obligation to report in due delay any security incident are implemented, in order to allow us fulfilling our own regulatory requirements.

We would also be exposed to a risk of loss or litigation and potential liability for any security breach on personal data for which we are data controller. The costs of above-mentioned processes together with legal penalties, possible compensation for damages and any resulting lawsuits arising from a breach may be extensive and may have a negative impact on reputation and materially adversely affect our business, results of operations and financial condition.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA, EMA and other similar regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such regulatory authorities; manufacturing standards; healthcare fraud and abuse, data privacy laws and other similar laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in governmental healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and drug candidates and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Intellectual Property

Our ability to compete may decline if we do not adequately protect our proprietary rights.

Our success depends on obtaining and maintaining proprietary rights to our drug candidates for the treatment of age-related diseases, as well as successfully defending these rights against third-party challenges. We will only be able to protect our drug candidates, and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our drug candidates is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we may not have been the first to file patent applications for our drug candidates or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art or other bases which could invalidate our patents.

Even if we have or obtain patents covering our drug candidates or compositions, we may still be barred from making, using and selling our drug candidates or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds and therapeutic products, and some of these relate to compounds we intend to commercialize. Numerous U.S. and foreign issued patents and pending patent applications owned by others exist in the allergy treatment field in which we are developing products. These could materially affect our ability to develop our drug candidates or sell our products if approved. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our drug candidates or compositions may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

In addition, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the EU will cease being enforceable in the UK absent special arrangements to the contrary. With regard to existing patent rights, the effect of Brexit should be minimal considering enforceable patent rights are specific to the UK, whether arising out of the European Patent Office or directly through the UK patent office.

Legal actions to enforce our proprietary rights (including patents and trademarks) can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or trademarks or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents or trademarks, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

Biotechnology patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of biotechnology companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering biotechnology compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. For example, Patent No. EP2790706 (protecting Patent family S3 in various European countries) is currently subject to an opposition procedure before the European Patent Office. A decision, which is susceptible to lead to the cancellation of Patent No. EP2790706, is expected in 2021-2022, it being specified that the Chinese patent protecting the same invention (Patent family S3) was invalidated by the Court of Revision of the Chinese Patent Office, further to a motion for invalidation brought by a third party based on similar arguments (including the insufficient description of the animal model used in the patent, the novelty of the patent, the extension beyond the application as filed and the inventive step). In addition, such interference, reexamination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights. This may also result in having the same invention covering differing claims in different countries and provide a different scope of protection in foreign countries.

If we fail to obtain and maintain patent protection and trade secret protection of our drug candidates, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court, or the Supreme Court, other federal courts, the United States Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of development of therapies, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on our drug candidates and our trademarks in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States, assuming that rights are obtained in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions or using our trademarks in all countries outside the United States, or from selling or importing products made using our inventions or commercialized under identical or similar trademarks in and into the United States or other jurisdictions. The statutory deadlines for pursuing patent and trademark protection in individual foreign jurisdictions are based on the priority dates of each of our patent and trademark applications.

Competitors may use our technologies or trademarks in jurisdictions where we do not pursue and obtain patent or trademark protection to develop their own products and further, may export otherwise infringing products to territories where we have patent or trademark protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents and trademarks in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biopharmaceuticals or biotechnologies. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, provided that (as a general rule and subject to local laws) the interests of public health so require (*e.g.*, if the treatment is made available to the public in insufficient quantity or quality or at abnormally high prices) and the patent owner is compensated. If the test of the safety and efficacy of Sarconeos (BIO101) in patients with SARS-CoV-2 pneumonia is successful, we could be required to grant compulsory licenses for any patent or patent application protecting such treatment. In addition, many countries limit the enforceability of patents against third parties, including government authorities or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent or other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or other intellectual property at risk of being invalidated or interpreted narrowly, could put our patent or trademark applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Our Chief Executive Officer, who is a corporate officer (*mandataire social*) but not an employee of the Company under French law, is involved in our research and development activities. He has contributed to research results for which we have submitted patent applications in which he is listed as a co-inventor and other inventions that we expect may give rise to patent applications in the future for which we expect he will be included as a co-inventor. Under French intellectual property law, inventors who are employees of a company have legal rights that are typically circumscribed in France by a combination of French labor law and contractual arrangements. Because Mr. Veillet is our CEO, and not an employee, we have entered into an assignment agreement with him, pursuant to which he will be entitled to certain payments as consideration for his prior and future contributions to our research projects and inventions. See "Intellectual Property Agreement with Stanislas Veillet" in the "Business" section of this annual report for additional information.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the biotechnology industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our drug candidates, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs or compositions. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and the price of the ADSs. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- us or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business and financial condition. As a result, we could be prevented from commercializing current or future drug candidates.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our drug candidates, if approved.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products and methods do not or will not infringe the patents or other intellectual property rights of third parties.

The biotechnology industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our drug candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. Any claim relating to intellectual property infringement that is successfully asserted against us may require us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing another party's patents, for past use of the asserted intellectual property and royalties and other consideration going forward if we are forced to take a license. In addition, if any such claim were successfully asserted against us and we could not obtain such a license, we may be forced to stop or delay developing, manufacturing, selling or otherwise commercializing products.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our products. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease developing, selling or otherwise commercializing our drug candidates;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all;
- harm our reputation and cause potential partners or academic entities to avoid working with us; and
- in the case of trademark claims, redesign or rename trademarks we own to avoid infringing the intellectual property rights of third parties, which may not be possible and, even if possible, could be costly and time-consuming.

Any of these risks coming to fruition could have a material adverse effect on our business, results of operations, financial condition and prospects.

Issued patents covering our drug candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering our drug candidate, the defendant could counterclaim that the patent covering our drug candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions, e.g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our drug candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we

and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would have a material adverse impact on our business.

Risks Related to Government Regulation

While a key component of our strategy is achieving an EUA in the United States and conditional marketing authorization in the EU and other countries, the likelihood to be considered for such programs depends on the status of the COVID-19 pandemic.

Currently, there are a few vaccines in the world authorized for use against SARS-CoV-2. If vaccines become readily available and very efficient, the number of cases will drop significantly and the urgency to develop new treatments will be reduced. Under such conditions, regulatory agencies may be less willing to consider expedited and shortened processes for review and may require submissions to be based on more than one clinical study.

Even if we obtain regulatory approval for a drug candidate, our products will remain subject to regulatory scrutiny.

If our drug candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Inspections by regulatory authorities and the potential need for subsequent corrective actions may require additional investment or changes to our manufacturing or suppliers' manufacturing facilities, and may cause delays, interruptions, or complete stoppage of the manufacturing process. If certain drugs have a potential for misuse/abuse, manufacturers and manufacturers' facilities must also comply with certain drug diversion regulatory and compliance programs. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Given that we expect to have a global supply chain, our supply chain may also be affected by the FDA's enforcement activity at the U.S. border, such as import detentions, drug diversion oversight or refusals. Despite our investment in regulatory compliance, the FDA may raise issues with our regulatory compliance, and suppliers outside of our direct control may also fail to adhere to the FDA's regulatory requirements, in which case our supply chain and business plans may be interrupted. Further import detentions or holds may also occur while the FDA attempts to verify the imported products' compliance with the law. Such detentions or holds may affect our supply chain and business plans.

Authorities and policy makers are tightening controls on compliance by suppliers on environmental and social standards. We may be required to further tighten the audit of our suppliers, and to change suppliers in case of non-compliance. Independently, enforcement measures by government authorities such as import bans from suppliers suspected of such non-compliance may impact our supply chain.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions in the United States and the EU (both at EU and national level, for instances, in France) and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. In addition, under European regulation, certain of our drug candidates could be added to the list of drugs subject to additional monitoring. Such list concerns drugs for which there is no experience due to their recent marketing or a lack of data on their long-term use. This classification would lead to additional requirements regarding post-marketing surveillance measures of our products, which may require more resources on our end.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- seek an injunction or impose administrative, civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products, or require a product recall;
- refuse product importation, subject the import shipments to scrutiny, or place us or our suppliers on the Import Alert program; or
- refuse product importation, subject the import shipments to scrutiny, or place us or our suppliers on the Import Alert program.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA, EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, in Europe, the United States or elsewhere. For example, the new *European regulation on clinical trials on medicinal products for human use* published in the Official Journal of the European Union on May 27, 2014 will soon be applicable, upon the implementation of the European portal and database and could impact the administrative procedure that we will have to follow in order to obtain regulatory approval for our drug candidates. Depending on the date of our application for clinical trial authorization, we could be required to adapt quickly to the new requirements and procedures resulting from this new regulation, in particular regarding the new required deadlines that will require us to be reactive in the event of additional requests from the authorities. We are also anticipating further guidance from national regulators of Member States (such as ANSM for France) as those are involved in the process.

In addition, certain policies of the new Biden administration in the United States may impact our business and industry. Previously, the Trump administration enacted several executive actions, including the issuance of a number of Executive Orders, that restricted the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking. The Biden administration rescinded some of the Executive Orders, but it may also implement new policies and executive actions that could affect the FDA's ability to exercise its authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If any of our drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our drug candidates are approved, competitors could file ANDAs for generic versions of our drug candidates or 505(b)(2) NDAs that reference our small molecule drug products. If there are patents listed for our drug candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

We may seek orphan drug designation for certain future drug candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.

We may pursue orphan drug designation for certain of our future drug candidates. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, recommends orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population.

Even if we obtain orphan drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a drug candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designations are not in any way indicative of a drug's likelihood of receiving the final marketing authorization from FDA. The FDA does not evaluate a drug candidate's safety and effectiveness using the same standard as it would when reviewing a drug candidate's safety and effectiveness prior to granting final marketing approvals. The FDA may grant orphan drug designations to multiple drugs intended for the same indication. Even after an orphan drug is approved, the EMA or FDA can subsequently approve the same drug with the same active moiety for the same condition if the EMA or FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and may affect the prices we may set.

In the United States, the EU and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;

- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- creation of the Independent Payment Advisory Board, which, once empaneled, will have the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress; and

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drug candidates or put pressure on our product pricing. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize our drug candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or at the Member State level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Generally, pricing negotiations with governmental authorities can take many months after the receipt of regulatory approval and product launch. In some EU Member States, such as in France, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products candidates with available therapies in order to obtain favorable reimbursement for the indications sought or pricing approval. Should reimbursement for our drug candidates be unavailable in any country in which we seek reimbursement, or be limited or subject to additional clinical trials, or should pricing be set at unsatisfactory levels, then this might have an impact on our operating results. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to commercialize our drug candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the EU or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our drug candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our drug candidates, if approved. Such laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;

- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices and the introduction of such products into interstate commerce;

- the U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product;

- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- similar healthcare laws and regulations in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. For example, under French law, the regulation requires strict transparency of the links between the health care industry and other actors such as, but not limited to, health care practioners, and impose reporting on a public record all benefits granted to the various actors involved, in particular health professionals, as well as the existence of agreements concluded with these actors as well as remunerations paid. In addition to financial penalties, any violation of those requirements, such as misleading information or non-publication, could result in additional sanctions that may have harmful effect on the conduct of our business. More generally, as our business activity is heavily regulated and involves a significant interaction with government officials, our dealings with prescriber and authorities are subject to national anti-corruption laws of EU Member States. These laws notably prohibit us and our employees from improperly influencing government officials or commercial parties to obtain or retain business, direct business to any person or gain any advantage and also prohibit our third-party business partner's representatives and agents from engaging in corruption and bribery. Under these applicable anti-corruption laws, we may be held liable for the acts or the corrupt activities of our third-party bunisess partners, intermerdiares, representatives, contractors, channel partners and agents, even if we don't explicitly authorize or have knowledge of such activities. While we have a formal procedure that defines the process to be used to select our third-party partners, collaborate with them and monitor them in accordance with applicable anti-corruption laws, there is a risk that our third-party partners may act in violation of applicable laws, for which we may be ultimately held responsible. Any violation of applicable anti-corruption laws could result in whistleblower complaints, adverse media coverage, investigations, imposition of significant legal fees, severe criminal, civil and administrative sanctions, suspension or debarment from government contracts, all of which may have an adverse effect on our reputation, business, results of operations and financial condition. In addition, it is possible that as our business grows and evolves, we will become subject to additional compliance requirements, resulting for example from French the Sapin II law, which requires companies concerned by this regulation to implement a general anti-corruption compliance project under the control of the competent supervisory authority such as staff training, compliance documentation, audits and regular monitoring of commercial relationships. As the EU Commission has stated in one of its reports that the health sector is particularly vulnerable, our business may be subject to increased anti-corruption compliance monitoring.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

In addition, considering that our activity involves the processing of EU personal data, in particular sensitive data such as health data, our business activities are also subject to GDPR and other national data protection laws and guidelines with respect to such data, which implies that we must implement significant and continuous efforts to comply with these data protection regulations, as well as any applicable additional national health care regulations. The GDPR has allowed EU Member States to introduce additional requirements for the processing of health data. This means we must comply with both EU as well as national laws in order to conduct our activities as regards patient data. In particular, our GDPR compliance involves the precise identification of our data processing operations and the risks incurred, the implementation of an organization of our internal processes and the establishment of documentation relating to our compliance. Our GDPR compliance also means being very aware of the fulfilment of our third-party contractors' obligations and their own GPDR compliance, which requires us to impose strict contractual provisions on our third-party contractors as processors. Moreover, the transfer of data from the EU to our U.S. entities or others U.S. companies must be subject to a valid legal mechanism for the lawful transfer of data, which may have to require some of our third-party contractors who process personal data to take additional privacy and security measures. Non-compliance could cause us to incur potential disruption and expense related to our business processes. Any violations of these laws and regulations could also result in substantial penalties and could materially damage our reputation.

Furthermore, following the ECJ's decision to invalidate the EU—U.S. Privacy Shield as part of the Schrems II decision, any transfer or storage of EU data by our U.S. entities, other U.S. companies or contractual counterparties will require the implementation of additional safeguards, which given the current status of regulations, will most certainly require further protection measures in order to ensure an adequate level of protection as defined by the EU and national authorities.

We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We engage third-party investigators, CROs, and other consultants to design and perform preclinical studies of our drug candidates, and will do the same for any clinical trials. Also, once a drug candidate has been approved and commercialized, we may engage third-party intermediaries to promote and sell our products abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, collaborators, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

Our failure to maintain certain tax benefits applicable to French technology companies may adversely affect our results of operations.

As a French biotechnology company, we have benefited from certain tax advantages, including, for example, the research tax credit (*Crédit d'Impôt Recherche*), or CIR. The CIR is a French tax credit aimed at stimulating research and development. The CIR can be offset against French corporate income tax due and the portion in excess (if any) may be refunded at the end of a three fiscal-year period (or, sooner, for smaller companies such as ours). The CIR is calculated based on our claimed amount of eligible research and development expenditures in France and represented €3.1 million, €2.8 million and €3.3million as of December 31, 2018, 2019 and 2020, respectively. The French tax authority with the assistance of the Research and Technology Ministry may audit each research and development program in respect of which a CIR benefit has been claimed and assess whether such program qualifies in its view for the CIR benefit. The French tax authorities may challenge our eligibility to, or our calculation of certain tax reductions and/or deductions in respect of our research and development activities and, should the French tax authorities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, or we may not obtain the refunds for which we have applied, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the French Parliament decides to eliminate, or reduce the scope or the rate of, the CIR benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

Recent U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have an adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, at the end of 2017, the U.S. government enacted significant tax reform, with additional guidance from the U.S. tax authority still pending. Changes include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The 2017 legislation remains unclear in many respects and could be subject to potential amendments and technical corrections or even outright changes, particularly as a possible new U.S. presidential administration and a new U.S. Congress prepares to drive U.S. federal income tax policy starting in 2021. Additionally, current tax laws may continue to be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, or IRS, any of which could mitigate or increase certain adverse effects of prior legislation. In addition, it is unclear how future U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Risks Related to the Ownership of the ADSs and Ordinary Shares and Our Status as a Non-U.S. Company with Foreign Private Issuer Status

The requirements of being a U.S. public company may strain our resources, divert management's attention and affect our ability to attract and retain executive management and qualified board members.

As a U.S. public company, we will incur legal, accounting, and other expenses that we did not previously incur. Following our initial public offering of ADSs in the United States, we are now subject to the Exchange Act, including the reporting requirements thereunder, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq listing requirements and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources, particularly after we are no longer an "emerging growth company" and/or a foreign private issuer. For example, for so long as we remain a foreign private issuer, we will not be required to file with the SEC quarterly reports with respect to our business and results of operations, which are required to be made by domestic issuers pursuant to the Exchange Act.

Pursuant to Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include this attestation report on internal control over financial reporting issued by our independent registered public accounting firm. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of complying with Section 404 will significantly increase and management's attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may need to hire more employees in the future or engage outside consultants to comply with these requirements, which will further increase our cost and expense. If we fail to implement the requirements of Section 404 in the required timeframe, we may be subject to sanctions or investigations by regulatory authorities, including the SEC and the Nasdaq. Furthermore, if we are unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of the ADSs and our ordinary shares could decline, and we could be subject to sanctions or investigations by regulatory authorities. Failure to implement or maintain effective internal control systems required of public companies could also restrict our future access to the capital markets.

In addition, enhanced legal and regulatory regimes and heightened standards relating to corporate governance and disclosure for public companies result in increased legal and financial compliance costs and make some activities more time consuming. Further, being a U.S. public company and a French public company will have an impact on disclosure of information and require compliance with two sets of applicable rules. This could result in uncertainty regarding compliance matters and higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices.

The Public Company Accounting Oversight Board, or PCAOB, is currently unable to inspect the audit work and practices of auditors operating in France, including our auditor.

Our auditor, Ernst & Young et Autres, is registered with the Public Company Accounting Oversight Board, or PCAOB, in the United States. The PCAOB's cooperative arrangement with the French audit authority expired in December 2019. The expiration of this cooperation arrangement prevents inspections of registered firms in France until a new arrangement is concluded. Such inspections assess a registered firm's compliance with U.S. law and professional standards in connection with the performance of audits of financial statements filed with the SEC. As a result, our investors may not realize the potential benefits of such inspections until a new cooperative arrangement, which is currently under negotiation, is entered into and inspections in France resume. The current inability of the PCAOB to conduct inspections of auditors in France also makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside France that are subject to PCAOB inspections.

There was no public market for the ADSs prior to our U.S. initial public offering, and an active market may not develop in which investors can resell their ADSs.

Prior to our U.S. initial public offering, there was no public market for the ADSs. We cannot predict the extent to which an active trading market for the ADSs will develop or be sustained after the offering, or how the development of such a market might affect the market price for the ADSs. The initial public offering price of the ADSs in the offering was agreed upon between us and the underwriter based on a number of factors, including the trading price of our ordinary shares on the Euronext Growth Paris market, as well as certain market conditions in effect at the time of the offering, which may not be indicative of the price at which the ADSs will trade in the future. Investors may not be able to sell their ADSs at or above the price they paid. In addition, investors may not be able to successfully withdraw the underlying ordinary shares of the ADSs for the reasons discussed under the risk factor titled "*You may not be able to exercise your right to vote the underlying ordinary shares of the ADSs*" described below. In connection with any withdrawal of any of our ordinary shares represented by ADSs, the ADSs will be surrendered to the depositary. Unless additional ADSs are issued, the effect of such transactions will be to reduce the number of outstanding ADSs and, if a significant number of transactions are effected, to reduce the liquidity of the ADSs.

The market price of our equity securities may be volatile, and purchasers of our securities could incur substantial losses.

The market price for our securities may be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their securities at or above the price paid for the security. The market price for our securities may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations attributable to inconsistent trading volume levels of our securities
- additions or departures of key management or scientific personnel;
- lawsuits threatened or filed against us, disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- changes to coverage policies or reimbursement levels by commercial third-party payors and government payors and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- sales of ADSs or ordinary shares by us, our insiders or our other holders; and
- general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their securities and may otherwise negatively affect the liquidity of the trading market for our securities.

We may be exposed to significant foreign exchange risk. Exchange rate fluctuations may adversely affect the foreign currency value of the ADSs.

We incur portions of our expenses and may in the future derive revenues in currencies other than the euro, in particular, the U.S. dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. Therefore, for example, an increase in the value of the euro against the U.S. dollar could be expected to have a negative impact on our revenue and earnings growth as U.S. dollar revenue and earnings, if any, would be translated into euros at a reduced value. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. The ADSs will be quoted in U.S. dollars on the Nasdaq Capital Market and our ordinary shares are trading in euros on the Euronext Growth Paris. Our financial statements are prepared in euros. Fluctuations in the exchange rate between euros and the U.S. dollar will affect, among other matters, the U.S. dollar value of the ADSs.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, our business will be harmed and the price of our securities could decline as a result.

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the EMA, FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulatory authorities
- our ability to access sufficient, reliable and affordable supplies of compounds and raw materials used in the manufacture of our drug candidates;
- our ability to license and/or generate revenues other than through independent commercialization of our products;
- the efforts of our collaborators and/or other partners, including licensees, with respect to the commercialization of, in due course, our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of our drug candidates may be delayed, our business and results of operations may be harmed, and the trading price of our securities may decline as a result.

We may be at an increased risk of securities class action litigation following our U.S. initial public offering.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have broad discretion in the use of the net proceeds from our initial public offering in the United States and may use them in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion to apply the net proceeds that we received from our initial public offering in the United States. We may spend or invest these proceeds in a way with which our shareholders and ADS holders disagree. The failure by our management to apply these funds effectively could harm our business and financial condition. Pending their use, we may invest the net proceeds from the offering in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, the price of the ADSs and their trading volume could decline.

The trading market for the ADSs depends in part on the research and reports that securities or industry analysts publish about us or our business. If no or few securities or industry analysts cover our company, the trading price for the ADSs would be negatively impacted. If one or more of the analysts who covers us downgrades our equity securities or publishes incorrect or unfavorable research about our business, the price of our securities would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, or downgrades our securities, demand for our securities could decrease, which could cause the price of the ADSs or their trading volume to decline.

We do not currently intend to pay dividends on our ordinary shares and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our securities. In addition, French law may limit the amount of dividends we are able to distribute.

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on our securities for the foreseeable future and the success of an investment in these securities will depend upon any future appreciation in their value. Consequently, investors may need to sell all or part of their holdings after price appreciation, which may never occur, as the only way to realize any future gains on their investment. There is no guarantee that our securities will appreciate in value or even maintain the price at which investors have purchased them. Investors seeking cash dividends should not purchase our securities.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our statutory financial statements prepared and presented in accordance with accounting standards applicable in France. Article 34 of our By-laws imposes additional limitations on our ability to declare and pay dividends and there may be taxes imposed on you if we elect to pay a dividend. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France.

In addition, exchange rate fluctuations may affect the amount of euros that we are able to distribute, and the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. These factors could harm the value of the ADSs, and, in turn, the U.S. dollar proceeds that holders receive from the sale of the ADSs.

We have a significant number of outstanding warrants and convertible debt instruments, which may cause significant dilution to our shareholders, have a material adverse impact on the market price of our ordinary shares and make it more difficult for us to raise funds through future equity offerings.

As of February 26, 2021, we had 113,134,307 ordinary shares issued and outstanding. In addition, as of that date we had outstanding warrants to acquire up to 8,153,563 ordinary shares and 2,500,911 free ordinary shares that were granted to our two founders on December 22, 2020 and will be delivered to them on December 22, 2022 after a two-year vesting period. The issuance of ordinary shares upon the exercise of warrants and convertible debt instruments would dilute the percentage ownership interest of all shareholders, might dilute the book value per share of our ordinary shares and would increase the number of our publicly traded shares, which could depress the market price of our ordinary shares.

We are also subject to outstanding legal proceeding instigated by NEGMA Group Limited, or NEGMA, in which they have claimed 7,000,000 ordinary shares should be issued to them. See the section of this annual report titled "Business—Legal Proceedings."

In addition to the dilutive effects described above, the perceived risk of dilution as a result of the significant number of outstanding warrants and convertible debt may cause our shareholders to be more inclined to sell their shares, which would contribute to a downward movement in the price of our ordinary shares. Moreover, the perceived risk of dilution and the resulting downward pressure on our share price could encourage investors to engage in short sales of our ordinary shares, which could further contribute to price declines in our ordinary shares. The fact that our shareholders, warrant holders and convertible debt holders can sell substantial amounts of our ordinary shares in the public market, whether or not sales have occurred or are occurring could make it more difficult for us to raise additional funds through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, or at all.

Future sales, or the possibility of future sales, of a substantial number of the ADSs or our ordinary shares could adversely affect the price of the ADSs.

Future sales of a substantial number of the ADSs or ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of the ADSs. ADSs sold in our U.S. initial public offering may be resold in the public market without restriction, unless purchased by our affiliates. If ADS holders sell substantial amounts of ADSs in the public market, or the market perceives that such sales may occur, the market price of the ADSs and our ability to raise capital through an issuance of equity securities in the future could be adversely affected.

Approximately 5.4% of our ordinary shares are currently subject to lock-up agreements entered into in connection with our U.S. initial public offering. If, after the expiration of such lock-up agreements, these shareholders sell substantial amounts of our ordinary shares in the public market, or the market perceives that such sales may occur, the market price of our securities could be adversely affected.

The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a French company with limited liability. Our corporate affairs are governed by our bylaws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our board of directors are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our board of directors is required by French law to consider the interests of our company, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, yours.

U.S. investors may have difficulty enforcing civil liabilities against our company and directors and senior management and the experts named in this annual report.

Certain members of our board of directors and senior management and certain experts named in this annual report are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. In particular, there is some doubt as to whether French courts would recognize and enforce certain civil liabilities under U.S. securities laws in original actions or judgments of U.S. courts based upon these civil liability provisions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered but is intended to punish the defendant. French law provides that a shareholder, or a group of shareholders, may initiate a legal action to seek indemnification from the directors of a corporation in the corporation's interest if it fails to bring such legal action itself. If so, any damages awarded by the court are paid to the corporation and any legal fees relating to such action may be borne by the relevant shareholder or the group of shareholders.

The enforceability of any judgment in France will depend on the particular facts of the case as well as the laws and treaties in effect at the time. The United States and France do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws.

If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with the applicable state and federal law. To our knowledge, the enforceability of a contractual pre-dispute jury trial waiver in connection with claims arising under the federal securities laws has not been finally adjudicated by the United States Supreme Court. However, we believe that a contractual pre-dispute jury trial waiver provision is generally enforceable, including under the laws of the State of New York, which govern the deposit agreement, by a federal or state court in the City of New York, which has non-exclusive jurisdiction over matters arising under the deposit agreement. In determining whether to enforce a contractual pre-dispute jury trial waiver provision, courts will generally consider whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. It is advisable that you consult legal counsel regarding the jury waiver provision before entering into the deposit agreement.

If you or any other owner or holder of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under federal securities laws, you or such other owner or holder may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not permitted by applicable law, an action could proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any owner or holder of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder. By agreeing to the jury trial waiver provision in the deposit agreement, investors will not be deemed to have waived our compliance with or the depositary's compliance with the federal securities laws and the rules and regulations promulgated thereunder.

Our Articles of Association and By-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our Articles of Association and/or French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of voting rights of a public company listed on a regulated market in a Member State of the EU or in a state party to the European Economic Area, or EEA, Agreement, including France, has the right to force out minority shareholders following a tender offer made to all shareholders;

- under French law, a non-resident of France as well as any French entity controlled by non-French residents may have to file an administrative notice with French authorities in connection with a direct or indirect investment in us, as defined by administrative rulings; see the section of this annual report titled "Limitations Affecting Shareholders of a French Company";

- a merger (i.e., in a French law context, a stock for stock exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the EU would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;

- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;
- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, for the remaining duration of such director's term of office, provided that prior to such decision of the board of directors, the number of directors remaining in office exceeds the minimum required by law and our bylaws, and subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;
- our board of directors can be convened by our chairman (directly or upon request of our managing director), or, when no board meeting has been held for more than three consecutive months, by directors representing at least one third of the total number of directors;
- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;
- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice;
- under French law, certain investments in any entity governed by French law relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France or controlled by entities not French or not resident in France are subject to prior authorization of the Ministry of Economy; see "Limitations Affecting Shareholders of a French Company";
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;
- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;
- our bylaws can be changed in accordance with applicable laws;
- the crossing of certain thresholds has to be disclosed and can impose certain obligations;
- transfers of shares shall comply with applicable insider trading rules and regulations and, in particular, with the Market Abuse Directive and Regulation dated April 16, 2014; and
- pursuant to French law, our bylaws, including the sections relating to the number of directors and election and removal of a director from office, may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

You may not be able to exercise your right to vote the ordinary shares underlying your ADSs.

Holders of ADSs may exercise voting rights with respect to the ordinary shares represented by the ADSs only in accordance with the provisions of the deposit agreement. The deposit agreement provides that, upon receipt of notice of any meeting of holders of our ordinary shares, the depositary will fix a record date for the determination of ADS holders who will be entitled to give instructions for the exercise of voting rights. Upon timely receipt of notice from us, if we so request, the depositary will distribute to the holders as of the record date (1) the notice of the meeting or solicitation of consent or proxy sent by us and (2) a statement as to the manner in which instructions may be given by the holders.

Purchasers of ADSs may instruct the depositary of the ADSs to vote the ordinary shares underlying their ADSs. Otherwise, purchasers of ADSs will not be able to exercise voting rights unless they withdraw the ordinary shares underlying the ADSs they hold. However, a holder of ADSs may not know about the meeting far enough in advance to withdraw those ordinary shares. If we ask for a holder of ADSs' instructions, the depositary, upon timely notice from us, will distribute notice of the upcoming vote and arrange to deliver our voting materials to him or her. We cannot guarantee to any holder of ADSs that he or she will receive the voting materials in time to ensure that he or she can instruct the depositary to vote his or her ordinary shares or to withdraw his or her ordinary shares so that he or she can vote them. If the depositary does not receive timely voting instructions from a holder of ADSs, it may give a proxy to a person designated by us to vote the ordinary shares underlying his or her ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that a holder of ADSs may not be able to exercise his or her right to vote, and there may be nothing he or she can do if the ordinary shares underlying the ADSs are not voted as he or she requested.

Purchasers of ADSs may not be directly holding our ordinary shares.

A holder of ADSs will not be treated as one of our shareholders and will not have direct shareholder rights. French law governs our shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs held by ADS holders. The deposit agreement among us, the depositary and the owners and holders of ADSs, sets out ADS holder rights, as well as the rights and obligations of the depositary.

The right as a holder of ADSs to participate in any future preferential subscription rights or to elect to receive dividends in shares may be limited, which may cause dilution to ADS holders.

According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights for these securities on a pro rata basis unless they waive those rights at an extraordinary meeting of our shareholders (by a two-thirds majority vote) or individually by each shareholder. However, ADS holders in the United States will not be entitled to exercise or sell such rights unless we register the rights and the securities to which the rights relate under the Securities Act of 1933, as amended, or the Securities Act, or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary will not make rights available to ADS holders unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under the Securities Act. Further, if we offer holders of our ordinary shares the option to receive dividends in either cash or shares, under the deposit agreement the depositary may require satisfactory assurances from us that extending the offer to holders of ADSs does not require registration of any securities under the Securities Act before making the option available to holders of ADSs. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our rights offerings or to elect to receive dividends in shares and may experience dilution in their holdings. In addition, if the depositary is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

Purchasers of ADSs may be subject to limitations on the transfer of their ADSs and the withdrawal of the underlying ordinary shares.

ADSs, which may be evidenced by ADRs, are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason subject to a holder of ADSs' right to cancel his or her ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares. In addition, a holder of ADSs may not be able to cancel his or her ADSs and withdraw the underlying ordinary shares when he or she owes money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than a U.S. company. This may limit the information available to holders of ADSs.

We are a foreign private issuer, as defined in the SEC's rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to public companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, while we currently make annual and semi-annual filings with respect to our listing on Euronext Growth Paris and expect to file financial reports on an annual and semi-annual basis, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies and will not be required to file quarterly reports on Form 10-Q or current reports on Form 8-K under the Exchange Act. Accordingly, there will be less publicly available information concerning our company than there would be if we were not a foreign private issuer.

As a foreign private issuer, we are permitted and we expect to follow certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq's corporate governance standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with the corporate governance standards of Nasdaq.

As a foreign private issuer listed on the Nasdaq Capital Market, we will be subject to Nasdaq's corporate governance standards. However, Nasdaq rules provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq's corporate governance standards as long as notification is provided to Nasdaq of the intention to take advantage of such exemptions. We intend to rely on exemptions for foreign private issuers and follow French corporate governance practices in lieu of Nasdaq's corporate governance standards, to the extent possible. Certain corporate governance practices in France, which is our home country, may differ significantly from Nasdaq corporate governance standards. For example, as a French company, neither the corporate laws of France nor our bylaws require a majority of our directors to be independent and we can include non-independent directors as members of our remuneration committee, and our independent directors are not required to hold regularly scheduled meetings at which only independent directors are present.

We are also exempt from provisions set forth in Nasdaq rules which require an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Consistent with French law, our bylaws provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting.

As a foreign private issuer, we are required to comply with certain Nasdaq rules and Rule 10A-3 of the Exchange Act, relating to audit committee composition and responsibilities. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.

Therefore, our shareholders may be afforded less protection than they otherwise would have under Nasdaq's corporate governance standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, the next determination will be made with respect to us on June 30, 2022. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. We will remain a foreign private issuer until such time that more than 50% of our outstanding voting securities are held by U.S. residents and any of the following three circumstances applies: (i) the majority of our executive officers or directors are U.S. citizens or residents; (ii) more than 50% of our assets are located in the United States; or (iii) our business is administered principally in the United States.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly more than costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers such as the ones described herein and exemptions from procedural requirements related to the solicitation of proxies.

We are an "emerging growth company" under the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make the ADSs less attractive to investors.

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find the ADSs less attractive because we may rely on these exemptions. If some investors find the ADSs less attractive as a result, there may be a less active trading market for the ADSs and the price of the ADSs may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the closing date of our U.S. initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

U.S. holders of ADSs may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

Generally, if, for any taxable year, at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, U.S. holders of the ADSs may suffer adverse tax consequences, including having gains realized on the sale of the ADSs treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on the ADSs by individuals who are U.S. holders, and having interest charges apply to certain distributions by us and the proceeds of sales of the ADSs. See Item 10.E “Taxation” of this annual report for additional details.

Our status as a PFIC will depend on the composition of our income (including whether we receive certain non-refundable grants or subsidies and whether such amounts and reimbursements of certain refundable research tax credits will constitute gross income for purposes of the PFIC income test) and the composition and value of our assets, which may be determined in large part by reference to the market value of the ADSs, which may be volatile, from time to time. Our status may also depend, in part, on how quickly we utilize the cash proceeds from our U.S. initial public offering. Based on the current composition of our gross income and assets and on reasonable assumptions and projections, we believe that it is more likely than not that we would not have been considered a PFIC for our taxable year ending December 31, 2020; and, based on a similar analysis, we do not expect to be considered a PFIC for our taxable year ending December 31, 2021. However, there can be no assurance that we will or will not be considered a PFIC for these years or any future taxable year.

Investments in our securities may be subject to prior governmental authorization under the French foreign investment control regime.

Pursuant to the provisions of the French Monetary and Financial Code (code monétaire et financier), any investment by any non-French citizen, any French citizen not residing in France, any non-French entity or any French entity controlled by one of the aforementioned persons or entities that will result in the relevant investor (a) acquiring control of an entity registered in France, (b) acquiring all or part of a business line of an entity registered in France, or (c) for non-EU or non-EEA investors crossing, directly or indirectly, alone or in concert, a 25% threshold of voting rights in an entity registered in France, in each case, conducting activities in certain strategic industries, such as the industry in which we operate, is subject to the prior authorization of the French Ministry of Economy, which authorization may be conditioned on certain undertakings.

In the context of the ongoing COVID-19 pandemic, the Decree (décret) n°2020-892 dated July 22, 2020 as modified by the Decree (décret) n°2020-1729 dated December 28, 2020, has created, until December 31, 2021, a new 10% threshold of the voting rights for the non-European investments in listed companies, in addition to the 25% abovementioned threshold.

The foreign investment control regime described above applies to companies engaged in activities essential to protecting public health as well as biotechnology-related research and development activities.

Therefore, any investor meeting the above criteria willing to acquire all or part of our business with the effect of crossing the applicable share capital thresholds set forth by the French Monetary and Financial Code will have to request this prior governmental authorization before acquiring our ordinary shares or ADSs. We cannot guarantee that such investor will obtain the necessary authorization in due time. The authorization may also be granted subject to conditions that deter a potential purchaser. The existence of such conditions to an investment in our securities could have a negative impact on our ability to raise the funds necessary to our development. In addition, failure to comply with such measures could result in significant consequences for the investor (including the investment to be deemed null and void). Such measures could also delay or discourage a takeover attempt, and we cannot predict whether these measures will result in a lower or more volatile market price of our ADSs or ordinary shares.

We must maintain effective internal control over financial reporting, and if we are unable to do so, the accuracy and timeliness of our financial reporting may be adversely affected, which could hurt our business, lessen investor confidence and depress the market price of our securities.

We must maintain effective internal control over financial reporting in order to accurately and timely report our results of operations and financial condition. In addition, as a public company listed in the United States, the Sarbanes-Oxley Act will require, among other things, that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's annual report on internal control over financial reporting, pursuant to Section 404 of the Sarbanes-Oxley Act, in connection with issuing our consolidated financial statements as of and for the year ending December 31, 2022 and the filing of our second annual report with the SEC.

The rules governing the standards that must be met for our management to assess our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act are complex and require significant documentation, testing and possible remediation. These stringent standards require that our audit committee be advised and regularly updated on management's review of internal control over financial reporting. We are in the process of designing, implementing, and testing the internal control over financial reporting required to comply with this obligation. This process is time-consuming, costly, and complicated. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company," which may be up to five fiscal years following the date of our U.S. initial public offering.

Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company listed in the United States. If we fail to staff our accounting and finance function adequately or maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the United States, our business and reputation may be harmed and the price of our ADSs may decline. Furthermore, investor perceptions of us may be adversely affected, which could cause a decline in the market price of our securities.

Item 4. Information on the Company.

A. History and Development of the Company

We were incorporated as a *société anonyme*, or SA, on September 27, 2006. We are registered at the Paris *Registre du Commerce et des Sociétés* under the number 492 002 225. Our principal executive offices are located at Sorbonne University—BC 9, Bâtiment A 4ème étage, 4 place Jussieu 75005 Paris, France and our telephone number is +33 1 44 27 23 00. Our website address is *www.biophytis.com*. Our agent for service of process in the United States is Puglisi & Associates. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not a part of this annual report.

Our actual capital expenditures for the years ended December 31, 2018, 2019 and 2020 amounted to €113 thousand, €642 thousand and €484 thousand, respectively. These capital expenditures primarily consisted of patents rights acquired from our CEO. To date, we have expensed all research and development costs as incurred, as we do not currently meet the conditions to capitalize expenditures on drug development activities, as provided in IAS 38 *Intangible Assets*. Our research and development costs for the years ended December 31, 2018, 2019 and 2020 amounted to €9,513 thousand, €9,089 thousand and €9,921 thousand, respectively. These research and development costs primarily consisted of expenses incurred in connection with the development of our drug candidates such as personnel-related costs, expenses incurred under our agreements with CROs, clinical sites, contract laboratories and costs of acquiring preclinical study and clinical trial materials. We expect our capital expenditures and research and development costs to remain significant as we continue our research and development efforts and advance the clinical development of Sarconeos (BIO101) and Macuneos (BIO201), in the United States, Europe and elsewhere. We anticipate our capital expenditures and research and development costs in 2021 to be financed from our existing cash and cash equivalents, from the funding line of convertible notes set up with Atlas and from proceeds from our U.S. initial public offering. For the near future, our investments will mainly remain in France where our research and development facilities are currently located.

The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. Our website address is www.biophytis.com. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this annual report is not part of this annual report.

B. Business Overview

Overview

We are a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19. Our goal is to become a leader in the emerging field of aging science by delivering life-changing therapies to the growing number of patients in need. To accomplish this goal, we have assembled an experienced and skilled group of industry professionals, scientists, clinicians and key opinion leaders from leading industry and academic institutions from around the world.

A number of degenerative diseases associated with aging have been characterized in the last century, including sarcopenia and AMD. The pathophysiology of these and many other age-related diseases is not yet well understood, and effective treatment options are lacking. The global population of people over the age of 60 is expected to double from approximately 962 million in 2017 to 2.1 billion by 2050, according to estimates from the United Nations' World Population Prospects: the 2017 Revision. We believe that the need for effective therapeutics for age-related diseases will continue to grow throughout the 21st century. In addition, healthcare costs, including costs associated with treatments and long-term care for age-related diseases associated with this demographic shift, are expected to rise proportionally, as effective treatment options are currently lacking. We believe that developing treatments to slow disease progression and reduce the risk of severe disability associated with age-related diseases is of the utmost importance.

As we age, our physical, respiratory, visual and cognitive performances gradually decline due, in part, to the cumulative deleterious effect of multiple biological and environmental stresses, including current and emerging viral infections, to which we are exposed during our lifetime. The functional decline can be much faster in some individuals as a consequence of, among other things, the degenerative processes affecting specific cells, tissues and organs. Through evolution, cells, tissues and organisms have developed natural means or pathways to counteract and balance the effects of the many stresses they face. This natural ability to compensate for stress and remain functional, called biological resilience, degrades over time. The decline in biological resilience contributes to the acceleration of these degenerative processes and the impairment of functional performances, which, in turn, can lead to severe disability, reduced health-span and ultimately death. This occurs as we age, but can occur at a younger age, when genetic mutations exist, or in the case of infection and inflammation.

The COVID-19 virus was first identified in Wuhan, in the Hubei Province in China in December 2019. It was recognized as a worldwide pandemic by WHO in March 2020. There are many ongoing clinical studies to develop medical responses to COVID-19. A few anti-viral agents (including Veklury (remdesivir) and bamlanivimab (LY-CoV55)) have already received authorizations in the United States and the EU; in addition, certain anti-inflammatory agents (including Il-6 antagonists and dexamethasone), have been shown to be effective in patients who are on a respirator. Moreover, a few vaccines have now been authorized around the globe; while many more remain in development. Age, co-morbidities, heavy smoking, male gender and several ethnic backgrounds are associated with worse outcomes. Our therapeutic approach is aimed at targeting and activating key biological resilience pathways that can protect against and counteract the effects of the multiple biological and environmental stresses, including inflammatory, oxidative, metabolic and viral stresses that lead to age-related diseases.

Our lead drug candidate, Sarconeos (BIO101), is an orally administered small molecule in development for the treatment of neuromuscular diseases. Sarconeos (BIO101) is a plant-derived pharmaceutical-grade purified 20-hydroxyecdysone. We have completed preclinical studies, including chronic toxicology and safety pharmacology studies, and a Phase 1 clinical trial in healthy human volunteers, which are necessary for pursuing further clinical development of Sarconeos (BIO101). Our early data suggests that Sarconeos (BIO101) stimulates biological resilience and muscle metabolism in cellular models, and preserves strength, mobility and respiratory capacity in animal models of certain neuromuscular diseases. While we are still in the early stages of development, we believe that these results support further investigation and clinical development of Sarconeos (BIO101) in patients with certain neuromuscular and respiratory diseases.

The initial indication we are seeking approval for is sarcopenia, an age-related degeneration of skeletal muscle, which is characterized by a loss of muscle mass, strength and function in elderly people (adults 65 years of age and older) leading to reduced mobility, or mobility disability, and increased risk of adverse health events and hospitalization, and potential death resulting from falls, fractures, and physical disability. There is currently no approved medication for sarcopenia, which is present in the elderly (greater than 65 years old) with an estimated prevalence range between six to 22% worldwide. We are currently testing the safety and efficacy of Sarconeos (BIO101) in an ongoing global, randomized, double-blind, placebo-controlled clinical study (SARA-INT), with 233 elderly patients with sarcopenia at risk of mobility disability. The enrollment to this study was completed in March 2020. The COVID-19 pandemic has resulted in the closure of study sites and changes to the protocol for this study. Such changes and revisions were submitted to and reviewed by the applicable IRBs. Despite the interruption of in-office visits and other disruptions that were imposed due to the COVID-19 pandemic, we were able to retain most of the study participants. The last patient completed his final on-treatment visit in December 2020. Despite the impediments, a total of 196 participants completed the SARA-INT study. Currently, we are conducting final assessment on the last patients in this clinical trial. We would expect to announce top-line results from this study during the second quarter of 2021.

Sarconeos (BIO101) is also in development to treat patients with severe respiratory manifestations of COVID-19. We are currently testing the safety and efficacy of Sarconeos (BIO101) in an ongoing global, multicenter, double-blind, placebo-controlled, group-sequential, and adaptive two-part Phase 2-3 study (COVA) in patients with SARS-CoV-2 pneumonia. Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus. Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like cardiovascular disease, diabetes, chronic respiratory disease and cancer are more likely to develop serious illness. Part 1 of COVA is a Phase 2 exploratory PoC study to provide preliminary data on the activity, safety and tolerability of Sarconeos (BIO101) in the target population, which is hospitalized patients with severe respiratory manifestations. Part 2 of COVA will be a Phase 3 pivotal randomized study to provide further evidence of safety and efficacy of Sarconeos (BIO101) after 28 days of dosing. The study has regulatory approvals to take place in the United States, Brazil, France, Belgium and the United Kingdom. The first COVA participant was enrolled in August 2020. On January 8, 2021, the independent DMC of COVA reviewed the safety data analysis from the first 20 patients who were enrolled in the study, and recommended beginning recruitment for Part 2 of COVA. Following the DMC's recommendation to begin the recruitment for Part 2 of COVA, authorization was obtained from the applicable regulatory authorities (national regulatory agencies and/or central IRB and/or local Ethics Committees) in Brazil and the United States for most clinical centers in the two countries for the start of Part 2. Similar authorizations to begin Part 2 of COVA were subsequently obtained from the applicable regulatory authorities in France and in Belgium. Enrollment for Part 1 was completed on January 21, 2021. Enrollment for Part 2 of the study is expected to be completed in the first quarter of 2021. The first IA is anticipated to occur in the first quarter of 2021, subject to any COVID-19-related delays and the impact of the current pandemic on our operational capacities, with results of the study and submission for EUA with the FDA and conditional marketing authorization with the EMA expected in the second quarter of 2021 (subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic).

We are also developing Sarconeos (BIO101) for DMD, a rare genetic neuromuscular disease in male children and young adults, which is characterized by an accelerated degeneration of muscle and is responsible for a loss of mobility, respiratory failure and cardiomyopathy, leading to premature death. There is currently no cure and limited treatment options for DMD, which affects approximately 2.8 out of 100,000 people worldwide (approximately 20,000 new cases annually worldwide), based on our estimates from publicly available information. In 2018, we received orphan drug designation for Sarconeos (BIO101) in DMD from the FDA and the EMA. In December 2019, we received an IND "may proceed" letter from the FDA (USA) and we received a CTA approval from the FAMHP (Belgium) to start the MYODA study, and to investigate Sarconeos (BIO101) in non-ambulatory patients with signs of respiratory deterioration. In the "may proceed" letter, the FDA noted that it had significant concerns with the design of the study, and that the results of the study, as originally designed to enroll ambulatory and non-ambulatory patients and measure muscle function deterioration through a composite score, would not be capable of providing interpretable data sufficient to support a marketing application. In its letter, the FDA recommended that we revise the study population and primary endpoint. We have incorporated the FDA's recommendations and revised the protocol to focus on non-ambulatory patients with signs of respiratory deterioration and changed the primary endpoint to respiratory function. The revised protocol will be submitted as an amendment to the FDA and other regulatory authorities for review. While the FDA has not reviewed these changes yet, we do not expect the FDA to object to the revised protocol, given that we made the changes that the FDA requested. We hope to start this study, which will be a global, double-blind, placebo-controlled, group-sequential, Phase 1-3 seamless study, in the first half of 2021, subject to any COVID-19-related delays and the impact of the pandemic on our operational capabilities.

Our second drug candidate, Macuneos (BIO201), is an orally administered small molecule in development for the treatment of retinopathies. It is a plant-derived pharmaceutical-grade purified norbixin. We have completed preclinical cellular and animal studies of Macuneos (BIO201) for the treatment of retinopathies. While we are still in the early stages of development, we believe that the results from our preclinical studies support continued investigation into whether Macuneos (BIO201) may stimulate biological resilience and protect the retina against phototoxic damage that leads to vision loss. The initial indication we plan to seek approval for is dry AMD, a common eye disorder among people over the age of 50 that affects central vision, impairing functions such as reading, driving, and facial recognition, and has a major impact on quality of life and the ability to live independently. There are currently no approved treatments for dry AMD. Based on our estimates from publicly available information, AMD affects approximately 8.5% of the global population (ages 45 to 85) and is expected to increase over time as the population ages. We plan to commence a Phase 1 clinical trial (MACA-PK) in healthy volunteers in the second half of 2021, subject to regulatory review and approval, which is pending, any COVID-19-related delays and the impact of the pandemic on our operational capabilities.

We are also exploring Macuneos (BIO201) as a potential treatment for Stargardt disease, which shares many of the characteristics of dry AMD. Stargardt disease is the most common form of inherited macular degeneration that typically develops in childhood and leads to vision loss and, in some cases, blindness. We plan to explore clinical development of Macuneos (BIO201) for Stargardt disease in early 2022 following our MACA-PK Phase 1 clinical trial, subject to any COVID-19-related delays and the impact of the current pandemic on our operational capabilities.

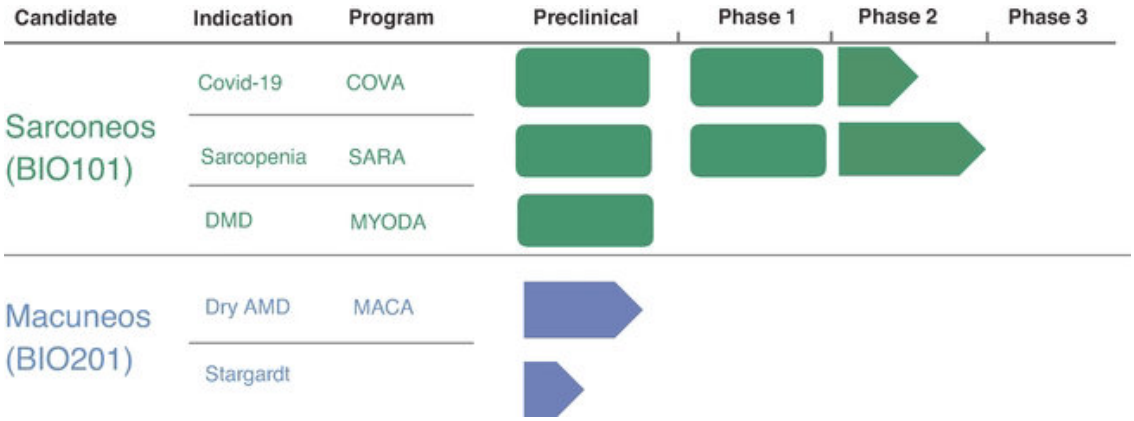
Subject to our entering into commercialization agreements in relation to two patent applications we recently filed, which are further described below as patent families S8 and S9, we hold exclusive commercialization rights through licenses for each of our drug candidates. We currently plan to develop our drug candidates through clinical PoC (typically Phase 2), and then seek licensing and/or partnership opportunities for further clinical development through regulatory approval and commercialization.

We have developed our lead clinical drug candidate Sarconeos (BIO101), preclinical drug candidate Macuneos (BIO201), and a preclinical pipeline of life-cycle extension products, consisting of BIO103 and BIO203, through a drug discovery platform in collaboration with Sorbonne University in Paris, France based on work with medicinal plants. Plants are major sources of small molecules, called secondary metabolites, which they produce as a defense mechanism to various environmental stresses, including attack from predatory and pathogenic species (*e.g*., insects, bacteria and fungi). Our drug discovery platform is based on a reverse pharmacology approach that tests a collection of bioactive secondary metabolites along with chemical analogs that we have synthesized in phenotypic screens of various age-related diseases. Our long-term goal is to advance the field of aging science with the continued discovery and development of new drug candidates that treat age-related diseases by stimulating biological resilience pathways that are involved in the aging process and/or age-related diseases.

We have assembled an executive team of scientific, clinical, and business leaders with broad expertise in biotechnology and clinical drug development. Stanislas Veillet, our co-founder, Chairman and Chief Executive Officer, has held positions in the biotechnology, pharmaceutical and nutritional industries for the last 25 years. He holds a Ph.D. in genetics and has authored more than a dozen patents. Our other co-founder and Scientific Advisor, René Lafont, is a biochemist (Ecole Normale Supérieure), Professor Emeritus and former Dean of the Department of Life Sciences at Sorbonne University. He has authored over 250 scientific publications and a dozen patents and is also notably a Laureate of Karlson Foundation in Germany and the recipient of the Jaroslay Heyrovsky medal of the Czech Academy of Sciences. Dr. Samuel Agus, our Chief Medical Officer, holds a Doctor in Medicine, is a board-certified neurologist with academic training in biostatistics and bioinformatics, and has over 15 years of clinical development experience in the pharmaceutical industry. Waly Dioh, our Chief Operating Officer holds a doctorate in phytopathology (Paris XI), and spent most of his career with research and development teams in Monsanto Company, initially in France to set up a genoptyping platform, and then in the United States. Pierre Dilda, our Chief Scientific Officer holds a doctorate in pharmacology from the University of Paris V, Faculty of Medicine, Paris. He has 25 years' experience in advancing small molecule drug candidates in pharma, biotech and academic environments. Evelyne Nguyen, our Chief Financial Officer, graduated from the Institut de Gestion (France). She has over 30 years of corporate finance and business development experience with biotech and pharma companies (*i.e*., Bristol Myers Squibb, LFB and Nicox SA), and led numerous cross border transactions.

Our Clinical Pipeline

We are developing a portfolio of programs targeting biological resilience pathways that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases. Our current pipeline of drug candidates is illustrated below.



Sarconeos (BIO101)

We are developing Sarconeos (BIO101) for the treatment of certain neuromuscular diseases, including sarcopenia and DMD. Both are diseases of muscular degeneration, but with different complex causes and pathophysiologies (*i.e.*, age-related versus genetic). However, similar key muscular processes are impaired in each of these diseases as well as other muscle wasting conditions, including metabolism, mitochondrial function, stem cell proliferation and loss of biological resilience, which are mediated through multiple signaling pathways. Early cellular and animal model data suggest that Sarconeos (BIO101) directly targets muscle tissue and cells, and improves several key muscle cell functions, including protein syntheses, regeneration and energy production. Additional studies suggest it may have a positive impact on ALI, which may evolve towards ARDS in COVID-19 patients. We believe that Sarconeos (BIO101) may have the potential to improve muscle and respiratory function and preserve strength, mobility and respiratory capacity in various muscle wasting and COVID-19-related ALI/ARDS.

Sarcopenia (the SARA clinical program)

Sarcopenia is an age-related degeneration of skeletal muscle. It is a major cause of mobility disability in the elderly, characterized by a loss of muscle mass, strength, balance and the ability to stand and/or walk, resulting in a loss of independence, increased risk of adverse health events and hospitalization, and potential death resulting from falls, fractures, and physical disability. We have observed activity of Sarconeos (BIO101) on cellular function and muscle performance in several cellular and animal models of various age-related and muscular wasting conditions. Based on the Phase 1 study (SARA-PK), with 54 healthy young and elderly adult subjects in 2017, we identified the two dosing levels (175 and 350 mg b.i.d.) for our ongoing SARA-INT trial. We are currently testing the safety and efficacy of the oral adult formulation of Sarconeos (BIO101) in an ongoing global, randomized, double-blind, placebo-controlled study (SARA-INT) with 233 elderly participants with sarcopenia at risk of mobility disability. Recruitment was completed in March 2020. The COVID-19 pandemic has resulted in the closure of study sites and changes to the protocol. Such changes and revisions were submitted to and reviewed by the applicable IRBs. Despite these interruptions of in-office study visits and other disruptions that were imposed due to the COVID-19 pandemic, we were able to retain most of the study participants. The last patient completed his final on-treatment visit in December 2020. Despite the impediments, a total of 196 participants completed the SARA-INT study. Currently, we are conducting final assessment on the last patients in this clinical trial. We expect to announce top-line results during the second quarter of 2021.

If approved by regulatory authorities for commercial use, we believe there is market potential for Sarconeos (BIO101) in sarcopenia, which is highly present in the elderly (greater than 65 years old) with an estimated prevalence range of between six to 22% worldwide. There is currently no approved medication for sarcopenia and no therapeutic agents are currently being tested in confirmatory or Phase 3 clinical trials. Based on our review of research in this area, we believe Sarconeos (BIO101) is currently the only drug candidate being tested in an interventional Phase 2 clinical trial for the treatment of sarcopenia. To our knowledge, there is currently no widely accepted standard of care for sarcopenia. Current non-medicinal treatment recommendations primarily focus on moderate physical activity, such as 30 minutes of walking per day or resistance-based (strength) training, as they exert effects on both the nervous and muscular systems that are critical to positive physiological and functional adaptations in older adults, and nutritional intervention. Other potential drug modalities that have been tested in the clinic for sarcopenia have yet to demonstrate effectiveness on clinically meaningful outcomes (strength and mobility) and/or safety in larger clinical trials and/or have not progressed through the clinic. Based on our understanding and discussions with regulatory agencies, including the FDA and EMA, functional mobility endpoints must be achieved in order to obtain marketing approval for sarcopenia.

COVID-19 (the COVA clinical program)

COVID-19 was declared as a worldwide pandemic by the WHO, in March 2020. As of the date of this annual report, the number of worldwide cases is approximately 117.3 million, with more than 2.6 million confirmed deaths. COVA is a global, multicenter, double-blind, placebo-controlled, group-sequential, and adaptive two-part Phase 2-3 study with a total of 310 hospitalized patients in both parts. Part 1 will include the first 50 patients and the data from all study participants will be analyzed together at the end of Part 2. We are using the adult oral formulation of Sarconeos (BIO101) at 350 mg b.i.d. During the study, two IAs will be performed by the DMC with the first one from the first 50 participants and the second IA on the safety and efficacy data from 155 participants, which will be used to re-assess the final sample size. The study was approved in the following countries: the United States, Brazil, France, Belgium and the United Kingdom. The first participant in Part 1 of the study was enrolled in August 2020 in Belgium. On January 8, 2021, the independent DMC of COVA reviewed the safety data analysis from the first 20 patients who were enrolled in the study, and recommended beginning recruitment for Part 2 of COVA. Following the DMC's recommendation to begin the recruitment for Part 2 of COVA, authorization was obtained from the applicable regulatory authorities (national regulatory agencies and/or central IRB and/or local Ethics Committees) in Brazil and the United States for most clinical centers in the two countries for the start of Part 2. Similar authorizations to begin Part 2 of COVA were subsequently obtained from the applicable regulatory authorities in France and in Belgium. Enrollment for Part 1 was completed on January 21, 2021. Enrollment for Part 2 of the study is expected to be completed in the first quarter of 2021. The first IA is anticipated to occur in the first quarter of 2021, subject to any COVID-19-related delays and the impact of the pandemic on our operational capabilities, with results and regulatory submission in the second quarter of 2021 (subject to any delays in patient recruitment or retention, interruptions in sourcing or supply chain, regulatory authorizations, COVID-19-related delays, and the impact of the current pandemic).

Due to the global pandemic, the rising number of COVID-19 cases, and the need for new treatments, especially for patients who are hospitalized with severe respiratory manifestations such as COVID-19 related ALI/ARDS, regulatory authorities are applying emergency approval programs. These programs include EUA in the United States, and the EMA conditional marketing authorization, under the guidance of the COVID-19 task-force, and similar programs in other countries. If an EUA or conditional marketing authorization is achieved, a separate regulatory process will be needed in order to obtain a full marketing authorization (*i.e.*, non-emergency authorization and conditional marketing authorization) for the use of Sarconeos (BIO101) in respiratory failure linked to COVID-19.

If authorized by regulatory authorities for commercial use, we believe there is market potential for Sarconeos (BIO101) in hospitalized patients with COVID-19 who are not yet in ICUs. To our knowledge, there are currently only a few drugs approved for COVID-19 treatments (such as Veklury (Remdesivir), which was approved for certain patient populations, and bamlanivimab (LY-CoV55)) and based on our research, none are specifically targeting the modulation of the RAS, to restore respiratory function. However, there have been multiple clinical trials testing repositioned drugs and new drug candidates or vaccines in 2020. A few vaccines have now been authorized around the globe; while many more remain in development.

DMD (the MYODA clinical program)

DMD is rare neuromuscular genetic disease in male children and young adults, which is characterized by accelerated degeneration of muscle and is responsible for a loss of mobility, respiratory failure and cardiomyopathy, leading to premature death. It is the most common form of muscular dystrophy in children. DMD is caused by mutations in the dystrophin gene that result in the absence or very low levels of functional dystrophin, a cytoskeletal protein that protects muscle cells.

We have observed a positive effect on muscle function, mobility, and respiratory capacity (a major disability in later stage DMD disease progression) in *mdx* mice models of DMD that were treated with Sarconeos (BIO101). In June 2018, we received orphan drug designation from the FDA and EMA for Sarconeos (BIO101) in DMD. We received an IND "may proceed" letter from the FDA in the United States and CTA approval from the FAMHP in Belgium in the second half of 2019 to initiate clinical development with our MYODA clinical program, which is based on a global, double-blind, placebo-controlled, group-sequential, Phase 1-3 seamless study, in non-ambulatory DMD patients, with signs of respiratory deterioration. We will use the pediatric oral formulation of Sarconeos (BIO101) to test the safety and efficacy of the product on respiratory functions, as measured by PEF, as the primary endpoint. In the "may proceed" letter from the FDA, the FDA noted that it had significant concerns with the design of our study, and that the results of the study, as originally designed to enroll ambulatory and non-ambulatory patients and measure muscle function deterioration through a composite score, would not be capable of providing interpretable data sufficient to support a marketing application. In its letter, the FDA recommended that we revise the study population and primary endpoint. We have incorporated the FDA's recommendations and revised the protocol to focus on non-ambulatory patients with signs of respiratory deterioration and changed the primary endpoint to respiratory function. The revised protocol will be submitted as an amendment to the FDA and other regulatory authorities for review. We hope to initiate the study in the first half of 2021, subject to any COVID-19-related delays and the impact of the pandemic on our operational capabilities.

If approved by regulatory authorities for commercial use, we believe there is market potential for Sarconeos (BIO101) in DMD, which affects approximately 2.8 out of 100,000 people worldwide (approximately 20,000 new cases annually worldwide), based on our estimates from publicly available information, resulting in premature death. There is currently no cure for DMD and there are only limited treatment options that aim to control the symptoms and slow the disease progression. In many countries, corticosteroids are the standard drug therapy. However, corticosteroids typically only slow the progression of muscle weakness and delay the loss of ambulation by up to two years, and their benefit for non-ambulatory boys with signs of respiratory deterioration, is not clear. Corticosteroids have also been associated with adverse side effects and are generally not suitable for long-term administration. There are three targeted therapies (*i.e.,* therapies targeting a specific dystrophin mutation by exon skipping or with stop codons) available on the market (two in the United States and one in Europe). As these therapies each target a specific gene mutation, they can only address the approximately 20% of the overall DMD patient population with those genetic mutations. In addition, there are only a few treatments that are in clinical development that target treatment of ambulatory children. There are very few early stage programs that target treatment of non-ambulatory patients with signs of respiratory deterioration.

We believe that Sarconeos (BIO101) directly targets muscle tissue and cells, increases key muscle cell functions that are impaired independent of the genetic mutation that causes the disease, and has the potential to be used complementarily with corticosteroids, current targeted therapies and other gene therapies under development. We also believe that because Sarconeos (BIO101) targets various impaired muscle tissues and cells relevant to muscle strength, mobility and respiratory function, it has the potential to be used in all stages of DMD progression, including both ambulatory and non-ambulatory patients. Due to the high unmet need, specifically in the population of non-ambulatory patients, with signs of respiratory deterioration, we decided to focus on this sub-population, at this stage.

Macuneos (BIO201)

Dry AMD (the MACA clinical program)

AMD is an age-related degeneration of the macula, the central part of the retina. It is one of the leading causes of irreversible vision loss and blindness in people over the age of 50 worldwide, according to the Bright Focus Foundation's Age-Related Macular Degeneration: Facts & Figures Fact Sheet. Approximately 85 to 90% of AMD patients suffer from the dry (atrophic) form, called dry AMD, according to estimates provided by the American Macular Degeneration Foundation. Based on our estimates from publicly available information, we believe that dry AMD affects approximately 170 million people worldwide and is expected to increase over time as the population ages. Dry AMD affects central vision and impairs many functions affecting quality of life and independent living such as reading, driving, and facial recognition. The prevalence of dry AMD increases significantly with advancing age.

We have observed that Macuneos (BIO201) appears to potentially protect the retina against phototoxic damage caused by A2E (a by-product of the visual pigment cycle) accumulation that leads to vision loss in several cellular and animal models of dry AMD and Stargardt disease. We are conducting chronic and acute animal toxicology studies to support IND and CTAs. We plan to commence a Phase 1 clinical trial (MACA-PK) in healthy volunteers in the second half of 2021, subject to regulatory review and approval, which is pending, any COVID-19-related delays and the impact of the current pandemic on our operational capabilities. We expect the MACA-PK Phase 1 clinical trial will assess the safety, PK and PD of Macuneos (BIO201).

If approved by regulatory authorities for commercial use, we believe that there is market potential for Macuneos (BIO201) in dry AMD. Therapeutic options for dry AMD have proven challenging with no currently approved drugs that can slow or reverse the disease progression.

We intend to investigate whether Macuneos (BIO201) may also be an effective treatment for Stargardt disease, the most common form of inherited juvenile macular degeneration. The pathophysiology of Stargardt disease is similar to that of AMD, in that it may also be characterized by accelerated retinal degeneration.

Our Strategy

We are focused on the development of therapeutics that improve functional outcomes for patients suffering from age-related diseases. Our goal is to build Biophytis into a leading biotechnology company focused on targeting biological resilience pathways that slow the degenerative processes associated with age-related disease progression in order to improve the lives of millions of patients that have limited or no treatment options. We currently plan to develop our drug candidates through clinical PoC (Phase 2/3) and then seek licensing and/or partnership opportunities for further clinical development through regulatory approval and commercialization. To achieve our goal, we are pursuing the following strategies:

- ***Demonstrate clinical proof of concept (PoC) of Sarconeos (BIO101) in sarcopenia.*** Our resources and business efforts are primarily focused on advancing the clinical development of Sarconeos (BIO101) for the treatment of neuromuscular disorders, with an initial focus on sarcopenia. Our goal is to demonstrate clinical PoC safety and efficacy of Sarconeos (BIO101) to treat sarcopenia in our ongoing SARA-INT Phase 2 clinical trial. Upon successful completion, we plan to pursue licensing and/or partnership opportunities to advance Sarconeos (BIO101) into a confirmatory or Phase 3 clinical trial necessary to secure marketing approval. We believe this indication has significant value and that establishing clinical PoC may help attract partners for further clinical development and commercialization.

- ***Demonstrate the therapeutic benefit and obtain conditional approval of Sarconeos (BIO101) for COVID-19 patients.*** Complete a two-part Phase 2/3 trial in hospitalized COVID-19 patients with severe respiratory manifestations and file for an EUA in the United States. We will also seek to obtain a conditional marketing authorization from the EMA in the EU by using expedited procedures implemented at the EU level to support the development and evaluation of treatments for COVID-19, and apply for similar conditional marketing authorization in other countries, such as Brazil. In parallel, we will work to make Sarconeos (BIO101) ready for launch, through manufacturing and supply-chain upscaling and market-access preparations. We plan for a commercial launch in these countries, upon EUA or traditional regulatory approval, by licensing the product to global or regional pharmaceutical companies. An EUA differs from a traditional approval in that, among other things, it may be revoked at the conclusion of a public health emergency, and there may be limitations to its uses. However, EUA can be effective for quickly supplying medical countermeasures needed during public health emergencies. We also plan to conduct additional studies, as needed, to obtain regulatory approval for commercial distribution.

- ***Initiate clinical development of Sarconeos (BIO101) in DMD.*** Our efforts are also focused on leveraging our knowledge and the development of Sarconeos (BIO101) in sarcopenia to commence and advance the clinical development of Sarconeos (BIO101) for the treatment of non-ambulatory DMD patients with signs of respiratory deterioration, independent of genetic mutation and across the disease spectrum. We have already received an IND "may proceed" letter from the FDA in the United States and a CTA approval from FAMHP in Belgium. In the "may proceed" letter from the FDA, the FDA noted that it had significant concerns with the design of the study, and that the results of the study, as originally designed to enroll ambulatory and non-ambulatory patients and measure muscle function deterioration through a composite score, would not be capable of providing interpretable data sufficient to support a marketing application. In its letter, the FDA recommended that we revise the study population and primary endpoint. We have incorporated the FDA's recommendations and revised the protocol to focus on non-ambulatory patients with signs of respiratory deterioration and changed the primary endpoint to respiratory function. The revised protocol will be submitted as an amendment to the FDA and other regulatory authorities for review. We hope to initiate this study in the first half of 2021, subject to any COVID-19-related delays and the impact of the pandemic on our operational capabilities. The pandemic may also pose limitations on starting a study in a very vulnerable population.

- ***Advance the development of our second drug candidate, Macuneos (BIO201).*** We are also working on continuing the preclinical development of our second drug candidate, Macuneos (BIO201), for the treatment of retinopathies, with an initial focus on dry AMD. We plan to start a Phase 1 clinical trial (MACA-PK) in healthy volunteers, in the second half of 2021, subject to regulatory review and approval, which is pending, and the impact of the current pandemic on our operation capabilities.

- ***Expand our presence in the United States to support co-development in Europe and the United States.*** We plan to continue the expansion of our company in the United States and Europe. In 2018, we opened offices in Cambridge, Massachusetts to support our growing clinical, regulatory, and operational efforts, and we hired a U.S.-based Chief Medical Officer. Our goal is to continue to build our clinical and regulatory operations to support further clinical trials and, if successful, apply for regulatory approval in both the United States and Europe. We plan to work with patient associations, regulatory agencies, government and third-party payors and other key constituencies in both regions.

- ***Expand our pipeline and explore potential strategic partnerships and alliances to maximize the value of our development programs.*** We plan to continue to leverage our collaborations with leading scientific and academic institutions in order to pursue new INDs for our existing drug candidates, including Sarconeos (BIO101), BIO103, Macuneos (BIO201) and BIO203. We believe that our drug candidates may be applicable for additional age-related disease research and potential application. We plan to explore the commercial potential of our drug candidates after establishing clinical PoC through Phase 2/3.

Our Drug Candidates

SARCONEOS (BIO101)

Our lead drug candidate, Sarconeos (BIO101), is an orally administered small molecule in development for the treatment of neuromuscular diseases. We have completed preclinical studies and are in various stages of further clinical development for the treatment of neuromuscular diseases. While preclinical studies provide limited data, based on results from our cellular and animal studies, we believe Sarconeos (BIO101) stimulates biological resilience through activation of the MAS Receptor, which may preserve muscle strength, mobility and respiratory function in various age-related conditions.

The initial indication we are seeking approval for is sarcopenia, an age-related degeneration of skeletal muscle, which is characterized by a loss of muscle mass, strength, function and mobility disability, and increased risk of adverse health events and potential death resulting from falls, fractures, and physical disability. There is currently no approved medication for sarcopenia, which is highly prevalent in the elderly (adults 65 years of age and older) with an estimated prevalence between six to 22% worldwide.

In addition, MAS activation could potentially counter the deleterious effects of the SARS-CoV-2 infection. Data from models of ALI suggest a further protective role of Sarconeos (BIO101) on the pulmonary tissue. We therefore started investigating Sarconeos (BIO101) in patients with severe respiratory manifestations of COVID-19. Currently, the treatment options to these patients, many of whom are elderly, are limited.

We are also developing Sarconeos (BIO101) for DMD, the most common form of muscular dystrophy in children leading to early mortality. We are focusing on non-ambulatory patients with signs of respiratory deterioration.

History and Development of Sarconeos (BIO101)

In collaboration with Sorbonne University in Paris, France, we began our drug discovery efforts with a class of plant secondary metabolites called phytoecdysteroids, which are produced by plants to protect against insect attack. Phytoecdysteroids are analogs of the insect molting hormones ecdysone, which protects the plants by acting as endocrine disrupters and/or feeding deterrent. Phytoecdysteroids are found in various medicinal plants throughout the world and are used in traditional medicines as tonics or anti-diabetics.

We utilized a reverse pharmacology approach starting with phenotypic screens of a collection of phytoecdysteroids that had been gathered for over 30 years by scientists from Sorbonne University, along with chemical analogs that we have synthesized for their ability to stimulate protein synthesis in muscle cells. We selected 20-hydroxyecdysone for clinical development based on its safety profile, pharmacological activity and potential in maintaining key muscle functions, including mobility and strength. This compound was tested in animal models submitted to different stresses, including metabolic stress (high fat dieting or diabetic models), age-related stress (sarcopenia and disuse models), and genetic-related stress (DMD and Spinal Muscular Atrophy models). We will also be testing the compound for infectious-related disease stress (COVID-19). Once pharmacological effects were detected, we identified the molecular target(s) and potential mechanism-of-action.

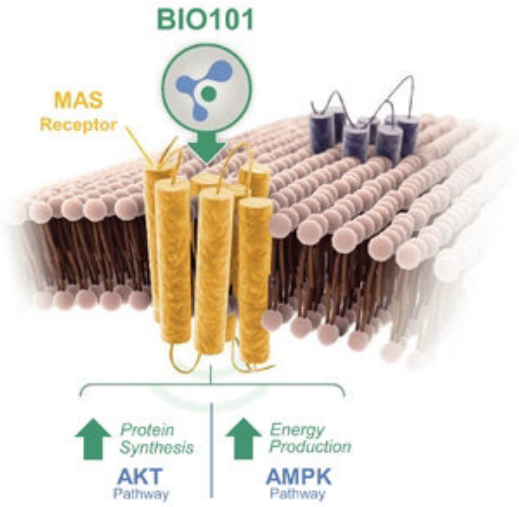
Potential Mechanism-of-Action

The MAS Receptor, the protective arm of the Renin-Angiotensin System (RAS)

Our preclinical studies demonstrate that Sarconeos (BIO101) activates the MAS Receptor in muscle cells, a key component of the RAS. The RAS is a fundamental endocrine system that is known to control fluid balance and blood pressure, playing a key role in cardio-vascular function. It is also involved in the regulation of smooth, cardiac and skeletal muscle metabolism, and plays a key role in muscle function and mobility in disease states. It is made up of two different arms that counter-regulate each other: (i) the “classical” arm (or ACE / angiotensin-II (Ang-II) / Ang-II receptor type 1 (AT1R) axis), and (ii) the “protective” arm (or ACE2 / angiotensin 1-7 (Ang-1-7) / MAS Receptor axis). Ang-II blood concentration has been shown to be increased with aging and in various neuromuscular diseases, such as sarcopenia and respiratory diseases that are caused by viruses such as SARS-CoV-2. Ang 1-7, the endogenous ligand of the MAS Receptor, opposes the numerous actions of Ang-II on muscle and cardio respiratory functions.

We believe Sarconeos (BIO101), through the activation of the MAS Receptor, triggers two key downstream signaling-pathways: (i) the P13K/AKT/mTOR pathway, or the AKT pathway, which is known to be responsible for increasing protein synthesis, (ii) the AMPK/ACC pathway, or the AMPK pathway, which is known to be involved in stimulating energy production. We have demonstrated that Sarconeos (BIO101) activates major signaling pathways such as the AKT pathway and potentially the AMPK pathway in C2C12 myotubes and human muscle cells through western blot analysis. The AKT pathway and AMPK pathway have all been shown to be impaired in muscle wasting conditions.

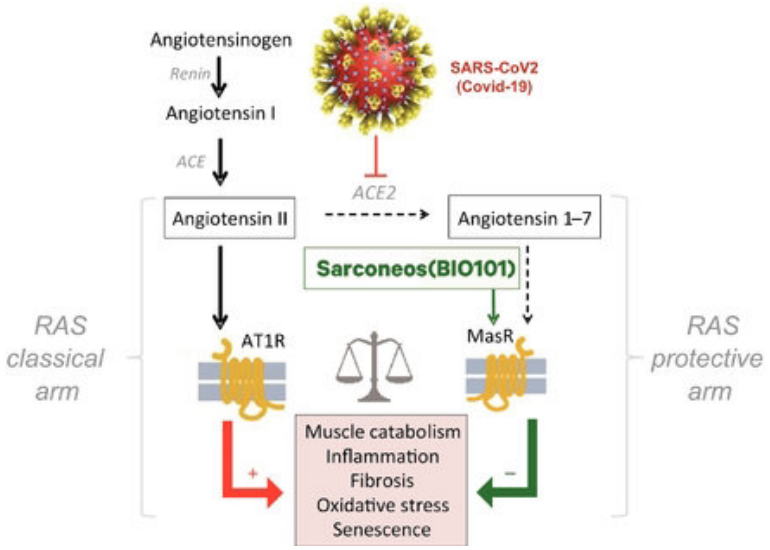
The potential mechanism-of-action through activation of the MAS Receptor is illustrated in the diagram below:



We believe that the AKT and AMPK pathway are potentially the key factors for (i) preserving muscle mass and increasing muscle strength under muscle wasting conditions and (ii) increasing muscle strength and improved endurance, respectively. We have also observed in preclinical studies that activation of the MAS Receptor by Sarconeos (BIO101) shares many common properties with Ang-1-7 at the cellular level. However, Sarconeos (BIO101) did not show an effect on blood pressure or heart rate when compared to enalapril, an angiotensin-converting enzyme, or ACE, inhibitor.

The activation of MAS Receptor is thought to be a key component of the cardio-respiratory function. When it comes to COVID-19, SARS-CoV-2 infection, by down-regulation of ACE2 expression and activity, reduces the conversion of Ang-II to Ang-1-7 resulting in excessive levels of Ang-II. This imbalance between the “classical” and “protective” arms of the RAS due to excessive activation of AT1R and limited activation of MAS Receptor which explain some of the observations in clinical practice reported in COVID-19 patients. Therefore, we believe that restoration of the balance of the RAS, by directly activating MAS Receptor downstream of ACE2, would be a particularly relevant avenue to treat patients infected with SARS-CoV-2.

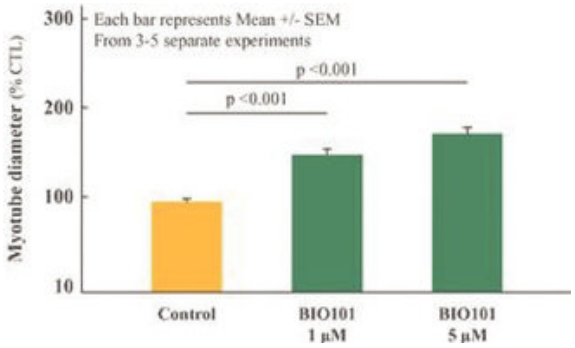
The potential mechanism-of-action through activation of MAS Receptor downstream of ACE2 which rebalances RAS in SARS-Cov2 infected subjects is as follows:



Preclinical proofs of concept

Effect on myocyte differentiation into myotubes (in vitro)

Our preclinical data in C2C12 cell lines and human cell models suggest that Sarconeos (BIO101) enlarges myotubes, the main structural units of muscle, warranting continued research. We believe that this is important for limiting muscle mass loss and increasing muscle strength under muscle wasting conditions. As depicted below, results from an *in vitro* study demonstrate that human myotubes are larger in muscle cells treated with Sarconeos (BIO101) as compared to untreated control cells.



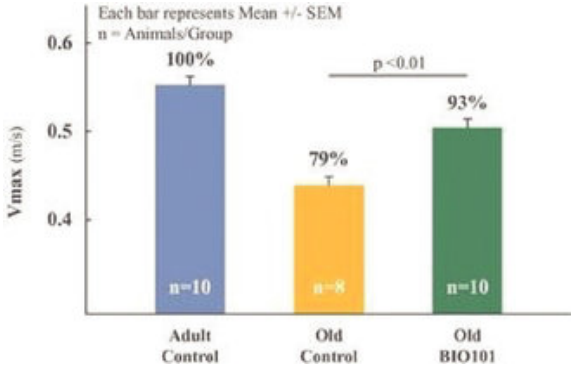
Effect of Sarconeos (BIO101) on mean myotube diameter

We believe Sarconeos (BIO101) directly targets muscle tissue and cells, and improves several key muscle cell functions, including protein synthesis, regeneration and energy production through key signaling pathways that are impaired in muscle wasting conditions, regardless of the disease stage, state of disease progression or severity, and may have the potential to improve muscle function and preserve strength, mobility and respiratory capacity in various neuromuscular diseases, independent of cause (*i.e.*, age-related or genetic) and pathophysiology.

Preclinical Development of Sarconeos (BIO101) in Sarcopenia.

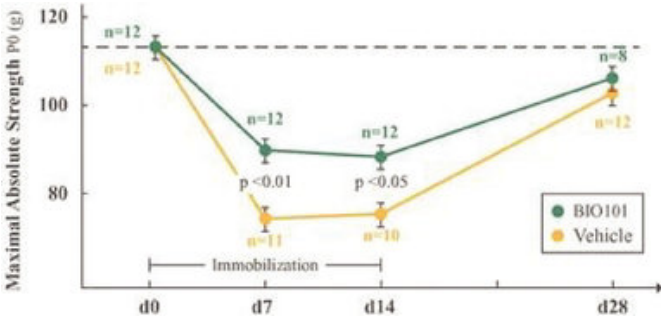
We have conducted numerous *in vivo* experiments in C57Bl/6J mouse models to assess the activity of Sarconeos (BIO101) within the context of aging, specifically studying a high fat diet and immobilization. Key *in vivo* results are summarized below.

Beneficial effect on mobility in mice. We administered Sarconeos (BIO101) at 50 mg/kg/day or a placebo to "old" mice (22 months old at the beginning of the study) that were fed a high-fat diet over 14 weeks. The mice were exercised on a treadmill and maximum running velocity (Vmax) was recorded after 14 weeks of treatment. Untreated "adult" mice (12 months old at the beginning of the study) were also fed a high-fat diet and exercised similarly to determine a positive control velocity. As shown in the graph below, "old" control mice had a Vmax that was approximately 21% less than "adult" control mice ($p<0.001$) demonstrating the effects of aging. Further, results showed that "old" mice treated with Sarconeos (BIO101) demonstrated a significant improvement in Vmax as compared to "old" control mice ($p<0.01$), compensating almost completely for the loss of mobility due to aging. These results were presented in December 2016 at the Society on Sarcopenia, Cachexia and Wasting Disorders, or SCWD, conference in Berlin, Germany.



Effect of chronic Sarconeos (BIO101) treatment over 14 weeks on maximum running velocity in old mice

Preservation of muscle strength after immobilization in mice. To model muscle wasting associated with impaired mobility, we immobilized young mice (13 weeks old) and began administering either Sarconeos (BIO101) at 50 mg/kg/day or a placebo control (vehicle). After 14 days, we removed the immobilization and continued administration of Sarconeos (BIO101) for an additional 14 days. The absolute strength of hind limb muscle was recorded at various times over the 28-day period. As shown in the graph below, mice treated with Sarconeos (BIO101) demonstrated a preservation of muscle strength while immobilized compared to vehicle control. We believe these results support continued research to investigate whether Sarconeos (BIO101) could be an effective treatment to preserve muscle function under conditions of disuse or immobility.

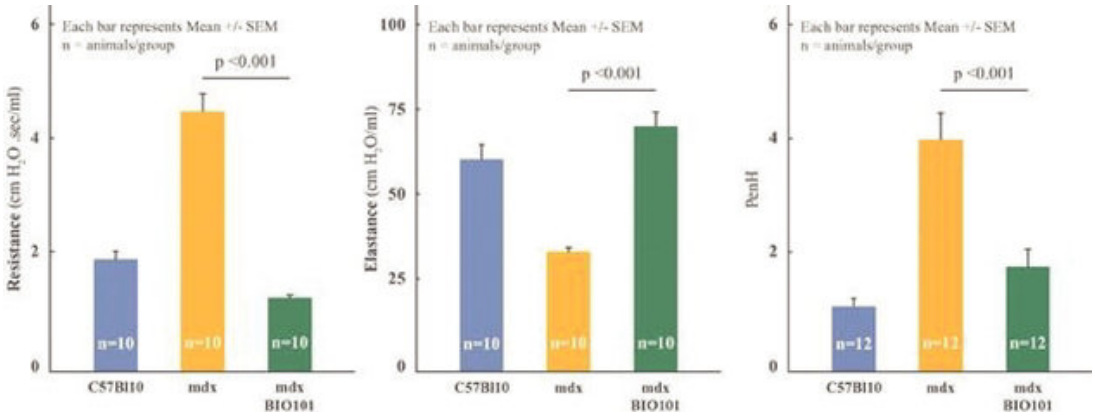


Effect of chronic Sarconeos (BIO101) treatment over 28 days on maximal absolute strength in hind limb-immobilized mice

Preclinical Development of Sarconeos (BIO101) in DMD

We have conducted various *in vivo* experiments in *mdx* mice, a commonly used model of DMD. The results from these *mdx* mice studies are consistent with the results on cellular activity and functional outcomes from both *in vitro* and *in vivo* studies of Sarconeos (BIO101) in sarcopenia. We believe these results provide additional support for our belief that Sarconeos (BIO101) has the potential for improving mobility and muscle strength. In addition, we believe these results suggest that Sarconeos (BIO101) may increase respiratory function and decrease fibrosis. Key *in vivo* results in DMD are summarized below.

Improved respiratory function in mice. The loss of respiratory function is a major health issue for later-stage, non-ambulatory patients with DMD. Recent results have shown that chronic (eight weeks) daily administration of 50/mg/kg of Sarconeos (BIO101) ameliorates the time-dependent degradation of respiratory function observed in C57BL10-*mdx* mice as compared to C57BL10 control mice. This protective effect on respiratory function is not only associated with breathing parameters as suggested by enhanced pause, or PenH, measurements, but also by an improvement of deep airway structure of the respiratory system shown by FlexiVent experiments, which are a common measurement for *in vivo* lung function. PenH is calculated as follows: (PIP/PEP) x Pause, where PIP is the maximum change in chamber pressure during inspiration, PEP is the maximum change in chamber pressure during expiration, and Pause equals (TE-TR)/TE, where TE is expiratory time and TR is relaxation time. As shown in the three graphs below, C57BL10-*mdx* mice treated with Sarconeos (BIO101) exhibited improved respiratory function as measured by resistance, elastance and PenH of the lung. These results were presented in March 2019 at the annual international congress of Myology in Bordeaux, France.



Effect of chronic Sarconeos (BIO101) treatment on resistance, elastance and airway reactivity (PenH).

Improved mobility and muscle strength in mice. We studied the effect of chronic oral administration of 50 mg/kg/day of Sarconeos (BIO101) on mobility and strength over eight weeks in C57BL10-*mdx* mice. Mobility was measured by running distance and strength was measured by maximum absolute strength (force) in the four-limb grip-test test. Results show that Sarconeos (BIO101) treatment improved mobility in certain animal models, as C57BL10-*mdx* mice treated with Sarconeos (BIO101) ran 2.4x farther than untreated control C57BL10-*mdx* mice. Results show that Sarconeos (BIO101) treatment improved muscle strength in animal models, as C57BL10-*mdx* mice treated with Sarconeos (BIO101) showed an approximate 14% improvement in strength as compared to untreated control C57BL10-*mdx* mice.

Effect of Sarconeos (BIO101) on mobility (running distance) and muscle strength (four-limb grip-test force).

These *in vivo* results on muscle functionality (mobility and strength) in mice are consistent with cellular and molecular changes observed in our previous preclinical studies, including (i) improved energy metabolism (mitochondrial respiration and spare respiratory capacity), (ii) improved myoblast differentiation, and (iii) confirmed activation of the AKT Pathway involved in anabolism known for being impaired in DMD muscle. These results were presented in October 2018 at the World Muscle Society, or WMS, conference in Mendoza, Argentina (Dilda et al., 2018).

Improved lesion profile in mice. We have observed that Sarconeos (BIO101) treatment may improve the histological (muscular lesion) profile of muscle in mice, consistent with the improvements in physical performance and muscle function (mobility and strength), as mentioned above. We performed histopathological analysis of muscle from C57BL10-control mice, C57BL10-*mdx* mice and C57BL10-*mdx* mice treated with Sarconeos (BIO101). Muscles from C57BL10-*mdx* mice exhibited anisocytosis (atrophy of muscle fibers), as well as chronic inflammation associated with fibrosis as compared to healthy muscles from control mice. Observations of muscle from C57BL10-*mdx* treated mice showed that chronic administration of Sarconeos (BIO101) decreased anisocytosis and inflammation as compared to muscles from C57BL10-*mdx* mice. These results were presented in October 2017 at the WMS conference held in Saint Malo, France.

Preclinical Development of Sarconeos (BIO101) in COVID-19

ALI is acute hypoxic respiratory insufficiency caused by non-cardiogenic pathogenic factors and may develop to acute respiratory distress syndrome (ARDS) in severe cases. One of the important causes of ALI is virus infection that in some cases (including SARS-CoV-2) can deregulate the expression of RAS components by accelerating the imbalance of RAS and the occurrence and development of ALI/ARDS. Of particular interest, BIO101's active principle ingredient, or API, has shown lung anti-inflammatory and lung protective effects in various *in vivo* models of ALI known for being associated with severe RAS imbalance. Additionally, as stated below, BIO101 treatment also improved deep airway structure and mechanical properties (resistance, compliance and elastance) of lungs. Altogether, these observations strongly suggest that BIO101 could have a protective effect against ARDS observed in humans suffering from severe forms of COVID-19. We have not yet performed this preclinical study, and this will be performed by University of Liège in Belgium concurrently with the ongoing COVA clinical trial.

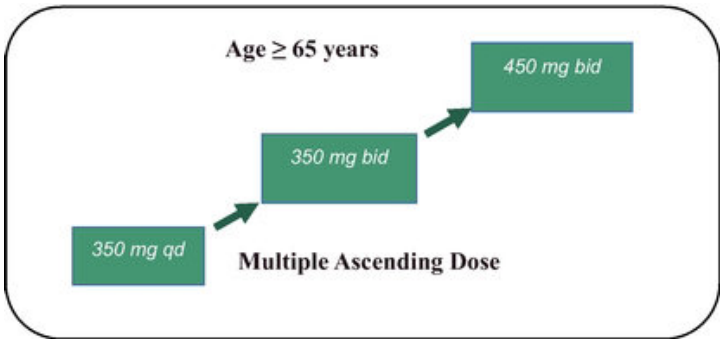
Sarconeos (BIO101) clinical development

Phase 1 Clinical Trial (SARA-PK)

We conducted a dose-escalating Phase 1 clinical trial (SARA-PK) to evaluate the safety, PK and PD effects of Sarconeos (BIO101) in 54 healthy adult and elderly subjects. Based on the results of the SARA-PK Phase 1 clinical trial, we have chosen 175 and 350 mg b.i.d. (twice daily) as the safe, active dosing levels for the SARA-INT Phase 2 clinical trial.

Single Ascending Dose. In the single ascending dose, or SAD, phase, subjects were dosed once with Sarconeos (BIO101) at a range between 100 to 1,400 mg or placebo. No abnormal clinical vital signs and/or serious adverse events were reported as treatment emergent adverse events, or TEAE. All TEAEs were mild in severity and were resolved by the end of the study. No serious adverse events, or SAEs, were reported in the SAD phase.

Multiple Ascending Dose. The multiple ascending dose, or MAD phase was conducted with three selected doses of Sarconeos (BIO101) that were orally administered to 30 patients in total broken into three groups of older adults between 65 and 85 years over 14 days. Each group consisted of eight active and two placebo per dose.



No abnormal clinical vital signs and/or adverse events were reported. Study results indicated that several patients experienced TEAEs, the most common were headache and nausea, with one participant reporting an event of food poisoning at the follow-up visit and dizziness postural (vertigo) and are described in the table below. All TEAEs were indicated as mild or moderate and were resolved by the end of the study. No SAEs associated with Sarconeos (BIO101) were reported in the MAD phase.

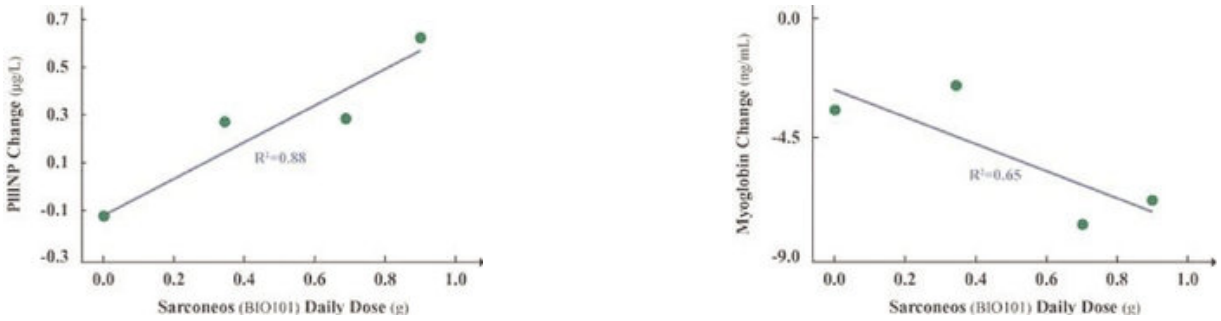
No. of treated subjects with TEAE

Dose	(Type of TEAE)	No. of placebo subjects with TEAE
350 mg q.d. (once daily)	2 subjects (mainly wound and pain in extremity).	3 subjects (mainly musculoskeletal and connective tissues (back pain, spasms and stiffness) and nervous system (dizziness and headache)).
350 mg b.i.d. (twice daily)	7 subjects (mainly gastrointestinal (constipation, diarrhea and bloating), and musculoskeletal and connective tissue (back pain, spasms and stiffness)).	
450 mg b.i.d. (twice daily)	8 subjects (mainly gastrointestinal (constipation, diarrhea and bloating), musculoskeletal and connective tissue disorders (back pain, spasms and stiffness) and nervous system (dizziness and headache)).	

The pharmacokinetic analysis showed a short half-life between 3 to 4 hours and that the steady state was reached from the second day of administration in the MAD phase. No accumulation of Sarconeos (BIO101) was observed at 350 mg q.d. in the MAD phase (accumulation ratio of 1.14); however, a small accumulation was observed at 350 and 450 mg b.i.d. in the MAD phase (accumulation ratio of 1.31). We determined the optimal dosing of 175 and 350 mg b.i.d. from a PK modeling study.

We also evaluated the effects of Sarconeos (BIO101) on PD markers. Results showed a tendency towards a decreased plasma level in muscle catabolism markers (myoglobin, creatine kinase) and in markers of the RAS (aldosterone and renin). This is consistent with the proposed mechanism-of-action of Sarconeos (BIO101) and is coherent with the activity of Sarconeos (BIO101) on the RAS.

As shown in the graphs below, Sarconeos (BIO101) treatment over 14 days showed (i) a dose-dependent effect on muscle growth and repair, as measured by plasma Procollagen type III N-terminal peptide (PIIINP), a common marker of muscle growth, repair and fibrosis, and (ii) a dose-dependent negative correlation of muscle wasting, as measured by plasma myoglobin, a common marker of muscle catabolism.



Effect of Sarconeos (BIO101) treatment for 14 days on the evolution of PD markers related to muscle anabolism (PIIINP) and to muscle catabolism (myoglobin)

Results from the SARA-PK Phase 1 clinical trial were released in April 2017 in an oral presentation at the International Conference on Frailty & Sarcopenia Research, in Barcelona, Spain. The results confirmed the dosing levels (175 and 350 mg b.i.d.) for the ongoing SARA-INT Phase 2 clinical trial.

Sarcopenia, our initial indication for Sarconeos (BIO101)

Sarcopenia is an age-related degeneration of skeletal muscle. It is a major cause of mobility disability in the elderly, characterized by a loss of muscle mass, strength, balance and the ability to stand and/or walk, resulting in a loss of independence, increased risk of adverse health events and hospitalization, and potential death resulting from falls, fractures, and physical disability. If approved by regulatory authorities for commercial use, we believe there is market potential for Sarconeos (BIO101) in sarcopenia, which is highly prevalent in the elderly with an estimated prevalence between six to 22% worldwide. There is currently no approved medication for sarcopenia.

Sarcopenia was first defined in 1989 and officially classified as a disease in 2016 based on the establishment of a code from the WHO's International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), used by physicians, researchers and health systems. There is currently no widely accepted standard of care for sarcopenia, however, to our knowledge, current non-medicinal treatment recommendations primarily focus on moderate physical activity, such as 30 minutes of walking per day or resistance-based (strength) training, as they exert effects on both the nervous and muscular systems that are critical to positive physiological and functional adaptations in older adults, and nutritional intervention. According to the International Clinical Practice Guidelines for Sarcopenia (ICFSR): Screening, Diagnosis and Management (Dent et al., *J Nutr Health Aging. 2018;22(10):1148-1161*) there is moderate certainty of evidence for the beneficial effects of physical therapy in treating patients with sarcopenia as most of the evidence for physical activity comes from studies of non-sarcopenic older adults or those with mild-moderate sarcopenia and large anecdotal effects. The efficacy of more structured physical activity programs along with certain supplementation (*i.e.* dietary protein intake and/ or nutrients) for the treatment of sarcopenia is being assessed in various studies, including the SPRINTT trial. However, no consensus on nutritional intervention currently exists.

Over the past two decades, other potential drug modalities have been tested in the clinic for sarcopenia, mainly myostatin inhibitors. However, these treatments have yet to demonstrate effectiveness on clinically meaningful outcomes (strength and mobility) and/or safety in larger clinical trials. Based on our review of publicly available information, we believe that Sarconeos (BIO101) is the only drug candidate currently being tested in late-stage Phase 2 or Phase 3 clinical trials for sarcopenia. Based on our understanding and discussions with regulatory agencies, including the FDA and EMA, functional mobility endpoints must be achieved in order to obtain marketing approval in sarcopenia.

Sarconeos (BIO101) for sarcopenia (the SARA program)

Phase 2 Clinical Trial (SARA-OBS and SARA-INT)

The SARA clinical program contains 2 studies:

- SARA-OBS was an observational study that recruited 218 participants, of whom 185 have completed the 6-months follow-up, between April 2017 and April 2019. This study was designed to characterize the target population of elderly patients (65 years old and above), who are at risk for mobility disability. This study was executed in 11 sites, in the United States, France, Italy and Belgium. The study was finalized and a preliminary analysis of the SARA-OBS study was presented at the 12th Annual Congress of SCWD in Berlin, Germany in December 2019. The first presentation of the final results was given at the virtual 13th annual congress of SCWD on December 12, 2020.

- SARA-INT is a global, double-blind, placebo-controlled study, with 233 participants, who receive Sarconeos (BIO101) at doses of 175 or 350 mg b.i.d. or placebo, for 6 months. This study is executed in 22 centers in the United States and Belgium. Recruitment was completed in March 2020 and despite impediments posed by the COVID-19 pandemic, such as the interruption of in-office study visits and other disruptions, we were able to retain most of the study participants. The last patient completed his final on-treatment visit in December 2020 and top-line results from this study are expected during the second quarter of 2021.

Inclusion criteria of the SARA Phase 2 program are based on a Short Performance Physical Battery, or SPPB, score 8 out of 12 (as an index of loss of motor function) and the Foundation for the National Institutes of Health guidelines, which are summarized in the table below:

Inclusion criteria	**Cutoff**
Age	65 years and above
SPPB score(1):	8 or lower
DEXA body composition(2)	Male: ALM/BMI(3) index <0.789 or an absolute ALM index <19.75 Females: ALM/BMI index <0.512 or an absolute ALM index <15.02
Physical activity	30 minutes / day

(1) The SPPB is an objective assessment tool for evaluating lower extremity functioning in older people. The SPPB summary score has three components (standing balance, 4-meter gait speed, and five-repetition sit-to-stand) with a possible range between 0 to 12.

(2) Dual energy x-ray absorptiometry, or DEXA, measures body composition.

(3) ALM means Appendicular (*i.e.*, upper or lower limbs) Lean Mass; and BMI means Body-Mass Index

(4) Trial participants are asked to try to exercise at least 30 minutes per day for 5 days out of every week. In order to monitor physical activity (mobility/disability), trial participants participating in the study will wear an actimeter (ADAMO Care Watch), developed by Italian company Caretek.

The primary endpoint of the study is gait-speed over the 400-meter walk test (400MWT), which represents a measure of the participant's mobility function. The key secondary endpoints are: (i) the chair-stand test, which is one of the mobility criteria that make up the SPPB test, (ii) the analysis of responders in the 400MWT, which are defined as those who improve more than 0.1 m/sec compared to baseline, and (iii) patient reported outcomes (PROs) as evaluated by the Short-form health survey (SF-36), including the Physical Function domain (PF-10) of the questionnaire.

SARA-OBS Study

Objectives and Study Design. The SARA-OBS study aims to characterize sarcopenia in patients over the age of 65 at risk of mobility disability. The mobility and physical performance of these participants, including body composition was evaluated over a six-month period. This observational phase included two visits, one at the baseline and one at the end of the study, supplemented by a telephone interview at three months to determine whether participants were complaining of a poor physical condition. The SARA-OBS study was designed and structured as a pre-selection for the SARA-INT Phase 2 clinical trial.

Participants could consent to enroll in the SARA-INT Phase 2 clinical trial at the end of the observation period but needed to be rescreened and reconsented prior to inclusion.

Results. Baseline characteristics of the 218 participants were presented in December 2018 at the Society on Sarcopenia, Cachexia and Wasting Disorders conference in Maastricht, Netherlands and the virtual 13th annual congress of SCWD on December 12, 2020 and are summarized in the table below. We believe these characteristics are consistent with other clinical trials of sarcopenia patients, including the SPRINTT and LIFE trials.

Age:	79.29
BMI:	29.3
SPPB:	6.12
Gait speed:	<0.8 m/s
6-minute walk test:	295.14 meters

The final results, on the main endpoints, for the 185 completers are:

	Baseline	M6	Change	P-value
400MWT	0.866	0.835	–0.027	0.064
SPPB score	6.562	7.078	0.439	0.439
6MWT	297.561	284.841	–16.655	0.006
Chair-stand	1.732	1.774	0.007	0.929
Handgrip	23.739	24.464	0.957	0.077

400MWT = 400-meters walk-test; SPPB score = Short-Performance Physical Battery; 6MWT = 6-minute walk-test; Chair-stand = the chair-stand component of the SPPB

SARA-INT Phase 2 Study:

Objectives and Endpoints. The objectives and endpoints of the study are summarized below:

Objectives:

- Evaluate the safety and effectiveness of two doses, 175 and 350 mg b.i.d. (twice daily) of Sarconeos (BIO101) administered orally with a meal for 26 weeks against a placebo in participants over 65 at risk of impaired mobility; and
- Measure treatment effect on improvement of physical function and on decrease of risk of mobility disability after six-month treatment.

Primary Endpoint:

- The change from baseline in the time it takes to complete 400MWT. A minimum clinically significant benefit is set at 0.05 meter per second in the mean difference between groups.

Key Secondary Endpoints:

- Change from baseline in the time it takes to rise from a chair, which is one of the mobility criteria that make up the SPPB test;
- 400MWT responder analysis;
- Change from baseline and responder analysis on standard patient reported outcome (PRO), including:
  - Short-form Health-survey (SF-36); and
  - Physical Function domain (PF-10) of the SF-36 questionnaire.

Other Secondary, Tertiary and Exploratory Endpoints:

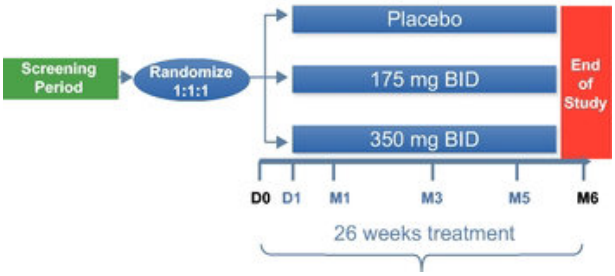
- Change from baseline 6-minute walk test;
- Change from baseline in ALM measured by DEXA body composition;
- Change in baseline in the total score of the SPPB test;
- Change from baseline in muscle strength of the upper and lower limbs (handgrip/knee extension);
- Change from baseline on the stair-power-climbing-test;
- Change from baseline in the sarcopenia quality-of-life (SarQOL) questionnaire;
- The rate of success in completing the 400MWT; and
- Plasma parameters including safety markers, biomarkers of the RAS (renin, aldosterone), inflammation (IL-6, CRP and hsCRP), and muscle metabolism (PIIINP, myoglobin, creatine kinase MM and creatine kinase MB).

In addition, two pre-defined subgroup analyses will be performed:

- a "very low walking speed subpopulation," defined as having a gait speed® 0.8 m/s in the 4-meter walk test, a component of the SPPB; and
- "subpopulation with sarcopenic obesity" defined by a body fat percentage of > 25% for men and > 35% for women.

These subpopulations represent sarcopenia patients that are at a significantly high-risk for deterioration and adverse outcomes. A treatment benefit in these populations will be of significant importance, to prevent further deterioration and reduce the risk for poor outcomes.

Trial Design: The trial design is summarized below:



Prospective participants will be screened for a period of up to eight weeks prior to inclusion in the trial. The interventional phase comprises of an inclusion visit (D0) where baseline measurements will be taken on the first day and dosing will start the following day (D1), a one-month safety visit (M1), a three-month follow-up visit (M3) with safety and reduced measurements in connection with the primary endpoint, a five-month telephone interview (M5), and a final six-month visit (M6) with safety and full measurements. Participants that exhibit poor physical function or deterioration of their physical function may be asked to bring the date of their next planned visit forward or go directly to the end-of-study visit.

In addition, we will conduct a population PK sub-study (SARA-POP-PK) to evaluate PK values after one month, three months and six months of administration in a subgroup of participants at certain European centers. This sub-study will allow us to determine the levels of exposure of participants during the various visits while evaluating the occurrence of adverse events related to the doses administered.

Clinical Centers. A total of 233 elderly patients with sarcopenia at risk of mobility disability were recruited in 22 clinical investigation centers in the United States and Belgium. Recruitment was completed in March 2020. During the first wave of the pandemic, clinical study sites were closed and we revised the protocols to continue our clinical trials. We informed the IRBs that oversee the clinical trials and received approvals for modifications resulting from COVID-19. Despite these and other impediments, we have been able to retain most of the participants. A total of 196 participants completed the SARA-INT study. The last patient completed his final on-treatment visit in December 2020 and top-line results from this study are expected during the second quarter of 2021.

Market Opportunity

Sarcopenia is a major cause of mobility disability in the elderly, resulting in a loss of independence, increased risk of adverse health events and hospitalization, and ultimately death. Sarcopenia is highly prevalent in adults greater than 65 years of age with an estimated prevalence between six to 22% worldwide. It poses a major public health issue and is steadily increasing as the global population ages. If approved by regulatory authorities for commercial use, we believe there is a market potential for Sarconeos (BIO101) in sarcopenia, as there is currently no approved medication for Sarcopenia and an unmet medical need for therapeutic treatments.

Over the past two decades, other companies have launched multiple clinical development programs to treat sarcopenia, primarily with drug candidates falling in one of two classes: (i) myostatin inhibitors and (ii) selective androgen receptor modulators, or SARMs. Myostatin inhibitors, which primarily aim to increase muscle mass by blocking myostatin (myostatin acts as an essential negative regulator of muscle bulk), have been found to increase muscle mass in early clinical trials. However, they have yet to demonstrate effectiveness on clinically meaningful mobility outcomes (strength and mobility) or safety in larger clinical trials and/or have not progressed through the clinic. Both steroidal and non-steroidal SARMs have been tested as therapeutic agents for several medical conditions, including muscle-wasting diseases, but none have progressed through clinical development mainly due to safety concerns. Based on our review of publicly available information, currently, neither myostatin inhibitors nor SARMs are being tested in late-stage clinical trials for sarcopenia. Based on our review of research in this area, we believe Sarconeos (BIO101) is currently the only drug candidate being tested in an interventional Phase 2 clinical trial for the treatment of sarcopenia and has the potential to improve the vital functional outcomes of mobility disability necessary for regulatory approval.

Sarconeos (BIO101) for treatment of severe respiratory manifestation of COVID-19

COVID-19 was first identified in Wuhan, in the Hubei Province in China, in December 2019. It was recognized as a worldwide pandemic by the WHO in March 2020. As of the date of this annual report, approximately 94 million people have been identified as having been infected with the SARS-CoV-2 virus, and more than 2.0 million have died because of COVID-19.

COVID-19 is caused by the SARS-CoV-2 virus. In its severe form, COVID-19 is associated with a plethora of complications, including:

- Acute pneumonia and ARDS;
- Cardiac injury, including myocarditis and pericarditis;
- Renal failure;
- Hepatitis;
- Vasculitis and thromboembolic events, leading to cardiac and cerebral strokes and pulmonary thromboembolism;
- Coagulopathy;
- Muscle injury; and
- Long-term symptoms such as fatigue, depressive symptoms and respiratory difficulties.

There are many ongoing clinical studies for COVID-19. A few anti-viral agents (including Veklury (remdesivir) and bamlanivimab (LY-CoV55)) have already received authorizations in the United States and the EU; in addition, certain anti-inflammatory agents, (including Il-6 antagonists and dexamethasone), have been shown to be effective in patients who are on a respirator. Moreover, a few vaccines have now been authorized around the globe; while many more remain in development. Age, co-morbidities, heavy smoking, male gender and several ethnic backgrounds are associated with worse outcomes.

Ample evidence points towards the membrane-bound ACE2, as the entryway of SARS-CoV-2, into the cells (in a manner similar to the previously described coronavirus-associated severe acute respiratory syndrome (SARS)). Data is emerging that in COVID-19 increased levels of Ang-II are observed and are linked to the severity of the clinical syndrome. Despite the difficulty in measuring Ang-1-7, some evidence has emerged, that the levels of these peptides are indeed decreased in COVID-19 as well.

While we do not yet have evidence of the benefit of Sarconeos (BIO101) in animal models of COVID-19, it is very plausible to hypothesize, that by activation of the MAS-receptor, Sarconeos (BIO101) could mitigate some of the downstream effects of the interaction between SARS-CoV-2 and ACE2. Indeed, studies that were conducted in a model of ALI have shown that 20-hydroxyecdysone can mitigate inflammation and reduce the levels of inflammatory markers. We are planning to conduct studies in animal models of COVID-19, in parallel with the COVA clinical program. These animal studies will be performed by University of Liège in Belgium.

SARS-CoV-2 infection, by down-regulation of ACE2 expression and activity, reduces the conversion of Ang-II to Ang-1-7 resulting in excessive levels of Ang-II. Indeed, Ang-II levels in COVID-19 patients are significantly higher than in non-infected individuals and, more importantly, are linearly associated with viral load and lung injury. Moreover, the plasma levels of Ang-1-7 are significantly lower in COVID-19 patients versus healthy controls and particularly between COVID-19 patients admitted to ICUs compared to those who are not. Because most of SARS-CoV-2 deleterious effects including inflammation, fibrosis, thrombosis, pulmonary damage, point towards an imbalance of the RAS, we strongly believe that acting on the protective arm of RAS via its MAS Receptor downstream of ACE2 could have a beneficial effect in COVID-19-infected patients and, therefore, improve ARDS outcome.

Market opportunity

We believe there is a market opportunity for Sarconeos (BIO101) for the treatment of respiratory failure in COVID-19. The pandemic spread around the world since its first identification in Wuhan (China), with approximately 117.3 million cases reported and more than 2.6 million global deaths as of the date of this annual report, including more than 25.8 million cases and more than 436,000 deaths in the United States, according to the WHO. The COVID-19 pandemic is a major public health issue, with a major impact on the economy of hundreds of countries. Only a minority of patients, elderly or with comorbidities are developing severe forms of COVID-19, requiring hospitalization, while the majority develop mild or no symptoms.

To our knowledge, although there are multiple initiatives to develop treatments, only one anti-viral drug Veklury (Remdesivir) and one anti-inflammatory drug (Dexamethasone) have shown enough convincing clinical evidence to be approved in Europe and in the United States, No treatment targeting specifically the stimulation of respiratory function in COVID-19 patient has been approved and Sarconeos (BIO101) has the potential to be the first drug of its class approved in this indication for emergency use.

It is not clear how long the COVID-19 pandemic will last and we are still analyzing the impact a vaccination will have when it becomes available. However, we expect that in the next few years the COVID-19 disease will follow a seasonal pattern.

Sarconeos (BIO101) for Duchenne Muscular Dystrophy (DMD)

DMD is a rare, genetic neuromuscular disease in male children and young adults, which is characterized by an accelerated degeneration of muscles and is responsible for a loss of mobility, respiratory failure and cardiomyopathy, leading to premature death. It is the most common form of muscular dystrophy in children, affecting approximately 2.8 out of 100,000 people worldwide (approximately 20,000 new cases annually worldwide), based on our estimates from publicly available information. DMD is caused by mutations in the dystrophin gene that result in the absence or very low levels of functional dystrophin, a cytoskeletal protein that protects muscle cells.

The absence of dystrophin in muscle severely weakens the structural and membrane stability of the muscle fibers. During normal muscle contraction and stretching the muscle fibers become damaged and eventually undergo necrosis (*i.e.*, cell death). In order to compensate for the increased necrosis, muscle tissue regeneration is accelerated. This process soon becomes exhausted and muscle degeneration accelerates as muscle fibers are replaced by fat and connective tissue (fibrosis), resulting in the loss of muscle strength and mobility. DMD evolves according to a very well understood progression with symptoms that are similar to those associated with accelerated aging across all stages. DMD progression can be summarized as follows:

- muscle damage characterized by loss of myofibers, inflammation, and fibrosis beginning at an early age;
- lower extremity muscle weakness and progressive loss of muscle function beginning in the first few years of life;
- decline of ambulation and respiratory function after the age of seven;
- total loss of ambulation where the use of a wheelchair is essential in the pre-teenage or early teenage years;
- progressive loss of upper extremity function during mid to late-teens; and
- respiratory and/or cardiac failure, resulting in death around the age of 30.

Our Clinical Development Plans of Sarconeos (BIO101) in DMD (the MYODA program)

We have developed a formulation that is suitable to treat children, especially with swallowing difficulties. We have weight-adjusted the dose range of Sarconeos (BIO101) that we aim to test in the pediatric patient population based on modeling of data from animal studies and the SARA-PK Phase 1 trial in healthy adult and elderly participants. The low end of the dose range is driven by efficacy studies and the upper end of the dose range is driven by safety margins (toxicology and Phase 1). At the low end of the dose range, differences caused by the variance in animal models (*i.e.*, specie, age and size) could affect efficacy between animals and humans (both adults and children). At the high end of the dose range, differences in body composition, absorption and metabolism between the age and patient segments could affect safety margins and tolerability. We do not have actual experimental safety PK, PD or efficacy data from clinical testing in a pediatric patient population comprised of developing children (2-12 years), adolescents (12-16 years) or young adults. However, the MYODA clinical study is designed to fill this gap, by testing a range of doses in a dose escalating manner to address these potential differences in safety and efficacy.

We have designed our MYODA clinical program to specifically address the following known challenges in DMD clinical development:

- *Currently, DMD programs are very lengthy* and may take up to 10 years to finalize. With such a high unmet-need and a situation where young children lose function and experience a much shorter life span, there is a need to utilize fast and robust designs and expedite the development process.

- *A very crowded space, with a lot of competing development programs, which are mostly focusing on ambulatory patients,* leading to difficulties in recruitment, while there is very little development that targets non-ambulatory patients—a disease state, where deterioration in respiratory function is becoming a leading cause for mortality.

We received feedback from the Committee for Medicinal Products for Human Use ("CHMP") in December 2018 on our trial design concepts and will continue to work in concert with the relevant regulatory agencies. In the "may proceed" letter from the FDA, the FDA noted that it had significant concerns with the design of the study, and that the results of the study, as originally designed to enroll ambulatory and non-ambulatory patients and measure muscle function deterioration through a composite score, would not be capable of providing interpretable data sufficient to support a marketing application. In its letter, the FDA recommended that we revise the study population and primary endpoint. We have incorporated the FDA's recommendations and revised the protocol to focus on non-ambulatory patients with signs of respiratory deterioration and changed the primary endpoint to respiratory function. The revised protocol will be submitted as an amendment to the FDA and other regulatory authorities for review.

The MYODA study is expected to recruit up to 200 participants, as follows:

Part	Objective	Design	Doses of BIO101	Number of participants
1	To evaluate the safety, tolerability and PK profile of BIO101 and its main metabolites after a single dose (Day 1) and after multiple doses at Day 7, 14 and 56	Double-blind, placebo-controlled, ascending dose-cohorts	1.25, 2.5 and 5mg/kg, placebo	3 cohorts, 6 participants in each cohort
2	To evaluate the safety, tolerability, and efficacy on respiratory function, of BIO101 following 48 weeks double blind dosing, in a small population	Double-blind, placebo-controlled, parallel groups	5mg, placebo	An addition of 30 participants
3	To evaluate the safety, tolerability, and efficacy on respiratory function of BIO101 following 48 weeks double blind dosing, in a large population	Double-blind, placebo-controlled, parallel groups	5mg, placebo	An addition of participants, up to 200 in total

All the study participants will be treated for 48 weeks, followed by an open-label extension. Participants who are recruited during Part 1, to the lower dose cohorts, will be moved to a higher dose, once it is cleared to be used. An independent committee, will oversee the study, will review the safety data and allow moving from one dose cohort to the next and will conduct IAs to allow progression from one part of the study to the next.

Because of the high unmet need, we have decided to focus, at this stage, on DMD patients who are non-ambulatory and with evidence of respiratory deterioration. The primary endpoint will be Change from Baseline in Percent Predicted Peak Expiratory Flow (PEF % predictive) at Week 48 (assessed by hospital-based spirometry measurements) and the key secondary endpoint is Change from Baseline in Forced Vital Capacity (FVC % predictive) at Week 48 (assessed by hospital-based spirometry measurements). Additional endpoints include other measures of respiratory function, functional scales, muscle strength and goal-attainment.

Our study design and clinical trial protocols are subject to regulatory approval and will be submitted to regulatory agencies for review. We plan to work with the agencies to finalize the protocols. Additional challenges and risks remain with our innovative clinical trial program, including:

- *Challenges in achieving regulatory approval in each country for the MYODA clinical trial.* We received feedback from the CHMP in December 2018 on our trial design concepts and will continue to work in concert with the relevant regulatory agencies. However, the trial protocol and applications are not yet finalized and may be subject to further regulatory review, comments and changes prior to approval, if at all, at this stage, we have received approval to proceed from 2 countries: United States and Belgium. We will be seeking additional approval from other agencies.

- *Challenges in pediatric dosing of Sarconeos (BIO101).* We have modeled a weight-adjusted dosing regimen to treat children and young adults with Sarconeos (BIO101) based on data from animal studies and safety and PK observations from the SARA-PK Phase 1 trial in healthy adult and elderly volunteers.

Market Opportunity

We believe that there is market potential for Sarconeos (BIO101) in DMD, if approved by regulatory authorities for commercial use. DMD is the most common form of genetic muscular dystrophy in children, affecting approximately 2.8 out of 100,000 people worldwide (approximately 20,000 new cases annually worldwide), based on our estimates from publicly available information, resulting in premature death. In many countries, corticosteroids are the standard drug therapy. However, corticosteroids typically only slow the progression of muscle weakness and delay the loss of ambulation by up to two years. They have also been associated with adverse side effects and are generally not suitable for long-term administration.

DMD is caused by mutations in the dystrophin gene that result in the absence of very low levels of functional dystrophin, a cytoskeletal protein that protects muscle cells. Other therapeutic approaches aim to restore the expression of the dystrophin gene and thus restore protein function through exon-skipping. Currently, there are three marketed targeted treatments that can address approximate 20% of the overall DMD patient population globally with those genetic mutations.

In addition to these targeted therapies, gene therapies that are under development aim to introduce a gene coding for a truncated dystrophin protein that could limit immune reactions. These therapies typically suffer from low transfection rates resulting in low levels of dystrophin expression and potential severe immune reactions. This leaves room for combinations of genetic treatments with other disease modifying agents, regardless of the mutation. Additional approaches in development include: immune modulators, anti-fibrotic agents and agents that enhance muscle mass and function. We believe that Sarconeos (BIO101) directly targets muscle tissue and cells, may increase key muscle cell functions that are impaired independent of the genetic mutation that causes the disease, and has the potential to be used complementarily with corticosteroids, current targeted therapies and other gene therapies under development. We also believe that because Sarconeos (BIO101) targets various impaired muscle tissues and cells relevant to muscle strength, mobility and respiratory function, it may have the potential to be used in all stages of DMD progression, including both ambulatory and non-ambulatory patients. At this stage, we will focus on non-ambulatory patients with signs of respiratory deterioration.

Sarconeos (BIO101) for COVID-19 (The COVA program)

The COVA study is a global, multicenter, double-blind, placebo-controlled, group-sequential, and adaptive two-part Phase 2-3 study, testing the benefit of Sarconeos (BIO101) in patients 45 years old and older with severe respiratory manifestations of COVID-19. This study is intended to study Sarconeos (BIO101)'s effectiveness in hospitalized patients with severe respiratory manifestation. There will be 310 participants recruited for this study, as follows:

Part	Goal	Number of participants
1	Allow recruitment into Part 2, based on safety data. Obtain indication of activity of BIO101, about the effect of BIO101 in preventing further respiratory deterioration.	50 1:1 randomization
2	Re-assessment of the sample size for Part 2.	155 (an addition of 105 participants) 1:1 randomization
	Confirmation of the effect of BIO101 in preventing further respiratory deterioration and obtaining a conditional marketing authorization.	310, potentially increased by 50% (up to 465, based on interim analysis 2) 1:1 randomization

During the study parts, two IAs will be conducted by an independent DMC:

- IA1, on the data from the intervention period (28 days or until reaching the study endpoint, whatever comes first), of the 50 participants of Part 1:
    - To analyze the safety and tolerability of Sarconeos (BIO1010) in the target population and begin recruitment into Part 2; and
    - To obtain early evidence of activity of Sarconeos (BIO101)—the outcome of this will be disclosed only if there is a need to do so, in the interest of public health and based on consultation with the regulatory authorities.
- IA2, on the data from the intervention period, in half of the original sample size (i.e. the 50 participants of Part 1 and an addition or 105 participants from Part 2), to re-assess the final sample size of the study, based on the efficacy data. The sample size can be increased according to this analysis by up to 50%, to 465 participants in both parts.

The primary endpoint of the COVA study is: the proportion of participants with "negative" events (*i.e.* all-cause mortality and respiratory failure). The key secondary endpoint is: the proportion of participants with a "positive" event, i.e. discharge home due to improvement. Additional endpoints include: the proportion of all-cause mortality, time to events, function scales and biomarkers.

We have received an IND "may proceed" letter from the FDA (in the United States) and a CTA approval from ANVISA (Brazil), ANSM (France), MHRA (UK) and FAMHP (Belgium). A total of 17 centers are now actively recruiting in Belgium, Brazil, France and the United States among a targeted number of around 30 to be opened for the second part of the COVA study. Recruitment started in July 2020, and the following milestones are projected, subject to the overall development of the COVID-19 pandemic:

- Enrollment for Part 1 completed on: January 21, 2021
- Enrollment for Part 2 to be completed: Q1 2021
- Final results and submission to obtain EUA in the United States and conditional marketing authorization in Europe: Q2 2021.

On January 8, 2021, the independent DMC of COVA reviewed the safety data analysis from the first 20 patients who were enrolled in the study, and recommended beginning recruitment for Part 2 of COVA. Following the DMC's recommendation to begin the recruitment for Part 2 of COVA, authorization was obtained from the applicable regulatory authorities (national regulatory agencies and/or central IRB and/or local Ethics Committees) in Brazil and the United States for most clinical centers in the two countries for the start of Part 2. Similar authorizations to begin Part 2 of COVA were subsequently obtained from the applicable regulatory authorities in France and in Belgium. Enrollment for Part 1 was completed on January 21, 2021. Enrollment for Part 2 of the study is expected to be completed in the first quarter of 2021.

MACUNEOS (BIO201)

Our second drug candidate, Macuneos (BIO201), is an orally administered small molecule in development for the treatment of retinopathies. The initial indication we plan to seek approval for is dry AMD, followed by Stargardt disease.

History and Development of Macuneos (BIO201)

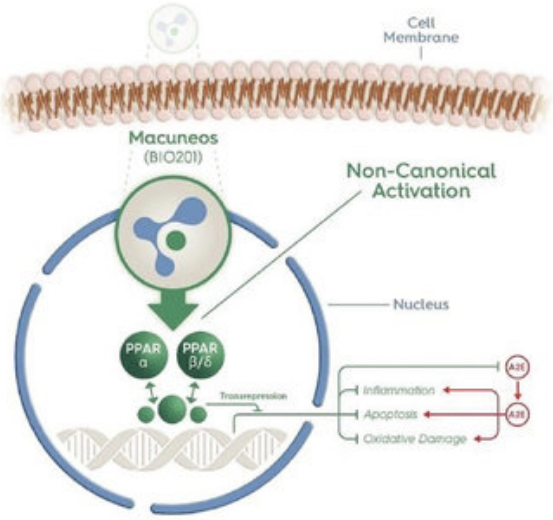
Utilizing our expertise in functional screens and assays, we expanded our drug discovery efforts to other age-related diseases, with a focus on retinopathies. Using cellular models developed with the Institute of Vision at Sorbonne University in Paris, we screened a variety of carotenoids and flavonoids for their ability to protect retinal pigment epithelium, or RPE, cells against the photo-oxidative stress induced by blue light in the presence of A2E, a phototoxic byproduct of the visual pigment cycle. We selected norbixin (an apo-carotenoid) for clinical development based on its pharmacological properties and safety profile in animal models of AMD and Stargardt disease. Next, we identified its molecular target(s) and identified a potential mechanism-of-action.

Potential mechanism-of-action

Inhibition of PPARs

Results from our preclinical studies support continued research to investigate whether Macuneos (BIO201) may protect RPE cells against the photo-oxidative stress induced by blue light in the presence of A2E through transrepression of peroxisome proliferator-activated receptors, or PPARs. PPARs are nuclear receptors which primarily regulates carbohydrate and lipid metabolism in regenerative tissues only, and inflammatory processes in neuronal tissues, such as the brain or retina. Based on the result from our preclinical studies, we believe that Macuneos (BIO201) potentially counteracts the phototoxic effects of A2E by inhibition of PPARα and PPARγ responsible for the anti-oxidative, anti-inflammatory and anti-apoptotic activity observed in the retina. We believe that the mode of action, or MOA, of BIO201 differs from the MOA of most PPAR activators that are typically associated with known side effects.

The potential mechanism-of-action of BIO201 is illustrated in the diagram on the below:



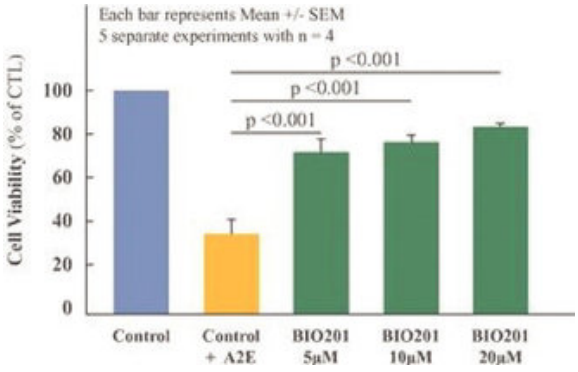
Macuneos (BIO201) is an antagonist of PPAR, involved in protecting retinal cells

Preclinical Development

Proof of concept in cellular models

In collaboration with the Institute of Vision, we used models of primary porcine RPE cell cultures to test the effect of Macuneos (BIO201). We believe this model best preserves functional defense mechanisms against photo-oxidative stress and better represents functioning human RPE cells as compared to existing stable cell lines. We exposed these RPE cells to blue light in the presence of A2E in order to explore the protective effect of Macuneos (BIO201) on RPE cell death.

Increased cell survival. Our preclinical data indicate that Macuneos (BIO201) may protect RPE cells from cell death, in a dose-dependent manner, against the photo-oxidative stress induced by blue light in the presence of A2E. These results were presented in 2016 at the annual meeting of the Association for Research in Vision and Ophthalmology, or ARVO, in Seattle, Washington, and published in *PLoSONE* (Fontaine et al; 2016).

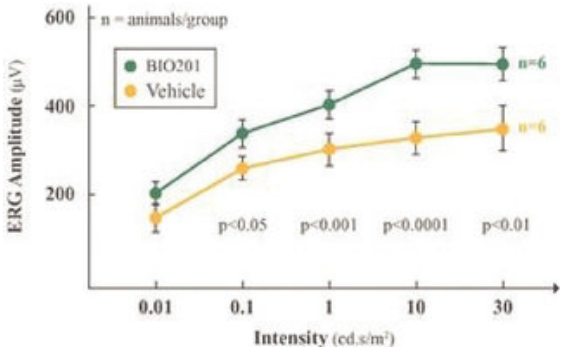


Effect of Macuneos (BIO201) on survival of RPE cells.

Proof of concept in animal models

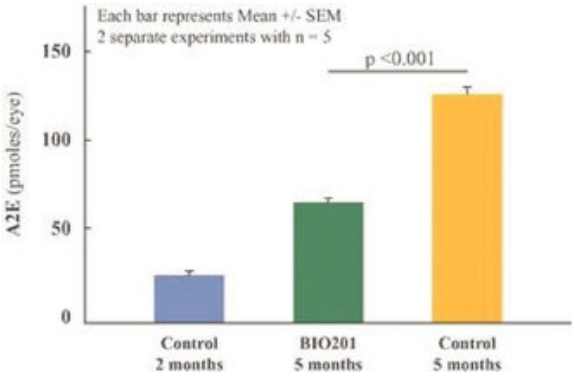
We have observed that Macuneos (BIO201) protects the retina after both oral and intra-vitreal administration in various animal models of AMD and Stargardt disease. The results from the studies, which are summarized below, were presented in 2016 at the annual meeting of the ARVO in Seattle, Washington.

Preservation of visual function in mice. We studied mice in which two genes encoding the proteins involved in the visual pigment cycle (the Abca4 transporter and the retinol dehydrogenase Rdh8) were absent. These animals, called Abca4-/- Rdh8-/-mice, accumulated A2E in their eyes and showed an early loss of electroretinogram amplitude. Our preclinical data suggest that chronic oral administration of Macuneos (BIO201) for three and six months may be effective in protecting the retina, as measured by electroretinography. This is a commonly used way to measure retinal function by looking at the electric signal transport from the retina to the brain. As shown in the figure below, Macuneos (BIO201) treated mice showed a less degraded electroretinogram as compared to the untreated control mice, meaning the treated mice have slower visual function loss. The six-month results were presented in 2018 at the annual meeting of the ARVO in Honolulu, Hawaii and recently published (Fontaine *et al*. *Aging*, 2020).



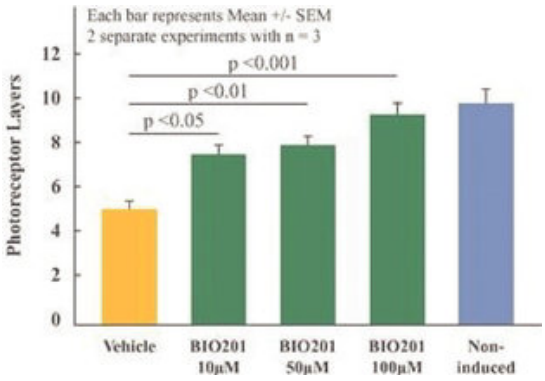
Effects of chronic oral administration of Macuneos (BIO201) on ERG Amplitude in Abca4[ib]-/[ib]- Rdh8[ib]-/[ib]-mice.

Reduced A2E Accumulation in mice. We studied the effect of Macuneos (BIO201) treatment on the accumulation of A2E in the retina of Abca4-/- Rdh8-/- mice. We began a three-month dosing regimen starting on mice that were 2 months of age. We observed that there was significant accumulation of A2E in vehicle Abca4-/- Rdh8-/-mice treated with placebo over three months as compared to control wild type mice at the beginning of the study, confirming a dysfunction of the visual cycle. Results demonstrated that chronic oral administration of Macuneos (BIO201) reduced A2E accumulation in the retina in treated Abca4-/- Rdh8-/-mice by approximately 45% as compared to vehicle control mice, which we believe is a key factor for maintaining visual function (Fontaine *et al*. *PloSOne* 2016).



Effects of chronic oral administration of Macuneos (BIO201) on A2E accumulation in Abca4-/—Rdh8-/—mice.

Dose-dependent protection of retina integrity in rats. In the classical blue light damage (BLD) rat model using normal albino rats, we observed that intra-peritoneal administration of Macuneos (BIO201) protected the retina in a dose-dependent manner, as measured by the number of remaining layers of photoreceptors. We demonstrated that there was an approximate 90% increase in the number of photoreceptors layers following the maximum dose of 100 µM of Macuneos (BIO201) as compared to the vehicle control. The results were published in *PLoSONE* (Fontaine *et al*. 2016).



Number of layers of photoreceptors in the blue light damage rat model after intraperitoneal injection of Macuneos (BIO201).

Based on this body of work, we believe that Macuneos (BIO201) may have significant clinical potential for the treatment of retinopathies, including dry AMD and Stargardt disease, and warrants continued investigation.

AMD

AMD is one of the leading causes of irreversible vision loss and blindness in the people over the age of 50 worldwide, according to the BrightFocus Foundation's Age-Related Macular Degeneration:

Facts & Figures Fact Sheet. AMD affects the central part of the retina, known as the macula, which is responsible for central vision and its sharpness. There are two types of AMD:

- Dry AMD is a multistage process leading to the progressive loss of vision. Early-stage dry AMD is characterized by small drüsen accumulation, which may not cause changes in vision, but as drüsen grow in size and increase in number, they may lead to a dimming or distortion of vision that people find most noticeable when they read. Intermediate stage dry AMD is defined by more abundant and larger drüsen and the appearance of early atrophies. Patients at this stage are at high-risk of advancing into geographic atrophy, or GA, a late stage form of AMD. Patients in the late stage of AMD may have blind spots in the center of their vision and may lose central vision.

- Wet AMD is a late stage form of AMD, which is characterized by abnormal growth of blood vessels from the choroid underneath the macula. This is called choroidal neovascularization. These blood vessels leak blood and fluid into the retina, causing distortion of vision that makes straight lines look wavy, as well as blind spots and loss of central vision. These abnormal blood vessels and their bleeding eventually form a scar, leading to permanent loss of central vision.

Approximately 85 to 90% of patients with AMD suffer from dry AMD. We believe that photo-oxidative and inflammatory stresses induced by the accumulation of A2E in RPE cells are the main factors responsible for the degenerative process of the retina in diseases such as AMD. We believe the biggest opportunity in treating dry AMD is preventing advancement into the later stages, GA or wet AMD, where vision loss is severe and can lead to visual disability.

Clinical Development Plans

We are currently conducting chronic and acute rodent and non-rodent toxicology studies that we believe will be sufficient to support our IND and clinical trial applications for our MACA clinical development program. We plan to commence a Phase 1 clinical trial (MACA-PK) in healthy volunteers to assess the safety, PK and PD of Macuneos (BIO201) in the second-half of 2021, subject to regulatory review and approval, which is pending, any COVID-19-related delays and the impact of the pandemic on our operational capabilities.

Market Opportunity

We believe that there is market potential for Macuneos (BIO201) in dry AMD, if approved by regulatory authorities for commercial use. AMD is one of the leading causes of irreversible vision loss and blindness in people over the age of 50 worldwide, and its prevalence increases with advancing age. Based on our review of publicly available data and to our knowledge, there is currently no approved medication for dry AMD, which represents between 85 to 90% of all AMD cases according to the American Macular Degeneration Foundation, and, based on our estimates from publicly available information, affects approximately 145 million people worldwide, and is expected to increase over time as the population ages.

There are a number of companies currently developing treatments for dry AMD, including anti-complement or neuroprotective agents that may treat or alter the progression of the disease. We believe the market for AMD will remain fragmented and will include stand-alone and combination treatments for all stages of the disease. We will continue to study Macuneos (BIO201) to determine its clinical safety and effectiveness, and to explore the feasibility of oral administration, and to further explain its mode of action.

Preclinical and Discovery Pipeline

Our preclinical pipeline currently consists of Macuneos (BIO201), as well as BIO103 and BIO203, which are chemically synthesized life-cycle extension products for Sarconeos (BIO101) and Macuneos (BIO201), respectively. We are testing these preclinical drug candidates in preclinical models for multiple age-related diseases. We plan to continue to identify new drug candidates through our drug discovery platform based on our functional assays and reverse pharmacology approach.

Competition

The biotechnology and pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our expertise in age-related diseases, scientific knowledge and intellectual property portfolio provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Not only must we compete with other companies that are focused on neuromuscular diseases and retinopathies, but any drug candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, tolerability, convenience, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA, EMA or other national regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

The main competitors for each target indication of our drug candidates include:

- ***Sarcopenia:*** We are not currently aware of any approved medications for sarcopenia. Pharmaceutical development of myostatin inhibitors and SARM have been halted, due to lack of evidence of benefit in multiple Phase 2 studies. Therapy development focuses mostly on exercise (including devices that can improve physical function), food supplements and dietary measures. Early stage development of cell therapy and agents that aim to improve muscle function has also started, but these have not yet reached human studies.

- ***COVID-19:*** There are many ongoing clinical studies for COVID-19. A few anti-viral agents (including Veklury (remdesivir) and bamlanivimab (LY-CoV55)) have already received authorizations in the United States and the EU; in addition, certain anti-inflammatory agents (including Il-6 antagonists and dexamethasone) have been shown to be effective in patients who are on a respirator. Moreover, a few vaccines have have now been authorized around the globe; while many more remain in development.

- ***Duchenne Muscular Dystrophy:*** Corticosteroids are the standard drug therapy for DMD patients in many countries throughout the world, this includes Emflaza (deflazacort, by PTC therapeutics), which was approved by the FDA in 2017, however their benefit for non-ambulatory patients with evidence of respiratory deterioration is limited. To our knowledge, three targeted therapies have been approved to date, which all are treatments that target the genetic mutation: Exondys51 (eteplirsen, by Sarepta), Vyondys53 (golodirsen, by Sarepta) and Amondys 45 (casimersen, by Sarepta) in the United States, and Translarna (ataluren, by PTC therapeutics) in Europe. While many new therapies are in development, most focus on ambulatory children. Only very few candidates, and in early stages, are being developed to treat patients who are non-ambulatory and with signs of respiratory deterioration.

- ***Dry Age-Related Macular Degeneration:*** Based on our review of research in this area, currently there are no approved therapeutic treatments for dry AMD. We believe that a number of other companies are developing drugs that may treat or alter the progression of the disease. Such competitors include, but are not limited to Allegro Ophthalmics, Apellis Pharmaceuticals, Astellas, Hemera Biosciences, Ionis Pharmaceuticals, Ophthotech Corporation, Roche and Stealth Biotherapeutics.

Manufacturing and Supply

We do not own or operate, and currently have no plans to establish any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for both preclinical studies and all phases of clinical trials, as well as for commercial manufacture if any of our drug candidates receive marketing approval for commercialization. We obtain key raw materials for Sarconeos (BIO101) and Macuneos (BIO201) from third-party suppliers. We are developing at the pilot scale the manufacturing processes and transfer them through agreements to third parties European and American Clinical Development Manufacturing Organization (CDMO). Batches that do not meet GMP and those that do meet GMP are produced in compliance with regulations for preclinical and clinical studies, including in view of the relevant guidelines adopted by the EMA and other regulatory authorities regarding the COVID-19 context. These batches allowed us to conduct all of our clinical programs. We plan to sign agreements with the same or alternative manufacturers for industrial scale-up to submit the regulatory applications for approval and market access, subject to the global COVID-19 pandemic conditions and the impact of the current pandemic on operational capabilities. We currently have sufficient quantity to conduct the planned clinical trials for Sarconeos (BIO101) for SARA-INT Phase 2, COVA Phase 2/3, and the two first parts of the MYODA clinical trial.

Sarconeos (BIO101)

BIO101, the API, of Sarconeos is a pharmaceutical grade small molecule, 20-hydroxyecdysone (>97% purity of the active molecule). We have produced the API for preclinical and clinical development by purifying the active molecule from *Cyanotis* sp *or Stemmacantha* sp, plants cultivated in China and used for medicinal purposes in Traditional Chinese Medicine. We currently rely on one supplier for the quantities of material required for all our studies. We have not entered into a long-term supply agreement with this supplier for commercial scale up. BIO101 is purified for pharmaceutical use (>97% purity of the active molecule) using proprietary and patented processes, in compliance with GMP for pharmaceuticals, by Patheon/ThermoFisher Scientific our manufacturing partner located in Germany. We have not entered into a long-term supply agreement with Patheon. However, we believe that the supply chain we have developed over the last five years has been sufficiently scaled up, and we have already secured sufficient quantities to conduct the planned clinical trials for Sarconeos (BIO101) for SARA-INT Phase 2, COVA Phase 2/3, and the first two parts of the MYODA clinical trial.

We believe we can secure sufficient quantities for regulatory approval and marketing authorization for Sarconeos BIO101 in COVID-19, using our current supply chain, by scaling up the production to industrial level capacity and GMP standards, subject to the impact of the current pandemic on operational capabilities. Depending on positive results of the clinical program, we will have to address significant upscaling of sourcing and manufacturing to support any commercial launch.

We are also evaluating alternative methods for producing Sarconeos (BIO101), such as new chemical synthesis or fermentation, and potential alternative plant sources, in order to optimize the supply chain to support our projected commercial needs.

Macuneos (BIO201)

BIO201, the API of Macuneos, is a pharmaceutical grade small molecule norbixin (>97% purity of the active molecule). We have produced the API for preclinical development by chemical conversion into norbixin of the natural molecule bixin, which has been previously purified from seeds of *Bixa orellana L.*, a plant traditionally used for medicinal purposes in the Amazon. At this time, we rely on one supplier for the plant quantities we will require for our MACA clinical program. We have not entered into a long-term supply agreement with this supplier. The pharmaceutical development of Macuneos (BIO201) is performed by Patheon using proprietary processes. The development of the manufacturing process, the production of the technical batches, the validation of analytical methods, as well as the stability studies are currently being planned for 2021 to produce the clinical batches of Macuneos (BIO201) for the MACA-PK Phase 1 clinical trial. We are evaluating alternative methods for producing Macuneos (BIO201), such as bio fermentation, in order to optimize the supply chain to support our projected commercial needs.

Research and Collaboration Agreements with Sorbonne University and Other Academic Research Institutions

We have entered into several research and collaboration agreements with Sorbonne University and other academic research institutions (*i.e*., the Centre National de la Recherche Scientifique (CNRS), the Institut National de la Recherche Agronomique, or INRA, Institut National de la Santé et de la Recherche Médicale, or INSERM, and Université Paris Descartes) in order to further strengthen our research and development strategies. The purpose of these agreements is to define the terms and conditions of our research (including its financing) and the results of such research. As of the date of this annual report, three research and collaboration agreements are still in force.

The research and collaboration agreements were entered into for an initial fixed term (six to 12 months), and have each been extended by amendments as long as research is ongoing. The agreements may be terminated by any party to the agreement in the event of a breach by another party that has not been remedied within one month of a notice of the breach.

Pursuant to the terms of the research and collaboration agreements, each of the parties to the agreements remains the owner of intellectual property it owned prior to the time of the agreement, and all parties will have equal ownership of any patents resulting from the research conducted pursuant to such agreements. The parties must jointly agree as to whether the results of research conducted pursuant to the agreement should give rise to the filing of a patent application. In the event that one party does not wish to file a patent application but another party does and agrees to bear alone the cost of such filing, it will have the right to do so and the party who declined to pursue registration of the patent will be required to assign its co-ownership interest of the patent and patent applications to the other party at no charge. For any patent application that is filed, we are responsible for managing the patent application and all intellectual property registrations in France or abroad. In the event that a party desires to assign its co-ownership interest in a patent (except in the event of an assignment between Sorbonne University and CNRS or to one of the inventors within the team dedicated to the research), the other parties to the agreement will have a preemptive right to acquire such party's co-ownership interest. We have an option to obtain exclusive commercial rights with respect to any products developed through the parties' research pursuant to the terms of the collaboration agreements (whether patentable or not), which the Company exercised regarding patent families S1 through S7 and patent families MI through MIV and still is in a position to exercise regarding ongoing researches and other patent families. The parties may use the results of research conducted pursuant to the agreements for other research purposes, subject to informing the other parties to the agreement if such research is to be carried out in collaboration with third parties.

Pursuant to the terms of the research and collaboration agreements, once a patent is filed, the parties to such agreement enter into (i) a co-ownership agreement providing for the respective rights and obligations of the co-owners of the patents, and (ii) a commercialization/license agreement providing for our right to commercialize products based on the patents in consideration for the payment of royalties to Sorbonne University and/or the other French academic research institutions involved, as applicable, the terms of which will supersede the collaboration agreement. Until these agreements are entered into, the provisions of the collaboration agreements will continue to govern ownership of the results and the rights to commercialize any products developed through such collaborations.

As of the date of this annual report, we have a research and collaboration agreement with Sorbonne University, CNRS and INSERM "(supervisory entities of the Institut de la Vision)" dated March 2, 2020, relating to AMD for which research is currently ongoing. Our research and collaboration agreement with Sorbonne University and CNRS dated July 1, 2016, as amended on March 22, 2017, which previously governed co-ownership of patent family S6, expired when a co-ownership agreement relating to patent family S6 was entered into on October 9, 2019.

We have a research and collaboration agreement with Sorbonne University and CNRS dated February 1, 2019 (as amended) relating to heart failure associated with DMD for which research is currently ongoing.

We also have a research and collaboration agreement with Université Paris Descartes and SATT Ile de France Innov relating to spinal muscular atrophy for which research is currently ongoing.

Intellectual Property

We seek to protect and enhance proprietary technology, investments, and improvements that are commercially important to our business by seeking, maintaining and defending patent rights. We also seek to and will continue to rely on regulatory protection afforded through orphan drug designations, data exclusivity, market exclusivity and patent term extensions where available.

Our industrial property protection policy covers our two key fields of innovation: (i) Sarconeos (BIO101) and our life-cycle extension drug candidate, BIO103, for the treatment of neuromuscular disorders, including sarcopenia spinal muscular atrophy (SMA) and DMD, respiratory function impairment resulting from a viral infection and (ii) Macuneos (BIO201) and our life-cycle extension drug candidate, BIO203, for the treatment of retinopathies, including dry AMD.

Current Intellectual Property Portfolio

Our patent portfolio covers 15 patent families, which include a total of 40 co-owned issued patents and a total of 36 co-owned patent applications. We have recently filed other patent applications which are currently under examination.

The issued patents in our portfolio consist of nine European patents, five U.S. patents, and 26 patents in other jurisdictions, including France, Australia, Brazil, China, Japan and Russia.

The pending patent applications in our portfolio consist of two European patent applications, five U.S. patent applications, and 29 patent applications pending in other jurisdictions, including France, Australia, Brazil, Canada, China, India, Japan, Mexico, Russia and South Korea.

Our patents and patent applications are all jointly owned by us and Sorbonne, and in some cases together with other academic research institutions (*i.e.*, CNRS, INRA and INSERM). We hold exclusive commercial rights through licenses of each of our drug candidates.

Our drug candidates rely upon one or more patent rights protecting various technologies, including rights related to:

- the use of phytoecdysones in the preparation of a composition to act on metabolic syndrome (Patent family No. S1 "*metabolic syndrome*");
- the use of phytoecdysones in stabilizing weight in overweight or obese subjects after dieting (Patent family No. S2 "*weight stabilization*");
- the use of phytoecdysones to improve muscular quality in obese and/or sarcopenic mammals (Patent family No. S3 "*muscular quality*");
- a process whereby new chemical entities are used in the preparation of medicines (Patent family No. S4 "*phytoecdysone analogue*");
- a process for extracting purified 20-hydroxyecdysone and the therapeutic use of these extracts to improve muscle function or treat cardiovascular disease (Patent family No. S5 "*20-hydroxyecdysone; extracts*");
- the use of 20-hydroxyecdysone components and their derivatives to treat myopathies and other muscular dystrophies (Patent family No. S6 "*20-hydroxyecdysone*");
- the use of phytoecdysones to prevent loss of muscular strength after immobilization (Patent family No. S7 "*Loss of muscle strength*");
- the use of phytoecdysones in a treatment of neuromuscular disease (Patent family No. S8 "*Phytoecdysones in neuromuscular diseases*");
- the use of phytoecdysones in a treatment of impaired respiratory function (Patent family No. S9 "*Phytoecdysones in respiratory diseases*);
- the use of a composition of bixin and norbixin to protect the skin against sun damage (Patent family No. MI "*Photo-protection*");
- the use of bixin and norbixin compounds to protect the eye against AMD (Patent family No. MII "*AMD*");
- the use of a composition using norbixin in the treatment of AMD (Patent family No. MIII "*Composition for protecting retinal epithelial cells*"); and

- the use of compounds from the family of flavonoids and anthocyanidins for the treatment, prevention and/or stabilization of AMD and/or Stargardt's disease, pigmentary retinopathy and/or diabetic retinopathy (Patent family MIV "*Use of 3-deoxyanthocyanidins for the treatment of eye diseases*").

Individual patent terms extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. In most countries in which we file patent applications, including the United States, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In certain instances, a patent term can be extended under certain circumstances.

For example, in the United States, the term of a patent that covers an FDA-approved drug may be eligible for a patent term restoration of up to five years to effectively compensate for the patent term lost during the FDA regulatory review process, subject to several limitations discussed below under "Our Intellectual Property Strategy." Also, in the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. Similar term extension mechanism may apply for patents filed with the Office Européen des Brevets (European patent office).

Our issued patents and patent applications (if issued) will expire as follows (unless extended):

Patent family No. S1:

- Patent No. FR2924346 expires November 30, 2027.
- Patent Nos. AU2008332981, CN102231986, BRPI0820455-1, EP2217255, RU2010126625 and US8236359 expire November 19, 2028.

Patent family No. S2:

- Patent No. FR2982489 expires November 10, 2031.
- Patent Nos. CN103957727, EP2775859, JP6346094 and JP6462918 expire November 12, 2032.

Patent family No. S3:

- Patent No. FR2983733 expires December 13, 2031.
- Patent No. EP2790706 expires December 13, 2032.

Patent family No. S4:

- Patent No. FR3021318 expires May 20, 2034.
- Patent Nos. AU2015263121, CN106536539, EP3145942, JP6621217, RU2724329, US9938315 and US10316056 expire May 20, 2035.

Patent family No. S5:

- Patent No. FR3065644 expires April 28, 2037.

Patent family No. S6:

- Patent No. FR3065642 expires August 31, 2037.

Patent family No. S7:

- Patent No. FR3078252 expires February 28, 2038.

Patent family No. S8:

- Patent No. FR3093640 expires March 15, 2039.

Patent family No. S9:

- Patent No. FR3093641 expires March 15, 2039.

Patent family No. MI

- Patent Nos. FR2947173 and FR2955767 expire June 25, 2029
- Patent Nos. BR1010113-6, EP2445476 and US9173823 expire June 25, 2030

Patent family No. MII

- Patent Nos. FR2975008 and FR2996773 expire May 13, 2031.
- Patent Nos. EP2717891, JP6421306, and JP6432913 expire May 14, 2032.

Patent family No. MIII

- Patent No. FR3035589 expires April 30, 2035.
- Patent Nos. EP3288551, JP6660401, MX/a/2017/013918, RU2715889 and US10314804 expire April 28, 2036.

Patent family No. MIV

- Patent No. FR1554761 expires May 27, 2035.
- Patent Nos. EP33302463, JP6738412, RU2730854 and US10513503 expire May 27, 2036.

In China, Patent No. ZL201280066803.6 from Patent family S3 was subject to a motion for invalidation brought by a third party based on several arguments, including the insufficient description of the animal model used in the patent, the novelty of the patent, the extension beyond the application as filed and the inventive step. Under Chinese patent law, the invalidity of a patent may be sought by any person or entity after the grant of the patent. The patent was invalidated in China following oral proceedings before the Court of Revision of the Chinese Patent Office. The arguments in favor of the invalidation by the Court of Revision of the Chinese Patent Office were not considered as relevant objections in the context of the European examination procedure leading to the grant of a European patent on May 8, 2019 (Patent No EP2790706). However, an opposition procedure to the European patent has been started, supposedly by the same opponent as in China (the latter remaining anonymous), and is currently in progress. The corresponding oral proceedings before the European Opposition Division are expected to take place in 2021. We do not expect the potential cancellation of this patent to have any material impact on our development plans for our product candidates, our patent portfolio or our business.

If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2027 to 2039. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Commercialization/License Agreements

As contemplated by the various research and collaboration agreements, we have entered into two commercialization/license agreements with respect to our patents which are co-owned with Sorbonne University and/or academic research institutions : (i) a commercialization/license agreement, dated January 1, 2016 by and between us and SATT Lutech (acting as agent for CNRS, INRA and Sorbonne University) and CNRS, INRA and Sorbonne University, as amended on April 2, 2019, November 6, 2020 and December 17, 2020, relating to patent families S1 through S9, or the S-Commercialization Agreement, and (ii) a commercialization/license agreement, dated January 1, 2016, by and between us and SATT Lutech (acting as agent for CNRS, INSERM and Sorbonne University) and CNRS, INSERM and Sorbonne University, as amended on December 17, 2020 relating to patent families MI through MIV, or the M-Commercialization Agreement.

Unless terminated sooner, these agreements will remain in effect until the expiration or invalidation of the last of the patents covered by such agreement. The terms of the agreements provide that they will automatically terminate upon our termination of activity, wind-up and/or liquidation, a breach of the agreement, or upon a force majeure event (as described in the agreement). In addition, we may terminate these agreements upon 30 days' notification to SATT Lutech and payment of a penalty equal to three times the annual guaranteed minimum amount, except where termination is justified by the denial of marketing authorizations.

We are required to make certain payments under the S-Commercialization Agreement and M-Commercialization Agreement as follows:

- under the S-Commercialization Agreement, (i) beginning in the year following the first marketing of a product and in any event no later than 2023, we will pay a guaranteed annual minimum amount of €40 thousand, which will be deducted from the amount of royalties due annually (as described below), (ii) for direct commercialization by the us, the agreement provides for annual single-digit royalties based on the net sales of products, distinguishing between sales of nutraceutical and medicinal products, and (iii) for indirect commercialization by a third party, the agreement provides for annual royalties (10-20%) based on income received from licensees, distinguishing (a) between the sales of nutraceutical products (10-20% royalties) and drug products (10-20% royalties or single-digit royalties) and (b) the product development phase (Phase 1, 2 or 3) at the time of the conclusion of the licensing agreement; and

- under the M-Commercialization Agreement, (i) since 2020, we are paying a guaranteed annual minimum amount of €15 thousand, which will be deducted from the amount of royalties due annually, when applicable (as described below), (ii) beginning in the year following the first marketing of a drug product and in any event no later than 2026, the Company will pay an annual guaranteed minimum amount of €50 thousand, which will be deducted from the amount of royalties due annually (as described below), (iii) for direct commercialization by the us, the agreement provides for annual single-digit royalties based on the net sales of products, distinguishing between sales of nutraceutical and medicinal products, and (iii) for indirect commercialization by a third party, the agreement provides for annual royalties (10-20%) based on income received from licensees, distinguishing (a) between the sales of nutraceutical products (10-20% royalties) and drug products (10-20% or single-digit royalties) and (b) the product development phase (Phase 1, 2 or 3) at the time of the conclusion of the licensing agreement. The payments made under the S-Commercialization Agreement and the M-Commercialization Agreement will end upon termination of these agreements.

Co-Ownership Agreements

As contemplated by the various research and collaboration agreements, we have entered into 10 co-ownership agreements with Sorbonne University and/or academic research institutions, covering all of our patent families except for (i) patent family S7, which is governed by legal provisions of the French intellectual property code, which applies by default, and (ii) patent families S8 and S9, which have only recently been filed and for which we expect to enter into similar co-ownership agreements in the near future. Until such time as agreements are signed in relation to patent families S8 and S9, co-ownership will be governed by legal provisions of the French intellectual property code, which apply by default.

Each of these co-ownership agreements is entered into for a term ending upon expiration or invalidation of the last of the patents covered by such agreement, or, in the case of the co-ownership agreements covering patent families MI, MIII and MIV, until expiration or invalidation of the last of the patents covered by the agreement or as long as the commercialization/license agreement remains in effect. These agreements may be terminated if one of the parties becomes the sole owner of the patents or in the event the parties no longer own the patents. In the event that assignment to a third party is contemplated, the other parties to the agreement will have a preemptive right to acquire such party's co-ownership share.

Intellectual Property Agreement with Stanislas Veillet

Our CEO, who is a corporate officer *(mandataire social)* but not an employee of the Company under French law, is involved in our research and development activities. He has developed inventions with us for which we have submitted patent applications in which he is listed as a co-inventor and other inventions that we expect may give rise to patent applications in the future for which we expect he will be included as a co-inventor. As an inventor, our CEO has certain rights under French intellectual property law. These rights are distinct from the statutory rights that usually apply to employee inventors under French law. In order to define a framework within which any intellectual property resulting from our CEO's research and development activities is properly assigned to us, we have entered into an agreement with our CEO, which has been approved by our board of directors, pursuant to which he is entitled to the following payments for his contributions:

- a first lump sum cash payment of €90 thousand to be paid within 30 days of filing of a patent application based on the assigned rights;
- a second lump sum cash payment of €90 thousand to be paid within 30 days of publication of a patent application based on the assigned rights; and
- a 6.5% royalty payment with respect to any license income and/or any net sales by us of products manufactured with the patents filed on the basis of the assigned rights.

These three payments will be capped at €2.1 million on a platform per platform basis, a platform being defined in the agreement as the research and development works which cover the same family of chemical molecules targeting the same molecular receptor or biological pathway for a family of pathologies which are clinically connected.

In the event that a third-party pharmaceutical and/or biotech company acquires 100% of our capital and voting rights, payments will be accelerated, so that the cap (€2.1 million per platform), less any amount previously paid in respect of a platform, will become immediately payable.

The agreement shall remain in effect until no further payments are due. However, the provisions of this agreement will only apply to results generated during the period in which our CEO occupies the position of a corporate officer of the Company or any of its affiliates. Any party to the agreement may, upon material breach of the agreement by the other party, terminate the agreement.

Trademarks

In addition to patent protection, we have trademark protection in many countries for our name (Biophytis) and our drug candidates (in particular, "Macuneos" and "Sarconeos"). In total, we hold 36 trademarks or trademark applications. None of our trademarks are subject to a third-party license.

Our Intellectual Property Strategy

Our patent policy is to file the first priority application regionally in France, then extend that patent application for international coverage by filing a related international application through the Patent Cooperation Treaty, or PCT. The PCT international application has the potential to be pursued in 142 PCT-contracting countries.

We determine which countries to pursue patent coverage in based on our business strategy. Our business strategy focuses on two main zones in which to pursue patent coverage via the PCT: (1) Europe, and in particular, the major European countries, United States, and Japan because these countries are where most of the main major pharmaceutical companies are concentrated, and (2) the BRIC zone, which is Brazil, Russia, India, and China; and sometimes Canada, Australia and South Korea.

Our objective for this international intellectual property strategy is to secure the earliest patents in these target countries and obtain the broadest and most effective scope of intellectual property protection in these countries. In addition to protecting our innovations by patents, they often have supplemental regulatory data exclusivity in connection with the marketing authorization of our products.

Government Regulation

Government authorities in the United States (including federal, state and local authorities) and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing, and export and import of pharmaceutical products and active pharmaceutical ingredients, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Government Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, placement on Import Alerts, debarment of personnel, employees or officers, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before drug candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests, preclinical animal studies, and toxicity data, all performed in accordance with the GLP regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent IRB or ethics committee representing each clinical site before each clinical study may be initiated;

- performance of adequate and well-controlled human clinical studies to establish the safety and efficacy of the drug candidate for each proposed indication;
- preparation of and submission to the FDA of a NDA after completion of all pivotal clinical studies;
- review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the drug candidate is produced to assess compliance with cGMP; and
- FDA review and approval of an NDA or Biologic License Application, or BLA, prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical studies may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical studies to commence.

Clinical Studies

Clinical studies involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, and the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical study site's IRB before the studies may be initiated, and the IRB must monitor the study until completed. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, such as ClinicalTrials.gov.

The clinical investigation of a drug is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks and preliminarily evaluate efficacy.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product approval.
- Phase 4. In some cases, the FDA may condition approval of an NDA for a drug candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may commit to conducting or voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies.

A confirmatory or pivotal study is a clinical study that adequately meets regulatory agency requirements for the evaluation of a drug candidate's efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are Phase 3 studies, but the FDA may accept results from Phase 2 studies if the study design provides a well-controlled and reliable assessment of clinical benefit, particularly in situations where there is an unmet medical need and the results are sufficiently robust. In such cases, the FDA may require post-market studies for safety and efficacy to be conducted for the drug candidate. The FDA may withdraw the approval if the results indicate that the approved drug is not safe or effective.

The FDA, the IRB or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Submission of an NDA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is subject to a substantial application user fee. Applications for orphan drug products are exempted from the NDA application user fees.

An NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

Once an NDA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for an investigational drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the investigational product application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows such recommendations.

The FDA's Decision on an NDA

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical study(ies), and/or other significant, expensive and time-consuming requirements related to clinical studies, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a REMS to mitigate risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications or a commitment to conduct one or more post- market studies or clinical studies. Such post-market testing may include Phase 4 clinical studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. The FDA may have the authority to withdraw its approval if post-market testing fails to verify the approved drug's clinical benefit, if the applicant does not perform the required testing with due diligence, or if the any other evidence demonstrates the approved drug is not safe or effective, among other reasons. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Expedited Review, Accelerated-Approval and Emergency Use Authorization Programs

The FDA has various programs, including fast track, priority review, breakthrough therapy, accelerated approval, and regenerative medicine advanced therapy or RMAT designations that are intended to expedite the development and approval of new drugs that address unmet medical needs in the treatment of serious or life-threatening diseases and conditions. To be eligible for a fast track designation, the FDA must determine, based on the request of an applicant, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA may review sections of the NDA for a fast-track product on a rolling basis before the complete application is submitted. If the applicant provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable. The applicant pays any required user fees upon submission of the first section of the NDA.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review of ten months. These six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. This evaluation takes into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act passed in July 2012, a sponsor can request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

Drugs designated as breakthrough therapies are also eligible for priority review and fast track designation. As part of this process, the FDA takes certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In addition, the 21st Century Cures Act in 2016 made the Regenerative Medicine Advanced Therapy, or RMAT, designation available for investigational drugs that are regenerative medicine therapies intended to treat, modify, reverse, or cure a serious condition, with preliminary clinical evidence indicating that the drug has the potential for addressing unmet medical needs for such condition. The RMAT designation is available for cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products that use such therapies or products. The advantages of RMAT designation include those of breakthrough and fast track designations, such as early interactions with the FDA and rolling review of applications, and the drug candidate with the RMAT designation may be eligible for accelerated approval. Requests for RMAT designations should be made with the IND application (if preliminary clinical evidence is available), but no later than the end-of-Phase-2 meeting.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for the FDA review or approval will not be shortened or will be withdrawn.

With the declaration of COVID-19 as a worldwide pandemic and public health emergency, several programs have been utilized, to expedite review of medications. These include:

- EUA authority allows the FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under section 564 of the Federal Food, Drug and Cosmetic Act, or FD&C Act, the FDA Commissioner may allow unapproved medical products, or unapproved uses of approved medical products, to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear (CBRN) threat agents when there are no adequate, approved, and available alternatives. The EUA allows temporary use of the medical product, based on efficacy data, which is usually not sufficient on its own for approval. For example, Veklury (Remdesivir) received an EUA for the treatment of COVID-19 for certain patient populations based on one double-blind study, which was conducted by the National Institutes of Health, or NIH, between February and April 2020. An EUA may be revoked at the conclusion of a public health emergency, and there may be certain limitations to its uses, such as label statements specifying that the product only has an EUA, and that it has not received the FDA's clearance or approval.

- In Europe, the EMA has put in place a COVID-19 task force, to provide scientific advice and review interim data, on a rolling basis, as a part of a conditional marketing authorization.

- In the United Kingdom, the MHRA has put in place a process for a temporary authorization for the supply of an unlicensed medicinal product for use in response to certain specific types of public health threat—under regulation 174.

Post-Approval Requirements

Drugs marketed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements.

Manufacturers are subject to periodic unannounced inspections by FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third- party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product;

- complete withdrawal of the product from the market or product recalls;

- fines, Form 483 observations, warning letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending NDAs or supplements to approved NDAs or suspension or revocation of product approvals;

- product seizure or detention, or refusal to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

It is expected that, with respect to COVID-19-related EUA programs, data collection post-approval will be required, either in the form of a clinical trial, or by other methods (e.g. real-world data). For example, Veklury (Remdesivir), received emergency use authorization from the FDA for treatment of COVID-19 patients, based on an additional double-blind, placebo-controlled study.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Hatch-Waxman Amendments and Exclusivity

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents, or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must send notice of the Paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve.

The FDA also cannot approve an ANDA or 505(b)(2) application until all applicable non-patent exclusivities listed in the Orange Book for the branded reference drug have expired. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug containing an active moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule responsible for the drug substance's physiological or pharmacologic action. During that five-year exclusivity period, the FDA cannot accept for filing (and therefore cannot approve) any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA that relies on the FDA's approval of the drug, provided that that the FDA may accept an ANDA four years into the NCE exclusivity period if the ANDA applicant also files a Paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

Other Healthcare Laws and Compliance Requirements

U.S. pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations. If pharmaceutical company operations are found to be in violation of any of such laws or any other applicable governmental regulations, these companies may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, exclusion from participation in federal and state healthcare programs and individual imprisonment.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations and the level of third-party reimbursement for such product. Third-party payor decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors often reduce reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also has a material adverse effect on sales. Even after the FDA approves a product, for example, the failure to obtain third-party payor coverage may impose a material adverse effect on sales. As federal and state governments continue to promulgate new policies and regulations, these policies and regulations may also impose a material adverse effect on sales. These laws and regulations may restrict, prohibit, or preventing us from implementing a wide range of pricing, discounting, marketing, promotion, sales commission, incentive programs, and other business activities. No uniform policy of coverage and reimbursement among third-party payors exists in the United States. Finally, although payors often rely upon Medicare coverage policy establishing their coverage and reimbursement policies. Instead, each payor makes independent and separate decisions regarding the extent of coverage and amount of reimbursement to be provided.

Healthcare Reform

In March 2010, former President Obama signed the Affordable Care Act, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollments in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the Affordable Care Act increases the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; requires collection of rebates for drugs paid by Medicaid managed care organizations; requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year for certain Medicare providers and suppliers, and further reduced payments to several types of Medicare providers.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, proposing to encourage importation from other countries and bulk purchasing.

CARES Act

In March 2020, the United States Congress passed the Coronavirus Aid, Relief, and Economic Security, or CARES, Act, a $2 trillion relief package created in response to the ongoing COVID-19 pandemic in the United States. Although Congress directed a significant portion of CARES Act aid to health care providers and institutions that serve on the "front line" of the COVID-19 crisis, Congress also allocated $940 million to the NIH, the U.S. government's primary agency responsible for biomedical research. Additionally, for companies that engage in research studies that involve routine costs payable by federal health care programs, such as Medicare and Medicaid, the CARES Act includes a number of measures designed to ease restrictions, enhance coverage, or even accelerate reimbursement for those routine costs in limited circumstances. Although CARES Act financial aid and easing of restrictions are specifically intended to address the COVID-19 emergency and are thus generally temporary, the sheer size and breadth of relief opportunities afforded under the law could positively impact life science and biotechnology companies' growth in the long term (*i.e.*, even beyond the pandemic), particularly for early stage companies engaged in COVID-19 related research.

Foreign Corrupt Practices Act

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

European Union Drug Development

In the European Union, our drug candidates may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union, national regulations and international standards for GCP, as well as in accordance with the new guidelines of the EMA and of the relevant national regulatory authorities regarding the COVID-19 context.

Clinical trials are currently governed by EU Clinical Trials Directive 2001/20/EC that set out common rules for the control and authorization of clinical trials in the European Union, as well as by the GCP Directive 2005/28/EC.

To improve the current system, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use was adopted in 2014. The Regulation aims at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials, and increasing their transparency, notably via a clinical trial information system set up by the EMA. The new Regulation expressly provides that it will not be applied before six months after the publication of a notice delivered by the European Commission on the European Union clinical trial portal and database. As such notice requires a successful (partial) audit of the database and as that database is still under development, there is no scheduled application date yet. Pursuant to the transitory provisions of the new regulation, the Clinical Trials Directive 2001/20/EC will still apply for three years after the implementation of the European Union clinical trial portal and database. Thus the sponsor has the possibility to choose between the requirements of the directive and the regulation for a period of three years from the entry into force of the regulation.

Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU Member States where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions, or SUSARs, to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred. The Directive also imposes an obligation of periodic notification so as to inform the EC of the progress of the clinical trial.

European Union Drug Review and Approval

In the EEA (which is comprised of the 27 (after the Brexit) Member States of the European Union plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. MAs may be granted either centrally (Community MA) or nationally (National MA).

The Community MA is issued centrally by the European Commission through the Centralized Procedure, based on the opinion of the EMA and is valid throughout the entire territory of the EU and will be recognized the other EEA Member States Norway, Iceland and Liechtenstein. The Centralized Procedure is mandatory for certain types of products such as orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of neurodegenerative disorders. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

The European Commission may also grant a “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medical products), if:

- the risk-benefit balance of the product candidate is positive;
- it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data;
- the product fulfills an unmet medical need; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacoviligance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations.

National MAs are issued nationally by the competent authorities of the Member States of the EEA and only cover their respective territory. National MAs are available for products not falling within the mandatory scope of the Centralized Procedure. We do not foresee that any of our current drug candidates will be suitable for a National MA as they fall within the mandatory criteria for the Centralized Procedure. Therefore, our drug candidates will be approved through Community MAs.

Under the above-described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Pursuant to Regulation (EC) No. 1901/2006, or the "Pediatric Regulation", all applications for marketing authorization for new medicines, as well as all applications for new indications of approved medicines, must include to be valid, in addition to the particulars and documents referred to in Directive 2001/83/EC, the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed between regulatory authorities and the applicant, unless the medicine is exempt because of a deferral or waiver of the EMA.

Before the EMA is able to begin its assessment of a Community MA application, it will validate that the applicant has complied with the agreed pediatric investigation plan. The applicant and the EMA may, where such a step is adequately justified, agree to modify a pediatric investigation plan to assist validation. Modifications are not always possible; may take longer to agree than the period of validation permits; and may still require the applicant to withdraw its marketing authorization application and to conduct additional non-clinical and clinical studies. Products that are granted a MA on the basis of the pediatric clinical trials conducted in accordance with the Pediatric Investigation Plan, or PIP, are eligible for a six-month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two-year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Orphan Drugs

In the European Union, Regulation (EC) No 141/2000 of the European Parliament and of the Council of December 16, 1999 on orphan medicinal products, as amended, states that a drug shall be designated as an orphan drug if its sponsor can establish that the three following cumulative conditions are met:

- the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition;
- the prevalence of the conditions is not more than five in ten thousand persons in the European Union when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the drug in the European Union would generate sufficient return to justify the necessary investment; and
- that there is no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Pursuant to Regulation (EC) No. 847/2000 of April 27, 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts "similar medicinal product" and "clinical superiority", an application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug before filing of a MA application.

The European Union offers incentives to encourage the development of designated orphan medicines (protocol assistance, fee reductions, etc.) and provides opportunities for market exclusivity. Pursuant to abovementioned Regulation (EC) No. 141/2000, products receiving orphan designation in the European Union can obtain market exclusivity for a certain number of years in the European Union following the marketing approval.

If a Community MA in respect of an orphan drug is granted, regulatory authorities will not, for a period of usually ten years, accept another application for a MA, or grant a MA or accept an application to extend an existing MA, for the same therapeutic indication, in respect of a similar drug. This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the drug concerned, that the above-mentioned criteria for orphan drug designation are no longer met, in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Pursuant to Regulation No. 1901/2006, for orphan medicinal products, instead of an extension of the supplementary protection certificate, the ten-year period of orphan market exclusivity should be extended to 12 years if the requirement for data on use in the pediatric population is fully met (i.e. when the request contains the results of all studies carried out under the approved PIP and when the declaration attesting the conformity of the request to this PIP is included in the MA).

Notwithstanding the foregoing, a MA may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the MA for the original orphan drug has given its consent to the second applicant;
- the holder of the MA for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

The abovementioned Regulation (EC) No. 141/2000 provides for other incentives regarding orphan medicinal products.

Post-Approval Controls

The holder of a MA must comply with EU requirements applicable to manufacturing, marketing, promotion and sale of medicinal products. In particular, the holder of the MA must establish and maintain a pharmacovigilance system and appoint a Qualified Person Responsible for Pharmacovigilance, or QPPV, who is responsible for oversight of that system and who will reside and operate in the EU. Key obligations include safety expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAs must include a risk management plan, or RMP, to submit to the EMA, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

Reimbursement

The European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. For example, in France, effective market access will be supported by agreements with hospitals and products may be reimbursed by the Social Security Fund. The price of medicines covered by national health insurance is negotiated with the French Economic Committee for Health Products, or CEPS. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our drug candidates.

Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other European Regulatory Matters

French Regulatory Framework for Clinical Development

In France, Directive No. 2001/20/EC has been implemented in French national law, establishing a system of prior authorization and requiring a prior favorable opinion from an ethics committee.

Parties to a CTA must use a CTA template (“unique agreement” or convention unique) to organize the conduct of interventional clinical trials with commercial purpose, as well as specific template exhibits to this agreement. The use of the unique agreement template is mandatory if the research takes place in a public health establishment, institution (“maison de sante”), or centre (“centre de sante”) in France. Once concluded, the CTA is communicated for information by the sponsor to the French national board of physicians (Ordre national des médecins) without delay.

The processing of personal data, including health data, collected during clinical trials has to comply with the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 and Law No 2018-493 of June 20, 2018 on the protection of personal data, implementing the Regulation (EU) 2016/679 requirements, as well as the guidelines of the French data protection authority, the *Commission Nationale de l’Informatique et des Libertés*, or CNIL. Regarding automatic processing operations for the purpose of research or clinical studies, formalities have to be completed before the CNIL, so as to obtain the authorization to process personal data. However, there are simplified standards.

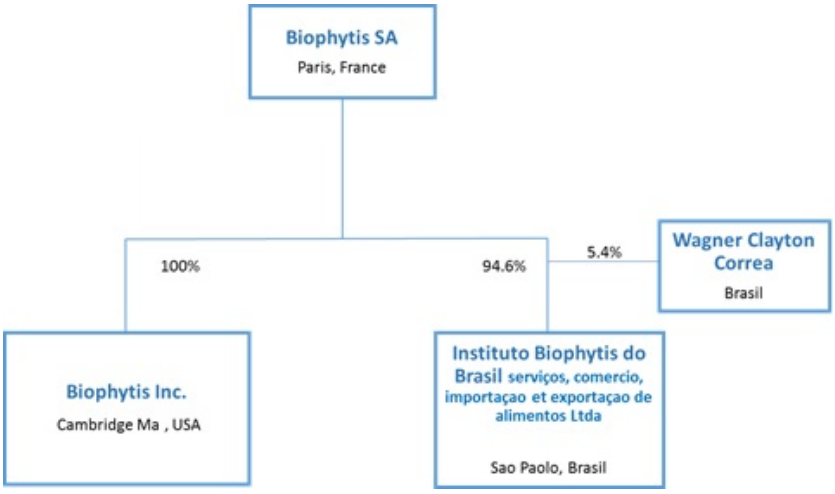
Law No. 2011-2012 of December 29, 2011, or Loi Bertrand, aimed at strengthening the health safety of medicinal and health products, as amended (and its implementing decrees), introduced into French law provisions regarding transparency of fees received by some healthcare professionals from health product industries, i.e. companies manufacturing or marketing health products (Article L.1453-1 of the French Public Health Code). The French Decree No. 2016-1939 of December 28, 2016 clarifies that companies manufacturing or marketing health care products (medicinal products, medical devices, etc.) in France shall publicly disclose (mainly on a specific public website available at: https://www.entreprises-transparence.sante.gouv.fr) the advantages and fees paid to healthcare professionals amounting to €10 or above, as well as the agreements concluded with the latter, along with detailed information about each agreement (the precise subject matter of the agreement, the date of signature of the agreement, its end date, the total amount paid to the healthcare professional, etc.). Another declaration must also be filed to the competent healthcare professional body. Several decrees have further extended the scope of these declarations. For instance, under Decree No. 2019-1530 of December 30, 2019, companies will also have to disclose agreements concluded with persons who present one or more health products in the media or social networks in such a way as to influence the public.

Law No. 2011-2012 also reinforced the French anti-gift rules. Further to subsequent modifications in 2017 and 2019, new Articles L. 1453-3 et seq. of the French Public Health Code amended the Anti-Gift regime and expanded the scope of the general prohibition of payments from pharmaceutical and device manufacturers to healthcare professionals to broadly cover any company manufacturing or marketing health products, regardless of whether or not payment for the products is reimbursed under the French social security system (new Articles L. 1453-3 et seq. of the French Public Health Code). Derogation must be submitted to the relevant healthcare professional body. Moreover, the penalties incurred for non-compliance with the requirements of the Anti-Gift regime by a healthcare company may lead to a fine of up to €750,000.

French Pharmaceutical Company Status

In France, there is a regulated status of pharmaceutical establishment and operating company, which allows us to manufacture and market drug candidates. Obtaining a pharmaceutical establishment license, either as a distributor or as a manufacturer requires the submission of an application file to the ANSM. The application package will vary depending on the type of application (distribution license or manufacturing license). The ANSM grants such license after verifying that the company has adequate premises, the necessary personnel and adequate procedures to carry out the proposed pharmaceutical activities.

C. Organizational Structure



D. Property, Plants and Equipment

We lease approximately 504 square meters of office space at Sorbonne University—BC 9, Bâtiment A 4ème étage, 4 place Jussieu, 75005 Paris, France for research and development and administrative activities. The lease agreement (convention d'occupation du domaine public) provides for a one-year renewable term. We paid an annual fee of €191,133.88 for the year 2020. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms. Our United States subsidiary, Biophytis, Inc., leases administrative offices at c/o NGIN 210 Broadway, Suite #201, Cambridge, Massachusetts 02138.

Item 4A. Unresolved Staff Comments.

Not applicable.

Item 5. Operating and Financial Review and Prospects.

Overview

We are a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases, including severe respiratory failure in patients suffering from COVID-19. Our goal is to become a leader in the emerging field of aging science by delivering life-changing therapies to the growing number of patients in need. To accomplish this goal, we have assembled an experienced and skilled group of industry professionals, scientists, clinicians and key opinion leaders from leading industry and academic institutions from around the world.

Our therapeutic approach is aimed at targeting and activating key biological resilience pathways that can protect against and counteract the effects of the multiple biological and environmental stresses, including inflammatory, oxidative, metabolic and viral stresses that lead to age-related diseases.

Our lead drug candidate, Sarconeos (BIO101), is in development for the treatment of neuromuscular diseases, including sarcopenia and DMD, and for the treatment of respiratory diseases, including COVID-19. Our second drug candidate, Macuneos (BIO201), is in development for the treatment of retinopathies, including dry AMD and Stargardt disease.

We are currently testing the safety and efficacy of Sarconeos (BIO101) in an ongoing global, randomized, double-blind, placebo-controlled clinical study (SARA-INT) with 233 elderly patients with sarcopenia at risk for mobility disability. We are also actively developing Sarconeos (BIO101) in an ongoing global, multicenter double-blind, placebo-controlled, group-sequential, and adaptive two-part Phase 2-3 study (COVA) with 310 patients 45 years old and older with severe respiratory symptoms of COVID-19. We received an IND "may proceed" letter from the FDA in the United States and CTA approval from the FAMHP in Belgium in the second half of 2019 to initiate clinical development with our MYODA clinical program, which is based on a global, double-blind, placebo-controlled, group-sequential, Phase 1-3 seamless study, in non-ambulatory DMD patients, with signs of respiratory deterioration

We hold exclusive commercialization rights through licenses for each of our drug candidates. We currently plan to develop our drug candidates through clinical PoC (typically Phase 2), and then seek licensing and/or partnership opportunities for further clinical development through regulatory approval and commercialization.

Financial Operations Overview

The following discussion sets forth certain components of our statements of operations as well as factors that impact those items.

Revenues

To date we have not generated any revenues from product sales, or otherwise, and we do not expect to recognize any revenue from the sale of products, even if we obtain regulatory approval for the products, in the near term. Our ability to generate revenue in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then commercialize our drug candidates.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred in connection with the development of our drug candidates, including:

- personnel-related costs, such as salaries, bonuses, benefits, travel and other related expenses, including share-based compensation;
- expenses incurred under our agreements with CROs, clinical sites, contract laboratories, medical institutions and consultants that plan and conduct our preclinical studies and clinical trials;
- costs associated with regulatory filings;
- costs of acquiring preclinical study and clinical trial materials, and costs associated with preclinical development formulation and process development;
- depreciation, maintenance and other facility-related expenses; and
- as an offset of our research and development expenses, the CIR.

To date, we have expensed all research and development costs as incurred, as we do not currently meet the conditions to capitalize expenditures on drug development activities, as provided in IAS 38 *Intangible Assets*.

Clinical development expenses for our drug candidates are a significant component of our current research and development expenses as we advance our drug candidates into and through clinical trials. Drug candidates in later stage clinical development generally have higher research and development costs than those in earlier stages of development, primarily due to increased size and duration of the clinical trials. We recognize costs for each grant project, preclinical study or clinical trial that we conduct based on our evaluation of the progress to completion, using information and data provided to us by our research and development vendors and clinical sites.

We expect our research and development expenses to increase for the foreseeable future as we progress our drug candidates into and through clinical trials. Furthermore, to the extent we undertake to commercialize any drug candidates approved for any indication for sale, our expenses will likely increase even more. The process of conducting the necessary clinical research to obtain regulatory approval of a drug candidate is costly and time consuming. We will require additional funding, beyond the proceeds raised in our U.S. initial public offering, to fund our continuing operations. The probability that any of our drug candidates receives regulatory approval and eventually is able to generate revenue depends on a variety of factors, including the quality of our drug candidates, early clinical data, investment in our clinical program and further clinical validation, competition, manufacturing capability and commercial viability. We may never succeed in obtaining regulatory approval for any of our drug candidates. As a result of these uncertainties, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of any of our drug candidates, if approved.

General and Administrative Expenses

General and administrative expenses include personnel costs, costs for outside professional services and other allocated expenses. Personnel costs consist of salaries, bonuses, benefits, travel and share-based compensation. Outside professional services consist of legal, accounting and audit services, commercial evaluation and strategy services, and other consulting services. We expect general and administrative expenses to increase in the near future with the expansion of our staff and management team to include new personnel responsible for finance, legal, information technology and later, sales and business development functions. We also expect to incur additional general and administrative costs as a result of operating as a U.S. public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, additional insurance expense, investor relations activities and other administrative and professional services. We also expect to incur additional expenses related to in-licenses, acquisitions or similar transactions that we may pursue as part of our strategy, including legal, accounting and audit services and other consulting fees.

Net Financial Income (Expense)

Net financial income (expense) includes amortized cost of the reimbursable advances, convertible notes and non-convertible bonds, fair value adjustments on financial instruments, including derivatives, other financial income and expense, the NEGMA financial indemnity, the financial income related to NEGMA returning to us damages paid and the provision in relation with the NEGMA litigation (as described in further detail in the paragraph "Results of Operations" below and in Note 14 to the audited consolidated financial statements). We expect to incur additional financial expenses related to financing agreements or similar transactions that we may enter into to finance our development.

COVID-19 Impact

We have, like many other companies, experienced disruptions due to the COVID-19 pandemic. Given the rapid changes associated with COVID-19, we have and are continuing to take the necessary precautions to protect our employees, partners and operations. For example, we have encouraged our employees in France and in the United States to work from home and to organize meetings and events in a virtual way whenever possible. We have also imposed restrictions on travel, which is now limited to professional imperatives only.

Our ongoing and planned clinical studies have been impacted by COVID-19. Our SARA-INT trial in sarcopenia has been impacted by the emergence of COVID-19 and subsequent lockdowns in Belgium and several American states (California and New York in particular). In light of the various measures adopted by governments and health authorities to restrict movement and protect the safety of patients, we have had to adapt our SARA-INT protocol in order to ensure the continuity of the trial, in particular by closing all on-site activities, organizing patient follow-up to take place at home, and expanding the treatment from six to nine months for some patients. Despite these interruptions of in-office study visits and other disruptions that were imposed due to the COVID-19 pandemic, we were able to retain most of the study participants. The last patient completed his final on-treatment visit in December 2020. Despite the impediments, a total of 196 participants completed the SARA-INT study. Currently, we are conducting final assessment on the last patients in this clinical trial. We expect to announce top-line results during the second quarter of 2021.

In addition, our MYODA program in DMD and MACA program for dry AMD, both planned for 2021, may be delayed as a result of COVID-19.

Our COVA trial to treat COVID-19 patients will depend strongly upon the evolution of the pandemic.

Critical Accounting Policies and Significant Judgments And Estimates

Our audited consolidated financial statements have been prepared in accordance with IFRS, as issued by the IASB. Some of the accounting methods and policies used in preparing our financial statements under IFRS are based on complex and subjective assessments by our management or on estimates based on past experience and assumptions deemed realistic and reasonable based on the circumstances. The actual value of our assets, liabilities and shareholders' equity and of our losses could differ from the value derived from these estimates if conditions change and these changes have an impact on the assumptions adopted. We believe that the most significant management judgments and assumptions in the preparation of our financial statements are described below. See Note 2.2 to our audited consolidated financial statements as of December 31, 2019 and 2020 and for each of the three years ended December 31, 2018, 2019 and 2020.

Founders' warrants and warrants granted to employees and executives

The fair value measurement of share-based payments is based on the Black-Scholes option valuation model, which makes assumptions about complex and subjective variables. These variables notably include the value of our shares, the expected volatility of the share price over the lifetime of the instrument, and the present and future behavior of holders of those instruments. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of share-based payments in accordance with IFRS 2 *Share-based Payment*.

Convertible Notes and Non-Convertible Bonds

During the year ended December 31, 2018, we issued non-convertible bonds with warrants attached to Kreos.

During the year ended December 31, 2019, we issued non-convertible bonds to Kreos and notes convertible into ordinary shares and/or redeemable for cash with warrants attached to NEGMA.

During the year ended December 31, 2020, we issued notes convertible into ordinary shares and/or redeemable for cash to ATLAS.

In accordance with IFRS 9 *Financial Instruments*, we measured the fair value of the equity instrument and the financial derivative instruments (related to the conversion option held by NEGMA and ATLAS) based on the Black-Scholes option valuation model, which makes assumptions about complex and subjective variables. These variables notably include the value of our shares, the expected volatility of the share price over the lifetime of the instrument, and the assumed present and future behavior (including estimated timing of exercise, conversion and other decisions) of holders of those instruments. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of financial instruments and equity instruments in accordance with IAS 32 *Financial Instruments: presentation*, and IFRS 9 *Financial Instruments*.

In accordance with IFRS 9 *Financial Instruments*, initial recognition of the convertible notes was recorded at the fair value of their debt component and subsequently this debt component is accounted for under the amortized cost method.

The conversion option of the convertible notes was bifurcated and classified in derivative instruments because the conversion price is not fixed and measured at fair value on the date of issuance based on the Black-Scholes option valuation model with recognition of the changes in fair value in profit or loss in each reporting period in accordance with IFRS 9 *Financial Instruments*.

Non-recognition of deferred tax assets net of deferred tax liabilities

The determination of the amount of deferred tax assets which can be recognized requires management to make estimates on both the period in which tax losses carried forward will be realizable, and the level of future taxable income.

As of December 31, 2018, 2019 and 2020, no deferred tax asset has been recognized in our financial statements except as a result of the expected taxable income to be derived from deferred tax liabilities.

We recognized in 2018:

- a deferred tax liability with respect to the equity component of the non-convertible bonds issued in 2018 for €72 thousand, as a decrease of equity on initial recognition under IAS 12 *Income Taxes*; and
- a deferred tax asset with respect to net operating losses (NOLs) carried forward as a result of the deferred tax liabilities generated, resulting in deferred tax income of €72 thousand in the statement of consolidated operations.

We recognized in 2019:

- a deferred tax liability with respect to the equity component of the non-convertible bonds issued in 2019 for €28 thousand, as a decrease of equity on initial recognition under IAS 12 *Income Taxes*; and
- a deferred tax asset with respect to net operating losses (NOLs) carried forward as a result of the deferred tax liabilities generated, resulting in deferred tax income of €28 thousand in the statement of consolidated operations.

No deferred tax liability nor deferred tax assets were recognized in 2020.

The JOBS Act

As an “emerging growth company” under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an “emerging growth company” to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We will not take advantage of the extended transition period provided under Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an “emerging growth company”, we intend to rely on certain of these exemptions including, without limitation, the exemptions from providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We will remain an “emerging growth company” until the earliest of: (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (2) the last day of the fiscal year following the fifth anniversary of the closing date of our U.S. initial public offering; (3) the date on which we have issued more than $1 billion in non-convertible debt during the previous three years; and (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

A. Operating Results

Comparison for the years ended December 31, 2019 and 2020

(Amounts in thousands of euros)	December 31, 2019	December 31, 2020
Revenue	—	—
Costs of sales	—	—
Gross margin	**—**	**—**
Research and development, net	(9,089)	(9,921)
General and administrative expenses	(6,593)	(4,021)
Operating loss	**(15,682)**	**(13,942)**
Financial expenses	(2,878)	(6,364)
Financial income	18	421
Change in fair value of derivative instruments	726	2,831
Net financial expense	**(2,134)**	**(3,112)**
Loss before taxes	**(17,816)**	**(17,054)**
Income taxes benefit	28	-
Net loss	**(17,788)**	**(17,054)**

Research and Development Expenses

Research and development expenses may be summarized as follows for the years ended December 31, 2019 and 2020.

(Amounts in thousands of euros)	December 31, 2019	December 31, 2020
Personnel expenses	(3,063)	(2,553)
Purchases and external expenses	(8,660)	(10,459)
Other	(214)	(251)
Research and development expenses	**(11,937)**	**(13,263)**
Research tax credit	2,807	3,328
Subsidies	41	14
Research tax credit and Subsidies	**2,848**	**3,342**
Research and development, net	**(9,089)**	**(9,921)**

Personnel costs, including stock-based payments for engineers and research personnel, were €3,063 thousand and €2,553 thousand for the years ended December 31, 2019 and 2020, respectively. The decrease in personnel expenses in 2020 compared to 2019 is related to the downsizing of our structure initiated during the second half of 2019 and also to a lower average salary for new employees in 2020.

Purchases and external expenses related to our research activity were €8,660 thousand and €10,456 thousand for the years ended December 31, 2019 and 2020, respectively. The increase in purchases and external expenses related to our studies and research costs is primarily related to the progression of our SARA-INT study and the launch of our COVA study. These expenses consisted primarily of the cost of CROs in conducting clinical trials and non-clinical regulatory studies.

Research and development expenses relate to activities in connection with conducting clinical trials, non-clinical studies of our drug candidates for the treatment of age-related diseases and the treatment of severe respiratory failure in patients suffering from COVID-19.

We have benefited from the Research Tax Credit (CIR) since our incorporation. The CIR amounted to €2,807 thousand and €3,328 thousand for the years ended December 31, 2019 and 2020, respectively. In December 2019, a portion of the CIR receivables for 2018 and 2019 were prefinanced by FONDS COMMUN DE TITRISATION PREDIREC INNOVATION 2020 with NEFTYS CONSEIL SARL as arranger, or NEFTYS. CIR receivables for 2018 (€3,133 thousand) and 2019 (€3,243 thousand) were subsequently reimbursed by the French Tax Authorities in January 2020 and June 2020, respectively. The prefinanced receivables were then reimbursed directly to NEFTYS. In December 2020, a portion of the CIR 2020 receivables was prefinanced by NEFTYS. This operation followed the same rules described above.

General and Administrative Expenses

General and Administrative expenses may be summarized as follows for the years ended December 31, 2019 and 2020.

(Amounts in thousands of euros)	**December 31, 2019**	**December 31, 2020**
Personnel costs	(1,998)	(1,796)
Purchases and external expenses	(2,393)	(2,188)
Other	(2,203)	(37)
General and administrative expenses	**(6,593)**	**(4,021)**

Personnel costs, including share-based payments, for general management and administrative staff were €1,998 thousand and €1,796 thousand for the years ended December 31, 2019 and 2020, respectively. This decrease is due to the downsizing of our G&A functions.

Purchases and external expenses were €2,393 thousand and €2,188 thousand for the years ended December 31, 2019 and 2020, respectively. These expenses consisted primarily of administrative expenses associated with being a public listed company in France, accounting and audit fees, and legal fees.

In its decision dated October 1, 2019, the French Financial Market Authority, or the AMF, imposed a financial penalty of €100 thousand on us for failing to immediately communicate to the market the privileged information relating to the significant delay in the entry in phase 2 of clinical studies of two drug candidates. The Company has settled this liability along with a late-filing penalty of €10 thousand. This amount is included in the general and administrative expenses in 2019.

The overall decrease in general and administrative expenses for the year ended December 31, 2020, is primarily due to the one-off fees related to our attempted 2019 Nasdaq listing application.

Net Financial Expense

Net financial expense may be summarized as follows for the years ended December 31, 2019 and 2020.

(Amounts in thousands of euros)	**December 31, 2019**	**December 31, 2020**
Financial interest and amortized cost of the convertible notes and non-convertible bonds	(2,526)	(4,374)
Change in fair value of derivative instruments	726	2,831
NEGMA financial indemnity	—	(385)
Provision in relation with the NEGMA litigation	—	(1,394)
Other financial expenses	(352)	(182)
Financial income related to NEGMA returning to Biophytis damages paid	—	419
Other financial income	4	2
Foreign exchange gains (losses)	14	(29)
Net financial expense	**(2,134)**	**(3,112)**

Net financial expense was €(2,134) thousand and €(3,112) thousand for the years ended December 31, 2019 and 2020, respectively.

On August 21, 2019, the Company signed an agreement with NEGMA providing for up to €24 million in financing to us through the issuance of multiple tranches of convertible notes with attached warrants (ORNANEBSA), at our sole discretion.

Pursuant to this agreement, the board of directors approved the issuance of the following convertible notes and warrants during the year ended December 31, 2019:

- A first tranche on August 21, 2019 of 300 ORNANE plus a commitment fee of 30 ORNANE, with attached warrants to purchase 585,936 shares (BSA_{T1}), resulting in gross proceeds to us of €3 million; and

- A second tranche on December 27, 2019 of 300 ORNANE, out of which 50% were paid by NEGMA as of December 31, 2019, resulting in gross proceeds to us of €1.5 million and with attached warrants to purchase 694,444 shares (BSA_{T2}).

In April 2020, we signed a new convertible bond financing of €24 million with ATLAS to continue the development of Sarconeos (BIO101). We issued a first tranche of €3 million on April 29, 2020, a second tranche of €3 million on June 19, 2020, and a third tranche of €3 million on August 28, 2020. As of the date of this annual report, there are no outstanding convertible notes issued to ATLAS, following redemption in cash of the remaining 30 notes.

Pursuant to the agreement, we may issue up to 600 additional ORNANE to ATLAS, which would provide for additional funding to us of up to €15 million.

On April 6, 2020, as part of the implementation of the Atlas agreement, we terminated the contract with NEGMA.

Following this termination, NEGMA undertook legal action in order to claim damages of €910,900 from us as well as the delivery of 7,000,000 ordinary shares, that NEGMA considers it was entitled to pursuant to the only ORNANES still held by NEGMA, issued in consideration for a loan of €1,400,000 in principal.

The sum of €910,900 claimed by NEGMA corresponds to the contractual penalties alleged by NEGMA under the terms of our agreement with NEGMA, which provided for the payment of such penalties in the event of conversion of bonds into shares when the stock price is below the par value of the shares. We vigorously dispute this legal action and these requests for payment and delivery of shares.

Pursuant to a summary judgment dated May 7, 2020, NEGMA obtained a decision partially responding to its claims ordering us, under penalty (which amounted to €7 thousand), to pay damages in an amount of €378 thousand and deliver 2,050,000 ordinary shares to NEGMA.

This delivery of 2,050,000 shares valued at €1,394 thousand was considered as a financial indemnity recorded as financial expense. The financial indemnity totaling €1,779 thousand was then recorded as financial expense during the period. The summary judgement does not extinguish the liability due to NEGMA.

The Company and NEGMA appealed the decision of the Paris Commercial Court (see Note 14).

On November 18, 2020, the Paris Court of Appeal ruled in our favor and ordered NEGMA to return to us the 2,050,000 shares previously delivered to NEGMA as well as the provision of €378 thousand. In addition, NEGMA is required to pay €41 thousand to us as additional compensation. The total income of €419 thousand was recorded under the financial result of the period.

As of December 31, 2020, the Company recognized the right to receive the 2,050,000 shares to be returned by Negma in equity for €1,394 thousand in counterparts of the offset of the financial indemnity previously recorded as financial expense.

As of December 31, 2020, we conducted an analysis of our exposure in connection with this litigation. While we recognize there remain uncertainties as to the final decisions of the courts, as of December 31, 2020, we estimated that our maximum risk would be:

- To proceed with the repayment of the financial debt of €1.4 million (see note 12.2); and

- To be ordered to pay compensation equivalent to that of the judgment of May 7, 2020 (without penalties) (*i.e.*, €1,394 thousand) in the event of an unfavourable judgment.

Therefore, we decided to accrue a provision for risk of €1,394 thousand as of December 31, 2020. This estimation will be reassessed in the future based the evolution of the litigations.

During the year 2020, 68 bonds held by NEGMA were converted into new shares generating the issuance of 3,400,000 shares under the formula mentioned above for tranche 1 and tranche 2.

NEGMA also exercised all BSA_{T2} during the year ended December 31, 2020 generating the issuance of 694,444 shares. All BSA_{T1} are still outstanding as of December 31, 2020.

Income taxes

In 2019, a deferred tax asset has been recognized through the consolidated statement of operations to offset the deferred tax liability related to the equity component of the non-convertible bonds and the convertible notes recorded in equity. Management expects that losses on ordinary activities will continue to be offset by unrecognized tax losses.

Comparison for the years ended December 31, 2018 and 2019

The following table sets forth our results of operations for the years ended December 31, 2018 and 2019.

(Amounts in thousands of euros)	**December 31, 2018**	**December 31, 2019**
Revenue	—	—
Costs of sales	—	—
Gross margin	**—**	**—**
Research and development, net	(9,513)	(9,089)
General and administrative expenses	(4,348)	(6,593)
Operating loss	**(13,861)**	**(15,682)**
Financial expenses	(215)	(2,878)
Financial income	17	18
Change in fair value of derivative instruments	—	726
Net financial expense	**(198)**	**(2,134)**
Loss before taxes	**(14,059)**	**(17,816)**
Income taxes benefit	72	28
Net loss	**(13,987)**	**(17,788)**

Research and Development Expenses

Research and development expenses may be summarized as follows for the years ended December 31, 2018 and 2019.

(Amounts in thousands of euros)	**December 31, 2018**	**December 31, 2019**
Personnel expenses	(2,962)	(3,063)
Purchases and external expenses	(9,539)	(8,660)
Other	(190)	(214)
Research and development expenses	**(12,691)**	**(11,937)**
Research tax credit	3,133	2,807
Subsidies	45	41
Research tax credit and Subsidies	**3,178**	**2,848**
Research and development, net	**(9,513)**	**(9,089)**

Personnel costs, including stock-based payments for engineers and research personnel, were €2,962 thousand and €3,063 thousand for the years ended December 31, 2018 and 2019, respectively.

Purchases and external expenses related to our research activity were €9,539 thousand and €8,660 thousand for the years ended December 31, 2018 and 2019, respectively. The decrease in purchases and external expenses related to our studies and research costs is mainly due to budgetary constraints on current programs in favor of the development of our SARA-INT study. This decision allowed us to accelerate patient recruitment in the SARA-INT study.

These expenses consisted primarily of the cost of CROs in conducting clinical trials and non-clinical regulatory studies of our drug candidates.

We have benefited from the Research Tax Credit (CIR) since our incorporation. The CIR amounted to €3,133 thousand and €2,807 thousand for the years ended December 31, 2018 and 2019, respectively. In December 2019, a portion of the CIR receivables for 2018 and 2019 were prefinanced by FONDS COMMUN DE TITRISATION PREDIREC INNOVATION 2020 with NEFTYS CONSEIL SARL as arranger, or NEFTYS. CIR receivables for 2018 (€3,133 thousand) and 2019 (€3,243 thousand) were subsequently reimbursed by the French Tax Authorities in January 2020 and June 2020, respectively. The prefinanced receivables were then reimbursed directly to NEFTYS.

General and Administrative Expenses

General and Administrative expenses may be summarized as follows for the years ended December 31, 2018 and 2019.

(Amounts in thousands of euros)	**December 31, 2018**	**December 31, 2019**
Personnel costs	(1,804)	(1,998)
Purchases and external expenses	(2,428)	(2,393)
Other	(116)	(2,203)
General and administrative expenses	**(4,348)**	**(6,593)**

Personnel costs, including share-based payments, for general management and administrative staff were €1,804 thousand and €1,998 thousand for the years ended December 31, 2018 and 2019, respectively, mainly due to the full impact in 2019 of the recruitment of a CFO for our U.S. subsidiary that occurred in late 2018.

Other purchases and external expenses were €2,428 thousand and €2,393 thousand for the years ended December 31, 2018 and 2019, respectively. These expenses consisted primarily of administrative expenses associated with being a public listed company in France, accounting and audit fees, and legal fees.

The overall increase in general and administrative expenses for the year ended December 31, 2019, is primarily due to the recognition as expenses of the €2,225 thousand in fees related to our 2019 Nasdaq listing application, which was later withdrawn.

Net Financial Expense

Net financial expense may be summarized as follows for the years ended December 31, 2018 and 2019.

(Amounts in thousands of euros)	**December 31, 2018**	**December 31, 2019**
Other financial expenses	(38)	(352)
Financial interest and amortized cost of the convertible notes and non-convertible bonds	(189)	(2,526)
Change in fair value of derivative instruments	—	726
Other financial income	10	4
Foreign exchange gains (losses)	19	14
Net financial expense	**(198)**	**(2,134)**

Net financial expense was €(198) thousand and €(2,134) thousand for the years ended December 31, 2018 and 2019, respectively.

On September 10, 2018, we signed a venture loan agreement and bonds issue agreement with Kreos (as described in further detail below). The first and second tranches of non-convertible bonds were issued on September 10, 2018, the third tranche was issued on December 17, 2018, and the last one was issued on March 1, 2019, for total gross proceeds to us of €10 million. In accordance with IFRS 9 *Financial instruments*, the non-convertible debt component is measured according to the amortized cost method.

On August 21, 2019, we signed an agreement with NEGMA providing for up to €24 million in financing to us through the issuance of multiple tranches of convertible notes with attached warrants (ORNANEBSA), at our sole direction.

Pursuant to this agreement, the board of directors approved the issuance of the following convertible notes and warrants during the year ended December 31, 2019:

- a first tranche on August 21, 2019 of 300 ORNANE plus a commitment fee of 30 ORNANE, with attached warrants to purchase 585,936 shares, resulting in gross proceeds to us of €3 million; and

- a second tranche on December 26, 2019 of 300 ORNANE, of which 50% were paid by NEGMA as of December 31, 2019, resulting in gross proceeds to us of €1.5 million, together with attached warrants to purchase 694,444 shares.

In accordance with IFRS 9 *Financial Instruments*, initial recognition of the convertible notes was recorded at the fair value of their debt component and subsequently this debt component is accounted for under the amortized cost method. The conversion option of the convertible notes was bifurcated and classified in derivative instruments because the conversion price is not fixed and measured at fair value on the date of issuance (based on the Black-Scholes valuation model) with recognition of the changes in fair value in each reporting period in the statement of consolidated operations.

An aggregate of 242 convertible notes (par value of €10 thousand each) were converted in 2019, which resulted in the elimination of the financial instrument and reclassification of the debt to equity upon share issuance with the net impact of the conversion using the nominal value of the debt being reflected in "Financial interest and amortized cost of the convertible notes and non-convertible bonds" in the table above.

Income taxes

In 2018 and 2019, a deferred tax asset has been recognized through the consolidated statement of operations to offset the deferred tax liability related to the equity component of the non-convertible bonds and the convertible notes recorded in equity. Management expects that losses on ordinary activities will continue to be offset by unrecognized tax losses.

B. Liquidity and Capital Resources

As of December 31, 2020, we had cash and cash equivalents of € 5,847 thousand. We purchased a fixed term deposit contract (recorded in other current financial assets) for a total of €12,500 thousand. Our total cash, cash equivalents and other current financial assets amounted in total to €18,771 thousand.

We received approximately €13.49 million ($16.35 million, using the exchange rate of €1.00 = $1.212 on February 12, 2021, the closing date) in net proceeds from our U.S. initial public offering of ADSs, which closed on February 12, 2021. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in bank accounts and fixed bank deposits primarily in France.

Our operations have been financed primarily by capital contributions from our founders, capital increases carried out between 2006 and 2020, convertible debt instruments with warrants, non-convertible bonds and net proceeds from the initial public offering of our ordinary shares on the Euronext Growth Market in France in 2015 and, into 2021, from the proceeds from our U.S initial public offering. Our primary uses of capital are, and we expect will continue to be, third-party expenses associated with the planning and conduct of preclinical studies and clinical trials, costs of process development services and manufacturing of our drug candidates, and compensation-related expenses.

We do not expect to generate significant revenue from product sales unless and until we out-license one or more drug candidates or we obtain regulatory approval for and commercialize our current or any future drug candidates, either directly or through others. We anticipate that we will continue to generate losses for the foreseeable future, and we expect our losses to increase as we continue the development of and seek regulatory approvals for our drug candidates and begin to commercialize any approved products.

We are subject to numerous risks applicable to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. We expect to incur additional costs associated with operating as a public company in the United States and we anticipate that we will need substantial additional funding in connection with our continuing operations.

Our future funding requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our preclinical studies and clinical trials and other related activities;
- the cost of formulation, development, manufacturing of clinical supplies and establishing commercial supplies of our drug candidates and any other drug candidates that we may develop, in-license or acquire;
- the cost, timing and outcomes of pursuing regulatory approvals;
- the cost and timing of establishing administrative, sales, marketing and distribution capabilities, to the extent we undertake to commercialize our products directly;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish, including any required milestone and royalty payments thereunder; and

- the emergence of competing technologies and their achieving commercial success before we do or other adverse market developments.

Our ability to achieve and maintain profitability will depend upon the successful development, regulatory approval and commercialization of our drug candidates and achieving a level of revenues adequate to support our cost structure. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional capital. If we need to raise additional capital to fund our operations and complete our ongoing and planned clinical trials, funding may not be available to us on acceptable terms, or at all.

We plan to continue to fund our operations and capital funding needs through a combination of equity offerings, debt financings and collaborations. The sale of additional equity would result in additional dilution to our shareholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, sell assets where possible or suspend or curtail planned programs. In addition, lack of funding would limit any strategic initiatives to in-license or acquire additional drug candidates or programs.

As of December 31, 2020, we had capital resources consisting of cash, cash equivalents, and other current financial assets of €18.7 million ($22.9 million, translated solely for convenience into dollars at an exchange rate of €1.00 = $1.223, the noon buying rate of the Federal Reserve Bank of New York on December 31, 2020). Since December 31, 2020, we have received approximately €13.49 million ($16.35 million, using the exchange rate of €1.00 = $1.212 on February 12, 2021, the closing date) in net proceeds from our U.S. initial public offering of ADSs, which closed on February 12, 2021.

As of February 26, 2021, we also issued an aggregate of 377 210 ordinary shares upon the conversion of share subscription warrants and founders' warrants for a total consideration of €101.8 thousand. We also repaid €567 thousand of the carrying amount of the Kreos loan.

We expect that our existing capital resources as adjusted by the effect of those events, and including our ability to draw down on our credit facility with ATLAS (up to €15 million), together with the proceeds from our U.S. initial public offering, will be sufficient to fund our current operations at least for the next 12 months. However, this estimate is based on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. In any event, we will need additional funding to pursue preclinical and clinical activities, obtain regulatory approval for, and commercialize our drug candidates.

Cash Flows

	Year Ended December 31,		
(Amounts in thousands of euros)	**2018**	**2019**	**2020**
Net cash (used in) provided by:			
Operating activities	(12,057)	(15,272)	(9,864)
Investing activities	(104)	(278)	(12,713)
Financing activities	6,771	7,500	22,074
Effect of exchange rate changes on cash and cash equivalents	(61)	(18)	13
Net increase (decrease) in cash and cash equivalents	(5,451)	(8,069)	(490)

Operating Activities

Net cash used in operating activities were €12,057 thousand, €15,272 thousand and €9,864 thousand for the years ended December 31, 2018, 2019 and 2020, respectively. The increase in net cash used from 2018 to 2019 is mainly related to the €2,225 thousand in fees incurred in connection with our 2019 Nasdaq listing application, which was later withdrawn. The decrease in net cash used from 2019 to 2020 is mainly related to the one-off fees related to the postponed Nasdaq listing in July 2019 and the decrease in research tax credit receivables from 2019 to 2020.

Investing Activities

Net cash used in investing activities was €104 thousand, €278 thousand and €12,713 thousand for the years ended December 31, 2018, 2019 and 2020, respectively. As part of the Intellectual Property Agreement signed with our CEO, we acquired, in 2019, from our CEO the rights to use patents for €630 thousand, which are amortized over 19 years, €270 thousand of which was paid in 2019 and €180 thousand in 2020.

In 2020, the Company purchased short-term deposits for €12,500 thousand, classified as other current financial assets in accordance with IAS 7.

Financing Activities

Net cash provided by financing activities were €6,771 thousand, €7,500 thousand and €22,074 thousand for the years ended December 31, 2018, 2019 and 2020, respectively.

Between September and December 2018, we issued three tranches of non-convertible bonds to Kreos for €2,500 thousand each for total gross proceeds to us of €7,500 thousand. A guarantee deposit of €240 thousand was withheld by Kreos from the proceeds received by us. The amount withheld will be deducted from the last installment to be repaid by us. In relation to these debt issuances, we incurred costs of €305 thousand.

On March 1, 2019, we issued one tranche of non-convertible bonds to Kreos for €2,500 thousand. A guarantee deposit of €80 thousand was withheld by Kreos from the proceeds received by us. The amount withheld will be deducted from the last installment to be repaid by us. In relation to these debt issuances, we incurred costs of €50 thousand. In 2019, we repaid €2,292 thousand.

On August 21, 2019, we issued one tranche of convertible notes with attached warrants to NEGMA for €3,000 thousand (300 convertible notes), plus a commitment fee of 30 convertible notes. On December 26, 2019, we issued a second tranche out of which 50% were paid by NEGMA, resulting in gross proceeds to us of €1.5 million (150 convertible notes). 242 convertible notes were converted in 2019 resulting in the issuance of 10,499,841 ordinary shares.

In December 2019, a portion of the research tax credit receivables for 2018 and 2019 were prefinanced by NEFTYS for total gross proceeds of €5,029 thousand. We incurred issuance costs of €62 thousand and amortized costs of €134 thousand. A guarantee deposit of €475 thousand was withheld by NEFTYS from the proceeds received by us.

We also received net proceeds of €73 thousand from conditional advances in 2019 compared to €329 thousand in 2018, and we paid interest of €1,080 thousand in 2019 compared to €135 thousand in 2018.

In 2020, we issued an aggregate of 49,295,005 ordinary shares in four capital increases that occurred in February, June, July and October for total gross proceeds to us of €23,486 thousand. In relation to these equity transactions, we incurred costs of €3,496 thousand.

Pursuant to a summary judgement dated May 7, 2020, we were required to pay damages in an amount of €385 thousand and deliver 2,050,000 ordinary shares to NEGMA. Following the decision of the Paris Court of Appeal in November 2020, we received an indemnity from NEGMA of €419 thousand.

Proceeds from the subscription of warrants and the exercise of warrants amounted to €271 thousand and €862 thousand, respectively, for 2020. The subscription and the exercise of the investors' warrants by our CEO in April 2020 was settled against the €630 thousand due to our CEO following our acquisition of patents rights (€177 thousand for the subscription of warrants and €453 thousand for the exercise of warrants).

In April, June and August 2020, we issued three tranches of convertible notes to ATLAS for €3,000 thousand each. As of December 31, 2020, 330 convertible notes had been converted in accordance with the formula above, resulting in the issuance of 17,178,683 new shares pursuant to Tranche 1, 2 and 3. 30 notes issued with the third tranche have been repaid in cash for a total amount of €750 thousand. In relation to these debt issuances, we incurred costs of €435 thousand.

In addition to our repayment of €750 thousand to ATLAS, we repaid €3,214 thousand of the Kreos non-convertible bonds in 2020 compared to €2,292 thousand in 2019.

We did not receive proceeds from conditional advances in 2020 compared to €73 thousand in 2019, but repaid €136 thousand in 2020. We paid interest of €908 thousand and €1,080 thousand for 2020 and 2019, respectively.

In December 2020, a portion of the research tax credit receivables for 2020 was prefinanced by NEFTYS for total gross proceeds of €2,083 thousand. We incurred issuance costs of €41 thousand and amortized costs of €79 thousand. A guarantee deposit of €169 thousand was withheld by NEFTYS from the proceeds received by us. The prefinanced receivables for CIR 2018 and 2019 were reimbursed to NETFTYS for €4,589 thousand in 2020 after we received the CIR from the French Tax Authorities.

Cash and Funding Sources

Research Tax Credit

We have benefited from the CIR since our incorporation. The CIR is usually payable by the government in the year following its recognition when there is no taxable net income to be offset if certain business size criteria are met. The CIR for 2017 was reimbursed in 2018 for €2,545 thousand. In December 2019, a portion of the CIR receivables for 2018 and 2019 were prefinanced by NEFTYS. CIR receivables for 2018 (€3,133 thousand) and 2019 (€3,243 thousand) were reimbursed by the French Tax Authorities in January 2020 and June 2020, respectively. The prefinanced receivables were then reimbursed directly to NEFTYS.

In December 2020, a portion of the CIR receivables for 2020 (€1,964 thousand) was prefinanced with NEFTYS. The CIR for 2020 is expected to be reimbursed in 2021.

Reimbursable Advances

A reimbursable advance was granted to us by BPI France on August 7, 2008. This was a non-interest-bearing reimbursable advance of €230 thousand for the clinical development of an extract of quinoa active on metabolic syndrome. Following the successful completion of the project and the extension of the repayment terms granted by BPI France (formerly OSEO), this advance was repaid by means of quarterly payments made between March 31, 2016 and December 31, 2018. As of December 31, 2018, we have fully satisfied this conditional advance.

A reimbursable advance was granted to us by BPI France on February 4, 2015. This was a non-interest-bearing reimbursable advance of €260 thousand for the "in vitro, in vivo, and pharmacokinetic characterization of a candidate drug." Following the successful completion of the project and the extension of the repayment terms granted by BPI France, this advance is being repaid by means of quarterly payments made between June 30, 2017 and March 31, 2022. The payment schedule has been postponed by six months automatically by BPI France as part of the financial support measures for companies in the management of the COVID-19 crisis. As a result, the last payment will occur in September 30, 2022.

A reimbursable advance was granted to us by BPI France on November 28, 2016. This is a non-interest-bearing reimbursable advance of €1,100 thousand for the production of clinical batches, in the preclinical regulatory phase and clinical Phase 1 of Sarconeos (BIO101), for the treatment of sarcopenic obesity. The agreement with BPI France provides that the advance would be paid to us in two tranches, with the first of €600 thousand paid at the signing date of the agreement, and the second €500 thousand to be paid at the end of the program. We received €500 thousand during the year ended December 31, 2018 related to the second tranche. Following the successful completion of the project, this advance is being repaid by means of quarterly payments made between December 31, 2018 and September 30, 2023. The payment schedule has been postponed by six months automatically by BPI France as part of the financial support measures for companies in the management of the COVID-19 crisis. As a result, the last payment will occur in March 31, 2024.

On June 3, 2019, we entered into a collaboration agreement with the French Muscular Dystrophy Association (AFM-Telethon), pursuant to which AFM-Telethon has provided funding of €400,000 to us. This is a non-interest-bearing reimbursable advance of €400,000 for certain preclinical studies and preparations for our MYODA program. Under the terms of the agreement, subject to regulatory approval to conduct the MYODA clinical trial in Europe and conclusive results from the collaboration, we will submit to AFM-Telethon a new research project for further collaboration on the clinical development of Sarconeos (BIO101) in DMD. If funding for the new research project is approved by AFM-Telethon, we will negotiate in good faith the terms of a new collaboration agreement with AFM-Telethon. If entered into, the new collaboration agreement will grant certain rights to AFM-Telethon that may, in the event we later decide to abandon or not pursue the development of Sarconeos (BIO101), entitle AFM-Telethon to continue the development and/or commercialization of Sarconeos (BIO101) and/or any pharmaceutical product derived from Sarconeos (BIO101) for the purpose of guaranteeing the access of such products to DMD patients. The advance will be repaid upon our obtaining authorization to commence a Phase 3 clinical trial of Sarconeos (BIO101) for the treatment of DMD. In addition, we will be required to repay the advance if we are unable to come to an agreement with AFM-Telethon on further funding of our MYODA clinical program or we materially breach the agreement and AFM-Telethon requests reimbursement.

Loans from Lending Institutions

We signed a loan agreement with BPI France (formerly OSEO) on November 4, 2008 for the partial financing of an innovation program in the amount of €150 thousand. This loan was repaid in quarterly installments of €7.5 thousand through August 31, 2018 (term of the loan). We have fully satisfied this loan.

Non-convertible bonds issued to Kreos

In September 2018, we entered into a venture loan agreement and bonds issue agreement with Kreos providing for up to €10 million in financing to us. Pursuant to the terms of the agreements, Kreos agreed to subscribe for up to €10 million in non-convertible bonds, to be issued by us in up to four tranches of €2.5 million each, with a warrant to purchase 442,477 ordinary shares attached to the first tranche. As required under the terms of the agreements, we pledged a security interest in our assets for the benefit of Kreos. We also granted a security over the business as a going concern (*nantissement de fonds de commerce*), including a portion of our patents, to Kreos.

Each tranche of non-convertible bonds bears a 10% annual interest rate and must be repaid in 36 monthly installments of €320,004 per month commencing in April 2019. The first and second tranches were issued to Kreos on September 10, 2018. The third tranche was issued to Kreos on December 17, 2018. The final tranche was issued on March 1, 2019.

In connection with the first tranche, we issued 442,477 warrants to Kreos giving them the right to purchase 442,477 new ordinary shares at an exercise price of €2.67 per share over a 7-year period from the issue date.

Pursuant to the terms of the agreements, we have the right, at any time but with no less than 30 days prior notice to Kreos, to prepay or purchase the bonds, exclusively in full. The prepayment will be equal to (i) the principal amount outstanding, plus (ii) the sum of all interest repayments which would have been paid throughout the remainder of the term of the relevant tranche discounted by 10% per annum.

Convertible notes issued to NEGMA

In August 2019, we signed an agreement with NEGMA providing for up to €24 million in financing to us through the issuance of multiple tranches of convertible notes with attached warrants (ORNANEBSA), at our sole discretion.

On August 21, 2019, a first tranche of 300 ORNANE plus a commitment fee of 30 ORNANE, with attached warrants to purchase 585,936 ordinary shares (BSA_{T1}), was issued resulting in gross proceeds to us of €3 million. On December 27, 2019, a second tranche of 300 ORNANE, out of which 50% were paid by NEGMA in 2019, with attached warrants to purchase 694,444 ordinary shares (BSA_{T2}), was issued resulting in gross proceeds to us of €1.5 million.

On April 6, 2020, in the context of the execution of an issuance and subscription agreement with ATLAS, we terminated the contract with NEGMA.

Following this termination, NEGMA undertook legal action in order to claim damages of €910,900 from us as well as the delivery of 7,000,000 of our ordinary shares that NEGMA considers it was entitled to pursuant to the only Biophytis ORNANES still held by NEGMA, issued in consideration for a loan of €1,400,000 in principal.

The sum of €910,900 claimed by NEGMA corresponds to the contractual penalties alleged by NEGMA under the terms of the NEGMA contract 2019, which provided for the payment of such penalties in the event of conversion of bonds into shares when the stock price is below the par value of the shares. Biophytis vigorously disputes this legal action and these requests for payment and delivery of shares.

Pursuant to a summary judgment dated May 7, 2020, NEGMA obtained a decision partially responding to its claims ordering us under penalty (which amounted to €7 thousand), to pay damages to NEGMA in an amount of €378 thousand and to deliver to NEGMA 2,050,000 of our ordinary shares. This delivery of 2,050,000 shares to NEGMA were valued at €1,394 thousand and were considered as a financial indemnity. The financial indemnity, including damages totaling €1,779 thousand was then recorded as financial expense during the period (€1,394 thousand against equity and €385 thousand (including €7 thousand in penalties) paid to NEGMA). The summary judgement does not extinguish the potential liability due to NEGMA. We appealed this decision to the Court of Appeals of Paris. By decision dated November 18, 2020, the Court of Appeal reversed the May 7, 2020 order and ordered NEGMA to pay the costs of the trial and appeal proceedings. As a result, NEGMA was ordered to return the 2,050,000 ordinary shares to us and pay us an amount of €378 thousand. NEGMA has satisfied these obligations as of the date of this annual report by paying €419 thousand (including penalty interest and legal costs) and delivering 2,050,000 ordinary shares to us on January 19, 2021. In addition, NEGMA initiated proceedings on the merits in order to obtain what had not been awarded by the May 7, 2020 court order. Since the decision of the Court of Appeals of Paris dated November 18, 2020, NEGMA has modified its claims on the merits in order to obtain 7,000,000 shares. The hearing in the proceedings on the merits took place on February 8, 2021 for closing arguments. As of the date of this Annual Report, the decision has not been rendered.

In 2019, 242 convertible notes had been converted resulting in the issuance of 10,499,841 ordinary shares. In 2020, 68 bonds held by NEGMA were converted into ordinary shares generating the issuance of 3,400,000 shares.

NEGMA also exercised all BSA_{T2} in 2020 generating the issuance of 694,444 shares. All BSA_{T1} are still outstanding as of December 31, 2020.

Convertible bonds issued to ATLAS

In April 2020, we signed a new convertible bond financing of €24 million from ATLAS to continue the development of Sarconeos (BIO101).

The 960 3-year note warrants require their holder to exercise them, at our request, in tranches of 120 warrants each. Each warrant grants its holder the right to one ORNANE. Note warrants may not be transferred and will not be subject to a request for admission to trading on the Euronext Growth market.

The ORNANE have a par value of €25,000 and are issued at a subscription price of 0.97% of the nominal value. They do not bear interest and have a 24-month maturity from issuance. Holders of ORNANE may request at any time to convert them during their maturity period, and at that time, we will be able to redeem the ORNANE in cash. At the end of the maturity period, and if the ORNANE have not yet been converted or redeemed, the holder will have to convert them.

ORNANE may be transferred by their holders only to Affiliates and will not be subject to a request for admission to trading on the Euronext Growth market.

We issued a first tranche of €3 million on April 29, 2020, a second tranche of €3 million on June 19, 2020 and a third tranche of €3 million on August 28, 2020. As of the date of this annual report, there are no outstanding convertible notes issued to ATLAS, following redemption in cash of the remaining 30 notes in 2020. A commitment fee of €375 thousand was withheld from the proceeds received for the first tranche. Other issuance costs were incurred by us for approximately €66 thousand (€16 thousand for the first tranche, €23 thousand for the second tranche and €27 thousand for the third tranche).

As of December 31, 2020, 330 convertible notes had been converted resulting in the issuance of 17,178,683 ordinary shares.

Public Offering of Share Subscription Warrants

On April 3, 2020, we decided to launch a public offering of share subscription warrants. The main objective of the transaction is to allow existing shareholders to participate in the new COVA program and our future development, and eventually to consolidate its equity.

Upon completion of the public offering, we issued 7,475,708 share subscription warrants, after full exercise of the extension clause.

The subscription price was €0.06 per warrant. The warrants can be exercised for a period of 5 years from April 30, 2020, at an exercise price of €0.27 per new share.

Each warrant will give its holder the right to subscribe to one new Biophytis share.

Total subscriptions amounted to €449 thousand. In 2020, warrants were exercised for €833 thousand.

The subscription and the exercise of the investors warrants by our CEO was settled by the remaining amount of €630 thousand due our CEO as part of the Intellectual Property agreement (€177 thousand for the subscription of warrants and €453 thousand for the exercise of warrants).

C. Research and Development

For a discussion of our research and development activities, see “Item 4.B—Business Overview” and “Item 5.A—Operating Results.”

D. Trend Information

For a discussion of trends, see "Item 4.B—Business Overview," "Item 5.1—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

E. Off-Balance Sheet Arrangements

We do not have variable interests in variable interest entities or any off-balance sheet arrangements as defined under the SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our statements of financial position.

F. Tabular Disclosure of Contractual Obligations

The following table discloses aggregate information about material contractual obligations and periods in which payments were due as of December 31, 2020.

Future events could cause actual payments to differ from these estimates.

(Amounts in thousands of euros)	Year ended December 31, 2020 Total	2021 Less than 1 year	2022 - 2023 1 - 3 yrs	2024 - 2025 3 - 5 yrs	Thereafter More than 5 yrs
Non-convertible bonds(a)	4,800	3,840	960	—	—
Convertible notes—NEGMA(c)	1,400	1,400	—	—	—
Conditional advances	1,232	292	786	155	—
Financial liabilities related to the prefinancing of a portion of the research tax credit receivables	2,252	2,252	—	—	—
Bank overdrafts	—	—	—	—	—
Lease liability(b)	—	—	—	—	—
Operating lease obligations(b)	153	153	—	—	—
Licence agreements(d)	195	15	70	110	—
Total	10,032	7,951	1,816	265	—

(a) The contractual obligations related to non-convertible bonds include the principal repayments and the 10% annual interest payments.

(b) Given the contractual terms of our main leases (low-value asset leases and short-term agreements of less than 12 months), the mandatory application of IFRS 16 Lease as January 1, 2019 had no impact on our financial statements as of December 31, 2019 and 2020. Our lease arrangement with Sorbonne University was finalized in late 2020 and expires on December 15, 2021, unless otherwise agreed by the Parties. Our operating lease obligation as of the date of this annual report has been estimated at €153 thousand.

(c) The NEGMA contract was terminated in April 2020. Redemption value of the notes issued to NEGMA amounts to €1,400 thousand as of the date of this annual report. In April 2020, we signed a new convertible note financing of €24 million from ATLAS to continue the development of Sarconeos (BIO101) through the issuance of multiple convertible notes. Holders of ORNANE may request at any time to convert them during their maturity period, and at that time, we will be able to redeem the ORNANE in cash. At the end of the term, and if the ORNANE have not yet been converted or redeemed, the holder will have to convert them. We issued a first tranche of €3 million on April 29, 2020, a second tranche of €3 million on June 19, 2020 and a third tranche of €3 million on August 28, 2020. As of the date of this annual report, there are no outstanding convertible notes issued to ATLAS, as the Company has repaid in 2020 €863 thousand for the remaining 30 convertible notes that were issued to ATLAS with a redemption value of €750,000.

(d) We have signed several agreements to license industrial property to further our research and developments efforts with royalties due to the counterparties that are variable starting the year after the first marketing of a product and royalty arrangements. However, there are certain guaranteed annual minimum amounts due starting in various future years. These guaranteed annual minimum amounts are shown in the table above. Other than these minimum guaranteed amounts (as further described below), amounts of royalties to be paid after 2024 cannot be determined precisely and therefore, no royalties amounts are included in the table above.

The following table discloses the commitments given as part of the licensing agreements mentioned above:

Agreements for the exploitation of industrial property	Commitments given
SARCOB commercialization agreement—SATT Lutech Agreement of January 1, 2016, as amended on April 2, 2019, on November 6, 2020 and on December 17, 2020	This agreement covers the S1 through S9 patent families. The contractual structure of the consideration payable by us is as follows: firstly, in the year after the first marketing of a product and in any event at the latest, from 2023 onwards, we will pay a guaranteed annual minimum amount of €40 thousand, which will be deducted from the amount of royalties effectively due annually to SATT Lutech. With regard to the direct exploitation, the agreement provides for an annual royalty for a figure based on the net sales of products, distinguishing between sales of nutraceutical and medicinal products. With regards to indirect exploitation, the agreement provides for annual double-digit royalties based on income received from licensees, distinguishing: (i) between the sales of nutraceutical products (double-digit royalties) and drug products (two or one-digit royalties) and (ii) the product development phase (Phase 1, 2 or 3) at the time of the conclusion of the licensing agreement. The royalty payments will end upon termination of the agreement.
MACULIA commercialization agreement—SATT Lutech Agreement of January 1, 2016, as amended on December 17, 2020	This agreement covers the MI through MIV patent families. The contractual structure of the consideration payable by us is as follows: firstly, in the year following the first marketing of a nutraceutical product and in any event no later than in 2020, we will pay an annual guaranteed minimum amount of €15 thousand. In the same way, we will pay a guaranteed minimum amount of €50 thousand in the event of marketing of a drug product and in any event no later than from 2026. These amounts will be deducted from the amount of royalties effectively due annually to SATT Lutech. For direct exploitation, the agreement also provides for an annual royalty of a figure based on net sales of products, distinguishing between sales of nutraceutical and medicinal drugs. For indirect exploitation, it also provides for annual double-digit royalties based on income received from licensees, distinguishing (i) between the sales of nutraceuticals (double-digit royalties) and drug products (one or two-digit royalties) and (ii) the product development phase of these products (Phase 1, 2 or 3) at the time of conclusion of the licensing agreement. The royalty payments will end upon termination of the agreement.

G. Safe Harbor

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Special Note Regarding Forward-Looking Statements.”

Item 6. Directors, Senior Management and Employees.

A. Directors and Senior Management

The following table presents information about our officers and directors as of the date of this annual report.

NAME	AGE	POSITION
Executive Officers		
Stanislas Veillet	55	Chairman of the Board, Chief Executive Officer and Director
Evelyne Nguyen	59	Chief Financial Officer
René Lafont	75	Scientific Advisor
Waly Dioh	52	Chief Operating Officer
Pierre J. Dilda	51	Chief Scientific Officer
Key Employees		
Samuel Agus	53	Chief Medical Officer (1)
Non-Employee Directors		
Dimitri Batsis	55	Director
Nadine Coulm	58	Director
Jean M. Franchi	54	Director
Jean Mariani	71	Director

(1) Employed by Biophytis, Inc., our wholly-owned subsidiary in the United States.

There are no family relationships among any of our executive officers or directors, except that René Lafont is the uncle of Stanislas Veillet's spouse. Unless otherwise indicated, the current business addresses for our executive officers and directors is Sorbonne University—BC 9, Bâtiment A 4ème étage, 4 place Jussieu 75005 Paris, France.

Biographies

Executive Officers

Stanislas Veillet is the co-founder of Biophytis. He has served as our President since the Company's inception and served as Chief Executive Officer (*Directeur Général*) and chairman of our board since May 2015. He began his career in Brazil as a researcher at the *Centre de coopération international en recherché agronomique pour le développement*, or CIRAD from 1989 to 1993, before obtaining a Ph.D. in Genetics. From 1994 to 2001, Mr. Veillet managed a biotechnology laboratory for the Cargill Group, then Pharmacia-Monsanto, to develop a high throughput platform for whole genome sequencing. From 2002 to 2006, he managed the Life Sciences Department of the Danone Group, where he developed several products, including Danacol and Danaten for the prevention of cardiovascular diseases. Mr. Veillet has a degree in Engineering and a Ph.D. in Genetics from AgroParisTech. Mr. Veillet is also a member of the board of directors and chairman of the compensation committee of Drone Volt S.A.

Evelyne Nguyen has served as Chief Financial Officer since January 2020. Before joining us, she worked at Bristol Myers Squibb from 1987 to 1992, then as Chief Financial Officer, EVP Finance & Strategy, then EVP Biomanufacturing for LFB, a French biopharmaceutical company from 1997 to 2012. From 2013 to 2014, she served as Chief Financial Officer at Nicox SA. From 2015 to 2019, she served at ANMPartners, a company specializing in providing strategic and financial advice for companies in the healthcare industry, which she founded. Ms. Nguyen holds a MBA in Finance and Management from Institut Supérieur de Gestion and an executive degree from Stanford University.

René Lafont is the co-founder of Biophytis and has been a scientific advisor since September 2019. He previously served as our Chief Scientific Officer from June 2011 to September 2019. He is also a Professor Emeritus at Sorbonne University and served as the Dean of the Department of Life Sciences from 2000 to 2005. He was appointed a Professor at UPMC (now Sorbonne University) in 1985 and was named a Professor Emeritus in 2008. Dr. Lafont graduated with a Master in chemistry, biochemistry and physiology from the Ecole Normale Supérieure, or ENS, in Paris and a state doctorate in biology from ENS and Paris University. Dr. Lafont has been credited with 185 scientific articles and 59 reviews and book chapters.

Waly Dioh has served as our Chief Operating Officer since October 2019 and previously served as Vice President of Clinical Development from October 2015 to October 2019 and as our Director of Research and Development from October 2006 to October 2015. Previously, Mr. Dioh worked at Monsanto Company, initially in France and then in the United States. Mr. Dioh received a DUES in natural sciences from Dakar University in Senegal, a masters in biology/plant pathology from Pierre and Marie Curie University Paris VI in Paris, France, a PhD in plant pathology from his doctorate from the University of Paris XI, Orsay in Paris, France and an MBA from the ESLSCA Business School in Paris, France.

Pierre J. Dilda has served as our Chief Scientific Officer since October 2019 and previously served as our Vice President of Research from 2015 to 2019. Before joining us, he was Senior Research Fellow at the Lowy Cancer Research Center at the University of New South Wales (UNSW) in Sydney, Australia, from 2006 to 2015, where he was responsible for advancing several cancer therapeutics. Dr. Dilda holds a bachelor's degree in biochemistry and a Masters in biochemistry and immunology from the University of Paris VII (Denis Diderot), Faculty of Sciences, Paris, France, and a Masters in physiology and physiopathology and a PhD in pharmacology from the University of Paris V, Faculty of Medicine, Paris, France.

Key Employee

Samuel Agus has served as the Chief Medical Officer of Biophytis, Inc., our wholly-owned U.S. subsidiary since July 2018. From May 2017 to June 2018 he served as the Vice President, Chief Medical Officer of Hansa Medical AB (Publ), a biotechnology company. Prior to that, he served at various leadership positions in clinical development and medical affairs, in several pharmaceutical companies, such as Teva Pharmaceuticals industries, Solvay Pharmaceuticals, Abbott, Shire and H. Lundbeck A/S. Dr. Agus holds a doctorate in Medicine from The Hebrew University of Jerusalem. He is a board-certified neurologist (from Israel) and has had academic training in biostatistics and bioinformatics.

Non-Employee Directors

Dimitri Batsis has served as a director since May 2018. Mr. Batsis is a co-founder, Chief Executive Officer and Chairman of the web agency Zeni-Corporation, which was acquired by Keyrus group in 2007. Mr. Batsis is the founder and Chairman of the board of directors (since October 2020) of Drone Volt S.A., a company specializing in the design, meeting and commercialization of civilian drones, which he founded in May 2011. He also founded and has served as the Chief Executive Officer of Dimitri Batsis Investments since May 2012.

Nadine Coulm has served as a director since May 2015. Ms. Coulm served as the Vice President of Investor Relations and Financing for the Korian Group, which provides long-term care to the elderly, from March 2017 to August 2019. Previously, she served as the Vice President Financing and Investor Relations for FNAC Group, a consumer electronics company, from January 2013 to March 2017. From November 2006 to November 2011, she served as Vice President of Fianancial Communication and Investor Relations at Casino Group. From 1988 to 2006, she held various positions at Danone Group. She has over 30 years of experience in Corporate Finance, with a focus on Investor Relations and Financing. Ms. Coulm received an MBA in Finance from HEC Paris.

Jean M. Franchi has served as a director since June 2017. Ms. Franchi has also served as a Director of Dynacure since January 2021. Ms. Franchi currently serves as Chief Financial Officer of Replimune Group Inc. Previously, Ms. Franchi served as the Chief Financial Officer for Merrimack Pharmaceuticals from 2017 to 2019 where she streamlined the financial operations while strengthening the balance sheet through the retirement of debt, sales of assets, and navigating the review of strategic alternatives. Prior to Merrimack, Ms. Franchi held the position of Chief Financial Officer at other public and private biotechnology and life sciences companies, including Dimension Therapeutics from 2015 to 2017 and Good Start Genetics from 2012 to 2015. Ms. Franchi also spent 16 years at Genzyme (acquired by Sanofi in 2011) from 1995 to 2011, holding several positions including Senior Vice President of Finance and Senior Vice President of Corporate Finance in which she played an important role in the approximately $20+ billion acquisition of Genzyme by Sanofi. Ms. Franchi serves on the boards of directos of BioDesix, Inc. and Visioneering Technologies, Inc. Ms. Franchi earned a bachelor's degree in Business Administration from Hofstra University.

Jean Mariani has served as a director since October 2019. Dr. Mariani was employed by the Company from October 2017 to September 2019. Since October 2019, Dr. Mariani has served as president Successful Life SAS. He has served as a Professor Emeritus at Sorbonne University since October 2017. He has served as director of the team Brain Development Aging and Repair in the UMR UPMC-CNRS 8256 (Research laboratory) since 2014. He has been director of the University Hospital Department FAST (Fight Ageing and Stress) since 2013 and of the Institute of Longevity Charles Foix since 2008. He has been a professor and hospital practitioner since September 2005. He was member of the Scientific Council of the Faculty of Medicine Pierre et Marie Curie from 2011 to 2015. Dr. Mariani has been a member of the Scientific Council of the Ataxia Telangectasia Fund since 1997 and president of the Society for Research on Cerebellum and Ataxia since 2012. Dr. Mariani holds a PhD in Biochemistry. Dr. Mariani has been credited with 238 scientific articles and 23 book chapters.

B. Compensation

The aggregate compensation paid and benefits in kind granted by us to our current executive officers and directors, including share-based compensation, for the year ended December 31, 2020, was €2.1 million. For the year ended December 31, 2020, we allocated €96 thousand to be accrued to provide retirement indemnity to our directors or executive officers, except to the extent required by French law.

We implemented a 401(k) plan for the executive officers of Biophytis, Inc., our U.S. wholly-owned subsidiary, which became effective in January of 2019, through which we will match up to 4% of employee contributions.

Director Compensation

The following table sets forth the total compensation paid to our non-employee directors for service on our board of directors during the year ended December 31, 2020.

Name	Total Compensation(1) (€)
Stanislas Veillet	60,000
Dimitri Batsis	45,000
Nadine Coulm	60,000
Jean Franchi	42,500
Jean Mariani	55,000

(1) Represents meeting attendance fees paid to or earned by directors.

Chief Executive Officer Compensation

The following table sets forth information regarding compensation paid to or earned by our Chief Executive Officer during the year ended December 31, 2020.

Nature of Compensation	Amounts Paid or Earned (€)
Fixed remuneration(1)	250,000
Variable annual remuneration(2)	30,000
Benefits in kind(3)	33,896
Total	313,896

(1) Mr. Veillet receives a fixed annual remuneration of €250,000 payable over 12 months.

(2) Mr. Veillet was entitled to receive variable annual remuneration of up to €75,000 for the year ended December 31, 2019, based on satisfaction of the following annual targets: (i) finalization of patient recruitment for the SARA-INT clinical program before the end of fiscal year 2019, (ii) recruitment of the first patient for the MYODA clinical program before the end of fiscal year 2019, (iii) obtaining the results for the MACA-Phase clinical program by the end of fiscal year 2019, and (iv) securing a financing of at least €20,000,000 through the issuance of shares or bonds, a Nasdaq listing or any other financing before the end of fiscal year 2019. Based on partial satisfaction of these targets, the Compensation and Governance Committee determined that Mr. Veillet was entitled to receive €30,000, which amount was paid to him in July 2020.

(3) Mr. Veillet benefits from a "GSC" private unemployment insurance policy. In France, directors and officers do not have employee status and are not covered by the legal unemployment regime. "GSC" enables directors and officers to receive income in the event of unemployment.

Mr. Veillet is also entitled to receive reimbursement of expenses incurred within the context of performing his duties as Chairman and Chief Executive Officer.

Employment Agreements with Executive Officers and Change of Control Severance Benefits

We have entered into employment agreements with our executive officers, except for our CEO who is a corporate officer (*mandataire social*) and does not have an employment contract. Each of our executive officers is employed for a continuous term unless either we or the executive officer gives prior notice to terminate such employment. We may terminate the employment of our executive officers for just cause (*cause réelle et sérieuse*), at any time, with the notice and indemnification requirements provided by French law and the applicable collective bargaining agreement. An executive officer may terminate his or her employment at any time with the prior written notice period provided by French law and the applicable collective bargaining agreement.

Each executive officer has agreed to maintain the confidentiality of any confidential information, both during and after the employment agreement expires or is earlier terminated. In addition, all executive officers have agreed to be bound by a non-solicitation covenant that prohibits each executive officer from soliciting our customers, or soliciting or hiring our executive employees and those of our employees working in the same team as our executive officer, during his or her employment and for one year after the termination of his or her employment. In addition, our executive employees (other than René Lafont), are bound by a non-compete covenant that prohibits each executive officer from competing with us, directly or indirectly, during his or her employment and for six months after the termination of his or her employment.

In accordance with statutory provisions, Mr. Veillet may be freely removed from his position as Chairman and/or Chief Executive Officer by the board of directors. As director, he may be removed by decision of the shareholders. When the Chief Executive Officer does not hold the position of Chairman of the board of directors, he may be entitled to receive an indemnity in the event that he is removed without just cause. Mr. Veillet benefits from a "GSC" private unemployment insurance policy, the cost of which is borne by the Company as a benefit in kind.

Limitations on Liability and Indemnification Matters

Under French law, provisions of by-laws that limit the liability of directors are prohibited. However, French law allows *sociétés anonymes* to contract for and maintain liability insurance against civil liabilities incurred by any of their directors and officers involved in a third-party action, provided that they acted in good faith and within their capacities as directors or officers of the company. Criminal liability cannot be indemnified under French law, whether directly by the company or through liability insurance.

We expect to maintain customary liability insurance coverage for our directors and executive officers, including insurance against liability under the Securities Act, and we intend to enter into agreements with our directors and executive officers to provide contractual indemnification. With certain exceptions and subject to limitations on indemnification under French law, these agreements will provide for indemnification for damages and expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding arising out of his or her actions in that capacity. We believe that this insurance and these agreements are necessary to attract qualified directors and executive officers.

These agreements may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and executive officers, even though such an action, if successful, might otherwise benefit us and our shareholders. Furthermore, a shareholder's investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these insurance agreements.

Certain of our non-employee directors may, through their relationships with their employers or partnerships, be insured against certain liabilities in their capacity as members of our board of directors.

Equity Incentives

We believe our ability to grant equity incentives is a valuable and necessary compensation tool that allows us to attract and retain the best available personnel for positions of substantial responsibility, provides additional incentives to employees and promotes the success of our business. Due to French corporate law and tax considerations, we have historically granted two different equity incentive instruments to our directors, executive officers, employees and other service providers, including:

- founders' share warrants (otherwise known as *bons de souscription de parts de créateurs d'entreprise*, or BSPCE), which are granted to our officers and employees; and

- share warrants (otherwise known as *bons de souscription d'actions*, or BSA), which have historically only been granted to non-employee directors;

Our board of directors' authority to grant these equity incentive instruments and the aggregate amount authorized to be granted under these instruments must be approved by a two-thirds majority of the votes by our shareholders present, represented or voting by authorized means, at the relevant extraordinary shareholders' meeting. Once approved by our shareholders, our board of directors can grant share warrants (BSA) or founder's share warrants (BSPCE) for up to 18 months from the date of the applicable shareholders' approval. The authority of our board of directors to grant equity incentives may be extended or increased only by extraordinary shareholders' meetings. As a result, we typically request that our shareholders authorize new pools of equity incentive instruments at every annual shareholders' meeting.

All vested shares must be exercised within exercise periods set forth in the grant documents. In the event of certain changes in our share capital structure, such as a consolidation or share split or dividend, French law and applicable grant documentation provides for appropriate adjustments of the numbers of shares issuable and/or the exercise price of the outstanding warrants.

As of February 26, 2021, founders' share warrants and share warrants granted pursuant to equity incentive awards were outstanding allowing for the purchase of an aggregate of 3,455,610 ordinary shares at a weighted average exercise price of €0.61 per ordinary share.

Founder's Share Warrants (BSPCE)

Employee warrants may only be issued by growth companies meeting certain criteria. Most significantly, the issuer must have been registered for less than 15 years and 25% of the issuer's share capital must have been continuously held since the company's formation by natural persons or by holding companies, of which 75% of such holding company's share capital is held by natural persons. The calculation of such threshold does not include venture capital mutual investment fund (*fonds commun de placement à risques*), specialized professional funds (*fonds professionnels spécialisés*), private equity funds (*fonds professionnels de capital investissement*), local investment funds (*fonds d'investissement de proximité*) and innovation-focused mutual funds (*fonds commun de placement dans l'innovation*).

Founder's share warrants have traditionally been granted to certain of our employees and/or officers who were French tax residents because the warrants carry favorable tax and social security treatment for French tax residents. Since French law n°2019-486 of May 22, 2019 relating to the growth and transformation of companies, we may grant founder's share warrants to our directors. Similar to options, founder's share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors and at least equal to the fair market value of an ordinary share on the date of grant. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants. Founder's share warrants may only be exercised if, at the exercise date, the employee is employed by us. The table below summarizes our outstanding founder's share warrants to employees employed by us as of February 26, 2021.

Name	Number of ordinary shares underlying Founders' warrants	Date of General Meeting	Date of Board Meeting	Purchase Price per share (€)	Start Date for Exercise	Expiration Date	Exercise Price (€)	Number of Shares subscribed to date	Founders' warrants outstanding as of 2/26/2021
Stanislas Veillet	148,000(1)	6/16/2017	7/21/2017	0	7/21/2017	7/21/2021	3.30	0	148,000
	940,249(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	626,832
René Lafont	29,000(1)	6/16/2017	7/21/2017	0	7/21/2017	7/21/2021	3.30	0	29,000
	310,209(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	310,209
Waly Dioh	15,000(1)	6/16/2017	7/21/2017	0	7/21/2017	7/21/2021	3.30	0	15,000
	79,201(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	79,201
	158,401(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	158,401
Pierre Dilda	15,000(1)	6/16/2017	7/21/2017	0	7/21/2017	7/21/2021	3.30	0	15,000
	50,424(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	50,424
	100,848(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	100,848
Sam Agus	50,424(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	50,424
	100,848(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	100,848
Evelyne Nguyen	50,424(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	50,424
	100,848(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	100,848
Nadine Coulm	103,946(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	103,946
	207,892(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	207,892
Jean Franchi	103,946(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	103,946
	207,892(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	207,892
Dimitri Batsis	103,946(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	103,946
	207,892(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	207,892
Jean Mariani	103,946(2)	8/8/2019	4/3/2020	0	4/8/2020	4/8/2026	0.27	0	103,946
	207,892(3)	5/28/2020	12/22/2020	0	12/22/2020	12/22/2026	0.47	0	207,892

(1) These founder's share warrants are exercisable for (i) 33.33% between the grant date and the first anniversary of the grant date, (ii) for 66.66% between the first anniversary of the grant date and the second anniversary of the grant date and (iii) in full, beginning on the second anniversary of the grant date.

(2) These founder's share warrants are exercisable for (i) 33.33% between the grant date and the second anniversary of the grant date, (ii) for 66.66% between the second anniversary of the grant date and the fourth anniversary of the grant date and (iii) in full beginning on the fourth anniversary of the grant date.

(3) These founder's share warrants are exercisable for (i) 33.33% between the grant date and the second anniversary of the grant date, (ii) for 66.66% between the second anniversary of the grant date and the fourth anniversary of the grant date and (iii) in full beginning on the fourth anniversary of the grant date.

Share Warrants (BSA)

Similar to options, share warrants entitle a holder to exercise the warrant for the underlying vested shares at an exercise price per share determined by our board of directors. However, unlike options, the exercise price per share is fixed as of the date of implementation of the plans pursuant to which the warrants may be granted, rather than as of the date of grant of the individual warrants. The table below summarizes our outstanding share warrants as of February 26, 2021.

Name	Number of ordinary shares underlying share warrants	Date of General Meeting	Date of Board Meeting	Purchase Price per share (€)	Start Date for Exercise	Expiration Date	Exercise Price per share (€)	Number of Shares subscribed to date	Warrants outstanding as of 2/26/2021
Nadine Coulm	18,000(1)	6/16/2017	7/21/2017	18.00	11/28/2017	11/28/2021	3.30	0	18,000
	27,956(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	27,956
Jean Franchi	18,000(1)	6/16/2017	7/21/2017	18.00	11/28/2017	11/28/2021	3.30	0	18,000
	20,000(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000
Dimitri Batsis	329,218(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000

Jean Mariani	25,566(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	25,566
Stanislas Veillet	2,935,701(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	2,266,583	689,118
René Lafont	20,000(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000
Sam Agus	20,000(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000
Pierre Dilda	20,000(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000
Waly Dioh	26,428(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	26,428
Evelyne Nguyen	20,000(2)	8/8/2019	4/3/2020	0,06	4/30/2020	4/30/2025	0.27	0	20,000

(1) These share warrants are exercisable for (i) 33.33% between the subscription date and the first anniversary of the subscription date, (ii) for 66.66% between the first anniversary of the subscription date and the second anniversary of the subscription date and (iii) in full, beginning on the second anniversary of the subscription date.

(2) These share warrants are exercisable in full, beginning on the subscription date.

C. Board Practices

Board Composition

We currently have five directors, one of whom is a citizen or resident of the United States.

Under French law and our Articles of Association, our board of directors must be comprised of between three and 18 members. Within this limit, the number of directors is determined by our shareholders. Directors are elected, re-elected and may be removed at a shareholders' general meeting with a simple majority vote of our shareholders. Pursuant to our by-laws, our directors are elected for three-year terms. In accordance with French law, our by-laws also provide that our directors may be removed with or without cause by the affirmative vote of the holders of at least a majority of the votes of the shareholders present, represented by a proxy or voting by mail at the relevant ordinary shareholders' meeting, and that any vacancy on our board of directors resulting from the death or resignation of a director, provided there are at least three directors remaining, may be filled by vote of a majority of our directors then in office provided that there has been no shareholders meeting since such death or resignation. Directors chosen or appointed to fill a vacancy shall be elected by the board of directors for the remaining duration of the current term of the replaced director. The appointment must then be ratified at the next shareholders' general meeting. In the event the board of directors would be composed of less than three directors as a result of a vacancy, the remaining directors shall immediately convene a shareholders' general meeting to elect one or several new directors so there are at least three directors serving on the board of directors, in accordance with French law.

The following table sets forth the names of our directors, the years of their initial appointment as directors and the expiration dates of their current term.

Name	Current Position	Year of Initial Appointment	Term Expiration Year
Stanislas Veillet	Chairman	2015	2021
Dimitri Batsis	Director	2018	2021
Nadine Coulm	Director	2015	2021
Jean M. Franchi	Director	2017	2023
Jean Mariani	Director	2019	2023(1)

(1) Jean Mariani was appointed director by the board of directors on October 29, 2019 in replacement of Eric Rowinsky, who resigned from his office at the same date. The appointment of Jean Mariani as a director was ratified by the shareholders' meeting dated May 28, 2020 for a three-year term, which will expire at the end of the ordinary shareholders' meeting convened to approve the financial statements for the year ended December 31, 2022.

Director Independence

As a foreign private issuer, under the listing requirements and rules of Nasdaq, we are not required to have independent directors on our board of directors, except with respect to our audit committee, for which Nasdaq listing requirements permit specified phase-in schedules.

Nevertheless, our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from, and provided by, each director concerning such director's background, employment and affiliations, including family relationships, our board of directors determined that all of our directors, except for Mr. Veillet and Mr. Mariani, qualify as "independent directors" as defined under applicable rules of Nasdaq and the independence requirements contemplated by Rule 10A-3 of the Exchange Act. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our ordinary shares by each non-employee director and his or her affiliated entities (if any).

Our board of directors also determined that, except for Stanislas Veillet and Jean Mariani, all of our directors qualify as "independent directors" as defined by the Corporate Governance Code (*Code de Gouvernement d'Entreprise*) for small and mid-cap companies as published in September 2016 by MiddleNext and validated as a reference code by the French Financial Markets Authority (*Autorité des Marchés Financiers*).

Role of the Board in Risk Oversight

Our board of directors is primarily responsible for the oversight of our risk management activities and has delegated to the audit committee the responsibility to assist our board in this task. While our board oversees our risk management, our management is responsible for day-to-day risk management processes. Our board of directors expects our management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face.

Corporate Governance Practices

As a French société anonyme, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Capital Market, we will be subject to Nasdaq's corporate governance listing standards. However, Nasdaq's listing standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq's rules, with certain exceptions. Certain corporate governance practices in France may differ significantly from corporate governance listing standards. For example, neither the corporate laws of France nor our bylaws require that (i) a majority of our directors be independent, (ii) our compensation committee include only independent directors, or (iii) our independent directors hold regularly scheduled meetings at which only independent directors are present. Other than as set forth below, we currently intend to comply with the corporate governance listing standards of Nasdaq to the extent possible under French law. However, we may choose to change such practices to follow home country practice in the future.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act relating to audit committee composition and responsibilities. Rule 10A-3 of the Exchange Act provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least $33^{1}/_{3}\%$ of the outstanding shares of the company's common voting stock. Consistent with French law, our by-laws provide and will continue to provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months. See the section of this annual report titled "Description of Share Capital—Key Provisions of Our By-laws and French Law Affecting Our Ordinary Shares."

Board Committees

The board of directors has established an audit committee and a compensation and governance committee, which operate pursuant to rules of procedure adopted by our board of directors. The board of directors has also established a scientific committee, which is responsible for analyzing and reviewing our clinical and regulatory strategy. Subject to available exemptions, the composition and functioning of all of our committees will comply with all applicable requirements of the French Commercial Code, the by-laws, the Exchange Act, Nasdaq and SEC rules and regulations.

In accordance with French law, committees of our board of directors only have an advisory role and can only make recommendations to our board of directors based on their area of competence. As a result, all decisions will be made by our board of directors taking into account non-binding recommendations of the relevant board committee.

Audit Committee

The Audit Committee consists of at least two members appointed by our board of directors. The members of the Audit Committee may or may not be directors or shareholders of the Company; provided, however, that as far as possible, the members of the Audit Committee consists of independent members and, in any event, the Audit Committee must include at least one independent director. The Chairperson of the Audit Committee is appointed by our board of directors for the duration of his or her mandate as a board member.

The current members of our Audit Committee are Nadine Coulm (Chairwoman) and Jean Franchi, both independent directors. We intend to rely on the exemption available to foreign private issuers for the requirement that an audit committee be comprised of at least three members, although we may, in the future, look to expand this committee.

The duration of the mandates of the members of the Audit Committee is three years, ending at the first board meeting held after the Ordinary General Meeting called to approve the financial statements. The mandates of the members of the Audit Committee are renewable.

The Audit Committee is responsible for assisting the board of directors in:

- ensuring the truthfulness of the financial statements, the quality of internal controls and the quality and relevance of the financial information provided;
- assessing the existence and relevance of the financial control and internal audit procedures;
- assessing the relevance of the Company's accounting policy;
- examining the accounts of the Company, as well as the information issued before their submission to the board of directors;
- examining the changes and adaptations of accounting principles and rules used in the context of drawing up of financial statements, as well as their relevance;
- examining the candidates proposed to the positions of statutory auditor or substitute auditor, or proposing the appointment of the auditors;
- guaranteeing the independence and competence of auditors and ensuring the proper performance of their duties; and
- examining the significant risks for the Company and notably the off-balance-sheet risks and commitments.

In this capacity, the Audit Committee issues opinions, proposals and recommendations to our board of directors and regularly reports to it on its work.

The Audit Committee meets as often as it considers necessary, but at least four times a year, including twice a year before the meeting of the board of directors at which the annual and interim financial statements of the Company are reviewed.

Compensation and Governance Committee

The Compensation and Governance Committee consists of at least two members, appointed by our board of directors. The members of the Compensation and Governance Committee may or may not be directors or shareholders of the company; provided, however, that the Compensation and Governance Committee must include at least one independent director. No member of the board of directors exercising management functions within the Company may be a member of the Compensation and Governance Committee. The Chairman of the Compensation and Governance Committee is appointed by the board of directors of the Company for the duration of his or her mandate as Committee member.

The current members of our Compensation and Governance Committee are Dimitri Batsis (Chairman) and Nadine Coulm, both independent directors.

The duration of the mandates of the members of the Compensation and Governance Committee is three years, ending at the first meeting of the board of directors held after the Ordinary General Meeting called to approve the financial statements. The mandate of the members of the Compensation and Governance Committee is renewable.

The Compensation and Governance Committee is responsible for:

- making recommendations to the board of directors (i) on remuneration (fixed and variable) of company officers and key executives and notably contributing to the review of remuneration procedures, setting objectives and bonuses for objectives reached and incentives for the company's officers; (ii) the recruitment, training, development, retention of employees with remuneration programs; and (iii) the shareholder policy and incentive tools for managers and employees, taking into account the objectives of the Company and individual and collective performance, including the fixing and/or modification of the conditions for the award or exercise of securities granted to the officers or of the employees, and, where appropriate, the achievement of objectives permitting the exercise of the said securities, as provided under the terms and conditions of the said securities;

- participating in the implementation of the Company's governing bodies;

- identifying, assessing and proposing the appointment of independent directors with a view to the good governance of the Company; and

- pronouncing on any other issue relating to human resources which it considers appropriate or which is referred to it by the board of directors.

The Compensation and Governance Committee has only consultative powers. The Compensation and Governance Committee reports on its mission to the board of directors and communicates its recommendations, specifications, and opinions.

The Compensation and Governance Committee meets as often as it considers necessary, but at least twice a year.

Scientific Committee

The Scientific Committee consists of at least five members appointed by our board of directors. The members of the Scientific Committee may or may not be directors or shareholders of the Company. No member of the board of directors exercising management functions within the Company may be a member of the Scientific Committee.

The Chairperson of the Scientific Committee is appointed by the board of directors for the duration of his or her mandate as a board member.

The duration of the mandates of the members of the Scientific Committee is five years, ending at the first board meeting held after the Ordinary General Meeting called to approve the financial statements. The mandates of the members of the Scientific Committee are renewable.

Since October 26, 2017, the Scientific Committee has consisted of:

- Professor Jean Mariani, hospital practitioner at Charles Foix Hospital, Director of the Charles Foix Institute of Longevity, Chairman of the Scientific Committee;

- Professor José-Alain Sahel, Ophthalmologist, Chair of the Department of Ophthalmology at the University of Pittsburgh School of Medicine, director of the UPMC Eye Center, and the Eye and Ear Foundation Chair of Ophthalmology, Founder and Director of the Institute of Vision in Paris; Professor at the Sorbonne's medical school Université Pierre-et-Marie-Curie, member of the Academy of Sciences, Professor of Biomedical Sciences (Cumberlege Chair) at the Institute of Ophalmology, University College London and Visting Professor at the Hebrew University of Jerusalem, Israel;

- Professor René Lafont, Emeritus Professor at Sorbonne University, Scientific Advisor at Biophytis;

- Professor Ivana Kim, Associate Professor of Ophthalmology, Massachusetts Eye and Ear, Harvard Medical School; Co-Director of the Harvard Medical School Department of Ophthalmology AMD Center of Excellence; Associate Scientist, Massachusetts Eye and Ear;

- Professor Roger A. Fielding, Professor of Medicine at Tufts University School of Medicine, Professor of Nutrition at the Tufts University Friedman School of Nutrition Science and Policy and Tufts University; Lecturer, Physical Medicine and Rehabilitation, Harvard Medical School, Department of Physical Medicine and Rehabilitation; and Director and Senior Scientist at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University; and

- Professor Thomas Voit, Director of the Biomedical Research Center of the Great Ormond Street Hospital for Children NHS Foundation Trust and the Institute of Child Health, University College London; former Medical and Scientific Director of the Myology Institute and Director of an INSERM/CNRS research centre and former professor and director of the paediatric department at Essen University Hospital.

The Scientific Committee is responsible for assisting the board of directors in:

- The study of development plans for nutraceuticals or drug candidates, to formulate an opinion on their scientific or regulatory consistency;
- Analysis of the main scientific or clinical results, to participate in their interpretation and to formulate an opinion whether to continue, redirect or terminate a research project at certain key stages;
- The scientific assessment of new research projects, before they are submitted if they are the subject of an application for subsidies and/or before their actual start-up, in order to position the project in the global scientific and regulatory context and to specify its innovative character; and
- The study of the main scientific and regulatory dossiers prepared by the Company for approval and suggestions for possible additions/improvements, before being filed with the regulatory agencies (FDA, EFSA, EMA, etc.).

The Scientific Committee meets as often as it considers necessary, but at least once a year.

The Scientific Committee reports on its mission to the board of directors and communicates its recommendations, specifications, and opinions.

D. Employees

As of the date of this annual report, we have 23 employees, all of whom are full-time, 19 of whom are engaged in research and development activities and 4 of whom are engaged in general and administrative activities. As of the date of this annual report, 19 of our employees are located in France and 4 of our employees are located in the United States. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good. France-based employees are subject to the national collective bargaining agreement for the pharmaceutical industry (the *convention collective nationale de l'industrie pharmaceutique*).

E. Share Ownership

For information regarding the share ownership of our directors and senior management, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

Item 7. Major Shareholders and Related Party Transactions.

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 26, 2021 for:

- each beneficial owner of more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares that can be acquired within 60 days of February 26, 2021. The percentage ownership information shown in the table is based upon 113,134,307 ordinary shares outstanding as of February 26, 2021.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding ordinary shares subject to options and warrants held by that person that are immediately exercisable or exercisable within 60 days of February 26, 2021. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders. Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of Biophytis S.A., Sorbonne University—BC 9, Bâtiment A 4ème étage, 4 place Jussieu 75005 Paris, France.

Owner	Number of Ordinary Shares	Percentage
Directors and Executive Officers:		
Stanislas Veillet(1)	3,986,389	3.4%
Dimitri Batsis(2)	123,946	*
Nadine Coulm(3)	151,152	*
Jean M. Franchi(4)	141,946	*
Jean Mariani(5)	129,512	*
René Lafont(6)	219,069	*
Evelyne Nguyen(7)	70,424	*
Samuel Agus(8)	70,424	*
Pierre Dilda(9)	85,424	*
Waly Dioh(10)	136,036	*
All directors, executive officers and key employees as a group (10 persons)(11)	5,114,322	4.3%

* Represents beneficial ownership of less than 1%.

(1) The shares beneficially owned by Mr. Veillet include 837,118 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021. Of these shares, 440,000 ordinary shares have been pledged to Neuflize-ABN AMRO Bank as security for a personal loan.

(2) The shares beneficially owned by Mr. Batsis include 123,946 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(3) The shares beneficially owned by Ms. Coulm include 149,902 shares issuable upon the exercise of warrants that are currently exerciable or exercisable within 60 days of February 26, 2021.

(4) The shares beneficially owned by Ms. Franchi consist of 141,946 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(5) The shares beneficially owned by Mr. Mariani include 129,512 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(6) The shares beneficially owned by Mr. Lafont include 152,403 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(7) The shares beneficially owned by Ms. Ngyuen 70,424 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(8) The shares beneficially owned by Ms. Agus 70,424 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(9) The shares beneficially owned by Mr. Dilda consist of 85,424 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(10) The shares beneficially owned by Mr. Dioh include 111,036 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

(11) The shares beneficially owned by our officers and directors as a group include an aggregate of 1,872,135 shares issuable upon the exercise of warrants that are currently exercisable or exercisable within 60 days of February 26, 2021.

B. Related Party Transactions

Since January 1, 2018, we have engaged in the following transactions with our directors, executive officers and holders of more than 5% of our outstanding voting securities and their affiliates, which we refer to as our related parties.

Transactions with Our Affiliates, Principal Shareholders, Directors and Executive Officers

Intellectual Property Agreement with Stanislas Veillet

Our CEO, who is a corporate officer (mandataire social) but not an employee of the Company under French law, is involved in our research and development activities. He has developed inventions with us for which we have submitted patent applications in which he is listed as a co-inventor and other inventions that we expect may give rise to patent applications in the future for which we expect he will be included as a co-inventor. As an inventor, our CEO has certain rights under French intellectual property law. These rights are distinct from the statutory rights that usually apply to employee inventors under French law. In order to define a framework within which any intellectual property resulting from our CEO's research and development activities is properly assigned to us, we entered into an agreement on May 22, 2019 and into an amendment agreement to this agreement on April 6, 2020, both of which were approved by our board of directors. Pursuant to this agreement (as amended), our CEO is entitled to the following payments for his contributions:

- a first lump sum cash payment of €90 thousand to be paid within 30 days of filing of a patent application based on the assigned rights;
- a second lump sum cash payment of €90 thousand, to be paid within 30 days of publication of a patent application based on the assigned rights; and
- a 6.5% royalty payment with respect to any license income and/or any net sales by us of products manufactured with the patents filed on the basis of the assigned rights.

These three payments will be capped at €2.1 million on a platform per platform basis, a platform being defined in the agreement as the research and development works which cover the same family of chemical molecules targeting the same molecular receptor or biological pathway for a family of pathologies which are clinically connected.

In the event that a third party pharmaceutical and/or biotech company acquires 100% of our capital and voting rights, payments will be accelerated, so that the cap (€2.1 million per platform), less any amount previously paid in respect of a platform, will become immediately payable.

The agreement shall remain in effect until no further payments are due. However, the provisions of this agreement will only apply to results generated during the period in which our CEO occupies the position of a corporate officer of the Company or any of its affiliates. Any party to the agreement may, upon material breach of the agreement by the other party, terminate the agreement.

As part of the Intellectual Property agreement signed with our CEO and its amendment, the total patents rights acquired from our CEO amounted to €630 thousand in 2019 and €270 thousand in 2020. Of this amount, €270 thousand was paid to the Company's CEO in 2019. As part of the subscription and the exercise of the investors warrants by our CEO, the remaining amount of €630 thousand was used to offset the amounts owed pursuant to such subscription and exercise. In September 2020, an additional €180 thousand were paid in cash following the publication of two patents in 2020.

Financing Activites

In April 2020, we issued 2,000,000 founder's share warrants, of which 940,250 share warrants were issued to Mr. Veillet. In December 2020, we granted 1,880,500 ordinary shares to Mr. Veillet that will be delivered on December 22, 2022 after a two-year vesting period.

Advances to Biophytis, Inc.

We have entered into a current account advance agreement with Biophytis, Inc., dated November 9, 2015, which provides for certain cash advances to be made to Biophytis, Inc. by us. The amounts advanced to Biophytis, Inc. under this agreement bear interest from the date such advances are made at the quarterly average effective rate of floating-rate loans with an initial maturity of more than two years, as used by credit institutions and published by the Banque de France. Biophytis, Inc. undertakes to reimburse us for the sums borrowed at any time, subject to budget constraints and immediately upon ceasing to be under our direct or indirect control. However, no repayment schedule has been set. Since January 1, 2018, the largest amount owed by Biophytis, Inc. to us under this agreement was €2,003,238. The outstanding amount owed by Biophytis, Inc. to us as of February 26, 2021 is €1,496,326.

We are also party to a debt compensation agreement with Biophytis, Inc., dated March 14, 2017, with retroactive effect as of January 1, 2017. This agreement provides that in exchange for services rendered to Biophytis, Inc., Biophytis, Inc. will pay us the amounts we invoice to them and that amounts billed to Biophytis, Inc. will bear interest at the quarterly average effective rate of floating-rate loans with an initial maturity of more than two years, as used by credit institutions and published by the Bank of France. Since January 1, 2018, the largest amount owed by Biophytis, Inc. to us was €1,302,621. The outstanding amount owed by Biophytis, Inc. to us as of February 26, 2021 is €0.

On March 22, 2019, we also entered into a services agreement with Biophytis, Inc., effective as of January 1, 2019. Pursuant to the terms of the agreement, Biophytis, Inc. has agreed to provide certain clinical and regulatory assistance to us (including supporting our clinical development efforts, assisting with the preparation and submission of regulatory and clinical documents to the various regulatory agencies and interacting with those agencies, and assisting with the preparation of other scientific communications) and certain financial and communication services (including financial and accounting support and investor relations services). In consideration for their services, we have agreed to reimburse Biophytis, Inc. for all of their direct and indirect costs and expenses in providing the services plus a 5% margin. The agreement is effective for one year and may be renewed for subsequent one year periods. On June 7, 2019, this agreement was amended to expand the financial services to be provided to us by Biophytis, Inc. under the agreement.

Advances to Biophytis Instituto Do Brasil Serviços, Comércio, Importação E Exportação de Alimentos Ltda.

Since 2009, we have entered into several loan contracts providing for advances to Biophytis Instituto Do Brasil Serviços, Comércio, Importacao E Exportaçao de Alimentos Ltda, or Biophytis Brazil. We own 94.6% of Biophytis Brazil's share capital and voting rights. Biophytis Brazil's other shareholder is M. Wayne Clayton Correa, manager of Biophytis Brazil. Since January 1, 2018, the largest aggregate amount outstanding under these loan contracts was €660,595. The outstanding amount owed by Biophytis Brazil to us as of Februrary 26, 2021 was €660,595. The terms of these loan contracts do not provide for interest or penalty in the event of default or late repayment. If Biophytis Brazil fails to pay the principal of the loan at the maturity date, we may extend the loan for a new term as agreed with Biophytis Brazil.

We have entered into a current account advance agreement with Biophytis Brazil dated December 28, 2020, with retroactive effect as of January 1, 2020, which provides for certain cash advances to be made to Biophytis Brazil by us. The amounts advanced to Biophytis Brazil under this agreement bear interest from the date such advances are made at the quarterly average effective rate of floating-rate loans with an initial maturity of more than two years, as used by credit institutions and published by the Banque de France. Biophytis Brazil undertakes to reimburse us for the sums borrowed at any time, subject to budget constraints and immediately upon ceasing to be under our direct or indirect control. However, no repayment schedule has been set.

We are also party to a debt compensation agreement with Biophytis Brazil, dated December 28, 2020, with retroactive effect as of July 1, 2020. This agreement provides that in exchange for services rendered to Biophytis Brazil, Biophytis Brazil will pay us the amounts we invoice to them, as soon as its financial resources allow it reasonably, and that amounts billed to Biophytis Brazil will bear interest at the quarterly average effective rate of floating-rate loans with an initial maturity of more than two years, as used by credit institutions and published by the Bank of France.

On December 28, 2020, we also entered into a services agreement with Biophytis Brazil, with retroactive effect as of July 1, 2020. Pursuant to the terms of the agreement, Biophytis Brazil has agreed to provide certain clinical and regulatory assistance to us (including supporting our clinical development efforts, assisting with the preparation and submission of regulatory and clinical documents to the various regulatory agencies and interacting with those agencies, and assisting with the preparation of other scientific communications). In consideration for their services, we have agreed to reimburse Biophytis Brazil for all of their direct and indirect costs and expenses in providing the services plus a 5% margin. The agreement is effective for one year and will be renewed by tacit agreement for subsequent one year periods.

Services Agreement with Blue Companion

We entered into a first services agreement with Blue Companion, dated May 16, 2017 (as amended on December 22, 2017 and December 7, 2018), providing for the development of a clinical data platform in relation to our SARA-OBS study. At the time we entered into this agreement, our then Chief Medical Officer, Susanna Del Signore (who left the Company in July 2018), had a controlling interest in Blue Companion and was its legal representative. The agreement provides for a fixed remuneration of €551,000. This agreement, as amended, was terminated on October 31, 2019.

We entered into a second services agreement with BlueCompanion, dated December 22, 2017 (as amended on July 20, 2018, October 31, 2019 and March 3, 2020), providing for the development of a clinical data platform in relation to our SARA-INT study. This agreement, as amended, is to expire on June 30, 2021. During the financial year ended on December 31, 2020, we paid Blue Companion a total remuneration equal to €181,845.67.

Services Agreement with Successful Life

On October 1, 2019, we entered into a services agreement with Successful Life SAS in which Jean Mariani, its legal representative, has a controlling interest. This agreement was entered into for a period of one year and was renewed by written amendment dated October 1, 2020 for an additional period of one year, tacitly renewable. This agreement has been terminated and a new agreement has been signed for a period of one year tacitly renewable with effect as from January 1, 2021 following the March 9, 2021 Board decision. This services agreement provides for the scientific and strategic advice in relation to the biology of aging. The agreement provides for a fixed remuneration of €450 per day within the cap of €32,400 per year and reimbursement of costs and expenses upon presentation of supporting documentation.

Escrow Agreement

In order to comply with the requirements of the order of the President of Paris Commercial Court, dated May 7, 2020, by which we were ordered to place in escrow 2,050,000 of our shares until their delivery to NEGMA, and as we did not hold a sufficient number of our own shares, we asked our CEO, by a letter dated May 19, 2020, to place in escrow some of the shares of the Company he owned. The letter (which was countersigned by our CEO) included a provision for the indemnification by the Company of our CEO for any loss he may suffer as a result of this arrangement. As the delivery of the shares to NEGMA took place on June 5, 2020, the escrow was released in full, including the shares in escrow owned by our CEO, which were returned to him.

CEO Share loan agreement

As part of the implementation of the financing agreement with NEGMA, our CEO entered into a loan agreement for his shares in the Company for the benefit of NEGMA in order to facilitate the various issuance and conversion transactions. This agreement was terminated in April 2020.

Director and Executive Officer Compensation

See “Item 6.B—Compensation” of this annual report for information regarding compensation of directors and executive officers.

Related Person Transaction Policy

Under French law, transactions between a company and its general managers, directors, shareholders holding more than 10% of the voting rights of the company and any company controlling a shareholder holding more than 10% of the voting rights of the company, other than transactions in the ordinary course of business and at arm’s length, must be (i) approved by the board of directors of the company prior to entering into the transaction, (ii) reported to the statutory auditors who must then prepare a report on such transaction, and (iii) ratified by the company’s shareholders at the annual general meeting.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information.

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

Our consolidated financial statements are appended at the end of this annual report, starting at page F-1, and are incorporated by reference herein.

Dividend Distribution Policy

We have never declared or paid any cash dividends on our ordinary shares. We do not anticipate paying cash dividends on our equity securities in the foreseeable future and intend to retain all available funds and any future earnings for use in the operation and expansion of our business.

Subject to the requirements of French law and our by-laws, dividends may only be distributed from our distributable profits, plus any amounts held in our reserves other than those reserves that are specifically required by law. Article 34 of our By-laws imposes additional limitations on our ability to declare and pay dividends and there may be taxes imposed on you if we elect to pay a dividend. Dividend distributions, if any, will be made in euros and converted into U.S. dollars with respect to the ADSs, as provided in the deposit agreement.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations, including those described in Note 14 of our consolidated financial statements for the year ended December 31, 2020 appended to this annual report.

On June 14, 2016, the *Autorité des marchés financiers*, the French securities regulator or AMF, notified us that it had opened an inquiry as to (i) whether we had timely disclosed to the market the change in the expected timeline for the clinical trials of two of our products, and (ii) whether we had provided the market with full and fair information regarding the approval of a clinical trial by a regulatory authority. On April 18, 2018, the AMF informed us that its inquiry had been completed and that its Board (*Collège*) had decided to refer the matter to its Sanctions Commission, limiting the scope to timely disclosure only and alleging a breach of Article 223-2 of the AMF General Regulation (i.e., delayed disclosure of information) by us and our Chief Executive Officer, as the legal representative of our corporate entity. As a result, the matter was investigated by the AMF Sanctions Commission (*Commission des sanctions*). The AMF Sanctions Commission appointed a *rapporteur*, who was charged with investigating the alleged breach and preparing a report to the Sanctions Commission. On March 19, 2019, the *rapporteur* interviewed us our Chief Executive Officer. During this interview, our Chief Executive Officer answered further questions regarding the alleged breach and agreed to provide further documentation to the *rapporteur* as requested. On June 28, 2019, the *rapporteur* issued his report, in which he concluded that our disclosures had not been timely made, but noted that the change in the expected timeline for our clinical trials was limited to three to six months and was not due to any unfavorable new information of a financial, regulatory or scientific nature, and that neither our Chief Executive Officer nor the Company had benefited in any way from such failure to timely disclose the information. The Sanctions Commission hearing was held September 13, 2019, and the Sanctions Commission's decision was handed down on October 1, 2019. Considering that the delay in communication was too long to meet the requirements of article 223-2 of the AMF General Regulations, the Sanctions Commission considered that the breach was committed and imposed a fine of €100,000 against the Company. As the breach was attributable to our Chief Executive Officer in his capacity as an executive officer of the Company pursuant to article 221-1 of the AMF General Regulations, the Sanctions Commission imposed a fine of €20,000 against him. The Sanctions Commission also ordered that the decision be published. We and our Chief Executive Officer appealed this decision by declaration dated December 3, 2019, lodged at the registry of the Court of Appeals of Paris. The AMF filed a counterclaim in which it requested that the sanctions against the Company and our Chief Executive Officer be increased to €150,000 and €50,000, respectively. The hearing before the Court of Appeals of Paris was held on October 8, 2020. The decision of the Court of Appeals was issued on December 10, 2020 and confirmed the decisions of the Sanctions Commission (i.e., a fine of €100,000 for the Company and a fine of €20,000 for our CEO).

On August 19, 2019, the Company, as borrower, entered into an agreement, or the NEGMA Agreement, with NEGMA, as lender, to issue bonds redeemable in cash and/or convertible into new and/or existing shares with attached warrants (*ORNANE BSA*), the execution of which proved to be conflicting. The Company terminated the NEGMA Agreement on April 6, 2020. Following the termination, NEGMA initiated summary proceedings before the Commercial Court of Paris (*Tribunal de commerce de Paris*) to obtain the legal escrow of 7,000,000 ordinary shares of the Company and payment of €910,000 as contractual penalties. Pursuant to an order dated May 7, 2020, the President of the Commercial Court of Paris partially granted NEGMA's claims and ordered the Company to (i) pay NEGMA an amount of €378 thousand as penalty and (ii) deliver 2,050,000 shares, or the May 7th Court Order. The Company complied with the court's order on June 5, 2020. The Company appealed the May 7th Court Order before the Court of Appeals of Paris. By decision dated November 18, 2020, the Court of Appeals of Paris reversed the May 7th Court Order and ordered NEGMA to pay the costs of the trial and appeal proceedings. As a result, NEGMA was ordered to return 2,050,000 ordinary shares to us and pay us the amount of €378 thousand. NEGMA has satisfied these obligations as of the date of this annual report by paying €419 thousand (including penalty interest and legal cost) and delivering 2,050,000 ordinary shares to us on January 19, 2021. NEGMA did not appeal this decision. In addition, NEGMA initiated proceedings on the merits in order to obtain what had not been awarded by the May 7th Court Order. Since the decision of the Court of Appeals of Paris dated November 18, 2020, NEGMA has modified its claims on the merits in order to obtain 7,000,000 shares. The hearing in the proceedings on the merits took place on February 8, 2021 for closing arguments. As of the date of this Annual Report, the decision has not been rendered.

Other than the legal proceeding described above, we are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

B. Significant Changes

Not applicable

Item 9. The Offer and Listing.

A. Offer and Listing Details

Our ADS have been listed on the Nasdaq Capital Market under the symbol "BPTS" since February 10, 2021. Prior to that date, there was no public trading market for ADSs. Our ordinary shares have been trading on Euronext Growth Paris under the symbol "ALBPS" since July 13, 2015. Prior to that date, there was no public trading market for our ordinary shares.

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs have been listed on the Nasdaq Capital Market under the symbol "BPTS" since February 10, 2021 and our ordinary shares have been trading on Euronext Growth Paris under the symbol "ALBPS" since July 13, 20215.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information.

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The information set forth in the final prospectus dated February 11, 2021 as part of our Registration Statement on Form F-1 (File No. 333-252225), declared effective by the SEC on February 9, 2021, under the headings "Description of Share Capital and Aricles of Association—Key Provisions of Our Articles of Incorporation and Articles of Association and French Law Affecting Our Ordinary Shares," "Description of Share Capital—Differences in Corporate Law" and "Limitations Affecting Shareholders of a French Company" is incorporated herein by reference.

C. Material Contracts

We entered into an underwriting agreement with H.C. Wainwright & Co., or H.C. Wainwright, as underwriter, on February 9, 2021, with respect to the ADSs sold in our U.S. initial public offering. We have agreed to indemnify H. C. Wainwright against certain liabilities, including liabilities under the Securities Act, and to contribute to payments H.C. Wainwright may be required to make in respect of such liabilities.

For additional information regarding our material contracts, please see "Item 4—Information on the Company", "Item 6—Directors, Senior Management and Employees," and "Item 7.B—Related Party Transactions" of this annual report.

D. Exchange Controls

Under current French foreign exchange control regulations there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do, however, require that all payments or transfers of funds made by a French resident to a non-resident such as dividend payments be handled by an accredited intermediary. All registered banks and substantially all credit institutions in France are accredited intermediaries.

E. Taxation

The following describes material U.S. federal income tax and French tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. holder (as defined below). This summary addresses these tax considerations only for U.S. holders that are initial purchasers of the ADSs and that will hold such ADSs as capital assets. This summary does not address all U.S. federal income tax and French tax matters that may be relevant to a particular U.S. holder. This summary does not address tax considerations applicable to a holder of ADSs that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations, including an "individual retirement account" or "Roth IRA" as defined in Section 408 or 408A of the Code (as defined below), respectively;
- an entity subject to special tax rules prescribed pursuant to Section 7874 of the Code (as defined below);
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold the ADSs as part of a "hedging," "integrated," "wash sale" or "conversion" transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- S corporations;
- certain former citizens or long term residents of the United States;
- persons that received ADSs as compensation for the performance of services;
- persons acquiring ADSs in connection with a trade or business conducted outside of the United States, including a permanent establishment in France;
- holders that own directly, indirectly, or through attribution 10% or more of the voting power or value of the ADSs and shares or, in the case of the discussion of French tax consequences, 5% or more of the voting stock or our share capital; and
- holders that have a "functional currency" other than the U.S. dollar.

For the purposes of this description, a "U.S. holder" is a beneficial owner of ADSs that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a domestic corporation; or

- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or a trust, if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust, or if such trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership (or any other entity treated as a partnership for U.S. federal income tax purposes) holds ADSs, the U.S. federal income tax consequences relating to an investment in the ADSs will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of acquiring, owning and disposing of the ADSs in its particular circumstances.

The discussion in this section is based in part upon the representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms.

Persons considering an investment in the ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of the ADSs, including the applicability of U.S. federal, state and local tax laws, French tax laws and other non-U.S. tax laws.

Material French Tax Considerations

The following describes the material French income tax consequences to U.S. holders of purchasing, owning and disposing of the ADSs. This discussion does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the ADSs to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

The description of the French income tax and wealth tax consequences set forth below is based on the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, or the Treaty, which came into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax guidelines issued by the French tax authorities in force as of the date of this annual report.

This discussion applies only to investors that are entitled to Treaty benefits under the “Limitation on Benefits” provision contained in the Treaty.

In 2011, France introduced a comprehensive set of new tax rules applicable to French assets that are held by or in foreign trusts. These rules provide inter alia for the inclusion of trust assets in the settlor’s net assets for the purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to securities (including ADSs) held in trusts. If ADSs are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax advisor regarding the specific tax consequences of acquiring, owning and disposing of securities (including ADSs).

U.S. holders are urged to consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of securities in light of their particular circumstances, especially with regard to the “Limitations on Benefits” provision.

Estate and Gift Taxes and Transfer Taxes

In general, a transfer of securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless (i) the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or (ii) the securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the Code général des impôts (French Tax Code, or FTC), purchases of shares or ADSs of a French company listed on a regulated market of the European Union or on a foreign regulated market formally acknowledged by the AMF are subject to a 0.3% French tax on financial transactions, or the TFT, provided that the issuer’s market capitalization exceeds €1 billion as of December 1 of the year preceding the taxation year.

A list of relevant French companies whose market capitalization exceeds €1 billion as of December 1 of the year preceding the taxation year within the meaning of Article 235 ter ZD of the FTC used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANNX-000467-23/12/2020 issued on December 23, 2020, we are currently not included in such list. Such list may be updated from time to time, or may not be published anymore in the future.

As a result, neither the ADSs nor the ordinary shares are currently within the scope of the TFT. However, following our U.S. initial public offering, purchases of our securities may be subject to TFT, provided that our market capitalization exceeds €1 billion.

In the case where Article 235 ter ZD of the FTC is not applicable, transfers of shares issued by a listed French company are subject to uncapped registration duties at the rate of 0.1% if the transfer is evidenced by a written statement ("acte") executed either in France or outside France. Although there is no case law or official guidelines published by the French tax authorities on this point, transfers of ADSs should remain outside of the scope of the aforementioned 0.1% registration duties.

Tax on Sale or Other Disposition

As a matter of principle, under French tax law, a U.S. holder should not be subject to any French tax on any capital gain from the sale, exchange, repurchase or redemption by us of ordinary shares or ADSs, provided such U.S. holder is not a French tax resident for French tax purposes and has not held more than 25% of our dividend rights, known as *"droits aux benefices sociaux,"* at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives (as an exception, a U.S holder resident, established or incorporated in a non-cooperative state or territory as defined in Article 238-0 A of the FTC should be subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights it holds).

Under application of the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty and entitled to Treaty benefit will not be subject to French tax on any such capital gain unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. U.S. holders who own ordinary shares or ADSs through U.S. partnerships that are not resident for Treaty purposes are advised to consult their own tax advisors regarding their French tax treatment and their eligibility for Treaty benefits in light of their own particular circumstances. A U.S. holder that is not a U.S. resident for Treaty purposes or is not entitled to Treaty benefit (and in both cases is not resident, established or incorporated in a non-cooperative State or territory as defined in Article 238-0 A of the FTC) and has held more than 25% of our dividend rights, known as *"droits aux benefices sociaux,"* at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives will be subject to a levy in France at the rate (i) of 12.8% for individuals, and (ii) corresponding to the standard corporate income tax set forth in Article 219-I of the FTC legal persons (i.e., 28% for financial years beginning on or after January 1, 2020, 26.5% for the financial years beginning on or after January 1, 2021, 25% for financial years beginning on or after January 1, 2022).

Taxation of Dividends

Dividends paid by a French corporation to non-residents of France are generally subject to French withholding tax at a rate (i) aligned on the standard corporate income tax rate set forth in Article 219-I of the FTC for financial years beginning January 1, 2020, for payments benefitting legal persons who are not French tax residents (i.e. 28% for financial years beginning on or after January 1, 2020, 26.5% for financial years beginning on or after January 1, 2021, 25% for financial years beginning on or after January 1, 2022), and (ii) equal to 12.8% for payments benefitting individuals who are not French tax residents. Dividends paid by a French corporation in a non-cooperative State or territory, as defined in Article 238-0 A of the FTC, will generally be subject to French withholding tax at a rate of 75%. However, eligible U.S. holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to the above-mentioned withholding tax rates, but may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is generally reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuer; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any.

For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complex, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisors regarding their eligibility for Treaty benefits in light of their own particular circumstances. Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that:

- such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000); or

- the depositary or other financial institution managing the securities account in the United States of such holder provides the French paying agent with a document listing certain information about the U.S. holder and its ordinary shares or ADSs and a certificate whereby the financial institution managing the U.S. holder's securities account in the United States takes full responsibility for the accuracy of the information provided in the document.

Otherwise, dividends paid to a U.S. holder will be subject to French withholding tax at the rate of 12.8%, 26.5% (reduced to 25% from January 1, 2022), or 75% if paid in a non-cooperative State or territory (as defined in Article 238-0 A of the FTC), and may then be reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid.

Certain qualifying pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Form 5000 and Form 5001, together with instructions, will be provided by the depositary to all U.S. holders registered with the depositary. The depositary will arrange for the filing with the French tax authorities of all such forms properly completed and executed by U.S. holders of ordinary shares or ADSs and returned to the depositary in sufficient time so that they may be filed with the French tax authorities before the distribution in order to immediately obtain a reduced withholding tax rate. Otherwise, the depositary must withhold tax at the full rate of 12.8%, 30% or 75% as applicable. In that case, the U.S. holders may claim a refund from the French tax authorities of the excess withholding tax, if any.

Wealth Tax

The French wealth tax (*impôt de solidarité sur la fortune*) has been repealed by the finance bill for 2018 (*loi de finances pour 2018*), dated December 30, 2017. The French wealth tax used to apply only to individuals and did not generally apply to securities held by an eligible U.S. holder who is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that such U.S. holder does not own directly or indirectly more than 25% of the issuer's financial rights and that the securities did not form part of the business property of a permanent establishment or fixed base in France. It has been replaced by a new real estate wealth tax (*impôt sur la fortune immobilière*) as from January 1, 2018. The scope of such new tax is narrowed to real estate assets (and certain assets deemed to be real estate assets) or rights, directly or indirectly through one or more legal entities and whose net taxable assets amount to at least €1,300,000. Our securities owned by a U.S. Holder should not fall within the scope of the new real estate wealth tax provided that such U.S. Holder does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights of the company.

Material U.S. Federal Income Tax Considerations

This section discusses the material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. holder. This description does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the acquisition, ownership and disposition of the ADSs.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof, in each case as in effect and available on the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the IRS will not take a position concerning the tax consequences of the acquisition, ownership and disposition of the ADSs or that such a position would not be sustained by a court. Holders should consult their own tax advisers concerning the U.S. federal, state, local and non-U.S. tax consequences of acquiring, owning and disposing of the ADSs in their particular circumstances.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a "passive foreign investment company," or a PFIC.

In general, and taking into account the earlier assumptions, for U.S. federal income tax purposes, a U.S. holder holding ADRs evidencing ADSs will be treated as the owner of the shares presented by the ADRs. Exchanges of shares for ADRs, and ADRs for shares, generally will not be subject to U.S. federal income taxation.

Distributions. Subject to the discussion under "*—Passive Foreign Investment Company Considerations,*" below, the gross amount of any distribution (including any amounts withheld in respect of foreign tax) actually or constructively received by a U.S. holder with respect to ADSs will be taxable to the U.S. holder as a dividend to the extent of the U.S. holder's pro rata share of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. holder to the extent of, and will be applied against and reduce, the U.S. holder's adjusted tax basis in the ADSs. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. holder as either long-term or short-term capital gain depending upon whether the U.S. holder has held the ADSs for more than one year as of the time such distribution is received. However, since we do not calculate our earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Non-corporate U.S. holders may qualify for the preferential rates of taxation with respect to dividends on ADSs applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if we are a "qualified foreign corporation" and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation (a) if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision, or (b) with respect to any dividend it pays on ADSs which are readily tradable on an established securities market in the United States. The Company, which is incorporated under the laws of France, believes that it qualifies as a resident of France for purposes of, and is eligible for the benefits of, the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital, signed on August 31, 1994, as amended and currently in force, or the U.S.-France Tax Treaty, although there can be no assurance in this regard. Further, the IRS has determined that the U.S.-France Tax Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. The ADSs have been approved for listing on the Nasdaq Capital Market, which is an established securities market in the United States. Once listed, we expect the ADSs to be readily tradable on the Nasdaq Capital Market. There can, however, be no assurance that the ADSs will be considered readily tradable on an established securities market in the United States in later years. Therefore, subject to the discussion under "*—Passive Foreign Investment Company Considerations*," below, such dividends will generally be "qualified dividend income" in the hands of individual U.S. holders, provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The dividends will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

A U.S. holder generally may claim the amount of any French withholding tax as either a deduction from gross income or a credit against its U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. holder's U.S. federal income tax liability that such U.S. holder's taxable income bears to such U.S. holder's worldwide taxable income. In applying this limitation, a U.S. holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." In addition, this limitation is calculated separately with respect to specific categories of income. The amount of a distribution with respect to the ADSs that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for French income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. holder. Each U.S. holder should consult its own tax advisors regarding the foreign tax credit rules.

In general, the amount of a distribution paid to a U.S. holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the depositary receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. Any foreign currency gain or loss a U.S. holder realizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss. If dividends received in a foreign currency are converted into U.S. dollars on the day they are received, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend.

Sale, Exchange or Other Taxable Disposition of the ADSs. A U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of ADSs in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or exchange and the U.S. holder's tax basis in those ADSs, determined in U.S. dollars. Subject to the discussion under "*—Passive Foreign Investment Company Considerations*" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in the ADSs generally will be equal to the cost of such ADSs. Capital gain from the sale, exchange or other taxable disposition of ADSs of a non-corporate U.S. holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. holder's holding period determined at the time of such sale, exchange or other taxable disposition for such ADSs exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. holder recognizes generally will be treated as U.S. source gain or loss for foreign tax credit limitation purposes.

For a cash basis taxpayer, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the settlement date of the purchase or sale. In that case, no foreign currency exchange gain or loss will result from currency fluctuations between the trade date and the settlement date of such a purchase or sale. An accrual basis taxpayer, however, may elect the same treatment required of cash basis taxpayers with respect to purchases and sales of the ADSs that are traded on an established securities market, provided the election is applied consistently from year to year. Such election may not be changed without the consent of the IRS. For an accrual basis taxpayer who does not make such election, units of foreign currency paid or received are translated into U.S. dollars at the spot rate on the trade date of the purchase or sale. Such an accrual basis taxpayer may recognize exchange gain or loss based on currency fluctuations between the trade date and the settlement date. Any foreign currency gain or loss a U.S. Holder realizes will be U.S. source ordinary income or loss.

Medicare Tax. Certain U.S. holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their "net investment income," which may include all or a portion of their dividend income and net gains from the disposition of ADSs. Each U.S. holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in the ADSs.

Passive Foreign Investment Company Considerations. If we are classified as a PFIC in any taxable year, a U.S. holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

PFIC Tests. We will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of our subsidiaries, either: (i) at least 75% of the gross income is "passive income", or the PFIC Income Test, or (ii) at least 50% of the average quarterly value of our total gross assets (which would generally be measured by fair market value of our assets, and for which purpose the total value of our assets may be determined in part by the market value of the ADSs and our ordinary shares, which are subject to change) is attributable to assets that produce "passive income" or are held for the production of "passive income", or the PFIC Asset Test.

Passive income for purposes of each of the PFIC Income Test and PFIC Asset Test generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of funds raised in offerings of the ADSs. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation's income. If we are classified as a PFIC in any year with respect to which a U.S. holder owns the ADSs, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns the ADSs, regardless of whether we continue to meet the tests described above.

For purposes of the PFIC Asset Test, the market value of our assets may be determined in large part by reference to the market price of the ADSs and our ordinary shares, which is likely to fluctuate. For purposes of both the PFIC Income Test and the PFIC Asset Test, the composition of our income and assets will be affected by how, and how quickly, we use the cash proceeds from our U.S. initial public offering. In addition, whether we are a PFIC for any taxable year under the PFIC Income Test may depend on whether we receive certain non-refundable grants or subsidies and whether such amounts and reimbursements of certain refundable research tax credits constitute gross income for purposes of that test in each year. Because PFIC status under each of the tests is a factual determination made annually after the end of each taxable year, there can be no assurance that we will not be considered a PFIC in any taxable year. Based on the current composition of our gross income and assets and on reasonable assumptions and projections, we believe that it is more likely than not that we would not have been considered a PFIC for our taxable year ending December 31, 2019, and, based on a similar analysis, we do not expect to be considered a PFIC for our taxable year ending December 31, 2019. However, there can be no assurance that we will or will not be considered a PFIC for these years or any future taxable year. Our U.S. counsel expresses no opinion regarding our conclusions or our expectations regarding our PFIC status.

If we are a PFIC, and you are a U.S. holder that does not make one of the elections described below, a special tax regime will apply to both (a) any gain realized on the sale or other disposition of ADSs and (b) any "excess distribution" by us to you (generally, your ratable portion of distributions in any year that are greater than 125% of the average annual distribution received by you in the shorter of the three preceding years or your holding period for the ADSs), unless the holder elects to treat the PFIC as a "qualified electing fund," or QEF, or makes a "mark-to-market" election, each as discussed below. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over your holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to you will not qualify for the lower rates of taxation applicable to "qualified dividend income" discussed above under "Distributions."

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

If a U.S. holder owns ADSs during any taxable year in which we are a PFIC, the U.S. holder generally will be required to file an IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) with respect to the Company, generally with the U.S. Holder's federal income tax return for that year.

PFIC Elections. Certain elections may alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs.

A U.S. holder may make a "mark-to-market" election with respect to its ADSs if the ADSs meet certain minimum trading requirements, as described below. If a U.S. holder makes a mark-to-market election, the U.S. holder generally will recognize as ordinary income any excess of the fair market value of the ADSs at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ADSs over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. holder makes the election, the U.S. holder's tax basis in the ADSs will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). The mark-to-market election is available only if we are a PFIC and the ADSs are "regularly traded" on a "qualified exchange." The ADSs will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the ADSs are traded on a qualified exchange on at least 15 days during each calendar quarter (subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement as disregarded). The Nasdaq Capital Market is a qualified exchange for this purpose and, consequently, if the ADSs are regularly traded, the mark-to-market election will be available to a U.S. holder.

As an alternative to making a mark-to-market election, the excess distribution rules may be avoided if a U.S. holder makes a QEF election effective beginning with the first taxable year in the holder's holding period in which we are treated as a PFIC with respect to such holder. A U.S. holder that makes a QEF election with respect to a PFIC is required to include in income its pro rata share of the PFIC's ordinary earnings and net capital gain as ordinary income and capital gain, respectively, subject to a separate election to defer payment of taxes, which deferral is subject to an interest chart.

In general, a U.S. holder makes a QEF election by attaching a completed IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund) to a timely filed (taking into account any extensions) U.S. federal income tax return for the year beginning with which the QEF election is to be effective. In certain circumstances, a U.S. holder may be able to make a retroactive QEF election. A QEF election can be revoked only with the consent of the IRS. In order for a U.S. holder to make a valid QEF election, the corporation must annually provide or make available to the holder certain information.

We do not currently intend to provide the information necessary for U.S. holders to make or maintain QEF elections if we were treated as a PFIC for any taxable year. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. investors are urged to consult their own tax advisers with respect to the consequences of acquisition, ownership and disposition of the ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of the ADSs.

Backup Withholding and Information Reporting. U.S. holders generally will be subject to information reporting requirements with respect to dividends on ADSs and on the proceeds from the sale, exchange or disposition of ADSs that are paid within the United States or through U.S.-related financial intermediaries, unless the U.S. holder is an "exempt recipient." In addition, U.S. holders may be subject to backup withholding on such payments, unless the U.S. holder provides a taxpayer identification number and a duly executed IRS Form W-9 or otherwise establishes an exemption. Backup withholding is not an additional tax, and the amount of any backup withholding will be allowed as a credit against a U.S. holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Certain Reporting Requirements With Respect to Payments of Offer Price. U.S. holders paying more than U.S. $100,000 for the ADSs generally may be required to file IRS Form 926 reporting the payment of the Offer Price for the ADSs to us. Substantial penalties may be imposed upon a U.S. holder that fails to comply. Each U.S. holder should consult its own tax advisor as to the possible obligation to file IRS Form 926.

Foreign Asset Reporting. Certain individual U.S. holders are required to report information relating to an interest in the ADSs, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return. In addition, U.S. holders should consider their possible obligation to file online a FinCEN Form 114—Foreign Bank and Financial Accounts Report, as a result of holding ADSs or ordinary shares. U.S. holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of the ADSs.

THE DISCUSSION ABOVE IS A SUMMARY OF THE MATERIAL FRENCH AND U.S. FEDERAL INCOME TAX CONSEQUENCES OF AN INVESTMENT IN THE ADSs OR ORDINARY SHARES AND IS BASED UPON LAWS AND RELEVANT INTERPRETATIONS THEREOF IN EFFECT AS OF THE DATE OF THIS ANNUAL REPORT, ALL OF WHICH ARE SUBJECT TO CHANGE, POSSIBLY WITH RETROACTIVE EFFECT. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN ADSs OR ORDINARY SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and file reports with the SEC under those requirements. Such reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F each year containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.biophytis.com*. We intend to post our annual report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as Biophytis S.A., that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. Subsidiary Information

Not required.

Item 11. Quantitative and Qualitative Disclosures About Market Risk.

Market risk

Interest rate risk

Interest rate risk reflects the Company's exposure to fluctuations in interest rates in the market.

Changes in interest rate could affect returns achieved on cash and fixed-term deposits but this risk is not considered material given the current low returns on deposits held by the Company.

Change in interest rate could affect the statement of consolidated operations for financial liabilities but this risk is considered as not significant given the implementation by the Company of debts bearing fixed interest rate.

Foreign exchange risk

The major risks linked to foreign exchange rate are considered not significant due to the low level of activity of its foreign subsidiaries.

The Company currently does not use hedging instruments to protect its activity from exchange rate fluctuations. However, any major development in its activity may result in an increase of its exposure to exchange rate risk. Should such increase materialize, the Company may consider adopting an appropriate policy to hedge such risks.

Equity risk

The Company does not hold long or short-term tradable securities on a regulated market.

Credit risk

Credit risk is linked to deposits with banks and financial institutions.

The Company seeks to minimize the risk related to banks and financial institutions by placing cash deposits with highly rated financial institutions. The maximum level of the credit risk corresponds to the book value of the financial assets. As outstanding receivables consist primarily of Research Tax Credit "CIR" granted by the French government, the Company does not carry significant credit risk.

Liquidity risk

Since our inception, we have funded our operations and growth by strengthening our shareholders' equity through capital increases (including the capital increase realized during its French IPO in July 2015), bank loans and notes, and obtaining public aid for innovation and reimbursement of CIR receivables, including the prefinancing arrangement initiated in 2019.

Significant research and development expenses have been incurred since inception generating negative cash flows from operating activities of €12,057 thousand, €15,272 thousand and €9,864 thousand for the years ended December 31, 2018, 2019 and 2020, respectively.

The Financial Statements have been approved on a going concern basis by the Board of Directors (refer to Item 17 note 2.1).

The Company will continue to have major funding requirements in the future to support the development of its drug candidates. The precise extent of funding required is difficult to predict.

Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

The Bank of New York Mellon, as depositary, registers and deliver ADSs. Each ADS represents 10 ordinary shares (or a right to receive 10 ordinary shares) deposited with Societe Generale, as custodian for the depositary in France. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

A deposit agreement among us, the depositary and the ADS holders sets out the ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

Fees and Charges

Pursuant to the terms of the deposit agreement, the holders of ADSs will be required to pay the following fees:

Persons depositing or withdrawing ordinary shares or ADS holders must pay:	For:
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	• Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property • Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	• Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs	• Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares
Expenses of the depositary	• Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) • Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or ordinary shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depository. Where the depository converts currency itself or through any of its affiliates, the depository acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliates in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation under to act without negligence or bad faith. The methodology used to determine exchange rates used in currency made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of Taxes

ADS Holders are responsible for any taxes or other governmental charges payable on the ADSs or on the deposited securities represented by any of the ADSs. The depositary may refuse to register any transfer of the ADSs or allow you to withdraw the deposited securities represented by the ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by the ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

Global Offering

On February 12, 2021, we completed our U.S. initial public offering of an aggregate of 12,000,000 ordinary shares represented by 1,200,000 ADSs, each ADS representing 10 ordinary share, at an offering price of $16.75 per ADS, for aggregate gross proceeds of €16.58 million ($20.1 million). The effective date of the registration statement on Form F-1, as amended (File No. 333-252225) for our offering was February 9, 2021. The offering commenced on February 9, 2021 and did not terminate before all of the securities registered in the registration statement were sold.

H.C. Wainwright acted as sole book-running manager for the Offering.

We received net offering proceeds of approximately €13.49 million ($16.35 million, using the exchange rate of €1.00 =$ 1.212 on February 12, 2021, the closing date) from the offering, after deducting underwriting discounts and commissions, management fee and offering expenses. The total expenses incurred by us in connection with the offering was approximately €3.1 million ($3.8 million), which included approximately €1.2 million ($1.5 million) in underwriting discounts and commissions, a management fee of €0.2 million ($0.2 million), and €1.7 million ($2.0 million) in offering expenses. None of the transaction expenses included payments to our directors or officers or their associates, persons owning more than 10% or more of our equity securities or our affiliates.

The net proceeds from our U.S. initial public offering have been used, and will continue to be used, as described in the final prospectus for the offering filed with the U.S. Securities and Exchange Commission on February 10, 2021. None of the net proceeds of our global offering have been paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

Item 15. Disclosure Controls and Procedures.

A. Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer (*principal executive officer*) and chief financial officer (*principal financial officer*), as appropriate, to allow timely decisions regarding required disclosure.

Our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of December 31, 2020, have concluded that, as of such date, our disclosure controls and procedures were effective and ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer (principal executive officer) and chief financial officer (principal financial officer), to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission’s rules and forms.

B. Management’s Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management’s assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

C. Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

D. Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this annual report that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert.

Our board of directors has determined that each of Jean Franchi and Nadine Coulm is an "audit committee financial expert" as defined by the rules and regulations of the Securities and Exchange Commission and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Each of Ms. Franchi and Ms. Coulm is independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.

Item 16B. Code of Business Conduct and Ethics.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at *www.biophytis.com*. The board of directors is responsible for administering the Code of Conduct, but has delegated day-to-day responsibility for administering and interpreting the Code of Conduct to our Chief Financial Officer, who has been appointed Compliance Officer under the Code of Conduct. Any waivers of the Code of Conduct for employees, executive officers and directors must be approved by the board of directors and promptly disclosed to our shareholders. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Item 16C. Principal Accountant Fees and Services.

Ernst & Young et Autres, or E&Y, served as our independent registered public accounting firm for 2019 and 2020. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	Year Ended December 31,	
	2019	**2020**
	(in € thousands)	
Audit Fees	50	220
Audit-Related Fees	562	208
Tax Fees	—	—
Other Fees	—	—
Total	612	428

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that E&Y provides, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit and are not reported under Audit Fees.

"Tax Fees" are the aggregate fees billed for professional services rendered by E&Y for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by E&Y.

Audit and Non-Audit Services Pre-Approval Policy

The audit committee has responsibility for reviewing the candidates for the position of (and proposing in some cases their appointment), setting compensation of and overseeing the work of the independent registered public accounting firm. The audit committee ensures the independence and competence of the independent registered public accounting firm. Unless a type of service to be provided by our independent registered public accounting firm has received general pre-approval from the audit committee, it requires specific pre-approval by the audit committee. The payment for any proposed services in excess of pre-approved cost levels requires specific pre-approval by the audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant.

Not applicable.

Item 16G. Corporate Governance.

As a French société anonyme, we are subject to various corporate governance requirements under French law. In addition, as a foreign private issuer listed on the Nasdaq Capital Market, we will be subject to Nasdaq's corporate governance listing standards. However, Nasdaq's listing standards provide that foreign private issuers are permitted to follow home country corporate governance practices in lieu of Nasdaq's rules, with certain exceptions. Certain corporate governance practices in France may differ significantly from corporate governance listing standards. For example, neither the corporate laws of France nor our bylaws require that (i) a majority of our directors be independent, (ii) our compensation committee include only independent directors, or (iii) our independent directors hold regularly scheduled meetings at which only independent directors are present. Other than as set forth below, we currently intend to comply with the corporate governance listing standards of Nasdaq to the extent possible under French law. However, we may choose to change such practices to follow home country practice in the future.

As a foreign private issuer, we are required to comply with Rule 10A-3 of the Exchange Act relating to audit committee composition and responsibilities. Rule 10A-3 of the Exchange Act provides that the audit committee must have direct responsibility for the nomination, compensation and choice of our auditors, as well as control over the performance of their duties, management of complaints made, and selection of consultants. However, if the laws of a foreign private issuer's home country require that any such matter be approved by the board of directors or the shareholders, the audit committee's responsibilities or powers with respect to such matter may instead be advisory. Under French law, the audit committee may only have an advisory role and appointment of our statutory auditors, in particular, must be decided by the shareholders at our annual meeting.

In addition, Nasdaq rules require that a listed company specify that the quorum for any meeting of the holders of common stock be at least $33^{1}/_{3}\%$ of the outstanding shares of the company's common voting stock. Consistent with French law, our by-laws provide and will continue to provide that a quorum requires the presence of shareholders having at least (1) 20% of the shares entitled to vote in the case of an ordinary shareholders' general meeting or at an extraordinary shareholders' general meeting where shareholders are voting on a capital increase by capitalization of reserves, profits or share premium, or (2) 25% of the shares entitled to vote in the case of any other extraordinary shareholders' general meeting. If a quorum is not present, the meeting is adjourned. There is no quorum requirement when an ordinary general meeting is reconvened, but the reconvened meeting may consider only questions which were on the agenda of the adjourned meeting. When an extraordinary general meeting is reconvened, the quorum required is 20% of the shares entitled to vote, except where the reconvened meeting is considering capital increases through capitalization of reserves, profits or share premium. For these matters, no quorum is required at the reconvened meeting. If a quorum is not present at a reconvened meeting requiring a quorum, then the meeting may be adjourned for a maximum of two months. See the section of this annual report titled "Description of Share Capital—Key Provisions of Our By-laws and French Law Affecting Our Ordinary Shares."

Item 16H. Mine Safety Disclosure.

Not applicable.

PART III

Item 17. Financial Statements.

See pages F-1 through F-48 of this annual report.

Item 18. Financial Statements.

Not applicable.

Item 19. Exhibits.

Exhibit No.	Description of Exhibit
1.1	By-laws (status) of the registrant (English translation) dated February 26, 2021
2.1	Form of Deposit Agreement (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-1/A (File No. 333-252225) filed on February 2, 2021)
2.2	Form of American Depositary Receipt (included in Exhibit 4.1) (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form F-1/A (File No. 333-252225) filed on February 2, 2021)
2.3	Description of Ordinary Shares
4.1	Venture Loan Agreement by and between Biophytis S.A. and Kreos Capital V (UK) Ltd., dated September 10, 2018 (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.2	Bonds Issue Agreement by and between Biophytis S.A. and Kreos Capital V (UK) Ltd., dated September 10, 2018 (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.3†	Goodwill Pledge Agreement by and between Biophytis S.A. and Kreos Capital V (UK) Ltd., dated September 10, 2018 (English translation) (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.4†	Accord d'Exploitation (License Agreement), dated January 1, 2016, by and among Biophytis S.A. and L'Universite Pierre et Marie Curie, Le Centre National de la Recherche Scientifique and L'Institut National de la Sante et de la Recherche Medicale (English translation) (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.5†	Accord d'Exploitation (License Agreement), dated January 1, 2016, by and among Biophytis S.A., L'Universite Pierre et Marie Curie, Le Centre National de la Recherche Scientifique and L'Institut National de la Recherche Agronomique (English translation) (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.6†	Amendment No. 1 to the License Agreement by and between Biophytis S.A., L'Universite Pierre et Marie Curie, Le Centre National de la Recherche Scientifique and L'Institut National de la Recherche Agronomique dated April 2, 2019 (English translation) (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.7†	Amendment No. 2 to the License Agreement by and between Biophytis S.A., Sorbonne Universite, Le Centre National de la Recherche Scientifique and L'Institut National de la Recherche Agronomique dated November 6, 2020 (English translation) (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.8†	Amendment No. 3 to the License Agreement by and between Biophytis S.A., Sorbonne Universite, Le Centre National de la Recherche Scientifique and L'Institut National de la Recherche Agronomique dated December 17, 2020 (English translation) (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)

4.9†	Amendment No. 1 to the License Agreement by and between Biophytis S.A., Sorbonne Universite, Le Centre National de la Recherche Scientifique and L'Institut National de la Sante et de la Recherche Medicale dated December 17, 2020 (English translation) (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.10†	Co-ownership Agreement relating to patents S1 by and between Biophytis S.A., Universite Pierre et Marie Curie and Le Centre de la Recherche Scientifique, dated July 10, 2008 with effect as from November 30, 2007 (English translation) (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.11†	Co-ownership Agreement relating to patents S2 by and between Biophytis S.A. and Universite Pierre et Marie Curie, dated March 29, 2016 with effect as from November 10, 2011 (English translation) (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.12†	Co-ownership Agreement Considered as Partial Transfer of Share Patent relating to patents S3 by and between Biophytis S.A., L'Institut National de la Recherche Agronomque and Universite Pierre et Marie Curie, dated July 6, 2017 with effect as from December 13, 2011 (English translation) (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.13†	Co-ownership Agreement relating to patents S4 by and between Biophytis S.A. and Universite Pierre et Marie Curie, dated November 18, 2016 with effect as from May 20, 2014 (English translation) (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.14	Co-ownership Agreement Constituting Partial Transfer of Shares by and between Biophytis S.A., Sorbonne Universite and Le Centre National de la Recherche Scientifique, dated October 9, 2019 (English translation) (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.15†	Co-ownership Agreement Considered as a Transfer of Sale relating to patents MI by and between the Institut Biophytis and Universite Pierre et Marie Curie, dated November 10, 2014 with effect as from June 25, 2009 (English translation) (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.16†	Co-ownership Agreement a Partial Assignment of Share relating to patents MII by and between the Institut Biophytis, Universite Pierre et Marie Curie and Le Centre de la Recherche Scientifique, dated May 11, 2017 with effect as from May 13, 2011 (English translation) (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.17†	Co-ownership Agreement Constituting the Partial Transfer of the Share relating to patents MIII by and between Biophytis S.A., Universite Pierre et Marie Curie, Le Centre de la Recherche Scientifique and Inserm Transfer SA, dated October 16, 2017 with effect as from April 30, 2015 (English translation) (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.18†	Co-ownership Agreement relating to patents MIV by and between Biophytis S.A., Universite Pierre et Marie Curie, Le Centre de la Recherche Scientifique and Inserm Transfer SA, dated December 18, 2017 with effect as from May 27, 2015 (English translation) (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.19†	Collaboration Agreement by and between Biophytis S.A., Sorbonne Universite, Le Centre de la Recherche Scientifique and Institut National de la Santé et de la Recherche Médicale dated March 2, 2020 (English translation) (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.20†	Collaboration Agreement by and between Biophytis S.A., Sorbonne Universite and Le Centre de la Recherche Scientifique dated February 1, 2019 (English translation) (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)

4.21†	Amendment No. 1 to the Collaboration Agreement by and between Biophytis S.A., Sorbonne Universite and Le Centre de la Recherche Scientifique (English translation) (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.22†	Collaboration Agreement by and between Biophytis S.A., Universite Paris Descartes and SATT Ile de France Innov with effect as from September 10, 2018 (English translation) (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.23	Services Agreement relating to the SARA INT clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated December 22, 2017 (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.24	Amendment 1 to the Services Agreement relating to the SARA INT clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated July 20, 2018 (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.25	Amendment 2 to the Services Agreement relating to the SARA INT clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated October 31, 2019
4.26	Amendment 3 to the Services Agreement relating to the SARA INT clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated March 3, 2020
4.27	Services Agrement regarding SARA DATA/OBS clinical platform between Biophytis S.A. and BlueCompanion Ltd., dated May 16, 2017 (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.28	Amendment 1 to the Services Agreement regarding SARA DATA/OBS clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated December 22, 2017 (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.29	Amendment 2 to the Services Agreement regarding SARA DATA/OBS clinical data platform between Biophytis S.A. and BlueCompanion Ltd., dated December 7, 2018 (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.30	Services Agreement by and between Biophytis S.A. and Biophytis, Inc., dated March 22, 2019 (English translation) (incorporated by reference to Exhibit 10.28 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.31	Amendment No. 1 to the Services Agreement by and between Biophytis S.A. and Biophytis, Inc., dated June 7, 2019 (English translation) (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.32	Assignment Agreement between Biophytis S.A. and Stanislas Veillet, dated May 22, 2019 (incorporated by reference to Exhibit 10.30 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.33	Amendment to Assignment Agreement between Biophytis S.A. and Sanislas Veillet, dated April 6, 2020 (incorporated by reference to Exhibit 10.31 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.34†	Consultant Service Agreement between Biophytis S.A. and Successful Life SAS, dated October 1, 2019 (English translation) (incorporated by reference to Exhibit 10.32 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.35	Amendment No. 1 to the Consultant Service Agreement between Biophytis S.A. and Successful Life SAS, dated October 1, 2020 (English translation) (incorporated by reference to Exhibit 10.33 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)

4.36	Amendment No. 2 to the Consultant Service Agreement between Biophytis S.A. and Successful Life SAS, dated March 9, 2020 (English translation)
4.37†	Issuance and Subscription Agreement for bonds with an option for exchange in cash and/or conversion into new or existing shares between Biophytis S.A. and Atlas Special Opportunities LLC (in the presence of Atlas Capital Markets), dated April 5, 2020 (incorporated by reference to Exhibit 10.34 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.38†	Amendment Agreement to the Issuance and Subscription Agreement for bonds with an option for exchange in cash and/or conversion into new or existing shares between Biophytis S.A. and Atlas Special Opportunities LLC (in the presence of Atlas Capital Markets), dated June 18, 2020 (incorporated by reference to Exhibit 10.35 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
4.39	Services Agreement by and between Biophytis S.A. and Institut Biophytis Do Brasil, dated July 1, 2020 (English translation) (incorporated by reference to Exhibit 10.36 to the Registration Statement on Form F-1 (File No. 333-252225) filed on January 19, 2021)
8.1	List of subsidiaries of the registrant
12.1	Certificate of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

† Confidential portions of the exhibit have been omitted.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

BIOPHYTIS S.A.

By: _____
Stanislas Veillet
Chief Executive Officer and Chairman

Date: _____, 2021

BIOPHYTIS S.A.

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Financial Statements for the Years Ended December 31, 2018, 2019 and 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the board of Directors and Shareholders of Biophytis S.A.,

[Report]

/s/ Ernst & Young et Autres

We have served as the Company's auditors since 2016.
Paris-La Défense, France

[Date], 2021

STATEMENTS OF CONSOLIDATED FINANCIAL POSITION

(amounts in thousands of euros)	Notes	AS OF DECEMBER 31, 2019	2020
ASSETS			
Patents and software	3	2,400	2,673
Property, plant and equipment	4	185	114
Other non-current financial assets	5, 9	382	413
Total non-current assets		**2,967**	**3,200**
Other receivables	7, 9	7,893	5,239
Other current financial assets	6	475	12,924
Cash and cash equivalents	8, 9	6,337	5,847
Total current assets		**14,705**	**24,010**
TOTAL ASSETS		**17,672**	**27,210**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Shareholders' equity			
Share capital	10	4,793	20,151
Premiums related to the share capital	10	45,237	17,821
Treasury shares	19	(17)	(42)
Foreign currency translation adjustment		(82)	(72)
Accumulated deficit - attributable to shareholders of Biophytis		(39,638)	(13,941)
Net loss - attributable to shareholders of Biophytis		(17,788)	(17,054)
Shareholders' equity - attributable to shareholders of Biophytis		**(7,495)**	**6,863**
Non-controlling interests		(31)	(31)
Total shareholders' equity		**(7,526)**	**6,832**
Liabilities			
Employee benefit obligations	13	142	188
Non-current financial liabilities	9, 12	5,398	1,833
Total non-current liabilities		**5,540**	**2,021**
Current financial liabilities	9, 12	9,846	7,262
Provisions	14	-	1,396
Trade payables	9, 15.1	7,866	7,985
Tax and social liabilities	15.2	1,263	1,446
Derivative financial instruments	12	451	-
Other creditors and miscellaneous liabilities	15.3	232	268
Total current liabilities		**19,658**	**18,357**
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		**17,672**	**27,210**

The accompanying Notes form an integral part of these consolidated financial statements

STATEMENTS OF CONSOLIDATED OPERATIONS

		FOR THE YEARS ENDED DECEMBER 31,		
(amounts in thousands of euros, except share and per share data)	**Notes**	**2018**	**2019**	**2020**
Revenue		-	-	-
Cost of sales		-	-	-
Gross margin		**-**	**-**	**-**
Research and development expenses, net	16.1	(9,513)	(9,089)	(9,921)
General and administrative expenses	16.2	(4,348)	(6,593)	(4,021)
Operating loss		**(13,861)**	**(15,682)**	**(13,942)**
Financial expenses		(215)	(2,878)	(6,364)
Financial income		17	18	421
Change in fair value of derivative instruments		-	726	2,831
Net financial expense	17	**(198)**	**(2,134)**	**(3,112)**
Loss before taxes		**(14,059)**	**(17,816)**	**(17,054)**
Income taxes benefit		72	28	-
Net loss		**(13,987)**	**(17,788)**	(17,054)
Attributable to shareholders of Biophytis		(13,987)	(17,788)	(17,054)
Non-controlling interests		-	-	-
Basic and diluted weighted average number of shares outstanding		13,374,426	16,882,661	59,974,486
Basic loss per share (€/share)	19	**(1.05)**	**(1.05)**	**(0.28)**
Diluted loss per share (€/share)	19	**(1.05)**	**(1.05)**	**(0.28)**

The accompanying Notes form an integral part of these consolidated financial statements

STATEMENTS OF CONSOLIDATED COMPREHENSIVE LOSS

	FOR THE YEARS ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Net loss for the year	**(13,987)**	**(17,788)**	**(17,054)**
Items that will not be reclassified to profit or loss			
Actuarial gains and losses	(42)	87	(14)
Items that will be reclassified to profit or loss			
Foreign currency translation adjustment	(64)	(18)	10
Other comprehensive income (loss)	**(106)**	**69**	**(4)**
Total comprehensive loss	**(14,093)**	**(17,719)**	**(17,058)**
Attributable to shareholders of Biophytis	(14,093)	(17,719)	(17,058)
Non-controlling interests	-	-	-

The accompanying Notes form an integral part of these consolidated financial statements

STATEMENT OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

(amounts in thousands of euros, except share data)	*Notes*	*Share capital – number of shares*	Share capital	Premiums related to the share capital	Accumulated deficit and net loss	Foreign currency translation adjustment	Share based payment	Split accounting impact related to convertible notes and non-convertible bonds	Treasury Shares	Shareholders' equity - Attributable to shareholders of Biophytis	Non-controlling interests	Shareholders' equity
As of January 1, 2018		*13,463,413*	**2,693**	**44,708**	**(30,951)**	**(0)**	**4,386**	**521**	**(138)**	**21,219**	**(31)**	**21,188**
Net loss for the period		-	-	-	(13,987)	-	-	-	-	(13,987)	-	(13,987)
Other comprehensive income (loss)		-	-	-	(42)	(64)	-	-	-	(106)	-	(106)
Total comprehensive income (loss)		**-**	**-**	**-**	**(14,029)**	**(64)**	**-**	**-**	**-**	**(14,093)**	**-**	**(14,093)**
Issuance of warrants attached to non-convertible bonds	12	-	-	-	-	-	-	289	-	289	-	289
Deferred tax liabilities on the issuance of warrants		-	-	-	-	-	-	(72)	-	(72)	-	(72)
Treasury shares net movements	10	-	-	-	-	-	-	-	(13)	(13)	-	(13)
Gains and losses, net related to treasury shares		-	-	-	(135)	-	-	-	-	(135)	-	(135)
Equity settled share-based payments	11	-	-	-	-	-	287	-	-	287	-	287
Costs incurred in relation to equity transactions (1)		-	-	(445)	-	-	-	-	-	(445)	-	(445)
As of December 31, 2018		*13,463,413*	**2,693**	**44,263**	**(45,115)**	**(64)**	**4,673**	**738**	**(151)**	**7,037**	**(31)**	**7,006**
Net loss for the period		-	-	-	(17,788)	-	-	-	-	(17,788)	-	(17,788)
Other comprehensive income (loss)		-	-	-	87	(18)	-	-	-	69	-	69
Total comprehensive income (loss)		**-**	**-**	**-**	**(17,701)**	**(18)**	**-**	**-**	**-**	**(17,719)**	**-**	**(17,719)**
Conversion of convertible notes	12	*10,499,841*	2,100	529	-	-	-	-	-	2,629	-	2,629
Issuance of warrants attached to non-convertible bonds	12	-	-	-	-	-	-	75	-	75	-	75
Deferred tax liabilities on the issuance of warrants		-	-	-	-	-	-	(28)	-	(28)	-	(28)
Treasury shares net movements	10	-	-	-	-	-	-	-	134	134	-	134
Gains and losses, net related to treasury shares		-	-	-	(131)	-	-	-	-	(131)	-	(131)
Equity settled share-based payments	11	-	-	-	-	-	63	-	-	63	-	63
Costs incurred in relation to equity transactions (1)		-	-	445	-	-	-	-	-	445	-	445
As of December 31, 2019		*23,963,254*	**4,793**	**45,237**	**(62,947)**	**(82)**	**4,736**	**785**	**(17)**	**(7,495)**	**(31)**	**(7,526)**
Net loss for the period			-	-	(17,054)	-	-	-	-	**(17,054)**	-	**(17,054)**
Other comprehensive income (loss)			-	-	(14)	10	-	-	-	**(4)**	-	**(4)**
Total comprehensive income (loss)			-		(17,068)	10	-	-	-	**(17,058)**	-	**(17,058)**
Conversion of convertible notes (2)	12	*20,578,683*	4,116	4,725	-	-	-	-	-	**8,841**	-	**8,841**
Share capital increase	12	*51,345,005*	10,268	14,612	-	-	-	-	-	**24,880**	-	**24,880**
Exercise of warrants	11	*4,870,155*	974	341	-	-	-	-	-	**1,315**	-	**1,315**
Subscription of warrants	11		-	449	-	-	-	-	-	**449**	-	**449**
Allocation of premiums to retained earnings (3)			-	(44,047)	(44,047)	-	-	-	-	-	-	-
Treasury shares net movements			-	-	-	-	-	-	(25)	**(25)**	-	**(25)**
Gains and losses, net related to treasury shares			-	-	61	-	-	-	-	**61**	-	**61**
Equity settled share-based payments	11		-	-	-	-	785	-	-	**785**	-	**785**
Biophytis shares to be received from Negma (4)	12.2.1				(1,394)					**(1,394)**		**(1,394)**
Costs incurred in relation to public offering on the Nasdaq	10		-	(787)	-	-	-	-	-	**(787)**	-	**(787)**
Costs incurred in relation to equity transactions (5)	10		-	(2,709)	-	-	-	-	-	**(2,709)**	-	**(2,709)**
As of December 31, 2020		*100,757,097*	**20,151**	**17,821**	**(37,301)**	**(72)**	**5,521**	**785**	**(42)**	**6,863**	**(31)**	**6,832**

(1) Costs directly attributable to the proposed issuance of shares in connection with a listing of the Company's equity securities on a U.S. stock exchange in 2018 were recognized as a reduction from shareholders' equity for €(445) thousand. Following the Company's decision to postpone the issuance of its shares, the related costs were recognized in the 2019 statement of consolidated operations.

(2) The amount of € 4,725 thousand in premiums related to share capital corresponds to the impact of the conversion of 398 bonds held by Atlas and Negma and the IFRS adjustment relating to the issue premium of €89 thousand which reflects the 8% discount due to the conversion ratio of 0.92 for Negma bonds and the 3% discount due to the conversion ratio of 0.97 for Atlas bonds.

(3) The general meeting held on May 28, 2020 decided the allocation of premiums to accumulated deficit.

(4) The judgment of the Paris Court of Appeal of November 18, 2020, in favour of Biophytis, ordered the return by Negma of the 2,050,000 Biophytis shares previously delivered following the judgment of May 7, 2020. As a result, the Company recognized as of December 31, 2020 the right to receive the 2,050,000 shares to be returned by Negma in equity for € 1,394 thousand in counterparts of the offset of the financial indemnity previously recorded as financial expense (see notes 12.2 and 14).

(5) Costs incurred by the Company in relation to private placements totaling €23.5 million that occurred in February, June, July and October 2020.

The accompanying Notes form an integral part of these consolidated financial statements

STATEMENTS OF CONSOLIDATED CASH FLOWS

(amounts in thousands of euros)	Notes	FOR THE YEARS ENDED DECEMBER 31, 2018	2019	2020
Cash flows from operating activities				
Net loss for the period		**(13,987)**	**(17,788)**	**(17,054)**
Adjustments to reconcile net loss to cash flows from operating activities				
Amortization and depreciation of intangible and tangible assets	3, 4	227	262	280
Additions of provisions, net of reversals	13, 14	108	(33)	1,428
Expenses associated with share-based payments	11	287	63	785
Change in deferred tax		(72)	(28)	-
Costs incurred in relation to equity transactions, initially recognized as a reduction from shareholders' equity		-	445	-
Financial interest and conversion penalty paid		135	1,080	118
Changes in fair value of derivative instruments	12.2	-	(726)	(2,831)
Interests on investment accounts		(9)	(4)	(1)
Financial indemnity, net, Negma (1)	12.2	-	-	(34)
Unwinding of conditional advances	12.1	(11)	62	65
Amortized cost of convertible notes and non-convertible bonds	12.2	54	1,728	4,374
Operating cash flows before change in working capital requirements		**(13,268)**	**(14,939)**	**(12,871)**
(-) Change in working capital requirements (net of depreciation of trade receivables and inventories)		**(1,211)**	**333**	**(3,007)**
(Decrease) increase in other non-current financial assets		17	-	(4)
(Decrease) increase in other receivables		1,372	2,943	(2,654)
Decrease (increase) in trade payables		(2,305)	(2,641)	(119)
Decrease (increase) in tax and social security liabilities		(282)	137	(183)
Decrease (increase) in other creditors and miscellaneous liabilities		(13)	(106)	(46)
Cash flows used in operating activities		**(12,057)**	**(15,272)**	**(9,864)**
Cash flows used in investing activities				
Acquisition of intangible and tangible assets	3, 4	(113)	(282)	(214)
Interests on investment accounts		9	4	1
Purchase of term deposits classified as other current financial assets (2)	6	-	-	(12,500)
Cash flows used in investing activities		**(104)**	**(278)**	**(12,713)**
Cash flows from financing activities				
Proceeds from share capital increase, net of Negma indemnity (1)	10	-	-	23,486
Costs paid in relation to equity transactions	10	(286)	-	(3,496)
Costs incurred in relation to the issuance of warrants attached to non-convertible bonds		(30)	-	-
Net financial indemnity received from Negma (1)	12	-	-	34
Subscription of warrants (BSA)	11	-	-	271
Exercise of warrants (BSA) and founders' warrants (BSPCE)	11	-	-	862
Proceeds from research tax credit prefinancing, net of guarantee deposit	12	-	4,355	1,964
Reimbursement of the prefinanced CIR receivables, net of guarantee deposit	12	-	-	(4,589)
Proceeds from conditional advances, net of repayment	12.1	329	73	(136)
Proceeds from borrowings, net of repayment		(23)	-	-
Financial interest paid		(135)	(1,080)	(908)
Proceeds from the issuance of convertible notes and non-convertible bonds	12.2	7,260	6,840	9,000
Repayment of convertible notes and non-convertible bonds	12.2	-	(2,292)	(3,964)
Costs incurred in relation to the issuance of convertible notes and non-convertible bonds	12.2	(305)	(350)	(435)
Repayment of obligations under finance lease		(47)	(47)	-
Change in short-term bank overdrafts		8	-	(15)
Cash flows from financing activities		**6,771**	**7,500**	**22,074**
Net effect of exchange rate changes on cash and cash equivalents		(61)	(18)	13
Increase (decrease) in cash and cash equivalents		**(5,451)**	**(8,069)**	**(490)**
Cash and cash equivalents at the beginning of the period		19,857	14,406	6,337
Cash and cash equivalents at the end of the period		14,406	6,337	5,847

(1) Pursuant to a summary judgment dated May 7, 2020, Negma obtained a decision partially responding to its claims ordering, under penalty (which

amounted to €7 thousand), Biophytis to pay damages in an amount of €378 thousand and deliver 2,050,000 Biophytis shares to Negma. This delivery of 2,050,000 shares valued at €1,394 thousand was considered as a financial indemnification recorded as a financial expense. On November 18, 2020, the Paris Court of Appeal ruled in favour of Biophytis and thus ordered Negma to return the 2,050,000 Biophytis shares previously delivered and the provision of €378 thousand. Negma was also ordered to pay additional penalties to Biophytis in the amount of €41 thousand. With respect to this litigation, the Company has made a risk provision of €1,394 thousand, which represents the best estimate of the Company's probable risk of loss as of December 31, 2020.

(2) The Company purchased term deposits of €12.5 million in 2020, which are considered by the Company to be liquid investments and presented as current financial assets.

The accompanying Notes form an integral part of these consolidated financial statements

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(in thousand euros unless otherwise noted, except for share and per share data)

Note 1: General information about the Company

Incorporated in September 2006, Biophytis is a clinical-stage biotechnology company focused on the development of therapeutics that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases.

Sarconeos (BIO101), the Company's leading drug candidate, is a small molecule, administered orally, and currently in clinical Phase 2b in sarcopenia (SARA-INT) in the United States and Europe. A pediatric formulation of Sarconeos (BIO101) is being developed for the treatment of Duchenne Muscular Dystrophy (DMD).

Since April 2020, Sarconeos (BIO101) is also being developed as a treatment for patients with COVID-19 related respiratory failure in a Phase 2/3 clinical study (COVA) in the United States, Europe and Latin America.

Biophytis is a French joint stock company (*société anonyme*) and has its registered office located at 14, avenue de l'Opéra, 75001 Paris, France (register Number at the Company's house: 492 002 225 RCS PARIS).

The ordinary shares of the Company are listed on Euronext Growth Paris (Ticker: ALBPS-ISIN: FR0012816825). The ADSs (American Depositary Shares) are listed on the Nasdaq Capital Market since February 10, 2021 under the symbol "BPTS".

Biophytis and its subsidiaries are referred to hereinafter as "**Biophytis,**" or the "**Company.**"

The following information constitutes the Notes to the consolidated financial statements for the years ended December 31, 2018, 2019 and 2020.

The consolidated financial statements of Biophytis, or the "**Financial Statements**", have been prepared under the responsibility of management of the Company and were approved and authorized for issuance by the Company's Board of Directors on March 9, 2021.

Note 2: Accounting principles, rules and methods

2.1 Principles used in preparing the Financial Statements

The Financial Statements are presented in thousands of euros unless stated otherwise. Some amounts may be rounded for the calculation of financial information contained in the Financial Statements. Accordingly, the totals in some tables may not be the exact sum of the preceding figures.

Statement of compliance

The Company has prepared its Financial Statements for the years ended December 31, 2020, December 31, 2019 and December 31, 2018 in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Boards, or IASB. The term "IFRS" refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (IFRS Interpretations Committee, or IFRS IC, and Standing Interpretations Committee, or SIC), whose application is mandatory for the periods presented.

Due to the listing of ordinary shares of the Company on Euronext Growth Paris (formerly known as Alternext Paris) and in accordance with the European Union's regulation No. 1606/2002 of July 19, 2002, the Financial Statements of the Company are also prepared in accordance with IFRS as adopted by the European Union, or EU, whose application is mandatory for the periods presented.

As of December 31, 2018, 2019 and 2020, all IFRS that the IASB has published and that are mandatory are the same as those endorsed by the EU and mandatory in the EU. As a result, the Financial Statements comply with IFRS as issued by the IASB and as adopted by the EU.

Going concern

The Board of Directors approved the Financial Statements on a going concern basis despite the 2020 loss of €17,054 thousand. This analysis takes into account:

- Cash and cash equivalents as of December 31, 2020 amounted to €5.8 million.
- Liquid investments recorded under current financial assets (Short-term deposit) amounted to €12.5 million as of December 31, 2020;
- The potential use of a funding line of convertible notes set up with Atlas that could lead up to additional funding of up to € 15 million (see Note 12.2); and
- The net proceeds of the Initial Public Offering on February 10, 2021 on Nasdaq Capital Market of approximately $16.35 million (or €13.49 million) after deducting underwriting discounts and commissions, management fee, and other offering expenses payable by the Company (see Note 23).

The Company believes that the level of cash and cash equivalents, supplemented by the liquid investments, the net proceeds of the Initial Public Offering and the use existing funding lines, is sufficient to cover the Company's cash requirements for the next 12 months from the date of approval of the Financial Statements.

Accounting methods

The accounting principles adopted for the Financial Statements as of and for the year ended December 31, 2020 are the same for the year ended December 31, 2019 with the exception of the following new standards, amendments and interpretations whose application was mandatory for the Company as of January 1, 2020:

- Amendments to References to the *Conceptual Framework* in IFRS Standards, issued on March 29, 2018 and whose application is mandatory from January 1, 2020;
- Amendments to IAS 1 and IAS 8: Definition of Material, issued on October 31, 2018 and whose application is mandatory from January 1, 2020;
- Amendments to IFRS 9, IAS 39 and IFRS 17: Interest Rate Benchmark Reform, issued on September 26, 2019 and whose application is mandatory from January 1, 2020; and
- Amendments to IFRS 3 *Business Combinations*, issued on October 22, 2018 and whose application is mandatory from January 1, 2020.

Adoptions of these standards have not had a material impact on the Financial Statements.

Recently issued accounting pronouncements that may be relevant to the Company's operations but have not yet been adopted are as follows:

- Amendments to IAS 1 *Presentation of Financial Statements: Classification of Liabilities as Current or Non-current and Classification of Liabilities as Current or Non-current – Deferral of Effective Date* issued on January 23, 2020 and July 15, 2020 respectively and whose application is for annual reporting periods beginning on or after January 1, 2023;
- Amendments to IFRS 3 *Business Combinations*, IAS 16 *Property, Plant and Equipment*, IAS 37 *Provisions, Contingent Liabilities and Contingent Assets*, Annual Improvements 2018-2020, all issued May 14, 2020 and whose application is for annual reporting periods beginning on or after January 1, 2022; and
- Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 *Interest Rate Benchmark Reform – Phase 2* issued on August 27, 2020 and whose application is for annual reporting periods beginning on or after January 1, 2021.

The Company has not early adopted these new accounting standards, amendments and interpretations. It currently does not anticipate any significant impact on its Financial Statements at adoption date.

2.2 Use of judgments and estimates

To prepare the Financial Statements in accordance with IFRS, judgments and estimates were made by the Company's management; these may have had an effect on the amounts presented under assets and liabilities, the contingent liabilities at the date of preparation of the Financial Statements and the amounts under income and expenses for the period.

Such estimates are based on the assumption of a going concern and are based on the information available at the time of their preparation. These estimates are ongoing and are based on past experience as well as diverse other factors judged to be reasonable and form the basis for the assessments of the book value of assets and liabilities. These estimates may be revised if the circumstances on which they are based change or as a result of new information. Actual results may differ significantly from such estimates if assumptions or conditions change.

The main judgments and estimates made by management relate to the following in particular:

- The fair value measurement of founders' warrants, warrants and free shares granted to employees and board members:
    - The fair value measurement of share-based payments is based on the Black-Scholes option valuation model which makes assumptions about complex and subjective variables. These variables notably include the value of the Company's shares, the expected volatility of the share price over the lifetime of the instrument, and the present and future behavior of holders of those instruments. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of share-based payments in accordance with IFRS 2 *Share-based Payment*; and
    - The valuation assumptions adopted are disclosed in Note 11.
- The fair value measurement of notes convertible into ordinary shares and/or redeemable in cash with attached warrants issued to Negma, notes convertible into ordinary shares and/or redeemable in cash with Atlas and non-convertible bonds with attached warrants issued to Kreos:
    - The fair value measurement of the derivative (related to the conversion option to Negma and to Atlas) and the equity instruments issued to Negma is based on the Black-Scholes option valuation model which makes assumptions about complex and subjective variables. These variables notably include the value of the Company's shares, the expected volatility of the share price over the lifetime of the instrument, and the present and future behavior of holders of those instruments. There is a high inherent risk of subjectivity when using an option valuation model to measure the fair value of derivative instruments and of the equity instruments in accordance with IAS 32 *Financial Instruments – Presentation* ("IAS 32") and IFRS 9; and
    - The valuation assumptions utilized are disclosed in Note 12.2.
- Non-recognition of deferred tax assets net of deferred tax liabilities:
    - The determination of the amount of deferred tax assets which can be recognized requires that management makes estimates on both the consumption period of tax losses carried forward, and the level of future taxable income, in terms of strategies for fiscal management; and
    - The accounting principles applied by the Company in terms of recognition of deferred tax assets are detailed in Note 2.21.

2.3 Consolidation scope and methods

Biophytis controls all the legal entities included in the consolidation. An investor consolidates an investee when it controls the investee. The investor controls an investee when it is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its control over the investee. This principle applies to all investees, including structured entities.

An investor must possess all of the following elements to be deemed to control an investee:

- Control over the investee, which is described as having existing rights that give the current ability to direct the activities of the investee that significantly affect the investee's returns;
- Exposure, or rights, to variable returns from its involvement with the investee; and

- Ability to exert control over the investee to affect the amount of the investor's returns.

The subsidiaries are consolidated beginning on the date on which the Company acquires control. They are deconsolidated beginning on the date on which control ceases to be exercised.

Intra-company transactions and balances are eliminated. The financial statements of the subsidiaries are prepared for the same reference period as those of the parent company, on the basis of the same accounting methods.

As of the date of publication of these Financial Statements, the Company has the control over the following two subsidiaries:

- Instituto Biophytis Do Brasil, a company incorporated in July 2006 under Brazilian law and registered in the state of Sao Paulo. Biophytis holds a 94.6% ownership stake in this subsidiary; and

- Biophytis Inc., a company incorporated in September 2015 under United States law and registered in the state of Delaware. Biophytis holds a 100% ownership stake in this subsidiary.

2.4 Foreign currency translation

For each entity, the Company determines the functional currency and items included in the Financial Statements of each entity are measured using that functional currency.

The parent company's functional currency is the euros (€), which is the reporting currency of the Company and represented in the Financial Statements.

2.4.1 Recognition of transactions in foreign currencies

Transactions in foreign currencies are converted into the Company's functional currency by applying the exchange rate at the date of the transactions. The monetary assets and liabilities denominated in foreign currencies are converted at the closing date into the functional currency using the rate of exchange on that date.

Foreign exchange gains and losses resulting from the conversion of monetary items correspond to the difference between the amortized cost denominated in the functional currency at the beginning of the period, adjusted for the impact of the effective interest rate and payments over the period, and the amortized cost denominated in the foreign currency converted at the exchange rate on the closing date.

The non-monetary assets and liabilities denominated in foreign currencies, which are valued at fair value, are converted into the functional currency using the rate of exchange on the date on which the fair value was determined. The translation differences resulting from these conversions are recognized in profit or loss, with the exception of the differences resulting from the conversion of equity instruments available for sale, of a financial liability designated as a hedge for a net investment in a business abroad, or of instruments qualified as cash flow hedges, which are recognized directly in shareholders' equity.

2.4.2 Translation of the financial statements of foreign subsidiaries

The financial statements of entities whose functional currency is not the euro are translated as follows:

- assets and liabilities are translated using the closing rate of the period;

- income statement items are translated using the average rate of the period; and

- equity items are translated using the historical rate.

The exchange differences arising on translation are directly recognized in shareholders' equity under "Foreign currency translation adjustment."

The exchange rates used for the preparation of the Financial Statements are as follows:

EXCHANGE RATE	Closing rate AS OF DECEMBER 31,			Average rate FOR THE YEAR ENDED DECEMBER 31		
	2018	2019	2020	2018	2019	2020
BRL	4.4440	4.5157	6.3735	4.3085	4.4134	5.8943
USD	1.1450	1.1234	1.2271	1.1810	1.1195	1.1422

2.5 Impact of the COVID-19 health crisis on the December 31, 2020 accounts

Given the rapid changes associated with COVID-19, the Company is taking necessary precautions to protect its employees, partners and operations.

The Company requested from its employees in France and the United States to work from home and to organize meetings and events in a virtual way when possible, except for essential activities in laboratories. Restrictions also apply to travels. Access to the premises and works performed must respect social distancing and other government recommendations. Different actions have been taken by the Company following the epidemic evolution.

With regard to the SARA-INT clinical trial in Sarcopenia, the SARS-Cov-2 pandemic led health authorities (FDA and EMA) to introduce restriction measures to preserve patient health and safety. These included keeping them at home and closing hospitals where clinical trials were conducted.

Biophytis had to adapt its protocol to allow the treatment and follow-up of patients at home. It should be noted that the patients in the SARA-INT study are mostly elderly, and therefore particularly vulnerable to COVID-19.

In August 2020, the Company provided an update on the SARA-INT program, announcing these measures, which resulted in a 3-month extension of the treatment time from the original protocol, following the review of the Data Safety Monitoring Board (DSMB), which took into account the correct risk profile of the product.

In general, the impact of COVID-19 on our clinical research and development advances will largely depend on future developments of the pandemic. These are highly uncertain and cannot be predicted with certainty and include issues such as: the rate and ultimate geographic spread of the disease; the duration of the pandemic travel restrictions and social distancing requirements in the United States, Brazil, the United Kingdom, France and other countries; disruptions to activity and closures; the impact on financial markets and the global economy; and the effectiveness of actions to contain, treat and prevent disease.

The impact of potentially ongoing and prolonged disruptions related to the COVID-19 pandemic may result in future difficulties or delays in the launch, recruitment, execution or completion of our ongoing and planned clinical trials, which could result in additional unforeseen costs.

SARA-INT Program

Regarding SARA-INT trial in sarcopenia: the protocol was adapted in order to ensure the continuity of the trial. In particular, patient follow-ups were organized to take place at home, preventing them from moving to investigation centers. These changes were based on recommendations from both the US Food and Drug Administration (FDA) guidance and the Data and Safety Monitoring Board (DSMB) designed to preserve patients' safety in ongoing clinical trials.

COVA Program

In April 2020, the Company launched a new clinical development program, COVA, with Sarconeos (BIO101) as a potential treatment for respiratory failure associated with COVID-19 in a Phase 2/3 clinical study in the United States, Europe and Latin America.

The pivotal multinational clinical trial is being conducted in two parts, the first of which will assess the treatment safety and provide an indication of activity of Sarconeos (BIO101) in 50 hospitalized patients with severe respiratory manifestations related to COVID-19.

Given the health crisis, the speed of implementation of new clinical studies against COVID-19 was critical.

The Biophytis' study obtained regulatory approvals to take place in the United States, Brazil, Belgium, the United Kingdom and ultimately in France. The first COVA participant was enrolled in August 2020, in Belgium. The first COVA participant in France occurred four months after Belgium.

Beyond Europe, given the opening of clinical centers in the United States and Brazil, Enrollment of 50 patients for Part 1 was completed on January 21, 2021.

The second part, which corresponds to a Phase 3 clinical study, started with the recruitments of patients in four countries: France, Belgium, United States and Brazil.

The results of the full study are expected in the second quarter of 2021.

MYODA Program

The COVID-19 health crisis has significantly impacted the launch of the MYODA study, which is now delayed to early 2022 depending on the pandemic evolution. Indeed, the sanitary conditions may have a significant impact on the health and the safety of the study population as the study targets children with a fragile health and affected by the Duchenne Muscular Dystrophy.

As of the approval date of the accounts by the Board of Directors, the Company noted limited impacts on its operations.

In addition, as part of the provisions provided by the French State, the Company has:

- requested to benefit from a deferral of its payment deadlines for social security contributions (amounting to €168 thousand), rents and various tax; and
- implemented partial activity measures for all staff from March 23, 2020 until June 30, 2020.

The compensation received from the French State for partial unemployment amounted to €46 thousand for the year ended December 31, 2020 and was recorded as a reduction of payroll expenses.

2.6 Intangible assets

2.6.1 Research and development expenses

Research and development costs are recognized as expenses when incurred. Costs incurred on development projects are recognized as intangible assets when the following criteria are fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

In the opinion of management, due to uncertainties inherent in the development of the Company's drug candidates, the criteria for research and development costs to be recognized as an intangible asset, as prescribed by IAS 38 *Intangible Assets*, have not been met and all research and development costs historically have been expensed.

2.6.2 Patents and software

Patents and software license acquisition costs are recorded as assets based on the costs incurred to acquire the related patents and licenses.

2.6.3 Amortization duration and expense

When intangible assets have a finite useful life, amortization is calculated using the straight-line method over this period, specifically:

Items	Amortization period
Development costs	Estimated useful life of the project
Acquired patents	Estimated useful life of the patents
Metabrain	*19 years*
Iris Pharma	*20 years*
Stanislas Veillet (BIO101)	*19 years*
Software	3 to 5 years

The value of intangible assets is tested when there is any indication that it may be impaired. The quantitative and qualitative factors are reviewed at each reporting date, in particular factors linked to research and development portfolio, pharmacovigilance, patents litigation and new competitors. When a factor indicates that an asset may have lost value, Biophytis estimates its recoverable value. The test consists of comparing the net book value of these assets with their recoverable amount. When the net book value exceeds the recoverable amount, an impairment loss is recognized for the difference.

2.7 Property, plant and equipment

Property, plant and equipment are valued at their cost of acquisition (purchase price and incidental expenses to ready the assets for their intended use) or their cost of production by the Company.

Assets are depreciated on a straight-line basis over their useful life. They are depreciated using the straight-line method over the following periods:

Items	Depreciation periods
General facilities, fixtures and fittings	3 to 15 years
Technical installations, equipment and tooling	5 to 7 years
Office and IT equipment	3 to 5 years
Furniture	3 to 5 years
Transport equipment	3 to 5 years

The depreciation expenses for property, plant and equipment are recognized in the statement of consolidated operations under:

- ”General and administrative expenses” for depreciation of facilities, fixtures and fittings, office and IT equipment, and furniture; and
- ”Research and development expenses” for depreciation of laboratory equipment.

2.8 Lease agreements

Items held under lease agreements as defined by IFRS 16, *Leases,* and that do not meet the criteria for accounting exemptions for tenants (low-value asset leases and short-term agreements of less than 12 months) are shown as right of use assets in the statements of consolidated financial position. The corresponding liability is reported under “Financial liabilities” as a lease liability. Lease payments that meet the exemptions criteria are recognized under expenses in the statements of consolidated operations on a straight-line basis over the term of the contract.

2.9 Recoverable value of non-current assets

Assets with an indefinite useful life are not depreciated and are subjected to an annual impairment test. Definite-lived assets are subject to an impairment test whenever there is any internal or external indicator that their value may be impaired.

2.10 Financial assets

As of December 31, 2019 and 2020, the financial assets of the Company are classified into two categories depending on their nature and objectives for keeping such assets in accordance with IFRS 9:

- financial assets at fair value through profit or loss; and
- financial assets at amortized costs.

All financial assets are initially recognized at their fair value plus acquisition costs. All purchases and sales of financial assets are recognized on the settlement date. Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all 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 as of December 31, 2020 and 2019 and short-term deposits presented in current financial assets as of December 31, 2020.

Gains or losses arising from changes in the fair value of the "financial assets at fair value through profit or loss" category as determined at each reporting date are presented in the statements of consolidated operations within "Financial income (loss)" in the period in which they arise. Other financial assets may also voluntarily be classified in this category.

Financial assets at amortized cost

Financial assets at amortized cost are mainly non-current financial assets, other current financial assets, loans and other receivables, and trade receivables measured at amortized cost using the effective interest rate method, adjusted for expected credit losses.

Impairment of financial assets measured at amortized cost

The Company considers that a financial asset is impaired according to the expected loss method in order to take into account any defaults during the asset holding period. The amount of the expected loss is recognized in the statements of financial position. Impairment losses are recognized in the statements of consolidated operations.

2.11 Cash, cash equivalents and financial instruments

Cash and cash equivalents recognized in the statements of consolidated financial position include bank deposits, cash at hand and short-term deposits with an initial maturity of less than three months.

Cash equivalents are easily convertible into a known amount of cash and are subject to an insignificant risk of changes in value. They are assessed at fair value and changes in value are recognized under "Financial income (loss)".

2.12 Fair value of financial instruments

Borrowings and financial debts (excluding derivative financial instruments) are initially recognized at fair value and subsequently measured at amortized cost, measured using the effective interest rate (EIR) method.

The fair value of trade receivables and trade payables is considered as their book value, given their very short payment maturities. The same principle applies to other receivables, other current financial assets and other current liabilities.

The Company has distinguished three categories of financial instruments depending on their valuation methods and uses this classification to disclose some of the information required by IFRS 7 *Financial Instruments: Disclosures*:

- Level 1: financial instruments listed on an active market;
- Level 2: financial instruments whose valuation methods rely on observable inputs; and
- Level 3: financial instruments whose valuation methods rely entirely or partly on unobservable inputs, an unobservable input being defined as one whose measurement relies on assumptions or correlations that are not based on the prices of observable market transactions for a given instrument or on observable market data on the valuation date.

The Company's financial instruments that are recognized at fair value through profit or loss are:

- short term deposits which are classified as Level 1; and
- derivative instruments in connection with convertible notes (see Note 12.2), which are classified as Level 3.

2.13 Liquidity agreement

Following its listing on the stock market "Alternext Paris" (now called Euronext Growth Paris), the Company signed a liquidity agreement with a specialized institution in order to limit the "intra-day" volatility of Biophytis' shares.

For this purpose, the Company made an initial advance payment of €300 thousand to this institution in order that the latter can take long or short positions in the Company's shares. Shares acquired under this arrangement are recorded as treasury shares of the Company at cost.

Gain and losses from the disposal of these treasury shares is recognized under shareholders' equity.

The cash reserve related to the liquidity agreement is presented under "Non-current financial assets."

2.14 Public subsidies

Conditional advances

The Company benefits from conditional advances. The detail of these public grants is provided in Note 12.1.

They are recognized in accordance with IAS 20 *Accounting for government's grants and disclosures of governments assistance*. These are financial advances granted at interest rates lower than those of the market and are valued at amortized cost in accordance with IFRS 9, as follows:

- The rate advantage is determined by using a discount rate corresponding to a market rate at the grant date. The amount resulting from the rate advantage obtained at the grant date of the conditional advance is considered as a subsidy recognized in the statements of consolidated operations; and
- The financial cost of the conditional advances calculated at market rates is subsequently recognized in financial expenses.

The subsidies related to the rate advantage are presented as a reduction under the "Research and Development" line item.

These advances are recognized in "Non-current financial liabilities" or "Current financial liabilities" depending on their maturities. In the event of failure of the project, the debt is written off and recognized as a subsidy.

Subsidies

Subsidies received by the Company are recognized as soon as the corresponding receivable becomes certain, taking into account conditions imposed for the grant of the subsidy.

Operating subsidies are deducted from research and development expenses.

Research tax credit

The Company benefits from certain provisions of the French General Tax Code relating to research tax credits.

The Company receives certain specific project-related research tax credits ("Crédit d'Impôt Recherche", or "CIR"), which are granted to companies incorporated in France as an incentive for technical and scientific research. Companies with expenses that meet the eligibility criteria receive a tax credit that (i) can be used to offset against corporate income tax due in the year, as well as in the following three financial years, in which it is granted, or, (ii) under certain circumstances, can be paid directly to the Company for its surplus.

If a company meets certain criteria in terms of sales, headcount or assets to be considered as a small / medium size company as defined by the European Union, it may request an immediate payment of the research tax credit. Biophytis meets such criteria.

The Company considers the research tax credit received from French Tax Authorities as government grants based on the fact that the tax credits are received independently from tax payments. The Company recognizes these credits as other current receivables given the expected time of collection. These credits are presented in the statements of consolidated operations as credits to research and development expense.

Research tax credits are subject to audit by the French Tax Authorities.

Employment and Competitiveness Tax Credit

The Employment and Competitiveness Tax Credit ("CICE") is a French tax scheme. The income received by the Company from CICE is recognized as a reduction of payroll expenses. The Company used this tax credit through its research and development efforts.

This tax scheme has been replaced by a social charge reduction since January 1, 2019.

2.15 Receivables

Receivables are valued at their nominal value.

Impairment allowances include expected losses as required by IFRS 9, rather than incurred losses. No impairment allowances were determined to be necessary as of December 31, 2020 or 2019.

Other receivables include the nominal value of the CIR research tax credit which is recognized when expenses eligible to the research tax credit are incurred.

2.16 Capital

Classification as equity depends on the specific analysis of the characteristics of each instrument issued. The Company's ordinary shares are classified as equity instruments.

Costs directly attributable to the issuance of shares are recognized, net of tax, as a reduction from shareholders' equity.

2.17 Share-based payments

Since its incorporation, the Company has implemented several compensation plans settled in equity instruments in the form of warrants ("BSA"), founders' warrants ("BSPCE") and free shares attributed to employees and board members.

In accordance with IFRS 2 *Share-based Payment*, the cost of transactions settled in equity instruments is recognized under expenses in the period in which the rights to benefit from the equity instruments are acquired by the holder.

The fair value of the warrants granted to employees is measured using the Black-Scholes option valuation model. The same is true for warrants granted to other individuals supplying similar services, the market value of the latter not being determinable.

The assumptions used in measuring the fair value of such compensation plan equity issuances are described in Note 11.

2.18 Employment benefit obligations

The French employees of the Company are entitled to retirement benefits provided for under French law, and include:

- a retirement benefit, paid by the Company at the time of their retirement (defined benefit plan); and
- payment of retirement pensions by the Social Security bodies, which are financed by contributions from companies and employees (defined contribution plan).

Retirement plans, related payments and other company benefits which are classified as defined benefit plans (plans in which the Company undertakes to guarantee a defined amount or level of benefit) are recognized in the statements of consolidated financial position on the basis of an actuarial valuation of the commitments at the end of the period, after deduction of the fair value of the related plan assets dedicated to them.

This valuation is based on the projected unit credit method, taking into account staff turnover and mortality rates. Any actuarial variances are recognized in consolidated shareholders' equity under "Other comprehensive income (loss)."

The payments made by the Company for defined contribution plans are recognized as expense in the statements of consolidated operations for the period to which they relate.

2.19 Provisions

A provision is recognized if, as a result of a past event, a company has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation.

The amount recognized as a provision is the best estimate of the expenditure required to settle the present obligation at the reporting date.

2.20 Financial liabilities

Financial liabilities are classified into two categories and include:

- financial liabilities recognized at amortized cost; and
- financial liabilities recognized at fair value through profit or loss.

Financial liabilities recognized at amortized cost

Borrowings and other financial liabilities, such as conditional advances, are recognized at amortized cost calculated using the effective interest rate. The portion of financial liabilities due in less than one year is presented under “current financial liabilities.”

During the year ended December 31, 2018, the Company issued three tranches of non-convertible bonds with warrants attached to the first tranche. This financial instrument includes: a debt component related to the non-convertible bonds (measured at amortized cost) and an equity instrument related to the warrants (measured at fair value at the issue date in equity instruments in accordance with IAS 32 / IFRS 9). The fourth tranche of non-convertible bonds was issued during the year ended December 31, 2019. Transaction costs are allocated to the debt component and the equity instrument in proportion to their respective estimated values.

The accounting treatment of this compound financial instrument is detailed in Note 12.2.2.

Financial liabilities recognized at fair value through profit or loss

During the year ended December 31, 2020, the Company issued notes convertible into ordinary shares and/or redeemable in cash, with attached warrants. This financial instrument includes: a debt component related to the convertible notes (measured at amortized cost), a derivative instrument related to the conversion option of the convertible notes (measured at fair value through profit or loss in accordance with IFRS 9) and an equity instrument related to the warrants (measured at fair value at the issuance date in equity instruments in accordance with IAS 32). Transactions costs are allocated to the debt component, the derivative instrument and the equity instrument in proportion to their respective estimated values.

The accounting treatment of this hybrid financial instrument is detailed in Note 12.2.1.

2.21 Income tax

The tax assets and liabilities payable for the fiscal year and the previous fiscal year are valued at the amount that the Company expects to recover from or pay to the tax authorities.

The tax rates and the tax regulations used to determine these amounts are those which have been enacted at the balance sheet date.

Deferred taxes are recognized using the liability method on temporary differences at the balance sheet date between the tax bases of assets and liabilities and their book values in the Financial Statements as well as on tax losses carried forward. The main temporary differences relate to tax losses carried forward.

Deferred tax assets are recognized in respect of tax losses that may be carried forward when it is probable that the Company will have future taxable profits to which these unused tax losses can be allocated. The determination of the amount of deferred tax assets that can be recognized requires management to make estimates both concerning the period during which the tax losses will be used and the level of future taxable profits taking into account tax strategies developed by management as well as any deferred tax liabilities that exist.

2.22 Segment information

The Company operates in only one segment: the development of drug candidates that slow the degenerative processes associated with aging and improve functional outcomes for patients suffering from age-related diseases.

The assets, liabilities and the operating loss presented in the Financial Statements are based on the parent company's operations located in France and the expansion of the Company into the United States which began in 2018. A majority of the research and development expenses and general and administrative expenses have been incurred in France and since 2018, such expenses have also been incurred in the United States.

2.23 Earnings per share

Basic earnings (loss) per share is calculated by dividing the net income (loss) attributable to shareholders of Biophytis by the weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per share is calculated by adjusting the net income (loss) attributable to shareholders of Biophytis and the weighted average number of ordinary shares in circulation by the effects of all potentially dilutive ordinary shares.

If the inclusion of instruments giving deferred access to capital (warrants, founders' warrants, free shares or convertible notes) creates an anti-dilutive effect, those instruments are not taken into account.

Note 3: Patents and software

(amounts in thousands of euros)	Patents	Software	Total
GROSS AMOUNT			
As of January 1, 2019	**2,300**	**29**	**2,329**
Addition	630	3	633
Disposal	-	-	-
As of December 31, 2019	**2,930**	**32**	**2,962**
Addition	450	-	450
Disposal	-	-	-
As of December 31, 2020	**3,380**	**32**	**3,412**
AMORTIZATION			
As of January 1, 2019	**413**	**6**	**419**
Increase	134	9	143
Decrease	-	-	-
As of December 31, 2019	**547**	**15**	**562**
Increase	168	9	177
Decrease	-	-	-
As of December 31, 2020	**715**	**24**	**739**
NET BOOK VALUE			
As of January 1, 2019	**1,887**	**23**	**1,910**
As of December 31, 2019	**2,383**	**17**	**2,400**
As of December 31, 2020	**2,665**	**8**	**2,673**

No impairment was recognized on intangible assets of the Company in the years ended December 31, 2019, and 2020, respectively. The Company determined there was limited impact of the COVID-19 pandemic on the Company's assets.

The Company co-owns certain patents with state-owned partners.

As part of the Intellectual Property agreement signed with the Company's CEO (see Note 20.2) and its amendment, the total patents rights acquired from the Company's CEO as of December 31, 2020 amounted to €1,080 thousand and are amortized over a 19-year period.

Of this amount, €270 thousand was paid to the Company's CEO in 2019 and €180 thousand in 2020. The remaining amount was applied to the CEO's subscription and the exercise of Founders warrants (see Note 10).

Note 4: Property, plant and equipment

(Amounts in thousands of euros)	Equipment and tooling	Equipment and tooling (finance lease)	Fixture and fittings	Office, IT equipment, furniture	Total
GROSS AMOUNT					
As of January 1, 2019	**279**	**181**	**90**	**90**	**640**
Addition	7	-	1	1	9
Exchange effect	(1)	-	(1)	1	(1)
As of December 31, 2019	**285**	**181**	**90**	**92**	**648**
Addition	30	-	-	5	35
Exchange effect	(18)	-	(5)	(3)	(26)
As of December 31, 2020	**297**	**181**	**85**	**94**	**657**
DEPRECIATION					
As of January 1, 2019	**153**	**107**	**38**	**47**	**345**
Increase	38	36	35	9	118
Exchange effect	(1)	-	(2)	3	-
As of December 31, 2019	**190**	**143**	**71**	**59**	**463**
Increase	40	37	18	9	104
Exchange effect	(18)	-	(4)	(1)	(23)
As of December 31, 2020	**212**	**180**	**85**	**67**	**544**
NET BOOK VALUE					
As of January 1, 2019	**126**	**74**	**52**	**43**	**295**
As of December 31, 2019	**95**	**38**	**19**	**33**	**185**
As of December 31, 2020	**85**	**1**	**-**	**26**	**114**

No impairment was recognized on tangible assets of the Company in the years ended December 31, 2019, and 2020, respectively.

Note 5 : Non-current financial assets

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Cash reserve related to the liquidity agreement	45	80
Guarantee deposit related to the non-convertible bonds	320	320
Miscellaneous	17	13
Total non-current financial assets	**382**	**413**

Note 6: Other current financial assets

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Guarantee deposit as part of the research tax credit prefinancing from NEFTYS (see note 12)	475	424
Short term deposits	-	12,500
Total other current financial assets	**475**	**12,924**

As of December 31, 2020, the Company owned three short-term deposits for a total amount of €12,500 thousand with an initial maturity of 6 months:

- A short-term deposit of €1,000 thousand with a maturity in March 2021 and an interest rate of 0.05%;
- A short-term deposit of €3,000 thousand with a maturity in March 2021 and an interest rate of 0.05%; and
- A short-term deposit of €8,500 thousand with a maturity in April 7, 2021 and an interest rate of 0.02%.

In accordance with IAS 7, these short-term deposits have been recorded under current financial assets.

Note 7: Other receivables

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Research tax credit (1)	5,940	3,199
Value added tax	1,786	1,562
Prepaid expenses	46	29
Suppliers – advances payment and debit balance	74	127
Receivable from CACEIS in relation with the exercises of BSA/BSPCE (3)	-	266
Miscellaneous	48	57
Total other receivables	**7,893**	**5,239**

(1) **Research tax credit (CIR)**

CIR is payable by the government in the year following its recognition when there is no taxable net income to be offset.

CIR recorded for the years ended December 31, 2019 and December 31, 2020 are:

- CIR 2019: €2,807 thousand; and
- CIR 2020: €3,328 thousand.

In December 2019, a portion of the CIR receivables for 2018 and 2019 were prefinanced with NEFTYS, a specialized funding agency (see note 12).

CIR receivables for 2018 and 2019 were reimbursed by the French Tax Authorities in January 2020 and June 2020, respectively. The prefinanced receivables were then reimbursed directly to NEFTYS.

In December 2020, a portion of the CIR receivables for 2020 was prefinanced with NEFTYS (see note 12).

(2) Prepaid expenses mainly relate to research services provided by an external provider.

(3) On December 31, 2020 a receivable from CACEIS, a company providing financial services to institutional investors, was recognized for €266 thousand following the exercise of warrants and founders' warrants on December 16, 2020.

Note 8: Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Bank accounts	6,337	3,347
Short term deposits	-	2,500
Total cash and cash equivalents	**6,337**	**5,847**

As of December 31, 2020, the Company owned one short-term deposits with a maturity on January 18, 2021 and an interest rate of 0.03%. Its nominal value is €2,500 thousand.

In accordance with IAS 7, this short-term deposit was recorded under cash and cash equivalents.

Note 9: Financial assets and liabilities and impacts on statements of consolidated operations

The Company's financial assets and liabilities are measured as follows as of December 31, 2019 and 2020, respectively:

	AS OF DECEMBER 31, 2019			
			Value – Statement of financial position (IFRS 9)	
(amounts in thousands of euros)	**Value – Statement of financial position**	**Fair value**	**Fair value through profit or loss**	**Amortized cost**
Non-current financial assets	382	382	-	382
Other receivables	7,893	7,893	-	7,893
Other current financial assets	475	475	-	475
Cash and cash equivalents	6,337	6,337	6,337	-
Total assets	**15,087**	**15,087**	**6,337**	**8,750**
Non-current financial liabilities	5,398	5,398	-	5,398
Current financial liabilities	9,846	9,846	-	9,846
Derivative financial instruments	451	451	451	-
Trade payables	7,866	7,866	-	7,866
Total liabilities	**23,561**	**23,561**	**451**	**23,110**

	AS OF DECEMBER 31, 2020			
			Value – Statement of financial position (IFRS 9)	
(amounts in thousands of euros)	**Value – Statement of financial position**	**Fair value**	**Fair value through profit or loss**	**Amortized cost**
Non-current financial assets	413	413	-	413
Other receivables	7,127	7,127	-	7,127
Other current financial assets	12,924	12,924	-	12,924
Cash and cash equivalents	5,847	5,847	5,847	-
Total assets	**26,311**	**26,311**	**5,847**	**20,464**
Non-current financial liabilities	1,833	1,833	-	1,833
Current financial liabilities	7,262	7,262	-	7,262
Trade payables	7,985	7,985	-	7,985
Total liabilities	**17,080**	**17,080**	**-**	**17,080**

The impact of the Company's financial assets and liabilities on the statements of consolidated operations are as follows for the years ended December 31, 2019 and 2020:

	FOR THE YEARS ENDED DECEMBER 31,					
	2018		2019		2020	
(amounts in thousands of euros)	Interest	Change in fair value	Interest	Change in fair value	Interest	Change in fair value
Profit or loss impact of liabilities						
Derivative liabilities	-	-	-	726	-	2,831
Liabilities at amortized cost: convertible notes and non-convertible bonds	(189)	-	(2,526)	-	(4,374)	-
Liabilities at amortized cost: advances	(33)	-	(33)	-	(24)	-

Note 10: Share capital

	AS OF DECEMBER 31,		
	2018	2019	2020
Share capital (in thousands of euros)	2,693	4,793	20,151
Number of outstanding shares	13,463,413	23,963,254	100,757,097
Nominal value per share (in euros)	0.20€	0.20€	0.20€

Share capital and issue premium

As of December 31, 2020, the share capital of the Company was €20,151,419.40 divided into 100,757,097 fully subscribed ordinary shares with a nominal value of €0.20 per share.

Outstanding shares exclude warrants ("BSA") granted to certain investors, free shares and founders' warrants ("BSPCE") granted to certain employees and members of the Board of Directors that have not yet been exercised.

As of December 31, 2020, the premiums of the Company were €17,821 thousand. It included the recognition of costs relating to capital increases for amount of €2,709 thousand and costs incurred as part of the IPO project for amount of €787 thousands.

The general meeting held on May 28, 2020 decided the allocation of premiums to accumulated deficit for amount of €44,047 thousand.

Changes in share capital

For the year ended December 31, 2018:

There were no changes in share capital during the year ended December 31, 2018.

Certain costs incurred in connection with a potential equity transaction that would result in the issuance of shares were recognized as a reduction from shareholders' equity.

For the year ended December 31, 2019:

242 bonds held by NEGMA Group Limited (see Note 12.2.1) were converted to the Company's new shares through the issuance of 10,499,841 shares with a nominal value of €0.20 per share, representing a share capital increase of €2,100 thousand and a premium of €320 thousand.

Following the Company's decision to postpone the issuance of its shares in connection with a listing of the Company's equity securities on the Nasdaq, related costs initially recognized as a reduction from shareholders' equity in 2018 were recognized in the 2019 statement of consolidated operations.

For the year ended December 31, 2020:

The Company completed several private placements during the period totaling €23,486 thousand (share capital increase of €9,859 thousand and an issue premium of €13,627 thousand), which can be detailed as follows:

- In February 2020: a private placement amounting to €3.3 million through the issuance of 12,394,071 new shares at a share price of €0.27. This transaction generated a share capital increase of €2,479 thousand and an issue premium of €868 thousand.
- June 2020:
  - issuance of 2,050,000 new shares at a share price of €0.68, reserved for Negma, pursuant to summary judgement dated May 7, 2020 (see Note 12.2). This transaction generated a capital increase of €410 thousand and an issue premium of €984 thousand.
  - a private placement of €4.0 million by issuing 6,060,606 new shares at a share price of €0.66. This transaction generated a capital increase of €1,212 thousand and an issue premium of €2,788 thousand.
- In July 2020: a private placement amounting to €6.1 million by issuing 9,563,732 new shares at a share price of €0.642. This transaction generated a capital increase of €1,913 thousand and an issue premium of €4,227 thousand.
- In October 2020: a private placement amounting to €10 million through the issuance of 21,276,596 new shares at a share price of €0.47. This transaction generated a share capital increase of €4,255 thousand and an issue premium of €5,745 thousand.

The Company converted certain bonds into new shares in the year ended December 31, 2020 which can be detailed as follows:

- 68 bonds held by Negma were converted into new shares generating the issuance of 3,400,000 shares with a share price of €0.20, or a capital increase of €680 thousand, with no issue premium.
- 330 bonds held by Atlas were converted into new shares generating the issuance of 17,178,683 shares with a share price of €0.20, representing a capital increase of €3,436 thousand and an issue premium of €4,725 thousand.

The costs incurred by the Company in connection with the 2020 share capital increases and the Initial Public Offering on Nasdaq Capital Market in February 2021 (see note 23) were recognized as a reduction from shareholders' equity for respectively €2,709 thousand and €787 thousand.

Following the exercise of warrants during the period, the share capital was increased by €1,315 thousand through the issuance of 4,870,155 new shares, with a nominal value of €0.20, or €974 thousand, and an issue premium of €341 thousand.

Distribution of dividends

The Company did not distribute any dividends during the years ended December 31, 2019 and 2020, respectively.

Capital management

The Company's policy is to maintain a solid capital base in order to preserve the confidence of investors and creditors and to support future growth.

In this respect, the Company entered into a liquidity agreement with Banque Parel. In connection with this liquidity agreement:

- 48,228 treasury shares were recognized at cost (€43 thousand) as a reduction from shareholders' equity as of December 31, 2020, and 83,479 treasury shares were recognized at cost (€17 thousand) as a reduction from shareholders' equity as of December 31, 2019; and
- €80 thousand of cash was included in non-current financial assets as of December 31, 2020, and €45 thousand of cash was included in non-current financial assets as of December 31, 2019.

Note 11: Warrants and founders' warrants

BSA warrants issued to investors

On July 10, 2015, as part of a bond agreement the Company issued investors warrants to subscribe for 270,414 shares at an exercise price of €6.00 per share for a non-refundable issue price of €162 thousand. These warrants have a term of 4 years. These BSA warrants are considered equity instruments and are recorded in shareholders' equity at their subscription price in accordance with IAS 32.

On April 3, 2020, the Company decided to launch a public offering of share subscription warrants. The main objective of the transaction is to allow existing shareholders to participate in the new COVA program and the future development of the Company, and eventually to consolidate its equity.

Upon completion of its public offering, the Company issued 7,475,708 share subscription warrants, after full exercise of the extension clause.

The subscription price was €0.06 per warrant. The warrants can be exercised for a period of 5 years from April 30, 2020, at an exercise price of €0.27 per new share.

Each warrant gives its holder the right to subscribe to one new Biophytis share. Total subscriptions amounted to €449 thousand. During the period ended December 31, 2020, warrants were exercised for €1,042 thousand.

The Company's CEO participated in the subscription and the exercise of the investors warrants which was settled by the amount of €630 thousand due to the Company's CEO as part of the Intellectual Property agreement (see Notes 3 and 20.2) (€177 thousand for the subscription of warrants and €453 thousand for the exercise of warrants).

These BSA warrants are considered equity instruments and are recorded in shareholders' equity at their subscription price in accordance with IAS 32.

Activity for BSA warrants issued to investors that were outstanding during the year ended December 31, 2019 are summarized in the table below:

		Number of outstanding warrants					Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2019**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2019**	
Warrants 2015D	07/10/2015	189,748	-	-	(189,748)	-	-
Total		**189,748**	-	**-**	**(189,748)**	**-**	**-**

Activity for BSA warrants issued to investors that were outstanding during the year ended December 31, 2020 are summarized in the table below:

			Number of outstanding warrants				Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2020**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2020**	
Warrants 2015-D	07/10/2015	-	-	-	-	-	-
Warrants 2020	04/07/2020	-	7,475,708	3,860,142	-	3,615,566	3,615,566
Total		-	**7,475,708**	**3,860,142**	**-**	**3,615,566**	**3,615,566**

BSA warrants issued to Bracknor

In 2017, the Company issued warrants for the benefit of Bracknor Fund Ltd with an average exercise price of €3.48 per ordinary share for the purpose of a funding line that was fully repaid and is now terminated. The number of shares that can be issued if the warrants are exercised is 431,184 ordinary shares as of December 31, 2020.

BSA warrants issued pursuant to equity-compensation plan

The following table summarizes the data related to the warrants issued pursuant to equity-compensation plans as well as the assumptions adopted for valuation in accordance with IFRS 2:

		Characteristics			Assumptions		IFRS2 Initial valuation (Black-Scholes) in thousands of euros
Type	**Grant date**	**Number of warrants granted**	**Maturity date**	**Exercise price**	**Volatility**	**Risk-free rate**	
Warrants 2015	08/04/2015	**54,000**	08/04/2019	€ 8.40	49.77%	-0.18%	**481**
Warrants 2017	07/21/2017	**72,000**	07/21/2021	€ 3.30	59.95%	-0.62%	**153**

All BSA warrants issued pursuant to equity-compensation plans were fully vested on the grant date.

Activity for BSA warrants issued pursuant to equity-compensation plans that were outstanding during the year ended December 31, 2019 are summarized in the table below:

		Number of outstanding warrants					Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2019**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2019**	
Warrants 2015	08/04/2015	48,000	-	-	(48,000)	-	-
Warrants 2017	07/21/2017	72,000	-	-	-	72,000	72,000
Total		**120,000**	**-**	**-**	**(48,000)**	**72,000**	**72,000**

Activity for BSA warrants issued pursuant to equity-compensation plans that were outstanding during the year ended December 31, 2020 are summarized in the table below:

		Number of outstanding warrants					Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2020**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2020**	
Warrants 2017	07/21/2017	72,000	-	-	-	72,000	72,000
Total		**72,000**	**-**	**-**	**-**	**72,000**	**72,000**

Founders' warrants ("BSPCE")

The following table summarizes the data related to BSPCE founder's warrants issued as well as the assumptions adopted for valuation in accordance with IFRS 2:

		Characteristics			Assumptions		IFRS 2 Initial valuation (Black-Scholes) in thousands of euros
Type	**Grant date**	**Number of warrants granted**	**Maturity date**	**Exercise price**	**Volatility**	**Risk-free rate**	
Founders' warrants 2015-1	05/22/2015	**195,000**	05/22/2019	€ 2.06	49.09%	-0.13%	**794**
Founders' warrants 2015-2	09/23/2015	**424,200**	09/23/2019	€ 10.70	53.16%	-0.19%	**2,591**
Founders' warrants 2015-3	12/04/2015	**20,000**	12/04/2019	€ 10.70	53.79%	-0.22%	**78**
Founders' warrants 2015-4	03/15/2016	**39,700**	03/15/2020	€ 6.09	56.74%	-0.41%	**83**
Founders' warrants 2017-1	07/21/2017	**227,000**	07/21/2021	€ 3.30	54.07%	-0.53%	**347**
Founders' warrants 2017-2	07/21/2017	**127,000**	07/21/2021	€ 3.30	57.25%	-0.65%	**421**
Founders' warrants 2019-1	04/03/2020	**1,333,333**	04/03/2026	€ 0.27	48.36%	-0.62%	**674**
Founders' warrants 2019-2	04/03/2020	**666,667**	04/03/2026	€ 0.27	53.32%	-0.56%	**356**
Founders' warrants 2020-1	12/22/2020	**999,393**	12/22/2020	€ 0.47	57.80%	-0.77%	**508**
Founders' warrants 2020-2	12/22/2020	**499,696**	12/22/2020	€ 0.47	57.91%	-0.77%	**284**

Activity for BSPCE founder's warrants that were outstanding during the year ended December 31, 2019 are summarized in the table below:

		Number of outstanding warrants					Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2019**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2019**	
Founders' warrants 2015-1	05/22/2015	152,000	-	-	(152,000)	-	-
Founders' warrants 2015-2	09/23/2015	384,500	-	-	(384,500)	-	-
Founders' warrants 2015-3	12/04/2015	20,000	-	-	(20,000)	-	-
Founders' warrants 2015-4	03/15/2016	39,700	-	-	(39,700)	-	-
Founders' warrants 2017-1	07/21/2017	227,000	-	-	(79,000)	148,000	148,000
Founders' warrants 2017-2	07/21/2017	116,334	-	-	(42,334)	74,000	74,000
Total		**939,534**	**-**	**-**	**(717,534)**	**222,000**	**222,000**

Activity for BSPCE founder's warrants that were outstanding during the year ended December 31, 2020 are summarized in the table below:

		Number of outstanding warrants					Number of shares which can be subscribed
Type	**Grant date**	**At 1/1/2020**	**Granted**	**Exercised**	**Lapsed**	**At 31/12/2020**	
Founders' warrants 2017-1	07/21/2017	148,000	-	-	-	148,000	148,000
Founders' warrants 2017-2	07/21/2017	74,000	-	(2,152)	(9,000)	62,848	62,848
Founders' warrants 2019-1	04/03/2020	-	1,333,333	(313,417)	(8,607)	1,011,309	1,011,309
Founders' warrants 2019-2	04/03/2020	-	666,667	-	(4,304)	662,363	662,363
Founders' warrants 2020-1	12/22/2020	-	999,393	-	-	999,393	999,393
Founders' warrants 2020-2	12/22/2020	-	499,696	-	-	499,696	499,696
Total		**222,000**	**3,499,089**	**(315,569)**	**(21,911)**	**3,383,609**	**3,383,609**

The vesting period of these BSPCE founder's warrants are summarized in the table below:

Type	Vesting period		
Founders' warrants 2017-1	1/3 as of 07/21/2017	1/3 as of 07/21/2018	1/3 as of 07/21/2019
Founders' warrants 2017-2	1/3 as of 07/21/2017	1/3 as of 07/21/2018	1/3 as of 07/21/2019
Founders' warrants 2019-1	1/3 as of 04/10/2020	1/3 as of 04/10/2022	1/3 as of 04/10/2024
Founders' warrants 2019-2	1/3 as of 04/10/2020	1/3 as of 04/10/2022	1/3 as of 04/10/2024
Founders' warrants 2020-1	1/3 as of 12/22/2020	1/3 as of 12/22/2022	1/3 as of 12/22/2024
Founders' warrants 2020-2	1/3 as of 12/22/2020	1/3 as of 12/22/2022	1/3 as of 12/22/2024

Free shares

		Characteristics			Assumptions		
Type	**Grant date**	**Number of warrants granted**	**Maturity date**	**Exercise price**	**Volatility**	**Risk-free rate**	**IFRS 2 Initial valuation (Black-Scholes) in thousands of euros**
Free shares 2020	12/22/2020	**2,500,911**	N/A	N/A	N/A	N/A	**2,311**

Activity for the free shares that were outstanding during the year ended December 31, 2020 are summarized in the table below:

		Number of outstanding free shares					Number of shares which can be subscribed
Type	**Grant date**	**As of 1/1/2020**	**Granted**	**Exercised**	**Lapsed**	**As of 12/31/2020**	
Free shares 2020	12/22/2020	-	2,500,911	-	-	2,500,911	2,500,911
Total		-	2,500,911	-	-	**2,500,911**	**2,500,911**

The vesting period of these free shares are summarized in the table below:

Type	Vesting period
Free shares 2020	Vesting period of 2 years followed by a holding period of 2 years

Stock based compensation expense recognized for the years ended December 31, 2019 and 2020.
(amounts in thousands of euros)

	DECEMBER 31, 2019				DECEMBER 31, 2020			
Type	**Probable cost of the plan**	**Cumulative expenses - beginning of period**	**Expense for the period**	**Cumulative expense to date**	**Probable cost of the plan**	**Cumulative expenses - beginning of period**	**Expense for the period**	**Cumulative expense to date**
Warrants 2017	153	153	-	153	153	153	-	153
Founders' warrants 2017-1	347	307	41	347	347	347	-	347
Founders' warrants 2017-2	369	347	22	369	389	389	-	369
Founders' warrants 2019-1	-	-	-	-	674	-	447	447
Founders' warrants 2019-2	-	-	-	-	356	-	52	52
Founders' warrants 2020-1	-	-	-	-	508	-	257	257
Founders' warrants 2020-2	-	-	-	-	284	-	1	1
Free shares 2020	-	-	-	-	2,311	-	28	28
Total			**63**				**785**	

Note 12: Borrowings and financial liabilities

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Conditional advances	1,006	893
Non-convertible bonds	4,392	940
Non-current financial liabilities	**5,398**	**1,833**
Conditional advances	274	274
Non-convertible bonds	3,025	3,454
Convertible notes	1,699	1,400
Financial liabilities related to the prefinancing of a portion of the research tax credit receivables (1)	4,834	2,134
Bank overdrafts	15	-
Current financial liabilities	**9,846**	**7,262**
Total financial liabilities	**15,244**	**9,095**

(1) Financial liabilities related to the prefinancing of a portion of the research tax credit (CIR) receivables

In December 2019, a portion of the CIR receivables for 2018 and 2019 were prefinanced by FONDS COMMUN DE TITRISATION PREDIREC INNOVATION 2020 with NEFTYS CONSEIL SARL as arranger, or NEFTYS. Consequently, the Company recorded:

- a liability for the amount due to NEFTYS at the time of CIR collection;
- a financial asset for the amounts deducted by NEFTYS on the receivables sold (considered as a guarantee deposit, see Note 6), and
- a current asset for the CIR research tax credits payable by the French State.

In accordance with IFRS 9, the financial liability due to NEFTYS was determined using the amortized cost method for each year:

- CIR 2018: €2,904 thousand; and
- CIR 2019: €1,930 thousand.

CIR receivables for 2018 and 2019 were reimbursed by the French Tax Authorities in 2020. The prefinanced receivables were then reimbursed directly to NEFTYS (see Note 6).

In December 2020, a portion of the CIR 2020 receivables was prefinanced by NEFTYS. This operation followed the same rules described above.

In accordance with IFRS 9, the financial liability due to NEFTYS in relation to the CIR 2020 was determined using the amortized cost method for €2,134 thousand.

Reconciliation of value on redemption to carrying amount

(amounts in thousands of euros)	Value on redemption as of DECEMBER 31, 2019	Value on redemption as of DECEMBER 31, 2020	Warrants discount	Derivative financial instruments	Issuance costs	Fair value of financial liabilities	Amortized cost	Carrying amount as of DECEMBER 31, 2020
Conditional advances	1,368	1,232	-	-	-	-	(65)	1,167
Non-convertible bonds	7,709	4,495	(319)	-	(355)	-	573	4,394
Convertible notes Negma	2,080	1,400	-	-	-	-	-	1,400
Bank overdrafts	15	-	-	-	-	-	-	-
Financial liabilities related to the prefinancing of a portion of the research tax credit receivables	5,029	2,252	-	-	(40)	-	(78)	2,134
Total financial liabilities	**16,201**	**9,379**	**(319)**	**-**	**(396)**	**-**	**431**	**9,095**

Breakdown of financial liabilities by maturity, at value on redemption

The maturity of financial liabilities is broken down as follows:

(amounts in thousands of euros)	AS OF DECEMBER 31, 2020	Current < 1 year	Non-current 1 to 5 years	Non-current > 5 years
Conditional advances	1,232	292	940	-
Non-convertible bonds	4,495	3,550	945	-
Convertible notes Negma	1,400	1,400	-	-
Convertible notes Atlas	-	-	-	-
Bank overdrafts	-	-	-	-
Financial liabilities related to the prefinancing of a portion of the research tax credit receivables	2,252	2,252	-	-
Total financial liabilities	**9,379**	**7,494**	**1,885**	**-**

12.1 Conditional advances

The table sets out the changes in conditional advances:

(amounts in thousands of euros)	BPI -Sarcob	BPI – BIO101	AFM – Téléthon	Total
As of January 1, 2019	**182**	**1,025**	**-**	**1,207**
(+) Proceeds from conditional advances	-	-	400	400
(-) Repayment	(52)	(275)	-	(327)
Subsidies	-	-	(34)	(34)
Financial expenses	6	24	4	33
As of December 31, 2019	**135**	**774**	**370**	**1,279**
(+) Proceeds from conditional advances	-	-	-	-
(-) Repayment	(26)	(110)	-	(136)
Subsidies	-	-	-	-
Financial expenses	3	13	8	24
As of December 31, 2020	**112**	**677**	**378**	**1,167**

Breakdown of conditional advances by maturity, at value on redemption

(amounts in thousands of euros)	BPI -Sarcob	BPI – BIO101	AFM – Téléthon	Total
As of December 31, 2020	**118**	**715**	**400**	**1,232**
Less than one year	72	220	-	292
One to five years	46	495	400	941
More than five years	-	-	-	-

12.1.1 BPI France conditional advance - "Sarcob" project

On February 4, 2015, Biophytis entered into an agreement with BPI France for an interest-free conditional advance of €260 thousand payable in milestone installments for the "in vitro, in vivo and pharmacokinetic characterization of a candidate drug."

The Company received €260 thousand in aggregate in connection with this agreement. The project has been successfully completed.

This initial repayment schedule pursuant to the successful completion of the project is:

- €6.5 thousand per quarter from June 30, 2017 to March 31, 2018 (4 payments);
- €13 thousand per quarter from June 30, 2018 to March 31, 2021 (12 payments); and
- €19.5 thousand per quarter from June 30, 2021 to March 31, 2022 (4 payments).

Following the COVID-19 health crisis, the Company managed to postpone the repayments of the first and second quarters of 2020 which extended the initial repayment schedule by two more quarters. The repayment schedule after considering these changes is as follows:

- €13 thousand per quarter from June 30, 2020 to March 31, 2021 (3 repayments);
- €19.5 thousand per quarter from June 30, 2021 to March 31, 2022 (4 repayments); and
- €32.5 thousand per quarter from June 30, 2022 to December 30, 2022 (2 repayments).

The commitments provided by the Company pursuant to this agreement can be found in Note 21.2.

Under IFRS, since the conditional advance does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates). The difference between the amount of the advance at historical cost and the advance discounted at market rates (3-month Euribor + 2.5 percentage points = 2.56%) is considered as a public grant.

12.1.2 BPI France conditional advance – "BIO101" project

On November 28, 2016, the Company entered into an agreement with BPI France for an interest-free conditional advance of €1,100 thousand payable in milestone installments for the "production of clinical batches, regulatory preclinical and clinical stages for Phase I of BIO101 for the sarcopenia obesity treatment."

The Company received €1,100 thousand in aggregate in connection with this agreement. The project has been successfully completed. The initial repayment schedule pursuant to the successful completion of the project is:

- €55 thousand per quarter from December 31, 2018 to September 30, 2023 (20 payments). The first quarterly repayment was made by the Company in January 2019.

Following the COVID-19 health crisis, the Company managed to postpone the repayments of the first and second quarters of 2020 which extended the initial repayment schedule by two more quarters. The repayment schedule after considering these changes is as follows:

- €55 thousand per quarter from June 30, 2020 to March 31, 2024 (11 repayments).

The commitments provided by the Company pursuant to this agreement can be found in Note 21.2.

Under IFRS, since the conditional advance does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates). The difference between the amount of the advance at historical cost and the advance discounted at market rates (3-month Euribor + 2.5 percentage points = 2.19%) is considered as a public grant.

12.1.3 Collaboration agreement with AFM-Telethon – « BIO 101 » project

Biophytis entered into a collaboration agreement effective as of June 3, 2019 with AFM-Telethon focusing on the development of its lead drug candidate, Sarconeos (BIO101) for the treatment of Duchenne Muscular Dystrophy (DMD) through its MYODA clinical program.

Under the terms of the collaboration, AFM-Telethon provided funding of €400,000 to Biophytis for certain additional preclinical studies and for the preparations for the MYODA clinical program, which may become repayable under certain circumstances. The repayment is scheduled over a two-year period (constant semi-annual reimbursement) pursuant to the approval to launch Phase 3 of the MYODA clinical program.

Under IFRS, since the conditional advance does not bear annual interest, it is treated as an interest-free loan for the Company (i.e. under conditions more favorable than market rates). The difference between the amount of the advance at historical cost and the advance discounted at market rates (3-month Euribor + 2.5 percentage points = 2.18%) is considered as a public grant.

12.2 Convertible notes and non-convertible bonds

12.2.1 Issuance of convertible notes to NEGMA

(amounts in thousands of euros)	NEGMA ORNANEBSA
As of January 1, 2019	**—**
(+) Proceeds received	4,500
(-) Warrants (“BSA”) discount	(75)
(-) Derivative instruments	(1,184)
(-) Transaction costs	(300)
(+) Fair value of financial liabilities	391
(+) Change in fair value of financial liabilities upon conversion	(210)
(+/-) Amortized cost	996
(-) Conversion	(2,420)
As of December 31, 2019	**1,699**
(+) Fair value of financial liabilities	(181)
(+/-) Amortized cost	562
(-) Conversion	(680)
As of December 31, 2020	**1,400**

On August 21, 2019, the Company signed an agreement with Negma Group Limited providing for up to €24 million in financing to the Company through the issuance of multiple tranches of convertible notes with attached warrants (ORNANEBSA), at the sole discretion of the Company.

Pursuant to this agreement, the Board of Directors decided the issuance of the following convertible notes and warrants during the year ended December 31, 2019:

- A first tranche on August 21, 2019 of 300 ORNANE plus a commitment fee of 30 ORNANE, with attached warrants to purchase 585,936 shares (BSA_{T1}), resulting in gross proceeds to the Company of €3 million; and
- A second tranche on December 27, 2019 of 300 ORNANE, out of which 50% were paid by Negma Group as of December 31, 2019, resulting in gross proceeds to the Company of €1.5 million and with attached warrants to purchase 694,444 shares (BSA_{T2}).

On April 6, 2020, as part of the implementation of the Atlas agreement described below, the Company terminated the contract with Negma.

Following this termination, Negma undertook legal action in order to claim damages of €910,900 from Biophytis as well as the delivery of 7,000,000 Biophytis shares, that Negma considers it was entitled to pursuant to the only Biophytis ORNANES still held by Negma, issued in consideration for a loan of €1,400,000 in principal.

The sum of €910,900 claimed by Negma corresponds to the contractual penalties alleged by Negma under the terms of the Negma Contract 2019, which provided for the payment of such penalties in the event of conversion of notes into shares when the stock price is below the par value of the shares. Biophytis vigorously disputed this legal action and these requests for payment and delivery of shares.

Pursuant to a summary judgment dated May 7, 2020, Negma obtained a decision partially responding to its claims ordering, under penalty (which amounted to €7 thousand), Biophytis to pay damages in an amount of €378 thousand and deliver 2,050,000 Biophytis shares.

This delivery of 2,050,000 shares valued at €1,394 thousand was considered as a financial indemnification recorded as a financial expense. The financial indemnification totaling €1,779 thousand was then recorded as a financial expense during the year ended December 31, 2020. The summary judgement did not extinguish the liability of €1,400,000 in principal due to Negma.

Biophytis and Negma appealed the decision of the Paris Commercial Court (see Note 14).

On November 18, 2020, Paris Court of Appeal ruled in Biophytis' favor and sentenced Negma to return to Biophytis the 2,050,000 shares previously delivered as well as the provision of €378 thousand. In addition, Negma was ordered to pay €41 thousand to Biophytis as additional compensation. The total income of €419 thousand was recorded in financial income during the year ended December 31, 2020.

As of December 31, 2020, the Company recognized the right to receive the 2,050,000 shares to be returned by Negma in equity for € 1,394 thousand against the reversal of the indemnification previously recorded as financial expense.

During the year 2020, 68 bonds held by Negma were converted into new shares generating the issuance of 3,400,000 shares under the formula mentioned above for tranche 1 and tranche 2.

Negma also exercised all BSA_{T2} during the year ended December 31, 2020 generating the issuance of 694,444 shares. All BSA_{T1} are still outstanding as of December 31, 2020.

Accounting treatment

In accordance with IFRS 9, the convertible notes were initially recognized at the fair value of their debt component and subsequently this debt component is accounted for under the amortized cost method.

The conversion option of the convertible notes was bifurcated and classified in derivative instruments due to the parity not fixed and measured at fair value on the date of issuance (based on the Black-Scholes valuation model) with recognition of the changes in fair value in the statement of consolidated operations in accordance with IFRS 9.

The table below summarizes the accounting treatment of the conversion option:

Conversion option	**Tranche 1**			**Tranche 2**		
Negma	**As of the issue date (08/21/2019)**	**As of December 31, 2019**	**As of December 31, 2020**	**As of the issue date (12/27/2019)**	**As of December 31, 2019**	**As of December 31, 2020**
Number of outstanding convertible notes	300	58	-	150	150	-
Number of shares issuable upon conversion	6,976,744	3,222,222	-	7,500,000	7,500,000	-
Conversion price	€ 0.43	€ 0.18	-	€ 0.20	€ 0.20	-
Expected term	3 months	1 month	-	3 months	3 months	-
Volatility	83.16%	101.29%	-	119.15%	119.15%	
Risk-free rate	-0.78%	-0.68%	-	-0.78%	-0.78%	
Value of the derivative instrument (in thousands of €)	**819**	**106**		**364**	**346**	**-**
Changes in fair value during the period (in thousands of €)		**(714)**	**(106)**		**(19)**	**(346)**

In accordance with IFRS 9, the discount of 8% was considered as an implied redemption premium recognized in financial expenses with a corresponding entry posted as an increase of the value of the related financial liability. Upon conversion of the notes, this amount included in financial liabilities is transferred to premiums related to share capital.

Pursuant to this agreement, when the conversion price is less than the nominal value of the share, a conversion penalty applies. This conversion penalty was considered as an implied redemption premium recognized in financial expenses (€301 thousand in 2019) and paid to Negma.

As of December 31, 2019, 242 convertible notes had been converted in accordance with the formula above, resulting in the issuance of 10,499,841 new shares pursuant to Tranche 1.

As of December 31, 2020, 310 convertible notes had been converted in accordance with the formula above, resulting in the issuance of 10,849,841 new shares pursuant to Tranche 1 and 3,050,000 new shares pursuant to Tranche 2.

Main characteristics of the warrants

The warrants are detached from ORNANE immediately. They may be transferred by their holders only to Affiliates and will not be subject to a request for admission to trading on the Euronext Growth market. They may be exercised for a period of five years from their date of issuance. Each warrant gives its holder a right to subscribe one new Biophytis share.

The strike price of the warrants is calculated using the following formula: Pe = 125% x P, where

- “Pe” is the warrant strike price,
- “P” is the conversion price, i.e., the lowest volume weighted average price over the 15 trading days preceding the date on which exercise is requested.

The number of warrants to be issued upon the issuance of the ORNANEBSA will be such that, when multiplied by the warrant’s strike price (determined according to the terms and conditions below), the resulting amount is equal to 12.5% of the par value of the tranche according to the following formula: n = (r x Vn)/(125% x P), where

- “n” is the number of warrants issued,
- “r” is the ratio of warrants issued as compared to the number of ORNANE, i.e., 12.5%,
- “P” is the conversion price, i.e., the lowest volume weighted average price over the 15 trading days preceding the date on which exercise is requested.

The warrants issued to Negma as part of each tranche were recognized at fair value (based on the Black-Scholes valuation model) in equity instruments at the issuance date in accordance with IAS 32.

Warrants	**Tranche 1**	**Tranche 2**
NEGMA	**As of the issue date (08/21/2019)**	**As of the issue date (12/27/2019)**
Number of outstanding warrants	585,936	694,444
Exercise price per share	€ 0.64	€ 0.27
Expected term	10 months	5 months
Volatility	71.11%	109.14%
Risk-free rate	-0.96%	-0.96%
Value of the equity instrument (in thousands of €)	**49**	**26**

The Company recognized:

- A deferred tax liability with respect to the equity instrument for €28 thousand in 2019, as a decrease of equity on initial recognition under IAS 12 *Income Taxes*; and

- A deferred tax asset with respect to net operating losses (NOLs) carried forward as a result of the deferred tax liabilities generated, resulting in a deferred tax benefit of €28 thousand in 2019 in the statement of consolidated operations.

12.2.2 Issuance of convertible notes to ATLAS

(amounts in thousands of euros)	**ATLAS ORNANE**
As of January 1, 2020	**-**
(+) Proceeds received	9 000
(-) Derivative instruments	(2 398)
(-) Issuance costs	(435)
(+) Fair value of financial liabilities	(270)
(+/-) Change in the fair value of financial liabilities	270
(+/-) Amortized cost	2 833
(-) Repayment	(750)
(-) Conversion	(8 250)
As of December 31, 2020	**-**

In April 2020, the Company signed a new convertible note financing of up to €24 million from ATLAS to continue the development of Sarconeos (BIO 101) through the issuance of multiple convertible notes. This contract replaces the Negma contract. The Company issued a first tranche of €3 million on April 29, 2020, a second tranche of €3 million on June 19, 2020 and a third tranche of €3 million on August 28, 2020.

A commitment fee of €375 thousand was withheld from the proceeds of the first tranche. Other issuance costs were incurred by the Company for approximately €66 thousand (€16 thousand for the first tranche, €23 thousand for the second tranche and €27 for the third tranche).

Main characteristics of the ORNANE note warrants

The 960 3-year “note warrants” require their holder to exercise them, at the Company’s request, in tranches of 120 warrants each. Each warrant grants its holder the right to one ORNANE. “Note warrants” may not be transferred and are not subject to a request for admission to trading on the Euronext Growth market.

Main characteristics of the ORNANE

The ORNANE (Notes) have a par value of €25,000 and are issued at a subscription price of 0.97% of the nominal value. They do not bear interest and have a 24-month maturity from issuance. Holders of ORNANE may request at any time to convert them during their maturity period, and at that time, the Company will be able to redeem the ORNANE in cash. At the end of the term, and if the ORNANE have not yet been converted or redeemed, the holder will have to convert them.

The holder may ask to convert the ORNANE at any time at the conversion parity determined by the following formula: N = Vn /(R x P), where

- "N" is the number of shares yielded by the conversion,
- "Vn" is the par value of the ORNANEs, i.e., 25,000 euros,
- "R" is the conversion ratio, i.e., 0.97,
- "P" is the conversion price, i.e., the lowest volume weighted average price over the 10 trading days preceding the date on which conversion is requested.

On the day of the conversion request, the Company may redeem the ORNANE in cash using the following formula: V = Vn/R x Pr, where

- "V" is the amount redeemed to the holder,
- "Pr" is the lowest price between (i) the weighted average closing price prior to the conversion and (ii) the lowest weighted average prices of the previous 10 trading days x 1.15.

ORNANE may be transferred by their holders only to Affiliates and will not be subject to a request for admission to trading on the Euronext Growth market.

Accounting treatment

In accordance with IFRS 9, the debt component of the convertible notes was measured according to the amortized cost method. The conversion option of the convertible notes was bifurcated and classified in derivative instruments due to the parity not fixed and measured at fair value on the date of issuance (based on the binomial valuation model) with recognition of the changes in fair value in profit or loss in accordance with IFRS 9.

The table below summarizes the accounting treatment of the conversion option:

Conversion option	**Tranche 1**		**Tranche 2**		**Tranche 3**	
ATLAS	**As of the issue date (04/29/2020)**	**As of December 31, 2020**	**As of the issue date (06/19/2020)**	**As of December 31, 2020,**	**As of the issue date (08/28/2020)**	**As of December 31, 2020**
Number of outstanding convertible notes	120	-	120	-	120	-
Number of shares issuable upon conversion	3,203,759	-	3,992,856	-	4,827,907	-
Conversion price	€ 0.94	-	€ 0.75	-	€ 0.62	-
Volatility	85.54%	-	68.05%	-	48.60%	-
Risk-free rate	-0.57%	-	0.55%	-	-0.59%	-
Fair value of the option	0.310	-	0.204	-	0.122	-
Value of the derivative instrument (in thousands of €)	**986**	**-**	**809**	**-**	**586**	**-**
Changes in fair value during the period (in thousands of €)		**(986)**		**(809)**		**(586)**

In accordance with IFRS 9, the discount of 3% was considered as an implied redemption premium recognized in financial expenses.

As of December 31, 2020, 330 convertible notes had been converted in accordance with the formula above, resulting in the issuance of 17,178,683 new shares pursuant to Tranche 1, 2 and 3. 30 notes issued with the third tranche have been repaid in cash for a total amount of €750 thousand.

As of December 31, 2020, all the convertibles notes issued for the benefit of Atlas has been converted. Pursuant to the agreement, we may issue up to 600 additional ORNANE to ATLAS, which would provide for additional funding to us of up to €15 million.

12.2.3 Issuance of non-convertible bonds to Kreos

(amounts in thousands of euros)	KREOS
As of January 1, 2019	**6,930**
(+) Proceeds received	2,420
(+) Guarantee deposit	80
(-) Transactions costs	(50)
(+/-) Amortized cost	328
(-) Repayment	(2,292)
As of December 31, 2019	**7,417**
(+) Proceeds received	—
(+) Guarantee deposit	—
(-) Transactions costs	—
(+/-) Amortized cost	189
(-) Repayment	(3,214)
As of December 31, 2020	**4,392**

On September 10, 2018, the Company signed a venture loan agreement and bonds issue agreement with Kreos, which provide for up to €10 million in financing to the Company through the issuance by the Company to Kreos of non-convertible bonds in four separate tranches of €2.5 million each, plus the issuance of attached warrants in connection with the first tranche. As required under the terms of the venture loan agreement, the Company pledged a security interest in the Company's assets for the benefit of Kreos. The Company also granted a security interest in the business as a going concern, including a portion of the Company's patents, to Kreos. Each tranche of non-convertible bonds bears a 10% annual interest rate and must be repaid in cash in 36 monthly installments commencing in April 2019.

Pursuant to the terms of the agreements, the Company has the right, at any time but with no less than 30 days prior notice to Kreos, to prepay or purchase the non-convertible bonds, exclusively in full. The prepayment will be equal to (i) the principal amount outstanding, plus (ii) the sum of all interest repayments which would have been paid throughout the remainder of the term of the relevant tranche discounted by 10% per annum.

The first and second tranches of non-convertible bonds were issued on September 10, 2018, the third tranche was issued on December 17, 2018, and the last one was issued on March 1, 2019, for total gross proceeds to the Company of €10 million.

Guarantee deposits totaling €320 thousand (€80 thousand per tranche) were withheld by Kreos from the proceeds received by the Company. The amount withheld will be deducted from the last installment to be repaid by the Company. It is presented under "Non-current financial assets."

The BSA warrants issued to Kreos as part of the first tranche give the holder the right to subscribe for up to 442,477 ordinary shares at an exercise price of €2.67 per share for a term of 7 years. These warrants were valued at €319 thousand and were recorded in equity and as a reduction of the debt value.

Accounting treatment

In accordance with IFRS 9, the non-convertible debt component is measured according to the amortized cost method, which amounted to €4.4 million as of December 31, 2020 and to €7.4 million as of December 31, 2019.

Note 13: Employee benefit obligation

The employee benefit obligation consists of the provision for retirement indemnity, assessed in accordance with the applicable collective bargaining agreement (i.e., the Collective Agreement of the "Pharmaceutical industry").

This commitment only applies to employees under French law. The main actuarial assumptions used for the valuation of the retirement indemnity are as follows:

	AS OF DECEMBER 31,	
	2019	**2020**
Retirement age	Voluntary retirement between 65 and 67 years old	
Collective agreement	Pharmaceutical industry	Pharmaceutical industry
Discount rate (IBOXX Corporates AA)	0.77%	0.33%
Mortality table	INSEE 2017	INSEE 2017
Salary increases	2.00%	2.00%
Turn-over	Medium	Medium
Social security contributions	43%	43%

The provision for the retirement indemnity has evolved as follows:

(amounts in thousands of euros)	**Employee benefit obligation**
As of January 1, 2019	**189**
Service cost	39
Interests cost	2
Actuarial gains and losses	(89)
As of December 31, 2019	**142**
Service cost	31
Interests cost	1
Actuarial gains and losses	14
As of December 31, 2020	**188**

Note 14: Provisions

(amounts in thousands of euros)	**As of 01/01/2020**	**Additions**	**Reversals**	**Release of surplus provisions**	**As of 12/31/2020**
Provisions for litigation (1)	-	1,394	-	-	1,394
Provisions for risks (2)	-	2	-	-	2
Total provisions	**-**	**1,396**	**-**	**-**	**1,396**

(1)Negma Litigation

Following the termination of the Negma contract on April 6, 2020, Negma undertook legal action in order to claim damages of €910,900 from Biophytis as well as the delivery of 7,000,000 Biophytis shares, that Negma considers it was entitled to pursuant to the only Biophytis ORNANES still held by Negma, issued in consideration for a loan of €1,400,000 in principal.

Pursuant to a summary judgment dated May 7, 2020, Negma obtained a decision partially responding to its claims ordering, under penalty (which amounted to €7 thousand), Biophytis to pay damages in an amount of €378 thousand, and deliver 2,050,000 Biophytis shares.

This delivery of 2,050,000 shares valued at €1,394 thousand was considered as a financial indemnification.

The indemnification of €385 thousand (including €7 thousand of penalties) was recorded as a financial expense in 2020. The summary judgement does not extinguish the liability due to Negma. Current financial liabilities as of December 31, 2020 include a bond of €1,400 thousand (see note 12.2).

On November 18, 2020, Paris Court of Appeal ruled in Biophytis' favor and sentenced Negma to return the 2,050,000 shares previously delivered as well as the provision €378 thousand. In January 2021, Negma has returned the shares and, before 2020, Negma repaid €419 thousand to Biophytis (including compensation and legal costs).

As of December 31, 2020, the Company recognized the right to be returned the 2,050,000 Biophytis shares previously issued to Negma in equity for € 1,394 thousand against the reversal of the financial indemnification previously recorded as financial expense (see note 12.2). Since the judgment of the Paris Court of Appeal, Negma initiated proceedings on the merits of its claim in order to obtain 7,000,000 Biophytis shares and €911 thousand of indemnity with late-payments interests at the rate LIBOR + 10%.

As of December 31, 2020, the Company has conducted an analysis of its exposure in connection with this litigation and estimated that its maximum risk would be:

- To proceed with the repayment of the financial debt of 1.4 million euros (see note 12.2); and
- To be ordered to pay compensation equivalent to that of the judgment of 7 May 2020 (without penalties) i.e. €1,394 thousand in the event of an unfavourable judgment.

Therefore, the Company decided to accrue a provision for risk of €1,394 thousand as of December 31, 2020.

This estimation will be reassessed in the future based on the evolution of the litigation.

(2) Provisions for risks

Provisions for risks are made of the additional contribution to pay when the free shares are granted at the term of the vesting period. This contribution is recognized on a straight-line basis over the vesting period.

Note 15: Current liabilities

15.1 Trade payables

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Research and development suppliers	4,953	5,408
General and administrative suppliers	2,913	2,577
Total trade payables	**7,866**	**7,985**

The change in trade payables to research and development suppliers is primarily due to the increase in expenses associated with the Company's ongoing clinical trials and research costs (refer to 16.1) and in particular, expenses related to the SARA clinical program and the launch of the COVA program.

The decrease in trade payables to general and administrative suppliers is primarily due to the reduction of the payment delays in 2020 and the payment of the 2019 suppliers balance which was partially postponed to 2020.

15.2 Tax and social liabilities

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2019**	**2020**
Personnel expenses	315	521
Social security expenses	466	790
Other taxes	482	136
Total tax and social liabilities	**1,263**	**1,446**

15.3 Other creditors and miscellaneous liabilities

	AS OF DECEMBER 31,	
(amounts in thousands of euros)	**2018**	**2019**
Attendance fees	230	242
Other	2	26
Total other creditors and miscellaneous liabilities	**232**	**268**

Note 16: Details of expenses and products by function

16.1 Research and Development expenses

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Personnel expenses	(2,962)	(3,063)	(2,553)
Purchases and external expenses	(9,539)	(8,660)	(10,459)
Other	(190)	(214)	(251)
Research and development expenses	**(12,691)**	**(11,937)**	**(13,263)**
Research tax credit	3,133	2,807	3,328
Subsidies	45	41	14
Research tax credit and subsidies	**3,178**	**2,848**	**3,342**
Research and development expenses, net	**(9,513)**	**(9,089)**	**(9,921)**

The decrease in personnel expenses in 2020 compared to 2019 is related to the downsizing of the Company's structure initiated during the second half of 2019 and also to a lower average salary for new employees in 2020.

Research and development expenses relate to activities in connection with conducting clinical trials, non-clinical studies of the drug candidates for the treatment of age-related diseases and the treatment of severe respiratory failure in patients suffering from COVID-19. The increase in purchases and external expenses between 2019 and 2020 is related to our studies and research costs linked to the progression of our SARA-INT study and the launch of our COVA study. These expenses consisted primarily of the cost of CROs in conducting clinical trials and non-clinical regulatory studies.

The decrease in purchases and external expenses related to the Company's studies and research costs in 2019 compared to 2018 is mainly due to budgetary constraints on current programs in favor of the development of the SARA study. This decision allowed the Company to accelerate patient recruitment in the SARA-INT study.

16.2 General and administrative expenses

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Personnel expenses	(1,804)	(1,998)	(1,796)
Purchases and external expenses	(2,428)	(2,393)	(2,188)
Other expenses	(116)	(2 203)	(37)
General and administrative expenses	**(4,348)**	**(6,593)**	**(4,021)**

Between 2018 and 2019, personnel expenses, including share-based payments, for general management and administrative staff increased by €0.2 million due to the full impact in 2019 of the recruitment of a CFO for its US subsidiary that occurred in late 2018. Personnel expenses, including share-based payments, for general management and administrative staff decreased by €0.2 million in 2020 due to the restructuring of the finance function, and the decrease of 2 employees.

Other purchases and external expenses consisted primarily of administrative expenses associated with being a public listed company in France, accounting and audit fees, and legal fees.

In its decision dated October 1, 2019, the French Stock Exchange Authority, the AMF, imposed a financial penalty of €100 thousand on Biophytis for failing to communicate as soon as possible to the market the privileged information relating to the significant delay in the entry in phase 2 of clinical studies of two drug candidates. The Company has settled this liability along with a late-filing penalty of €10 thousand. This amount is included in the general and administrative expenses in 2019.

The general and administrative expenses for the year ended December 31, 2019 is impacted by the recognition as other expenses of the one-off fees related to the postponed project of listing the Company's equity securities on the Nasdaq in July 2019.

16.3 Personnel expenses

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Wages and salaries	(4,479)	(4,998)	(3,564)
Share-based payments	(287)	(63)	(785)
Personnel expenses	**(4,766)**	**(5,061)**	**(4,349)**

The Company's average headcount is 21 as of December 31, 2020 compared to 20 as of December 31, 2019 and to 21 as of December 31, 2018.

Note 17: Net financial expense

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Financial interest and amortized cost of the non-convertible bonds and convertible notes (1)	(189)	(2,526)	(4,374)
Changes in fair value of derivative instruments (1)	-	726	2,831
Negma financial indemnity (2)	-	-	(385)
Provision in relation with the Negma litigation (2)	-	-	(1,394)
Other financial expenses	(38)	(352)	(182)
Financial income related to Negma returning to Biophytis damages paid (2)	-	-	419
Other financial income	10	4	2
Foreign exchange gains (losses)	19	14	(29)
Total net financial expense	**(198)**	**(2,134)**	**(3,112)**

(1) Refer to Note 12.2 Convertible notes and non-convertible bonds

(2) Refer to Note 14 Provisions

Note 18: Income taxes

The Company has estimated carried-forward tax losses of €94,226 thousand as of December 31, 2020 comprising:

- French tax losses which can be carried forward indefinitely for €92,949 thousand;
- U.S. subsidiary tax losses which can be carried forward for €1,276 thousand (being $1,566 thousand translated using the December 31, 2020 exchange rate), of which:
  - €931 thousand indefinitely;
  - €173 thousand expiring in 2037;
  - €132 thousand expiring in 2036; and
  - €40 thousand expiring in 2035.
- Brazilian subsidiary tax losses for €1 thousand which can be carried forward indefinitely.

The tax rate applicable to:

- Biophytis, is the current rate in France, i.e. 28%. This rate will decrease gradually to reach 25% in 2022.
- Instituto Biophytis Do Brasil, is the current rate in Brazil, i.e. 34%.
- Biophytis Inc., is the current rate in the United States, i.e. 21%.

In accordance with the accounting principles described in Note 2.21, no deferred tax asset has been recognized in the Financial Statements apart from those to offset deferred tax liabilities.

Reconciliation between theoretical tax and effective tax

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Net loss	(13,987)	(17,788)	(17,054)
Income taxes	72	28	-
Loss before taxes	**(14,059)**	**(17,816)**	**(17,054)**
Current tax rate in France	28.00%	28.00%	28,00%
Theoretical income tax (expense) benefit	**3,937**	**4,988**	**4,775**
Items not subject to tax deduction	845	608	1,695
Share based payments	(80)	(18)	(220)
Non recognition of deferred tax assets related to tax losses and temporary differences	(4,556)	(5,599)	(6,248)
Tax rate differences	(74)	48	(2)
Group income taxes (expense) benefit	**72**	**28**	**-**
Effective tax rate	*-0.5%*	*-0.2%*	0,0%

The permanent differences include the impact of the research tax credit (non-taxable operating income).

Nature of deferred taxes

	AS OF DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Temporary differences	95	44	64
Losses carried forward	13,155	18,239	23,505
Total of items with a nature of deferred tax assets	**13,250**	**18,283**	**23,569**
Temporary differences	(699)	(789)	(528)
Total of items with a nature of deferred tax liabilities	**(699)**	**(789)**	**(528)**
Net total of deferred tax assets (liabilities)	**12,551**	**17,494**	**23,041**
Unrecognized deferred tax	(12,551)	(17,494)	(23,041)
Net total of deferred tax	**-**	-	-

Note 19: Earnings (loss) per share

	FOR THE YEAR ENDED DECEMBER 31,		
	2018	**2019**	**2020**
Weighted average number of outstanding shares	13,463,413	16,966,140	60,022,714
Treasury shares	88,987	83,479	48,228
Weighted average number of outstanding shares (without Treasury shares)	13,374,426	16,882,661	59,975,486
Net loss (in thousands of euros)	(13,987)	(17,788)	(17,054)
Basic loss per share (€/share)	**(1.05)**	**(1.05)**	**(0.28)**
Diluted loss per share (€/share)	**(1.05)**	**(1.05)**	**(0.28)**

None of the Company's awards (warrants, free shares and founders' warrants) are dilutive as of December 31, 2020 (see Notes 11 and 12.2)

Note 20: Related Parties

20.1 Compensation due to executive officers

	FOR THE YEAR ENDED DECEMBER 31,		
(amounts in thousands of euros)	**2018**	**2019**	**2020**
Fixed compensation	1,313	1,405	960
Variable compensation	275	286	272
Benefits in kind	20	15	34
Directors fees	174	230	263
Share-based payments	252	53	581
Total compensation of executive officers	**2,034**	**1,989**	**2,110**

Post-employment benefits have not been granted to our Chief Executive Officer or members of the Board of Directors.

20.2 Intellectual Property Agreement signed with the Company's CEO

The Company's CEO, who is a corporate officer but not an employee of the Company under French law, is involved in our research and development activities. He has developed inventions with the Company for which the Company has submitted patent applications in which the Company's CEO is listed as a co-inventor and other inventions that the Company expects may give rise to patent applications in the future for which the Company expects he will be included as a co-inventor.

As an inventor, the Company's CEO has certain rights under French intellectual property law. These rights are distinct from the statutory rights that usually apply to employee inventors under French law.

In order to define a framework within which any intellectual property resulting from the Company's CEO's research and development activities is properly assigned to the Company, the Company has entered into an agreement, which has been approved by the Company's board of directors pursuant to which he is entitled to the following payments for his contributions:

(a) a first lump sum cash payment of €90 thousand to be paid within 30 days of filing of a patent application based on the assigned rights; and

(b) a second lump sum cash payment of €90 thousand to be paid within 30 days of publication of a patent application based on the assigned rights; and

(c) a 6.5% royalty payment with respect to any license income and/or any net sales by the Company of products manufactured with the patents filed on the basis of the assigned rights.

These three payments will be capped at €2.1 million on a platform per platform basis.

In the event that a third-party pharmaceutical and/or biotech company acquires 100% of the Company's capital and voting rights, payments will be accelerated, so that the cap (€2.1 million per platform), less any amount previously paid in respect of a platform, will become immediately payable.

Following the signature of this agreement, an amount of €450 thousand was due to the Company's CEO, as certain patent applications covered by the agreement had already been filed and therefore triggered payment of the first lump sum. Additional amounts of €180 thousand and €270 thousand were due to the Company's CEO in 2019 and 2020, respectively.

In April 2020, the Company entered into an amendment to the Intellectual Property agreement signed with the Company's CEO to cover two publications of patent applications not included under the existing contract. This amendment was approved by the Board of Directors on April 3, 2020, under which the Company's CEO is entitled to the payment of a lump sum in cash amounting to €180 thousand.

The total patents rights acquired from the Company's CEO as of December 31, 2020 amounted to €1,080 thousand and are amortized over a 19-year period.

€270 thousand was paid to the Company's CEO in 2019 and €180 thousand in 2020. The remaining amount of €630 thousand was used for the subscription and the exercise of the investors warrants by the Company's CEO (see Note 10).

20.3 Company's CEO's Share loan agreement with Negma

As part of the implementation of the financing agreement with Negma (see note 12.2), the Company's CEO has entered into a loan agreement for his shares in the Company for the benefit of Negma in order to facilitate the various issuance and conversion transactions.

Following the delivery of the 2,050,000 shares to Negma (see note 14) and the termination of the agreement, the share loan agreement was terminated.

20.4 Escrow Agreement

In order to comply with the requirements of the order of the President of Paris Commercial Court, dated May 7, 2020 by which the Company were ordered to place in escrow 2,050,000 of the Company's shares until their delivery to Negma, and as the Company did not hold a sufficient number of its own shares, the Company asked its CEO, by a letter dated May 19, 2020, to place in escrow some of the shares of the Company he owned. The letter (which was countersigned by the Company's CEO) included a provision for the indemnification by the Company of the Company's CEO for any loss he may suffer as a result of this arrangement. As the delivery of the shares to Negma took place on June 5, 2020, the escrow was released in full, including the shares in escrow owned by the Company's CEO, which were returned to him.

Note 21: Off-balance-sheet commitments

21.1 Commercial Leases

Leases on premises

As part of its activity, the Company signed operating leases for its administrative offices and laboratories, which are summarized below:

France:

Address:	Sorbonne Université (formerly Université Pierre et Marie Curie) 4, place Jussieu - 75005 Paris

Lease arrangement which expired on December 15, 2019

Surface area:	638.15 square meters
Period:	December 15, 2018 – December 15, 2019 (which can be renewed twice with a simple amendment)
Annual rent:	€215,011.87
Refurbishment costs:	Sorbonne Université agreed to contribute to the refurbishment costs up to €100 thousand

Lease arrangement (ongoing as of December 31, 2020)

Surface area:	504 square meters
Period:	December 15, 2020 – December 15, 2021
Annual rent:	€159,278.23
Refurbishment costs:	Sorbonne Université agreed to contribute to the refurbishment costs up to €50 thousand

United States:

Address:	210 Broadway, Suite 201, Cambridge, MA 02139
Period:	Started on October 1, 2018. Month to month rent, terminable with 30 days advance written notice
Monthly rent:	$6,100

Brazil:

The Company does not currently have a lease agreement in this jurisdiction.

21.2 Commitments linked to financial debts

Commitments given
(Amounts in thousands of euros)

Borrowing	Commitments given	Nominal amount	Residual amount as of 12/31/2020
BPI France conditional advance "Sarcob" project	The agreement provides for an annual repayment on March 31 of each year, effective on January 1, 2016, corresponding to 40% of the ex-tax proceeds from the sale or assignment of licenses, patents or know-how relating to all or part of the results of the aided project, received for the previous year and 40% of the ex-tax proceeds generated by the marketing or use by the beneficiary for its own purposes, of prototypes, pre-series or models produced as part of the aided project. These amounts shall be assigned as a priority and by offsetting them against the last payment to BPI France. The application of this mechanism will not lead the Company to pay more than the amount received.	260	117
BPI France conditional advance -"BIO101" project	The agreement provides for an annual repayment on March 31 of each year, effective on January 1, 2018, corresponding to 35.81% of the ex-tax proceeds from the sale or assignment of licenses, patents or know-how relating to all or part of the results of the aided project, received for the previous year and 35.81% of the ex-tax proceeds generated by the marketing or use by the beneficiary for its own purposes, of prototypes, pre-series or models produced as part of the aided project. These amounts shall be assigned as a priority and by offsetting them against the last payment to BPI France. The application of this mechanism will not lead the Company to pay more than the amount received.	1,100	715

Agreements for the exploitation of industrial property	Commitments given
SARCOB commercialization agreement - SATT Lutech Agreement dated January 1, 2016	It covers not only the family S IV patents covered by the consortium agreement, but also covers the family S I patents and family S II and S III patents. The contractual structure of the consideration payable by the Company is as follows: firstly, in the year after the first marketing of a product and in any event at the latest, from 2023 onwards, the Company will pay a guaranteed annual minimum amount of €40 thousand, which shall be deducted from the amount of royalties effectively due annually. On this point, with regard to the direct exploitation, the agreement provides for an annual royalty for a figure based on the net sales of products, distinguishing between sales of nutraceutical and medicinal products. With regards to indirect exploitation, it provides for annual double-digit royalties based on income received from licensees, distinguishing (i) between the sales of nutraceutical products (double-digit royalties) and drug products (two or one-digit royalties) and (ii) the product development phase (phase 1, 2 or 3) at the time of the conclusion of the licensing agreement.
MACULIA commercialization agreement - SATT Lutech Agreement dated January 1, 2016	The contractual structure of the consideration payable by the Company is as follows: firstly, in the year following the first marketing of a nutraceutical product and in any event no later than in 2020, the Company will pay an annual guaranteed minimum amount of €15 thousand. In the same way, the Company will pay a guaranteed minimum amount of €50 thousand in the event of marketing of a drug product and in any event no later than from 2026. These amounts will be deducted from the amount of royalties effectively due annually. For direct exploitation, it also provides for an annual royalty of a figure based on net sales of products, distinguishing between sales of nutraceutical and medicinal drugs. For indirect exploitation, it also provides for annual double-digit royalties based on income received from licensees, distinguishing (i) between the sales of nutraceuticals (double-digit royalties) and drug products (one or two-digit royalties) and (ii) the product development phase of these products (phase 1, 2 or 3) at the time of conclusion of the licensing agreement.

Note 22: Management and assessment of financial risks

Biophytis may find itself exposed to various types of financial risk, including market risk, liquidity risk and credit risk. Biophytis is implementing measures consistent with the size of the Company to minimize the potentially adverse effects of those risks on its financial performance.

Biophytis' policy prohibits the use of financial instruments for speculative purposes.

Market risk

Interest rate risk

Interest rate risk reflects the Company's exposure to fluctuations in interest rates in the market.

Changes in interest rate could affect returns achieved on cash and fixed-term deposits but this risk is not considered material given the current low returns on deposits held by the Company.

Change in interest rate could affect the statement of consolidated operations for financial liabilities but this risk is considered as not significant given the implementation by the Company of debts bearing fixed interest rate.

Foreign exchange risk

The major risks linked to foreign exchange rate are considered not significant due to the low level of activity of its foreign subsidiaries.

The Company currently does not use hedging instruments to protect its activity from exchange rate fluctuations. However, any major development in its activity may result in an increase of its exposure to exchange rate risk. Should such increase materialize, the Company may consider adopting an appropriate policy to hedge such risks.

Equity risk

The Company does not hold long or short-term tradable securities on a regulated market.

Credit risk

Credit risk is linked to deposits with banks and financial institutions.

The Company seeks to minimize the risk related to banks and financial institutions by placing cash deposits with highly rated financial institutions. The maximum level of the credit risk corresponds to the book value of the financial assets. As outstanding receivables consist primarily of Research Tax Credit "CIR" granted by the French government, the Company does not carry significant credit risk.

Liquidity risk

Since its incorporation, the Company has funded its operations and growth by strengthening its shareholders' equity through capital increases (including the capital increase realized during its French IPO in July 2015), bank loans and notes, and obtaining public aid for innovation and reimbursement of CIR receivables, including the prefinancing arrangement initiated in 2020.

Significant research and development expenses have been incurred since inception generating negative cash flows from operating activities of €12,057 thousand, €15,272 thousand and €9,864 thousand for the years ended December 31, 2018, 2019 and 2020, respectively.

The Financial Statements have been approved on a going concern basis by the Board of Directors (refer to Note 2.1).

The Company will continue to have major funding requirements in the future to support the development of its drug candidates. The precise extent of funding required is difficult to predict accurately and will depend in part on factors outside the Company's control. Areas subject to significant uncertainty include, but are not limited to:

- The Company's ability to conduct successful clinical trials, including the capacity to recruit patients in a timely-manner for the Company's clinical trials;
- the change in the regulatory landscape; and
- the approval for other drugs on the market that may potentially reduce the attractiveness for the Company's drug candidates.

Should the Company find itself unable to finance its own growth through partnership agreements, the Company would be dependent on other sources of financing, including equity and/or debt funding or research grants.

Note 23: Subsequent events

"COVA" Program

- On January 19, 2021, Biophytis announced that the independent Data Monitoring Committee (DMC) recommends start of recruitment for Part 2 of the Phase 2-3 Study ("the COVA study"). The DMC's recommendation is based on its review of the safety data analysis from the first 20 patients enrolled in the study.

  Based on the DMC recommendation, patient recruitment will start as soon as regulatory/ethics approvals or permissions are obtained in the relevant jurisdictions.

- On February 3, 2021, the Company announced the start of patient recruitment in Brazil and the USA for the part 2 of the Phase 2-3 COVA trial. Interim analysis of Part 1 is expected in Q1 2021. Results from the full study (Part 1 and Part 2) are expected in Q2 2021.

- On February 17, 2021, the Company announced the expansion of Patient Recruitment for Part 2 of the Phase 2-3 COVA Trial ("COVA Study") following Regulatory Authorities approvals in France and Belgium.

Negma litigation

Related to the dispute with Negma (see note 14), the Company received on January 19, 2021 the 2,050,000 Biophytis shares that Negma had to return following the Paris Court of Appeal on November 18, 2020.

The oral argument hearing was held on February 8, 2021, during which the parties presented their arguments. At the end of the hearing, the Tribunal asked Biophytis and Negma Group to provide a note on the economic effects of the contract at issue for February 12, 2021.

Deliberation is expected on March 16, 2021.

Initial Public Offering in the United States

- On January 20, 2021, Biophytis announced that it has publicly filed a registration statement on Form F-1 with the U.S. Securities and Exchange Commission (the "SEC") in relation to a proposed initial public offering of ordinary shares in the form of American Depositary Shares ("ADSs") in the United States (the "ADS Offering") and proposed Nasdaq listing in connection therewith.

- On February 3, 2021, the Company announced the launch of its Proposed Public Offering in the United States and its intention to offer and sell up to 12 million ordinary shares represented by 1.2 million American Depositary Shares ("ADSs"), with each ADS representing ten ordinary shares, in the United States (the "ADS Offering"). H.C. Wainwright & Co. is acting as sole book-running manager for the ADS Offering. Biophytis intends to grant to H.C. Wrainwright & Co. a 30-day option to purchase up to 1.8 million additional ordinary shares represented by 180,000 ADSs in the ADS Offering (the "Option"). The offering price is expected to be between $15.00 and $18.00 per ADS, or between €1.25 and €1.50 per ordinary share.

- On February 10, 2021, Biophytis announced pricing of its Initial Public Offering and the approval to List on Nasdaq Capital Market through a capital increase with 12 million new ordinary shares represented by 1.2 million Depositary Shares ("ADSs"), with each ADS representing 10 ordinary shares (the "ADS Offering"), at an initial public offering price of $16.75 per ADS (€1.38 per ordinary share), which represents a discount of 16.85% based on the closing price of $1.662 per share on February 9, 2021 and an exchange rate of €1.00 = 1.212$.

- On February 12, 2021, Biophytis announced the closing of the ADS Offering. The gross proceeds from the Offering were approximately $20.1 million (€16.58 million, using the exchange rate of €1.00 = $1.212 on February 12, 2021, the closing date) and the aggregate net proceeds to Biophytis, after deducting underwriting discounts and commissions, management fee, and other offering expenses payable by the Company, were approximately $16.35 million (€13.49 million). All of the securities sold in the Offering were offered by Biophytis. Biophytis' ADSs began trading on the Nasdaq Capital Market on February 10, 2021, under the ticker symbol "BPTS".

Exhibit 2.3

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the ordinary shares, the American Depositary Shares and the articles of association of BIOPHYTIS S.A. ("Biophytis" or the "Company") is a summary and does not purport to be complete. This summary is subject to, and qualified in its entirety by reference to, the complete text of the Company's articles of association, which are incorporated by reference as Exhibit 1.1 of the Company's Annual Report on Form 20-F to which this description is also an exhibit. The Company encourages you to read the Company's by-laws carefully.

As of December 31, 2020, BIOPHYTIS S.A. had the following series of securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Ordinary Shares, €0.20 nominal value per share*	*	The Nasdaq Capital Market*
American Depositary Shares, each representing 10 ordinary shares, €0.20 nominal value per share	BPTS	The Nasdaq Capital Market

** Not for trading, but only in connection with the registration of the American Depositary Shares.*

I. ORDINARY SHARES

The Company is a *société anonyme* organized under the laws of France and we are registered at the Paris *Registre du Commerce et des Sociétés* under the number 492 002 225.

As of December 31, 2020, the Company's outstanding share capital consisted of a total of 100,757,097 issued ordinary shares, fully paid and with a nominal value of €0.20 per share.

Key Provisions of Our Articles of Association and French Law Affecting Our Ordinary Shares

The description below reflects the terms of our articles of association, and summarizes the material rights of holders of our ordinary shares under French law. This is only a summary and is not intended to be exhaustive. For further information, please refer to the full version of our articles of association, which are included Exhibit 1.1 to the annual report on Form 20-F of which this description is also an exhibit.

Corporate Purpose (Article** 2 **of the Articles of Association)

Our corporate purpose in France and abroad includes:

- the creation, operation, leasing, lease management of all operating assets, factories, institutions, the taking of stakes in any company, as well as all attached or connected commercial, financial, industrial, securities and property operations, relating directly or indirectly to the activity of research production, distribution and marketing of any product and service beneficial to human or animal health;
- the research and development of drug candidates and nutraceuticals, particularly in the field of age-related diseases; and
- all financial, commercial, industrial, civil, securities or property operations, which may be associated directly or indirectly, in whole or in part, with one or other of the purposes specified above or any other similar or related purpose.

Directors

Quorum and Voting (Article 17 of the Articles of Association). The board of directors may only deliberate validly if at least half of the directors are present or considered to be present, subject to the adjustments made by the internal regulations (*règlement intérieur*) in the event of use of videoconferencing or another means of telecommunication.

Unless otherwise provided in the articles of association and subject to the adjustments made by the internal regulations in the event of use of videoconferencing or other means of telecommunications, decisions are taken by majority of votes of members who are present or represented or regarded as present. In the event of a tied vote, the Chairman of the session will have the deciding vote.

For the calculation of the quorum and majority, directors participating in the board meeting by videoconference or telecommunications media will be regarded as present under the conditions defined by the internal regulations of the board of directors. However, the effective presence or presence by representation will be necessary for all board of director decisions regarding the drafting of the annual financial statements and consolidated accounts and the drawing up of the management report and the report on the management of the group, as well as for decisions regarding the dismissal of the Chairman of the board of directors, the CEO and, as the case may be, the Deputy CEO.

Directors' Voting Powers on Proposal, Arrangement or Contract in which any Director Is Materially Interested (Article 21 of the Articles of Association). Except for those relating to current operations concluded under normal conditions, any agreement entered into, directly or indirectly through an intermediary, between the Company and any of our directors, CEO, deputy CEOs or with a shareholder holding more than 10% of the voting rights of the Company, or in the case of a corporate shareholder, the company which controls it, will be subject to prior authorization by the board of directors.

Agreements between the Company and another company will also be subject to prior authorization, if the CEO, one of the deputy CEOs or a director of the Company is the owner, partner with unlimited liability, manager, director, member of the supervisory board or, in general, a director of the Company.

Directors (other than legal entities) are forbidden from taking out loans in any form from the Company, to be granted current account or overdraft by it, or arranging for the Company to guarantee or endorse any commitments with regard to third parties.

Directors' Compensation (Article 20 of the Articles of Association). The General Meeting may allocate to the directors, as remuneration for their activities, by way of attendance fees, a fixed annual sum, which this meeting will determine without being bound by previous decisions. The amount of the same shall be attributed to operating expenses.

The board of directors will freely distribute among its members the global overall amounts allocated to directors in the form of attendance fees; it may notably allocate to the directors who are members of study committees, a higher share than that of the other directors.

The board of directors may allocate exceptional remuneration for assignments or mandates entrusted to the directors. The board of directors may authorize the reimbursement of travel costs and expenses incurred by the directors in the interest of the Company.

Board of Directors' Borrowing Powers. There are currently no limits imposed on the amounts of loans or borrowings that the board of directors may approve.

Directors' Age Limits. There are currently no age limits imposed for service on our board of directors. The Chairman of the board of directors must be under 75. The number of directors aging above 75 shall not be greater than one third of the total number of directors.

Directors' Share Ownership Requirements. None.

Rights, Preferences and Restrictions Attaching to Ordinary Shares

Dividends (Article 34 of the By-laws). We may only distribute dividends out of our "distributable profits," plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law.

"***Distributable profits***" consists of (a) the profits for the last closed financial period increased by (b) any retained earnings, less (c) losses carried forward increased by (d) amounts to be placed in reserve pursuant to the law or the articles of association.

Legal Reserve. Pursuant to French law, we must allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to our French subsidiary on an unconsolidated basis.

Approval of Dividends. Pursuant to French law, our board of directors may propose a dividend for approval by the shareholders at the annual ordinary general meeting.

Upon recommendation of our board of directors, our shareholders may decide to allocate all or part of any distributable profits to special or general reserves, to carry them forward to the next fiscal year as retained earnings or to allocate them to the shareholders as dividends. However, dividends may not be distributed when our net assets are or would become as a result of such distribution lower than the amount of the share capital plus the amount of the legal reserves which, under French law, may not be distributed to shareholders (the amount of our share capital plus the amount of our legal reserves which may not be distributed was equal to €20,151 thousand on December 31, 2020).

Our board of directors may distribute interim dividends after the end of the fiscal year but before the approval of the financial statements for the relevant fiscal year when the interim balance sheet, established during such year and certified by an auditor, reflects that we have earned distributable profits since the close of the last financial year, after recognizing the necessary depreciation and provisions and after deducting prior losses, if any, and the sums to be allocated to reserves, as required by law or the by-laws, and including any retained earnings. The amount of such interim dividends may not exceed the amount of the profit so defined.

Distribution of Dividends. Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our board of directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our board of directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash.

Timing of Payment. Pursuant to French law, dividends must be paid within a maximum of nine months after the close of the relevant fiscal year, unless extended by court order. Dividends not claimed within five years after the payment date shall be deemed to expire and revert to the French state.

Voting Rights (Article 14 of the Articles of Association). The voting rights attached to ordinary shares or dividend shares is proportional to the amount of capital they represent. Each share is entitled to one vote.

A double voting right has been established for all registered and fully paid-up shares registered in the name of the same beneficiary for at least two years.

Under French law, treasury shares or shares held by entities controlled by us are not entitled to voting rights and do not count for quorum purposes.

Rights to Share in Our Profit. Each share entitles its holder to a portion of the corporate profits and assets proportional to the amount of share capital represented thereby.

Rights to Share in the Surplus in the Event of Liquidation. If we are liquidated, any assets remaining after payment of the debts, liquidation expenses and all of the remaining obligations will first be used to repay in full the par value of our shares. Any surplus will be distributed pro rata among shareholders in proportion to the number of shares respectively held by them, taking into account, where applicable, of the rights attached to shares of different classes.

Repurchase and Redemption of Shares. Under French law, we may acquire our own shares for the following purposes only:

- to decrease our share capital, provided that such a decision is not driven by losses and that a purchase offer is made to all shareholders on a *pro rata* basis, with the approval of the shareholders at an extraordinary general meeting; in this case, the shares repurchased must be cancelled within one month from the expiry of the purchase offer;

- to provide shares for distribution to employees or managers under a profit-sharing, free share or share option plan; in this case the shares repurchased must be distributed within 12 months from their repurchase failing which they must be cancelled;

- to meet obligations arising from debt securities that are exchangeable into equity instruments; or

- under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and in accordance with the general regulations of, and market practices accepted by the Financial Markets Authority (AMF). This authorization may only be given for a period not exceeding eighteen months.

Under The Market Abuse Regulation (MAR) and in accordance with the General Regulations of the AMF *(Réglement Général de l'AMF)*, a corporation shall report to the competent authority of the trading value on which the shares have been admitted to trading or are traded, no later than by the end of the seventh daily market session following the date of the execution of the transaction, all the transactions relating to the buy-back program, in a detailed form and in an aggregated form.

No such repurchase of shares may result in us holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. Shares repurchased by us continue to be deemed "issued" under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

Sinking Fund Provisions. Our articles of association do not provide for any sinking fund provisions.

Liability to Further Capital Calls. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

Requirements for Holdings Exceeding Certain Percentages. None except as described below under "—Form, Holding and Transfer of Shares—Ownership of Shares by Non-French Persons".

Actions Necessary to Modify Shareholders' Rights

Shareholders' rights may be modified as allowed by French law. Only the extraordinary shareholders' meeting is authorized to amend any and all provisions of our articles of association. It may not, however, increase shareholder commitments without the prior approval of each shareholder.

Special Voting Rights of Warrant Holders

Under French law, the holders of warrants of the same class (*i.e.*, warrants that were issued at the same time and with the same rights), including founders' warrants, are entitled to vote as a separate class at a general meeting of that class of warrant holders under certain circumstances, principally in connection with any proposed modification of the terms and conditions of the class of warrants or any proposed issuance of preferred shares or any modification of the rights of any outstanding class or series of preferred shares.

Rules for Admission to and Calling Annual Shareholders' Meetings and Extraordinary Shareholders' Meetings

Access to, Participation in and Voting Rights at Shareholders' Meetings (Articles 27 &28 of the Articles of Association). Shareholders' meetings are composed of all shareholders. Each shareholder has the right to attend the meetings and participate in the discussions (1) personally, or (2) by granting proxy to any individual or legal entity of his choosing; or (3) by sending a proxy to the company without indication of the mandate, or (4) by voting by correspondence, or (5) by videoconference or another means of telecommunication in accordance with applicable laws that allow identification. For any proxy given by a shareholder without indication of the mandate, the chairman of the general meeting shall cast a vote in favor of the adoption of the draft resolutions presented or approved by the board of directors and a vote against the adoption of all other draft resolutions. The board of directors organizes, in accordance with legal and regulatory requirements, the participation and vote of the shareholders at the meeting, assuring, in particular, the effectiveness of the means of identification.

Participation in shareholders' general meetings, in any form whatsoever, is subject to registration or registration of shares under the conditions and time limits provided for applicable laws.

The final date for returning voting ballots by correspondence is set by the board of directors and disclosed in the notice of meeting published in the French Journal of Mandatory Statutory Notices (BALO). This date cannot be earlier than three days prior to the meeting.

The shareholder having voted by correspondence will no longer be able to participate directly in the meeting or to be represented. In the case of returning the proxy form and the voting by correspondence form, the proxy form is taken into account, subject to the votes cast in the voting by correspondence form.

Any shareholder may be represented at meetings by any individual or legal entity of his choosing, by means of a proxy form which is addressed to him by us (1) at his request, addressed to us by any means. This request must be received at the registered office at least five days before the date of the meeting; or (2) at our initiative.

The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, the other extraordinary, held on the same day or within a period of 15 days.

Any shareholder may vote by correspondence by means of a voting form, which is sent by us (1) upon request, addressed in writing (this request must be received at the registered office at least six days before the date of the meeting); or (2) at our initiative; or (3) in appendix to a proxy voting form under the conditions provided for by current laws and requirements. In any case this voting form is available on our website at least 21 days before the date of the meeting.

The voting by correspondence form addressed by a shareholder is only valid for a single meeting or for successive meetings convened with the same agenda.

Notice of Annual Shareholders' Meetings. Shareholders' meetings are convened by our board of directors, or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances. Meetings are held at our registered offices or at any other location indicated in the convening notice. A convening notice is published in the French Journal of Mandatory Statutory Notices (*Bulletin des Annonces Légales Obligatoires (BALO)*) at least 35 days prior to a meeting, as well as on our website at least 21 days prior to the meeting. In addition to the particulars relative to the company, it indicates, notably, the meeting's agenda and the draft resolutions that will be presented. The requests for recording of issues or draft resolutions on the agenda must be addressed to the company under the conditions provided for in the current legislation.

Subject to special legal provisions, the meeting notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the French Journal of Mandatory Statutory Notices (BALO). Further, the holders of registered shares for at least a month at the time of the latest of the insertions of the notice of meeting shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. The latter may at any time expressly request by registered letter to the Company with acknowledgment of receipt that the aforementioned means of telecommunication should be replaced in the future by a mailing.

The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.

The convening notice may be addressed, where appropriate, with a proxy form and a voting by correspondence form, under the conditions specified in our bylaws, or with a voting by correspondence form alone, under the conditions specified in our bylaws. When the shareholders' meeting cannot deliberate due to the lack of the required quorum, the second meeting must be called at least ten days in advance in the same manner as used for the first notice.

Agenda and Conduct of Annual Shareholders' Meetings. The agenda of the shareholders' meeting shall appear in the notice to convene the meeting and is set by the author of the notice. The shareholders' meeting may only deliberate on the items on the agenda except for the removal of directors and the appointment of their successors which may be put to vote by any shareholder during any shareholders' meeting. One or more shareholders representing a percentage of share capital required by French law, and acting in accordance with legal requirements and within applicable time limits, may request the inclusion of items or proposed resolutions on the agenda.

Shareholders' meetings shall be chaired by the Chairman of the board of directors or, in his or her absence, the meeting itself shall elect a Chairman. Vote counting shall be performed by the two members of the meeting who are present and accept such duties, who represent, either on their own behalf or as proxies, the greatest number of votes.

Ordinary Shareholders' Meeting. Ordinary shareholders' meetings are those meetings called to make any and all decisions that do not amend our by-laws. An ordinary meeting shall be convened at least once a year within six months of the end of each fiscal year in order to approve the annual and consolidated accounts for the relevant fiscal year or, in case of postponement, within the period established by court order. Upon first notice, the meeting may validly deliberate only if the shareholders present or represented by proxy or voting by mail, by videoconference or by means of telecommunication (to the extent the board of directors authorizes it when convening the shareholders) represent at least one-fifth of the shares entitled to vote. Upon second notice, no quorum is required. Decisions are made by a majority of the votes held by the shareholders present, or represented by proxy, or voting by mail, by videoconference or by means of telecommunications (to the extent the board of directors authorizes it when convening the shareholders). Pursuant to the French Law n° 2019-744, dated July 19, 2019, abstention from voting, blank votes or null votes by those present or those represented by proxy or voting by email are no longer counted as votes against the resolution submitted to a shareholder vote at any type of meeting.

Extraordinary Shareholders' Meeting. Only an extraordinary shareholders' meeting is authorized to amend our by-laws. It may not, however, increase shareholder commitments without the approval of each shareholder. Subject to the legal provisions governing share capital increases from reserves, profits or share premiums, the resolutions of the extraordinary meeting shall be valid only if the shareholders present, represented by proxy or voting by mail, by videoconference or by means of telecommunication (to the extent the board of directors authorizes it when convening the shareholders) represent at least one-fourth of all shares entitled to vote upon first notice, or one-fifth upon second notice. If the latter quorum is not reached, the second meeting may be postponed to a date no later than two months after the date for which it was initially called. Decisions are made by a two-thirds majority of the votes held by the shareholders present, represented by proxy, or voting by mail, by videoconference or by means of telecommunication (to the extent the board of directors authorizes it when convening the shareholders). Pursuant to the French Law n° 2019-744, dated July 19, 2019, abstention from voting, blank votes or null votes by those present or those represented by proxy or voting by email are no longer counted as votes against the resolution submitted to a shareholder vote at any type of meeting.

Adaptation of the rules of meeting and deliberations of general meetings due to the COVID-19 pandemic. Article 4 of Order no. 2020-321 of March 25, 2020, Adapting the Rules for Meetings and Deliberations of the Meetings and Governing Bodies of French Legal Entities and Entities without Legal Personality under Private Law due to the COVID-19 Epidemic, as amended by Article 2 of Order no. 2020-1497 of December 2, 2020, provides that the Shareholders' Meeting may exceptionally be held "behind closed doors" without the shareholders and other persons entitled to attend being physically present. These provisions are applicable until April 1, 2021.

Mechanisms for Delaying, Deferring or Preventing a Change in Control of the Company

Provisions contained in our Articles of Association and/or French corporate law could make it more difficult for a third party to acquire us, even if doing so might be beneficial to our shareholders. In addition, provisions of our bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to effect certain corporate actions. These provisions include the following:

- under French law, the owner of 90% of voting rights of a public company listed on a regulated market in a Member State of the European Union or in a state party to the European Economic Area, or EEA, Agreement, including France, has the right to force out minority shareholders following a tender offer made to all shareholders;

- under French law, a non-resident of France as well as any French entity controlled by non-French residents may have to file an administrative notice with French authorities in connection with a direct or indirect investment in us, as defined by administrative rulings;

- a merger (*i.e.*, in a French law context, a stock for stock exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of our board of directors as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;

- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;

- our shareholders have granted and may grant in the future our board of directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities, such as warrants, to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our shares;

- our shareholders have preferential subscription rights on a pro rata basis on the issuance by us of any additional securities for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;

- our board of directors has the right to appoint directors to fill a vacancy created by the resignation or death of a director, for the remaining duration of such director's term of office, provided that prior to such decision of the board of directors, the number of directors remaining in office exceeds the minimum required by law and by the bylaws, and subject to the subsequent approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our board of directors;

- our board of directors can be convened by our chairman (directly or upon request of our managing director), or, when no board meeting has been held for more than three consecutive months, by directors representing at least one third of the total number of directors;

- our board of directors meetings can only be regularly held if at least half of the directors attend either physically or by way of videoconference or teleconference enabling the directors' identification and ensuring their effective participation in the board's decisions;

- our shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice;

- under French law, certain investments in any entity governed by French law relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France or controlled by entities not French or not resident in France are subject to prior authorization of the Ministry of Economy;

- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove directors with or without cause;

- advance notice is required for nominations to the board of directors or for proposing matters to be acted upon at a shareholders' meeting, except that a vote to remove and replace a director can be proposed at any shareholders' meeting without notice;

- our bylaws can be changed in accordance with applicable laws;

- the crossing of certain thresholds has to be disclosed and can impose certain obligations;

- transfers of shares shall comply with applicable insider trading rules and regulations and, in particular, with the Market Abuse Directive and Regulation dated April 16, 2014; and

- pursuant to French law, our bylaws, including the sections relating to the number of directors and election and removal of a director from office, may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

Declaration of Crossing of Ownership Thresholds

Set forth below is a summary of certain provisions of our articles of association and of the French Commercial Code applicable to us. This summary is not intended to be a complete description of applicable rules under French law.

Our articles of association provide that any individual or legal entity coming to directly or indirectly own, alone or in concert, a number of shares representing a fraction of our capital or voting rights equal to 5%, 10%, 15%, 20%, 25%, 30%, 33.33%, 50%, 66.66%, 90% or 95% inform us of the total number of shares and voting rights and of securities giving access to the capital or voting rights that it owns immediately or over time, within a period of four trading days from the crossing of the said holding thresholds.

This obligation also applies under the same conditions when crossing each of the above-mentioned thresholds in a downward direction.

In case of failure to declare, shares or voting rights exceeding the fraction that should have been declared are deprived of voting rights at General Meetings of Shareholders for any meeting that would be held until the expiry of a period of two years from the date of regularization of the notification in accordance with Article L. 233-14 of the French Commercial Code, if the failure to declare has been determined.

These requirements are without prejudice to the threshold crossing declarations provided for under French law which impose a declaration to us and to the AMF upon crossing of the following thresholds no later than the Fourth trading day following the crossing: 50% and 95% of the capital or voting rights.

Further, and subject to certain exemptions, any shareholder crossing, alone or acting in concert, the 50% threshold shall file a mandatory public tender offer.

Changes in Share Capital

Increases in Share Capital. Pursuant to French law, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The shareholders may delegate to our board of directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital.

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; and
- exercising the rights attached to securities giving access to the share capital.

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; and
- subject to certain conditions, by way of offset against debt incurred by us.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings.

Reduction in Share Capital. Pursuant to French law, any reduction in our share capital requires shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our board of directors. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

Preferential Subscription Right. According to French law, if we issue additional securities for cash, current shareholders will have preferential subscription rights to these securities on a *pro rata* basis. Preferential subscription rights entitle the individual or entity that holds them to subscribe *pro rata* based on the number of shares held by them to the issuance of any securities increasing, or that may result in an increase of, our share capital by means of a cash payment or a set-off of cash debts. The preferential subscription rights are transferable during the subscription period relating to a particular offering. Since October 1, 2016, preferential subscription rights may only be exercised two business days prior to the day on which the subscription is opened until the second business day prior to its closing. Thus, the preferential subscription rights are transferable during the same period as their period of exercise. In accordance with French law, the period of exercise shall be no less than five business days.

The preferential subscription rights with respect to any particular offering may be waived at an extraordinary general meeting by a two-thirds vote of our shareholders or individually by each shareholder. Our board of directors and our independent auditors are required by French law to present reports to the shareholders' meeting that specifically address any proposal to waive the preferential subscription rights.

In the future, to the extent permitted under French law, we may seek shareholder approval to waive preferential subscription rights at an extraordinary general shareholders' meeting in order to authorize the board of directors to issue additional shares and/or other securities convertible or exchangeable into shares.

Form, Holding and Transfer of Shares

Form of Shares. The shares are nominative or bearer, if the legislation so permits, according to the shareholder's choice.

Further, in accordance with applicable laws, we may request at any time from the central depository responsible for holding our Shares, the information referred to in Article L. 228-2 of the French Commercial Code. Thus, we are, in particular and at any time, entitled to request the name and year of birth or, in the case of a legal entity, the name and the year of incorporation, nationality and address of holders of securities conferring immediate or long-term voting rights at its General Meetings of Shareholders and the amount of securities owned by each of them and, where applicable, the restrictions that the securities could be affected by.

Holding of Shares. In accordance with French law concerning the "dematerialization" of securities, the ownership rights of shareholders are represented by book entries instead of share certificates. Shares issued are registered in individual accounts opened by us or any authorized intermediary, in the name of each shareholder and kept according to the terms and conditions laid down by the legal and regulatory provisions.

Ownership of Shares by Non-French Persons. Neither French law nor our articles of association limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, (a) any non-French citizen, (b) any French citizen not residing in France, (c) any non-French entity or (d) any French entity controlled by one of the aforementioned persons or entities may have to file a declaration for statistical purposes with the Bank of France (Banque de France) within twenty working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. In particular, such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold. Violation of this filing requirement may be sanctioned by five years of imprisonment and a fine of up to twice the amount of the relevant investment. This amount may be increased fivefold if the violation is made by a legal entity.

Moreover, under French law, certain investments in any entity governed by a French law relating to certain strategic industries (such as research and development in biotechnologies and activities relating to public health) and activities by individuals or entities not French, not resident in France or controlled by entities not French or not resident in France are subject to prior authorization of the Ministry of Economy.

Assignment and Transfer of Shares. Shares are freely negotiable, subject to applicable legal and regulatory provisions. French law notably provides for standstill obligations and prohibition of insider trading.

Registration Rights

None of our security holders possess registration rights.

Differences in Corporate Law

The laws applicable to French *sociétés anonymes* differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the French Commercial Code applicable to us and the Delaware General Corporation Law relating to shareholders' rights and protections.

	France	**Delaware**
Number of Directors	Under French law, a *société anonyme* must have at least three and may have up to 18 directors. The number of directors is fixed by or in the manner provided in the by-laws.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the by-laws.
Director Qualifications	Under French law, a corporation may prescribe qualifications for directors under its by-laws. In addition, under French law, members of a board of directors of a corporation may be legal entities (with the exception of the Chairman of the board of directors), and such legal entities may designate an individual to represent them and to act on their behalf at meetings of the board of directors.	Under Delaware law, a corporation may prescribe qualifications for directors under its certificate of incorporation or by-laws.
Removal of Directors	Under French law, directors may be removed from office, with or without cause, at any shareholders' meeting without notice or justification, by a simple majority vote of the shareholders present and voting at the meeting in person or by proxy.	Under Delaware law, unless otherwise provided in the certificate of incorporation, directors may be removed from office, with or without cause, by a majority stockholder vote, though in the case of a corporation whose board is classified, stockholders may effect such removal only for cause.
Vacancies on the Board of Directors	Under French law, vacancies on the board of directors resulting from death or a resignation, provided that at least three directors remain in office, may be filled by a majority of the remaining directors pending ratification by the shareholders by the next shareholders' meeting.	Under Delaware law, vacancies on a corporation's board of directors, including those caused by an increase in the number of directors, may be filled by a majority of the remaining directors.
Annual General Meeting	Under French law, the annual general meeting of shareholders shall be held at such place, on such date and at such time as decided each year by the board of directors and notified to the shareholders in the convening notice of the annual meeting, within six months after the close of the relevant fiscal year unless such period is extended by court order.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the by-laws.

	France	**Delaware**
General Meeting	Under French law, general meetings of the shareholders may be called by the board of directors or, failing that, by the statutory auditors, or by a court appointed agent or liquidator in certain circumstances, or by the majority shareholder in capital or voting rights following a public tender offer or exchange offer or the transfer of a controlling block on the date decided by the board of directors or the relevant person.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the by-laws.
Notice of General Meetings	A convening notice is published in the French Journal of Mandatory Statutory Notices (BALO) at least 35 days prior to a meeting and made available on the website of the company at least 21 days prior to the meeting. Subject to special legal provisions, the meeting notice is sent out at least 15 days prior to the date of the meeting, by means of a notice inserted both in a legal announcement bulletin of the registered office department and in the French Journal of Mandatory Statutory Notices (BALO). Further, the holders of registered shares for at least a month at the time of the latest of the insertions of the notice of meeting shall be summoned individually, by regular letter (or by registered letter if they request it and include an advance of expenses) sent to their last known address. This notice may also be transmitted by electronic means of telecommunication, in lieu of any such mailing, to any shareholder requesting it beforehand by registered letter with acknowledgment of receipt in accordance with legal and regulatory requirements, specifying his e-mail address. The convening notice must also indicate the conditions under which the shareholders may vote by correspondence and the places and conditions in which they can obtain voting forms by mail.	Under Delaware law, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.

	France	Delaware
	The notice must specify the name of the company, its legal form, share capital, registered office address, registration number with the French Registry of Commerce and Companies (registre du commerce et des sociétés), the place, date, hour and agenda of the meeting and its nature (ordinary and/or extraordinary meeting).	
Proxy	Each shareholder has the right to attend the meetings and participate in the discussions (i) personally, or (ii) by granting proxy to any individual or legal entity of his choosing; or (iii) by sending a proxy to the company without indication of the mandate, or (iv) by voting by correspondence, or (v) by videoconference or another means of telecommunication in accordance with applicable laws that allow identification. The proxy is only valid for a single meeting or for successive meetings convened with the same agenda. It can also be granted for two meetings, one ordinary, the other extraordinary, held on the same day or within a period of 15 days.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period.
Shareholder action by written consent	Under French law, shareholders' action by written consent is not permitted in a *société anonyme.*	Under Delaware law, a corporation's certificate of incorporation (1) may permit stockholders to act by written consent if such action is signed by all stockholders, (2) may permit stockholders to act by written consent signed by stockholders having the minimum number of votes that would be necessary to take such action at a meeting or (3) may prohibit actions by written consent.
Preemptive Rights	Under French law, in case of issuance of additional shares or other securities for cash or set-off against cash debts, the existing shareholders have preferential subscription rights to these securities on a pro rata basis unless such rights are waived by a two-thirds majority of the votes held by the shareholders present at the extraordinary meeting deciding or authorizing the capital increase, voting in person or represented by proxy or voting by mail. In case such rights are not waived by the extraordinary general meeting, each stockholder may individually either exercise, assign or not exercise its preferential rights.	Under Delaware law, unless otherwise provided in a corporation's certificate of incorporation, a stockholder does not, by operation of law, possess preemptive rights to subscribe to additional issuances of the corporation's stock.

	France	**Delaware**
Sources of Dividends	Under French law, dividends may only be paid by a French *société anonyme* out of "*distributable profits*," plus any distributable reserves and "*distributable premium*" that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law. "*Distributable profits*" consist of the unconsolidated net profits of the relevant corporation for each fiscal year, as increased or reduced by any profit or loss carried forward from prior years. "*Distributable premium*" refers to the contribution paid by the stockholders in addition to the par value of their shares for their subscription that the stockholders decide to make available for distribution. Except in case of a share capital reduction, no distribution can be made to the stockholders when the net equity is, or would become, lower than the amount of the share capital plus the reserves which cannot be distributed in accordance with the law or the by- laws. Since October 1, 2016, preferential subscription rights may only be exercised two business days prior to the day on which the subscription is opened until the second business day prior to its closing. Thus, the preferential subscription rights are transferable during the same period as their period of exercise. In accordance with French law, the period of exercise shall be no less than 5 business days.	Under Delaware law, dividends may be paid by a Delaware corporation either out of (1) surplus or (2) in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year, except when the capital is diminished by depreciation in the value of its property, or by losses, or otherwise, to an amount less than the aggregate amount of capital represented by issued and outstanding stock having a preference on the distribution of assets.

	France	Delaware
Repurchase of Shares	Under French law, a corporation may acquire its own shares. Such acquisition may be challenged on the ground of market abuse regulations. However, the Market Abuse Regulation 596/2014 of April 16, 2014 (MAR) provides for safe harbor exemptions when the acquisition is made for the following purposes only: • to decrease its share capital, provided that such decision is not driven by losses and that a purchase offer is made to all shareholders on a pro rata basis, with the approval of the shareholders at the extraordinary general meeting deciding the capital reduction; • with a view to distributing within one year of their repurchase the relevant shares to employees or managers under a profit- sharing, free share or share option plan; • to meet obligations arising from debt securities that are exchangeable into equity instruments; or • under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and in accordance with the general regulations of the Financial Markets Authority (AMF). A simple exemption is provided when the acquisition is made under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and in accordance with the General Regulations of the Financial Markets Authority (AMF). A simple exemption is provided when the acquisition is made under a buy-back program to be authorized by the shareholders in accordance with the provisions of Article L. 22-10-62 of the French Commercial Code and in accordance with the General Regulations of the Financial Markets Authority (AMF). No such repurchase of shares may result in the company holding, directly or through a person acting on its behalf, more than 10% of its issued share capital.	Under Delaware law, a corporation may generally redeem or repurchase shares of its stock unless the capital of the corporation is impaired or such redemption or repurchase would impair the capital of the corporation.

	France	**Delaware**
Liability of Directors and Officers	Under French law, the directors and the officers are individually or jointly and severally liable, as the case may be, to the company or to third parties, either for breaches of the laws or regulations applicable to *société anonyme*, or for breaches of the Articles of Association, or for misconduct in their management. In addition, French law provides for cases of criminal liability of the directors and officers. The by-laws may not include any provisions limiting the liability of directors.	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	French law provides that, unless otherwise provided in the by-laws, each shareholder is entitled to one vote for each share of capital stock held by such shareholder.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.
Shareholder Vote on Certain Transactions	Generally, under French law, completion of a merger, dissolution, sale, lease or exchange of all or substantially all of a corporation's assets requires: • the approval of the board of directors; and • approval by a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting.	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

	France	Delaware
Dissent or Dissenters Appraisal Rights	French law does not provide for any such right but provides that a merger is subject to shareholders' approval by a two-thirds majority vote as stated above.	Under Delaware law, a holder of shares of any class or series has the right, in specified circumstances, to dissent from a merger or consolidation by demanding payment in cash for the stockholder's shares equal to the fair value of those shares, as determined by the Delaware Chancery Court in an action timely brought by the corporation or a dissenting stockholder. Delaware law grants these appraisal rights only in the case of mergers or consolidations and not in the case of a sale or transfer of assets or a purchase of assets for stock. Further, no appraisal rights are available for shares of any class or series that is listed on a national securities exchange or held of record by more than 2,000 stockholders, unless the agreement of merger or consolidation requires the holders to accept for their shares anything other than: • shares of stock of the surviving corporation; • shares of stock of another corporation that are either listed on a national securities exchange or held of record by more than 2,000 stockholders; • cash in lieu of fractional shares of the stock described in the two preceding bullet points; or • any combination of the above. In addition, appraisal rights are not available to holders of shares of the surviving corporation in specified mergers that do not require the vote of the stockholders of the surviving corporation.
Standard of Conduct for Directors	French law does not contain specific provisions setting forth the standard of conduct of a director. However, directors have a duty to act without self-interest, on a well-informed basis and they cannot make any decision against a corporation's corporate interest (*intérêt social*).	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well- informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

	France	**Delaware**
Shareholder Suits	The plaintiff must remain a shareholder through the duration of the legal action. There is no other case where shareholders may initiate a derivative action to enforce a right of a corporation. A shareholder may alternatively or cumulatively bring individual legal action against the directors, provided he has suffered distinct damages from those suffered by the corporation. In this case, any damages awarded by the court are paid to the relevant shareholder.	Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must: • state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and • allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or • state the reasons for not making the effort. • Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.
Amendment of Certificate of Incorporation	Under French law, any modification of the information reflected on the certificate of incorporation at the time of registration (i.e. legal form, registered office, share capital, year-end, company's name, directors, statutory auditors) must be filed with the French Registry of Commerce and Companies.	Under Delaware law, generally a corporation may amend its certificate of incorporation if: • its board of directors has adopted a resolution setting forth the amendment proposed and declared its advisability; and • the amendment is adopted by the affirmative votes of a majority (or greater percentage as may be specified by the corporation) of the outstanding shares entitled to vote on the amendment and a majority (or greater percentage as may be specified by the corporation) of the outstanding shares of each class or series of stock, if any, entitled to vote on the amendment as a class or series.

	France	**Delaware**
Amendment of By-laws	Under French law, only the extraordinary shareholders' meeting is authorized to adopt or amend the by-laws.	Under Delaware law, the stockholders entitled to vote have the power to adopt, amend or repeal by-laws. A corporation may also confer, in its certificate of incorporation, that power upon the board of directors.

Legal Name; Formation; Fiscal Year; Registered Office

Our legal and commercial name is Biophytis S.A. We were incorporated as a *société par actions simplifiée* under the laws of the French Republic on September 27, 2006 for a period of 99 years expiring on September 26, 2105, unless dissolved in advance or extended. The Company was transformed into a *société anonyme* on May 22, 2015. We are registered at the Paris Commerce and Companies Register under the number 492 002 225. Our principal executive offices are located at Sorbonne University—BC 9, Bâtiment A 4ème étage, 4 place Jussieu 75005 Paris, France and our telephone number is +33 1 44 27 23 00. Our registered office is 14, Avenue de l'Opéra, Paris, France. Our website address is *www.biophytis.com*. Our agent for service of process in the United States is Puglisi & Associates. Our fiscal year ends December 31.

II. AMERICAN DEPOSITARY SHARES

American Depositary Shares

The Bank of New York Mellon, as depositary, registers and delivers ADSs. Each ADS represents 10 ordinary shares (or a right to receive 10 ordinary shares) deposited with Societe Generale, as custodian for the depositary in France. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

An ADS holder may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in the ADS holder's name, or (ii) by having uncertificated ADSs registered in the ADS holder's name, or (B) indirectly by holding a security entitlement in ADSs through the ADS holder's broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If an ADS holder hold ADSs directly, he or she is a registered ADS holder. If an investor holds the ADSs indirectly, the investor must rely on the procedures of his or her broker or other financial institution to assert the rights of ADS holders described in this section.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

ADS holders will not be treated as shareholders and ADS holders will not have shareholder rights. French law governs shareholder rights. The depositary will be the holder of the shares underlying the ADSs. As a registered holder of ADSs, the ADS holders will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement.

Dividends and Other Distributions

How will ADS holders receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. ADS holders will receive these distributions in proportion to the number of shares the ADSs represent.

Distributions of Cash

The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, ADS holders may lose some of the value of the distribution.*

Distributions of Shares

The depositary may, and will if the company so requests in writing, distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Distribution of Rights

If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, ADS holders will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions

The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to ADS holders*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

ADS holders may surrender ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at the ADS holder's request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge ADS holders a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

ADS holders may surrender their ADR to the depositary for the purpose of exchanging their ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do ADS holders vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit ADS holders' voting instructions (and we are not required to do so), the depositary will notify the ADS holders of a shareholders' meeting and send or make voting materials available to them. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of France and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit voting instructions from our ADS holders, ADS holders may still send voting instructions, and, in that case, the depositary may try to vote as instructed, but it is not required to do so.

Except by instructing the depositary as described above, ADS holders won't be able to exercise voting rights unless they surrender their ADSs and withdraw the shares. However, ADS holders may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit voting instructions at least 45 days before the meeting date, (ii) the depositary does not receive voting instructions from the ADS holder by the specified date and (iii) we confirm in writing to the depositary that:

- we wish to receive a proxy to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider the ADS holder to have instructed it to give, and it will give, a discretionary proxy to a person designated by us to vote the number of deposited securities represented by the ADS holder's ADSs as to that question.

We cannot assure ADS holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that ADS holders may not be able to exercise voting rights and there may be nothing they can do if their shares are not voted as requested.*

In order to give ADS holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 45 days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to ADS holder had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when the ADS holder deposits or withdraws shares
Expenses of the depositary	Cable (including SWIFT) and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates, or the custodian or we may convert currency and pay U.S. dollars to the depository. Where the depository converts currency itself or through any of its affiliates, the depository acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained by it or its affiliates in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligation under to act without negligence or bad faith. The methodology used to determine exchange rates used in currency made by the depositary is available upon request. Where the custodian converts currency, the custodian has no obligation to obtain the most favorable rate that could be obtained at the time or to ensure that the method by which that rate will be determined will be the most favorable to ADS holders, and the depositary makes no representation that the rate is the most favorable rate and will not be liable for any direct or indirect losses associated with the rate. In certain instances, the depositary may receive dividends or other distributions in U.S. dollars that represent the proceeds of a conversion of foreign currency or translation from foreign currency at a rate that was obtained or determined by us and, in such cases, the depositary will not engage in, or be responsible for, any foreign currency transactions and neither it nor we make any representation that the rate obtained or determined by us is the most favorable rate and neither it nor we will be liable for any direct or indirect losses associated with the rate.

Payment of Taxes

ADS holders will be responsible for any taxes or other governmental charges payable on the ADSs or on the deposited securities represented by any of the ADSs. The depositary may refuse to register any transfer of the ADSs or allow ADS holders to withdraw the deposited securities represented by the ADSs until those taxes or other charges are paid. It may apply payments owed to ADS holders or sell deposited securities represented by the ADSs to pay any taxes owed and the ADS holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides, after consultation with the company to the extent practicable, it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask ADS holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without the ADS holders' consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, ADS holders are considered, by continuing to hold ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.*

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, *but*, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
- are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on the ADS holder's behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depositary has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit. In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Right to Receive the Shares Underlying ADSs

ADS holders have the right to cancel the ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;

- when the ADS holder owes money to pay fees, taxes and similar charges; or

- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertifiated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register the transfer.

In connection with an in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for ADS holders' inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send ADS holders copies of those communications or otherwise make those communications available to them if they ask it to. ADS holders have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

Jury Trial Waiver

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. By agreeing to the jury trial waiver provision in the deposit agreement, ADS holders will not be deemed to have waived our compliance with or the depositary's compliance with the federal securities laws and the rules and regulations promulgated thereunder.

Listing

The ADSs are listed on the Nasdaq Capital Market under the symbol “BPTS.” Our ordinary shares are currently listed on Euronext Growth Paris under the symbol “ALBPS.”

Transfer Agent and Registrar

The transfer agent and registrar for the ADSs is Computershare, Inc. Our share register is currently maintained by CACEIS Corporate Trust, 1-3 place Valhubert, 75013 Paris, registered under n°439 430 976. The share register reflects only record owners of our ordinary shares. Holders of ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying the ADSs. Holders of the ADSs have a right to receive the ordinary shares underlying the ADSs.

Exhibit 12.1

Certification by the Principal Executive Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Stanislas Veillet, certify that:

1. I have reviewed this annual report on Form 20-F of BIOPHYTIS S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March ___, 2021

Name: Stanislas Veillet
Title: Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 12.2

Certification by the Principal Financial Officer pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a)
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Evelyne Nguyen, certify that:

1. I have reviewed this annual report on Form 20-F of BIOPHYTIS S.A.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March ___, 2021

Name: Evelyne Nguyen
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 13.1

Certification by the Principal Executive Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of BIOPHYTIS S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stanislas Veillet, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March __, 2021

Name: Stanislas Veillet
Title: Chief Executive Officer and Chairman
(*Principal Executive Officer*)

Exhibit 13.2

Certification by the Principal Financial Officer pursuant to
18 U.S.C. Section 1350, as adopted pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of BIOPHYTIS S.A. (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Evelyne Nguyen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March __, 2021

Name: Evelyne Nguyen
Title: Chief Financial Officer
(*Principal Financial Officer*)