



AMENDMENT TO THE 2023 UNIVERSAL REGISTRATION DOCUMENT ABIVAX



This amendment to the universal registration document was filed on September 29, 2023 with the *Autorité des marchés financiers* (“**AMF**”), in its capacity as competent authority under Regulation (EU) 2017/1129, without prior approval in accordance with Article 9 of said Regulation.

The universal registration document may be used for the purposes of a public offering of financial securities or the admission of financial securities to trading on a regulated market if it is supplemented by a securities note and, where applicable, a summary and any amendments to the universal registration document. The whole then formed is approved by the AMF in accordance with Regulation (EU) 2017/1129.

This amendment (the “**Amendment**”) updates and should be read in conjunction with the 2023 universal registration document filed with the AMF on May 4th, 2023 (the “**2023 Universal Registration Document**”). This amendment includes and should be read in conjunction with the Company’s interim consolidated financial report as of and for the six months ended June 30, 2023, published on September 29, 2023.

The 2023 Universal Registration Document and this Amendment are available free of charge from Abivax, on the company’s website (www.abivax.com) and on the website of the AMF (www.amf-france.org).

GENERAL COMMENTS

Definitions

In this Amendment, and unless otherwise stated:

- the terms "Company" or "Abivax" refer to Abivax, headquartered at 7/11, boulevard Haussmann, 75009 Paris, registered in the Paris Trade and Corporate Register under number 799 363 718;
- the term "Group" refers to the group of companies formed by the Company and its subsidiary, Abivax, LLC;
- the terms "we", "us" or "our" refer to the Company or the Group, as appropriate.

Disclaimer

Market and competition information

This Amendment includes, in particular in Section 4 "Overview of Activities", information relating to the Group's markets and its competitive position. This information comes in particular from studies carried out by external sources. Publicly available information, which the Company considers reliable, has not been verified by an independent expert, and the Company cannot guarantee that a third party using different methods to collect, analyze or calculate data on these markets would achieve the same results.

Forward-looking information

This Amendment and the 2023 Universal Registration Document contain information on the Group's prospects and development strategy. These indications are sometimes identified by the use of the future, conditional or forward-looking terms such as "consider," "anticipate", "think," "aim," "expect," "intend," "must," "ambition," "estimate," "believe," "wish," "may" or, as the case may be, the negative form of those same terms, or any other similar variation or terminology. This information is not historical data and should not be construed as guarantees that the stated facts and data will occur. This information is based on data, assumptions and estimates considered to be reasonable by the Company. It is subject to change or modification due to uncertainties related in particular to the economic, financial, competitive or regulatory environment. This information is mentioned in various chapters of this Amendment and contains data on the Group's intentions, estimates and objectives concerning, in particular, the market in which it operates, its strategy, growth, results, financial position, cash flow and forecasts. The forward-looking information mentioned in this Amendment is given only as of the date of this Amendment. The Group operates in a competitive and ever-changing environment. It therefore cannot anticipate any risks, uncertainties or other factors that could affect its business, their potential impact on its business or the extent to which the materialization of a risk or combination of risks could have significantly different results from those mentioned in any forward-looking information, it being recalled that none of this forward-looking information constitutes a guarantee of actual results.

Risk factors

Investors are encouraged to carefully read the risk factors described in Section 3 "Risk Factors" of the 2023 Universal Registration Document, as amended by Section 5 of this Amendment, before making any investment decision. The realization of some or all of these risks could have a significant adverse effect on the Group's business, financial situation, results or future prospects. In addition, other risks, not yet identified or considered insignificant by the Company as of the date of this Amendment, could also have a significant adverse effect.

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1. PERSONS RESPONSIBLE FOR UPDATING THE UNIVERSAL REGISTRATION DOCUMENT

1.1 Identity of the person responsible for updating the Universal Registration Document

Marc de Garidel, Chairman and CEO (*Président Directeur Général*).

1.2 Statement by the person responsible for updating the Universal Registration Document

"I hereby certify that the information contained in this amendment is, to the best of my knowledge, in accordance with the facts and contains no omission likely to affect its import."

Paris, September 29, 2023

Marc de Garidel

Chairman and CEO (*Président Directeur Général*)

2. STATUTORY AUDITORS

Section 2.1. "Auditor" of the 2023 Universal Registration Document, is updated as follows:

Principal Statutory auditors:

PricewaterhouseCoopers Audit

Represented by Cédric Mazille

63, rue de Villiers, 92200 Neuilly-sur-Seine, France

Member of the Compagnie Régionale des Commissaires aux Comptes de Versailles et du Centre (Versailles and Centre Regional Association of Statutory Auditors).

Start date of initial term of office: appointed upon the incorporation of the Company on 4 December 2013.

Term of office: six financial years from the renewal of its mandate by the Annual General Meeting of Shareholders on June 7, 2019.

Expiry date of the current term of office: after the Annual General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2024.

The statutory auditors' schedule of fees appears in Note 16 of Section 18.1 of the 2023 Universal Registration Document.

Agili(3f)

Represented by Sylvain Boccon Gibod

69 boulevard des Canuts, 69004 Lyon

Member of the Compagnie Régionale des Commissaires aux Comptes de Lyon - Riom (Lyon - Riom Regional Association of Statutory Auditors).

Start date of initial term of office: appointed by the Annual General Meeting of Shareholders on June 5, 2023.

Term of office: six financial years from its appointment.

Expiry date of the current term of office: after the Annual General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2028.

Alternate statutory auditor: None."

3. RECENT SIGNIFICANT EVENTS

The main developments in the Group’s activities since the filing of the 2023 Universal Registration Document are presented in the press releases whose main content is set out below in this Chapter 2. The ensuing Chapters present the corresponding amendments to the various relevant chapters and sections of the 2023 Universal Registration Document.

In August 2023 and as further detailed in Section 3.7 below, the Company announced that it planned to conduct a registered public offering of its ordinary shares, in the form of American Depositary Shares (ADSs), in the United States subject to market and other conditions.

In this regard, the Company has filed and made public, on the date of this Amendment, a registration statement on Form F-1 with the U.S. Securities and Exchange Commission related to the offering of its ADSs in the United States and their listing on the NASDAQ Global Market. A placement of its ordinary shares will be conducted concomitantly in Europe and other countries outside of the United States. The timing, the number of securities to be sold and the price range for the proposed offering have not yet been determined.

In September 2023 and as further detailed in Section 3.10 below, the Company announced updated business and operational goals along with changes to the Company’s overall strategy, focused on preparing the Company for the potential commercialization of its investigational lead asset, obefazimod, in inflammatory bowel diseases (“IBD”).

As a result, the Company’s product pipeline has been updated as follows:

Drug Candidate	Regimen	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones	
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT) Initiated First Patient Enrolled in the US on Oct. 11, 2022						<ul style="list-style-type: none"> Induction trial topline data readout in Q1 2025 Maintenance trial topline data readout in Q1 2026
	Monotherapy	Crohn’s Disease (CD)	Phase 2a Trial Planned						<ul style="list-style-type: none"> IND filing expected in Q4 2023 Initiate Phase 2a trial in Q1 2024 (first patient in) Phase 2a induction topline results expected in 2H 2025
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)							<ul style="list-style-type: none"> Decision on combination agent expected in 2025¹
	Monotherapy	Other Inflammatory Indications							<ul style="list-style-type: none"> Declare indication for PoC trial in 2024

1. Decision subject to results of the Phase 3 monotherapy induction trials

The expected date for the induction trial topline data readout has been postponed from Q4 2024 to Q1 2025 due to longer than expected interactions with the European regulatory authorities prior to the launch of the Company’s phase 3 clinical program of obefazimod in ulcerative colitis in Europe. The Company does not expect this change to significantly alter the global calendar of development of obefazimod in ulcerative colitis.

With regards to the next steps for the development of obefazimod in Crohn’s disease, the Company decided to favor the conduct of a Phase 2a clinical trial instead of the conduct of a Phase 2b/3 clinical trial to gather additional proof of concept data prior to conducting more advanced clinical trials. At this stage, the Company does not expect this change in strategy to significantly alter the global cost nor calendar of development of obefazimod in Crohn’s disease.

The Company also decided to completely stop its ABX196 program as a result of significant external changes in the hepatocellular carcinoma treatment landscape and due to the lack of progress made in the negotiation of a development partnership.

3.1 Press release dated May 15, 2023

Under the terms of its press release dated May 15, 2023, Abivax announced that its ordinary and extraordinary general meeting would be held on June 5, 2023, at 10:00 am (CEST), at the offices of Dechert (Paris) LLP, located at 22 rue Bayard in Paris (75008), France.

The Shareholders' Meeting documents and information and the voting form have been made available to Shareholders under the terms and conditions specified by current French regulations, and are available on the Company's website. All documents are exclusively available in French.

3.2 Press release dated June 6, 2023

Under the terms of its press release dated June 6, 2023, Abivax announced the release of the results of its June 5, 2023, ordinary and extraordinary general meeting. The shareholders have adopted all the resolutions approved by the Board of Directors and, in particular, the financial statements for the 2022 financial year, the compensation policy applicable to the Chairman, the Chief Executive Officer and the directors, as well as delegations granted to the Board of Directors related to financial transactions. Shareholders also ratified the cooptation of Mr. Marc de Garidel as Board member and approved the appointment of Agili(3f) as co-statutory auditors for a period of six financial years.

Details on the vote results are available on the Company's website.

3.3 Press release dated June 6, 2023

Under the terms of its press release dated June 6, 2023, Abivax announced the appointment of Ida Hatoum as Chief People Officer. Ida will be responsible for Abivax's growth strategy in the United States and Europe, ensuring the appropriate staffing of the Company to successfully conduct the ongoing Phase 3 clinical program of obefazimod in ulcerative colitis as well as its subsequent commercialization and market access, provided the drug candidate obtains the required regulatory approvals. Ida will be based at Abivax's subsidiary on the US East Coast.

Ida Hatoum brings over 15 years of experience and a strong track record in talent acquisition and development and has occupied different People Operations leadership positions in the pharmaceutical and biotechnology industry. Prior to joining Abivax, Ida was Senior Vice President and Head of People Talent and Culture at CinCor Pharma, where she successfully managed and lead the recruitment strategy and organizational design of the Company during a period of strong growth. Ida holds a bachelor's in pharmacy from the University of Toledo, Ohio.

3.4 Press release dated June 8, 2023

Under the terms of its press release dated June 8, 2023, Abivax announced that, as of June 1st, the Abivax stock is represented in the MSCI Indexes. The MSCI Indexes reflect the evolution of the world's equity markets to support investors building effective portfolios based on risk and return assessments.

3.5 Press release dated June 15, 2023

Under the terms of its press release dated June 15, 2023, Abivax announced that it has received the "Capital Market Transaction of the Year Award" at the European Mediscience Awards 2023. Abivax received the award for its EUR 130M oversubscribed capital increase at market price in February 2023. The financing round was led by TCGX, with participation from existing investors such as Sofinnova Partners, Invus, Deep Track Capital, Venrock Healthcare Capital Partners, as well as from new investors such as Great Point Partners LLC, Deerfield Management Company, Commodore Capital, Samsara BioCapital, Boxer Capital and others.

3.6 Press release dated July 11, 2023

Under the terms of its press release dated July 11, 2023, Abivax announced the Appointment of June Lee, M.D. and Troy Ignelzi as Members of the Board of Directors.

In the frame of the new appointments, the composition of the Board's committees has been reviewed. The Audit Committee is comprised of three members: Troy Ignelzi (Chair), Corinna zur Bonsen-Thomas and Sofinnova Partners (represented by Kinam Hong). The Recruitment and Remuneration Committee is comprised of four members: June Lee (Chair), Corinna zur Bonsen-Thomas, Truffle Capital (represented by Philippe Pouletty) and Sofinnova Partners (represented by Kinam Hong).

June H. Lee, M.D. FACC, is a Venture Partner at 5AM Ventures. Dr. Lee is a physician-scientist with over 20 years in the biotechnology and pharmaceutical industry. Most recently, she was a Founder and CEO of Esker Therapeutics. She previously served as Executive Vice President, Chief Development Officer and Chief Operating Officer of MyoKardia where she built and led a world-class development organization that was acquired by Bristol Myers Squibb for USD 13.1 billion in November 2020. The lead program at MyoKardia, mavacamten, was recently approved by the FDA for use in obstructive hypertrophic cardiomyopathy patients as the first precision therapy in this indication. Prior to MyoKardia, Dr. Lee was a Professor of Medicine at the University of California, San Francisco (UCSF) School of Medicine, where she served as Director of Translational Research and built the Catalyst Program, an internal accelerator for early-stage technologies. As the therapeutic area head at Genentech, Dr. Lee led early clinical development programs in cardiovascular and metabolic diseases, infectious diseases, and respiratory diseases. Dr. Lee serves on numerous boards in the healthcare industry including the Board of Directors for Tenaya Therapeutics, Eledon Pharmaceuticals Inc. and GenEdit, and is a member of the Scientific Advisory Board for Foresite Labs. Dr. Lee has also served on the Advisory Board for Johns Hopkins University Center for Therapeutic Translation, and on the Board of Directors for CinCor Therapeutics, which was acquired by AstraZeneca for up to USD 1.8 billion in the first quarter of 2023. Dr. Lee received her undergraduate degree in chemistry at the Johns Hopkins University, earned her medical degree at the School of Medicine at University of California, Davis, and completed her clinical training in internal medicine and pulmonary and critical care at the University of California, Los Angeles (UCLA) and University of California, San Francisco (UCSF). Dr. Lee is based in the San Francisco, CA office.

Troy Ignelzi has extensive experience leading emerging and rapidly growing biopharmaceutical company finance and operations, including raising capital and building high-performing teams. He serves as the CFO of Karuna Therapeutics, where he is responsible for finance, including business support planning for the company's R&D and commercial preparation. In this role, Mr. Ignelzi has led Karuna's private and public financings, including multiple securities offerings, and developed the financial and operational business support infrastructure required for a public company. Before joining Karuna, Mr. Ignelzi was similarly successful at two other emerging biopharmaceutical companies, Esperion Therapeutics and scPharmaceuticals, where he led multiple private and public financings and developed the financial infrastructure and development strategies to support a public company and ensure long-term financial health. Earlier in his career, Mr. Ignelzi served in a variety of positions, including finance, business development and strategic planning, at Pharmalex, scPharmaceuticals, and Insys Therapeutics, as well as sales at Eli Lilly & Co. Mr. Ignelzi currently serves as the Chairman of the Board of Vedanta Biosciences and previously served as a member of the Board of Directors of CinCor Pharma (acquired by AstraZeneca). He earned his B.S. in Accounting at Ferris State University in Big Rapids, Michigan, U.S.

3.7 Press release dated August 10, 2023

Under the terms of its press release dated August 10, 2023, Abivax announced its plans to conduct a registered public offering of its ordinary shares, in the form of American Depositary Shares, in the

United States, subject to market and other conditions, and that it had confidentially submitted a draft registration statement on Form F-1 to the U.S. Securities and Exchange Commission. The timing, number of securities to be offered in the proposed offering and their price have not yet been determined.

3.8 Press release dated August 21, 2023

Under the terms of its press release dated August 21, 2023, Abivax announced that it has concurrently signed two structured debt financing transactions for a total amount of up to EUR 150M consisting of (i) up to EUR 75M from entities affiliated with Kreos Capital (“Kreos”) and Claret European Growth Capital (“Claret”) (the “Kreos / Claret Financing”) together with the issuance of warrants (*bons de souscription d’actions*) exercisable to receive up to EUR 8M worth of ordinary shares of the Company, par value of EUR 0.01 per share (“Ordinary Shares”), and (ii) up to EUR 75M from a fund advised by Heights Capital Management, Inc. (the “Heights Financing” and together with the Kreos / Claret Financing, the “Transaction”).

Overall Structure of the Transaction

The first tranches of the Kreos / Claret Financing and the Heights Financing, for EUR 25,000,000 and EUR 35,000,000, respectively, was expected to be drawn on or around August 22, 2023, and August 24, 2023, respectively, subject to satisfaction of customary closing conditions. In addition, the Company expected to concurrently grant to Kreos and Claret, for no additional consideration, warrants exercisable to receive to EUR 4,000,000 worth of Ordinary Shares. The subsequent tranches of the Kreos / Claret Financing and the Heights Financing are subject to certain conditions, as further set forth below.

As part of the Transaction, Abivax also repaid in full a total outstanding amount of EUR 32,762,852 under (i) the pre-existing debt agreements with Kreos for a total amount of EUR 7,660,993, and (ii) the pre-existing OCEANE bonds for a total amount of EUR 25,101,859 by way of set-off with the Heights Financing, thereby fully repaying such pre-existing indebtedness.

After giving effect to the repayment of EUR 32,762,852 of existing indebtedness, the net proceeds to Abivax from the first tranches of the Kreos / Claret Financing and the Heights Financing (once drawn on) were expected to be EUR 27,237,148 in total, consisting of EUR 17,339,007 from the Kreos / Claret Financing and EUR 9,898,141 from the Heights Financing.

The maximum proceeds from the Transaction (if all the tranches described below were drawn on), net of the refinancing of the existing indebtedness, were expected to be EUR 117,237,148 in total, consisting of EUR 67,339,007 for the Kreos / Claret Financing and EUR 49,898,141 for the Heights Financing.

Overall Structure of the Kreos / Claret Financing

The Kreos / Claret Financing consists of three tranches of EUR 25,000,000 each in aggregate principal amount. The first tranche in aggregate principal amount of EUR 25,000,000 takes the form of senior secured convertible bonds with warrants attached (the “Kreos / Claret OCABSA”) and was expected to be drawn on or around August 22, 2023, subject to satisfaction of customary closing conditions.

The second tranche in aggregate principal amount of EUR 25,000,000 takes the form of senior secured non-convertible bonds and may be drawn before March 31, 2024, subject to satisfaction of customary closing conditions. The drawdown of the second tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown. The “Debt-To-Market Capitalization Ratio” is calculated on any relevant date, by dividing (i) the indebtedness of Abivax (including amounts due under the

Kreos / Claret Financing but excluding amounts due under the Heights Financing), by (ii) the market capitalization of Abivax calculated by multiplying the number of outstanding Ordinary Shares by the closing price of the Ordinary Shares on such relevant date (“Market Capitalization”).

The third tranche in aggregate principal amount of EUR 25,000,000 takes the form of senior secured non-convertible bonds and may be drawn before July 31, 2024, subject to satisfaction of customary closing conditions. The drawdown of the third tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown (excluding the Heights Financing) and is conditional on Abivax raising a minimum of USD 125,000,000 in gross proceeds through a listing on Nasdaq before June 30, 2024.

The Kreos / Claret Financing provides for certain restrictive covenants (subject to customary exceptions) which include, among other things, restrictions on the incurrence of indebtedness, cross-default, the distribution of dividends and the grant of security interests. As security for the Kreos / Claret Financing, the lenders benefit from the grant of first-ranking collateral on Abivax’s principal tangible and intangible assets, including pledges over Abivax’s business (*fonds de commerce*) as a going concern and intellectual property rights in Abivax’s lead drug candidate, as well as pledges over Abivax’s bank accounts and receivables. Such securities apply to all tranches of the Kreos / Claret Financing.

As part of the Kreos / Claret Financing, both Kreos and Claret may receive, in addition to the Kreos / Claret OCABSA, warrants exercisable to receive Ordinary Shares valued at up to EUR 8,000,000 (in two tranches, the first – representing EUR 4,000,000 worth of Ordinary Shares – to be fully issued upon execution of the legal documentation and exercisable immediately, and the second – representing EUR 4,000,000 worth of Ordinary Shares – may be issued within 14 days of the date on which the conditions to draw the third tranche of non-convertible bonds of the Kreos / Claret Financing have been met, as described below).

The convertible bonds, the non-convertible bonds and the warrants of the Kreos / Claret Financing will not be listed on any market. The agreements relating to the Kreos / Claret Financing are governed by French law.

On the date of the press release, funds managed by Claret European Growth Capital did not hold any Ordinary Shares in Abivax and funds managed by Kreos held 99,583 Ordinary Shares in Abivax (representing approximately 0.23% of the share capital of the Company on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023).

Overall Structure of the Heights Financing

The EUR 75,000,000 Heights Financing consists of two tranches – aggregate principal amount of EUR 35,000,000 amortizing senior convertible notes and aggregate principal amount of EUR 40,000,000 amortizing senior convertible notes (collectively, the “Heights Convertible Notes”).

The first tranche in aggregate principal amount of EUR 35,000,000 was expected to be drawn on or around August 24, 2023, subject to satisfaction of customary closing conditions.

The second tranche in aggregate principal amount of up to EUR 40,000,000 may be drawn during the period from the date immediately following the three (3) month anniversary of the issuance of the first tranche to the first-year anniversary of the issuance of the first tranche. It may be drawn in up to two separate closings to provide Abivax with additional flexibility to request a partial drawdown. The amount available for drawdown under the second tranche will be determined based on Abivax’s Market Capitalization (based on seven (7) of the ten (10) trading days immediately preceding such

drawdown) and the average daily valued traded of Ordinary Shares (“ADVT”) over the three (3) month period preceding the drawdown, as further detailed below.

The Heights Financing is a senior, unsecured financing. The convertible bonds of the Heights Financing will not be listed on any market. The agreements relating to the Heights Financing are governed by French law.

On the of the press release, funds managed by Heights Capital Management, Inc. did not hold any Ordinary Shares.

Use of Proceeds and Cash Runway

The proceeds of the drawdown of the first tranche of the Kreos / Claret Financing and of the Heights Financing which, net of the refinancing of the existing indebtedness, amount to EUR 27,237,148 in the aggregate, are expected to be allocated mainly to the development of obefazimod for the treatment of adults with moderately to severely active UC and other potential chronic inflammatory indications, as well for working capital and general corporate purposes of the Company.

Following the arrival of its new CEO, Mr. Marc de Garidel, in May 2023, the Company is preparing for a more ambitious strategy, notably in order to further develop obefazimod, which is likely to require additional investment in comparison to the Company’s former plans. Based on the Company’s current assumptions and the net proceeds expected to be received from the drawdown of the first tranches of the Transaction, the Company expects its cash runway to extend until the end of Q2 2024.

Detailed Characteristics of the Kreos / Claret Financing

Main characteristics of the Kreos / Claret OCABSA (First Tranche)

The first tranche of the Kreos / Claret Financing consists of 25,000,000 convertible bonds with a par value of EUR 1.00 each and a fixed conversion price of EUR 21.2209. A warrant to subscribe or acquire new Ordinary Shares under certain conditions is attached to each Kreos / Claret convertible bond.

Interest on the Kreos / Claret OCABSA accrues at a 9.00% annual fixed interest rate, payable in quarterly installments. The Kreos / Claret OCBSA’s maturity date is March 31, 2027, it being specified that the scheduled date of final repayment is January 1, 2027.

The Kreos / Claret OCABSA are convertible into Ordinary Shares at any time from their issuance at the request of the holders at a fixed conversion price of EUR 21.2209 (corresponding to a 25% premium over the 15-day volume weighted average share price of Abivax (the “15-day VWAP”) prior to the date on which their issuance is decided), subject to standard adjustments, including anti-dilution and dividend protections.

The warrants included in the Kreos / Claret OCABSA will only become exercisable in case of prepayment in cash of the Kreos / Claret convertible bonds by Abivax. Upon exercise of the warrants, their holders will be able to subscribe to the same number of Ordinary Shares (and at the same price conditions) as they would have been able to subscribe had they converted the Kreos / Claret OCABSA which have been prepaid in cash. Any warrants not exercised on or prior to January 1, 2027, will become automatically null and void. For the avoidance of doubt, if Abivax does not prepay any Kreos / Claret OCABSA in cash prior to their scheduled repayment dates, none of the warrants will be exercisable.

A shareholder holding 1% of the share capital of the Company before the issuance of the Kreos / Claret OCABSA would hold 0.97% of the share capital in case of conversion of all of the Kreos / Claret OCABSA

into Ordinary Shares (on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023, and an assumed conversion price of EUR 21.2209).

Abivax is allowed to pre-pay the amounts due under the Kreos / Claret OCABSA at any time. In such case, Abivax will be required to pay a sum equal to (i) the principal outstanding at the time of the pre-payment (plus accrued interests), plus (ii) an aggregate of all remaining interest payments that would have been paid throughout the remainder of the term of the tranche, discounted to present value by applying a discount rate of 4%, plus (iii) an end-of-loan exit fee equal to 8.0% of the amounts drawn thereunder. In case of prepayment, the holders of the Kreos / Claret OCABSA will have the option to request a conversion of their Kreos / Claret OCABSA instead of a cash repayment, in which case, the end-of-loan exit fee is not payable by Abivax.

Main characteristics of the Kreos / Claret Non-Convertible Bonds (Second and Third Tranches)

The second and third tranches of the Kreos / Claret Financing are composed of a total of 50,000,000 amortized non-convertible bonds with a par value of EUR 1.00 each, divided into two tranches of EUR 25,000,000 each.

The second tranche in aggregate principal amount of EUR 25,000,000 may be drawn before the end of March 2024. The drawdown of the second tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown (excluding the Heights Financing).

The third tranche in aggregate principal amount of EUR 25,000,000 may be drawn before the end of July 2024. The drawdown of the third tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown (excluding the Heights Financing) and is conditional on Abivax raising a minimum of USD 125,000,000 in gross proceeds through a listing on Nasdaq before June 30, 2024.

A variable interest rate of 7.5% + European Central Bank Base Rate (MRO) (with a floor at 2.5% and a cap at 4%) applies to each tranche. These two tranches will be repaid monthly through March 31, 2027, after a deferred repayment of the principal (i) until October 1, 2024, for the second tranche, or February 1, 2025, if the conditions to draw the third tranche are met, and (ii) until February 1, 2025, for the third tranche.

Abivax is allowed to pre-pay the amounts due under the second and third tranches of the Kreos / Claret Financing any time. In such case, Abivax will be required to pay a sum equal to (i) the principal outstanding at the time of the pre-payment (plus accrued interests), plus (ii) an aggregate of all remaining interest payments that would have been paid throughout the remainder of the term of the applicable tranche, discounted to present value by applying a discount rate of 4%, plus (iii) an end-of-loan exit fee equal to 6.0% of the amounts drawn under the applicable tranche.

Main characteristics of the Kreos / Claret Warrants

As part of the Kreos / Claret Financing, Abivax has issued warrants to both Kreos and Claret for a global subscription price of EUR 1.00, giving them the right to subscribe to up to 214,198 new Ordinary Shares at an exercise price of EUR 18.6744 (corresponding to a 10% premium over the 15-day VWAP prior to the date on which their issuance is decided).

If the conditions for the drawdown of the third tranche of the Kreos / Claret Financing are met, Abivax will issue additional warrants to Kreos and Claret for a global subscription price of EUR 1.00 unless the third tranche is expressly declined by Abivax within 14 days. The exercise price of the additional warrants to be issued will be equal to 110% of the 15-day VWAP prior to the date on which their issuance is decided. The number of warrants to be issued will be calculated by dividing EUR 4,000,000

by the aforementioned exercise price. Of these additional warrants, 50% will be exercisable upon issuance and the remaining 50% shall only be exercisable if the third tranche of the Kreos / Claret Financing is drawn by Abivax.

The Kreos / Claret warrants can be exercised over a period of 7 years from their issuance date or up until the date of the successful closing of a tender offer for the Ordinary Shares, whichever is earlier. At the time of exercise of the Kreos / Claret warrants, the holders of the warrants are eligible to sell part of their warrants to Abivax in accordance with a put option agreement to allow for a cashless exercise.

A shareholder holding 1% of the share capital of Abivax before the issuance of the Kreos / Claret warrants would hold 0.995% of the share capital after exercise of the warrants (on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023, and an assumed exercise price of EUR 18.6744 for all warrants).

Detailed Characteristics of the Heights Financing

Main characteristics of the Heights Convertible Notes (First Tranche)

The first tranche of the Heights Financing is composed of 350 amortizing senior convertible notes with a nominal value of EUR 100,000 each and a fixed conversion price of EUR 23.7674 (corresponding to a 40% premium over the 15-day VWAP prior to the date on which their issuance is decided).

The Heights Convertible Notes are convertible into Ordinary Shares at any time from their issuance at the request of the holder at a fixed conversion price set at EUR 23.7674, subject to standard adjustments, including anti-dilution and dividend protections.

Interest on the Heights Convertible Notes accrues at a 6.00% annual fixed interest rate payable in quarterly installments in cash or, at the option of Abivax, in Ordinary Shares.

The Heights Convertible Notes will be repaid through sixteen quarterly installment payments, beginning three months after their issuance date (corresponding, for the first tranche, to a final repayment date on August 24, 2027). Installments are payable in cash or, at the option of Abivax, in Ordinary Shares.

Any interest or installment payments in shares will be made on the basis of a share price equal to 90% of the Market Price of the Ordinary Shares at the time of payment, where "Market Price" refers to the arithmetic average of the daily volume weighted average price ("VWAP") for the Ordinary Shares on the two (2) days with the lowest daily VWAPs out of the five (5) trading days immediately preceding the applicable date, but in no event greater than the VWAP of the Ordinary Shares on the applicable date. The Market Price may not be higher than the applicable conversion price. Issuances of Ordinary Shares may not be made at a price lower than a 15% discount to the 15-day VWAP at the time of the decision to issue the Heights Convertible Notes (i.e., EUR 14.4303 per Ordinary Share for the first tranche, the "Price Limit").

Upon the occurrence of certain events (including a change of control of the Company, a free float event or a delisting of the Ordinary Shares on Euronext Paris), any noteholder will have the option to require Abivax to redeem all, but not in part, of its Heights Convertible Notes at par plus accrued but unpaid interests. In the event that the Ordinary Shares are targeted by a public offer (in cash or in securities, in cash and securities, etc.) which may result in a change of control or filed following a change of control, upon conversion of the Heights Convertible Notes, Abivax shall (i) deliver new Ordinary Shares at the conversion price and (ii) pay a cash amount equal to the sum of the remaining coupons scheduled until the maturity date, and any accrued interest.

The terms and conditions of the Heights Convertible Notes include a standard negative pledge providing that any security granted in favor of other borrowed debt or debt instruments should also be granted in favor of the Heights Convertible Notes on an equal basis (with the exception of the securities issued pursuant to the Kreos / Claret Financing, as detailed herein).

A shareholder holding 1% of the share capital of Abivax before the issuance of the first tranche of Heights Convertible Notes would hold 0.96% of the share capital after conversion of such Heights Convertible Notes at the request of the holders (on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023, and an assumed conversion price of EUR 23.7674).

To the extent Abivax exercises its option for the repayment in shares of all or part of the principal or interests due under the Heights Convertible Notes, up to 2,830,201 new Ordinary Shares could be issued, representing 6.65% of Abivax's current share capital (on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023 and an assumed conversion price equal to the Price Limit of EUR 14.4303 per Ordinary Share).

Main characteristics of the Heights Convertible Notes (Second Tranche)

The second tranche of the Heights Financing is composed of up to 400 amortizing senior convertible notes with a nominal value of EUR 100,000 each, to be fully drawn after the three (3) month anniversary of the issuance of the first tranche and before the first-year anniversary of the issuance of the first tranche, i.e., by August 24, 2024 at the latest, in up to two separate closings to provide Abivax with additional flexibility to request a partial drawdown.

The amount available for drawdown under the second tranche will be determined based on Abivax's Market Capitalization (based on seven (7) of the ten (10) trading days immediately preceding such drawdown) ("Average Market Capitalization") and the ADVT of Ordinary Shares over the three (3) month period preceding the drawdown, as follows:

If the Average Market Capitalization is...	... and the ADVT is...	... then the Maximum Cumulated Amount Outstanding under both First and Second Tranches of the Heights Financing is equal to:
At least €700,000,000	At least €900,000	€45,000,000
At least €850,000,000	At least €1,250,000	€55,000,000
At least €1,000,000,000	At least €1,500,000	€65,000,000

The conversion price of the second tranche of the Heights Convertible Notes (if any) will be equal to 130% of the 15-day VWAP immediately preceding the date on which their issuance will be decided.

Except as set forth above, the second tranche of the Heights Convertible Notes will have similar characteristics to the first tranche of the Heights Convertible Notes.

Legal Framework of the Issuance

The Transaction has been approved by the Abivax Board of Directors, which met on August 16, 2023 and delegated its powers to the CEO to set the definitive terms of the Transaction and decide the issuance of the securities described above, in accordance with (i) the delegation of competence conferred by the 16th resolution of the combined annual and extraordinary shareholders' meeting of June 5, 2023, relating to a share capital increase or a securities issue with cancellation of preferred subscription rights to a certain category of beneficiaries pursuant to Article L. 225-138 of the French Commercial Code, and (ii) the provisions of Articles L. 22-10-49 and L. 228-40 of the French

Commercial Code. The CEO, using such delegation, set the definitive terms of the Transaction and decided the issuance of the securities being issued under the first tranches (i.e., the Kreos / Claret OCABSA, the first tranche of Kreos / Claret warrants and the first tranche of Heights Convertible Notes) on August 20, 2023.

The conversion or exercise of all the dilutive instruments which are being issued under the first tranches (i.e., the Kreos / Claret OCABSA, the first tranche of Kreos / Claret warrants and the first tranche of Heights Convertible Notes) would result in the issuance of up to 3,110,630 new Ordinary Shares, i.e., 7.31% of the current share capital of Abivax (on the basis of 42,547,568 Ordinary Shares composing the share capital of the Company on July 31, 2023, and excluding voluntary repayment by Abivax of installments and/or interests in Ordinary Shares under the Heights Financing).

It is being specified that the pre-existing OCEANE, which could be converted into up to 935,453 new Ordinary Shares, will be repaid in full by way of set-off against the subscription price of the Heights Convertible Notes.

Admission to trading of the any new Ordinary Shares issued will be made on the regulated market of Euronext Paris under the existing ISIN securities, identification code for Ordinary Shares (FR0012333284). Such new Ordinary Shares will be fully fungible with the existing Ordinary Shares.

For the Kreos / Claret Financing, calculations of the 15-day VWAP and Market Capitalization are based on the quotation of Abivax Ordinary Shares on Euronext Paris. For the Heights Financing, calculations of the 15-day VWAP, VWAP, the Market Capitalization, Market Price, the Average Market Capitalization, and the ADVT are derived from Bloomberg page ABVX FP Equity HP (or any successor page).

Settlement of the Transaction

Settlement of the Transaction and delivery of the Kreos / Claret OCABSA, the first tranche of Kreos / Claret warrants and the first tranche of Heights Convertible Notes was expected to occur on or around August 22, 2023 for the Kreos / Claret OCABSA, the first tranche of Kreos / Claret warrants and on or around August 24, 2023 for the first tranche of Heights Convertible Notes, subject to satisfaction of customary closing conditions.

No prospectus is required to be submitted for approval by the AMF in connection with the Transaction.

3.9 Press release dated August 23, 2023

Under the terms of its press release dated August 23, 2023, Abivax announced the appointment of Patrick Malloy as new Senior Vice President Investor Relations. Mr. Malloy brings 20 years of investor relations and commercial leadership experience in the biopharmaceutical sector. He is expected to play a crucial role in furthering the strategic international positioning of Abivax and obefazimod with the investor community.

Mr. Malloy joins Abivax from VectivBio AG (acquired by Ironwood Pharmaceuticals in June 2023), where he held the position of Senior Vice President, Investor Relations & Strategic Communications. Previously, he served as Vice President of Investor Relations and Corporate Communications at Arena Pharmaceuticals (acquired by Pfizer in 2022). Mr. Malloy spent over 16 years at Actelion Pharmaceuticals (acquired by Johnson and Johnson in 2017), where he held several commercial and corporate strategic leadership roles across the organization. Mr. Malloy will be based at the Abivax office on the U.S. East Coast.

3.10 Press release dated September 7, 2023

Under the terms of its press release dated September 7, 2023, Abivax announced updated business and operational goals along with changes to Abivax’s overall strategy, focused on preparing Abivax for the potential commercialization of its investigational lead asset, obefazimod, in IBD.

BUSINESS AND OPERATIONAL UPDATE

Strategic priorities

- Advance Obefazimod—Establish obefazimod as a potential first-line advanced therapy for the treatment of IBD. This goal is based on (i) robust Phase 2a and 2b clinical trial data in patients with moderately to severely active UC, as well as (ii) obefazimod’s novel mechanism of action that was demonstrated to enhance the expression of miR-124, a natural regulator of the inflammatory response. Initiation of the Phase 2a clinical trial in Crohn’s disease (“CD”) is expected in 2024 and evaluation of potential combination therapy opportunities in UC is ongoing.
- Optimize Opportunity in IBD in the Near Term with Phase 3 Data Beginning in 2025—Overcome limitations of currently available treatments for UC to establish obefazimod as a differentiated treatment option with the goal of providing convenient oral administration, safety, tolerability, and durable efficacy.
- Leverage Library of miR-124 Enhancers—Explore and expand development options of obefazimod in other inflammatory conditions and continue R&D work to identify additional drug candidates from Abivax’s proprietary small molecule library that includes additional miR-124 enhancers.

ABTECT Phase 3 clinical program in UC

Abivax’s focus is meeting enrollment goals of the ABTECT Phase 3 program with obefazimod for the treatment of moderately to severely active UC.

- Primary endpoint for both induction trials is clinical remission at 8 weeks; for the maintenance trial it is clinical remission at 52 weeks (which is week 44 of the maintenance trial).
- ABTECT top-line induction data readout is expected in Q1 2025; top-line maintenance trial data readout expected in Q1 2026.

Product pipeline and development milestone

Drug Candidate	Regimen	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT) Initiated First Patient Enrolled in the US on Oct. 11, 2022					<ul style="list-style-type: none"> • Induction trial topline data readout in Q1 2025 • Maintenance trial topline data readout in Q1 2026
	Monotherapy	Crohn’s Disease (CD)	Phase 2a Trial Planned					<ul style="list-style-type: none"> • IND filing expected in Q4 2023 • Initiate Phase 2a trial in Q1 2024 (first patient in) • Phase 2a induction topline results expected in 2H 2025
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)						<ul style="list-style-type: none"> • Decision on combination agent expected in 2025¹
	Monotherapy	Other Inflammatory Indications						<ul style="list-style-type: none"> • Declare indication for PoC trial in 2024

¹ Decision subject to results of the Phase 3 monotherapy induction trials

- Obefazimod in Crohn’s Disease—Based on existing supportive data, Abivax plans to advance obefazimod in moderately to severely active CD. Preparations for an expected Investigational New Drug application in Q4 2023 are ongoing. A Phase 2a trial of obefazimod in CD is expected to start recruitment in Q1 2024, with top-line induction results expected in 2H 2025.
- Obefazimod in Combination Therapy—Based on its early clinical profile, the use of obefazimod as a combination therapy for the treatment of moderately to severely active UC is expected to be explored.
- Obefazimod in Other Inflammatory Conditions—The anti-inflammatory effect of obefazimod observed during Phase 2 trials to date is encouraging and Abivax is exploring the potential of obefazimod in additional chronic inflammatory conditions. In 2024, Abivax expects to make decisions on other potential target indications.
- Compound miR-124 Library—R&D work on potential follow-on drug candidates to be selected from Abivax’s optimized compound library will continue. Pre-clinical development for the first selected follow-on drug candidate is expected to start in 2024 to further strengthen the pipeline.

Step-down dosing from 50 mg to 25 mg for approximately the third and fifth year of open-label maintenance treatment with obefazimod in UC patients

- UC patients treated with 50 mg of oral, once-daily, obefazimod completing approximately four years of treatment in the Phase 2a program and approximately two years of treatment in the Phase 2b program, if eligible (Mayo Endoscopic subscore = 0 or 1, normal or mild disease), could roll over into a follow-on, open-label, maintenance trial with a reduced dose of 25 mg.
- In an interim analysis (cut-off date of July 31, 2023) of the 71 eligible patients, 63 completed their 48-week visit, with a demonstrated disease control rate (stable or improved Modified Mayo Score) of 84% (53 of 63 patients) with the 25 mg once-daily dose of obefazimod.
- No new safety signals were detected in UC patients treated up to five years with oral, once-daily obefazimod.
- Full results expected to be submitted for presentation at upcoming medical conferences.

Strengthening of IP position

One of the two patents for obefazimod in the U.S. will be selected for Patent Term Extension (PTE) from 2035 to 2039. Potential extension of the method of use patents through PTE for obefazimod was assessed and confirmed by two globally recognized IP law firms. Composition of matter patent or method of use patent (both granted) would extend the product patent protection until 2035 or the use patent until 2040 in the EU.

Expansion of U.S. operations and leadership team

The establishment of an Abivax U.S. presence is currently in progress.

- U.S. employee presence has been strengthened to execute commercial launch preparation activities for obefazimod.
- The addition of new executive team members with global expertise commercializing drug candidates in the immunology and IBD market.

- Abivax U.S. office currently planned to open in the Greater Boston Area in Q4 2023.
- Dual source Contract Manufacturing Organization (CMO) presence to be established in North America to complement EU CMO.
- June Lee and Troy Ignelzi have joined the Abivax Board of Directors to add to existing skills and U.S. competencies and diversity.

FINANCIAL UPDATE

- With EUR 130M gross equity financing (EUR 123M net proceeds) raised in February 2023 and two additional structured debt agreements (EUR 27M net proceeds from the first tranches) signed in August 2023, Abivax has EUR 118M cash on hand (as of August 2023, unaudited) and expects its current cash runway to finance Abivax's operations through Q2 2024. With an additional EUR 90M financing that can be accessed by leveraging the existing debt agreements beyond the recent draw downs (subject to certain conditions precedent being met), Abivax could extend its cash runway into Q4 2024.
- The new strategic pre-clinical and clinical initiatives as described above, as well as the expansion of Abivax's clinical, medical and commercial capabilities, will require additional capital.
- To help ensure long-term financing and extend its current cash runway, Abivax is implementing a multi-pronged financing strategy. The final funding size and equity and debt allocation is expected to be made with the priority of funding Abivax's strategic initiatives.

3.11 Press release dated September 21, 2023

Under the terms of its press release dated September 21, 2023, Abivax announced presented its first-half 2023 financial results, as follows:

First-half 2023 financial highlights (IFRS figures)

Income Statement <i>in millions of euros</i>	H1/2023 <i>m€</i>	H1/2022 <i>m€</i>	Variation <i>m€</i>
Total operating income	2.3	2.3	(0.0)
Total operating expenses	(39.5)	(28.3)	(11.2)
<i>of which Research and Development costs</i>	(32.6)	(15.1)	(17.5)
<i>of which administrative costs and overheads</i>	(6.9)	(2.2)	(4.7)
<i>of which Goodwill impairment loss</i>	0.0	(11.0)	11.0
Operating loss	(37.3)	(26.0)	(11.2)
Financial gain (loss)	(14.7)	4.8	(19.5)
Net loss for the period	(52.0)	(21.2)	(30.8)

Balance Sheet <i>in millions of euros</i>	30/06/2023 <i>m€</i>	31/12/2022 <i>m€</i>	Change <i>m€</i>
Net financial position	70.8	(11.7)	82.5
of which other financial assets and other receivables and assets*	12.8	11.2	1.7
of which fixed-term deposits (maturing in > 1 year)	0.0	0.0	0.0

of which fixed-term deposits (maturing in < 1 year)	0.0	0.0	0.0
of which available cash and cash equivalents (of which financial liabilities)	114.4 (56.4)	27.0 (49.8)	87.4 (6.6)
Total Assets	171.1	75.5	95.5
Total Shareholders' Equity	80.5	7.2	73.3
* Excluding items of the liquidity contract (liquidity and own shares) and deposits			

- Operating loss of EUR -37.3M as of June 30, 2023 (EUR -11.2M compared to EUR -26.0M as of June 30, 2022), with revenues, Research Tax Credit, in H1 2023 amounting to EUR +2.3M, aligned with H1 2022.
- R&D expenses increased by EUR -17.5M to EUR -32.6M compared to EUR -15.1M as of June 30, 2022. In H1 2023, R&D expenses were predominantly driven by the progress of obefazimod development in inflammatory indications (95% of the total R&D expenses), especially with the conduct of the ABTECT Phase 3 program of obefazimod in ulcerative colitis (UC), whereas H1 2022 was dedicated to preparatory work for the Phase 3 program of obefazimod in UC.
- G&A expenses were EUR -6.9M as of June 30, 2023 (17% of total operating costs) compared to EUR -2.2M (8%) as of June 30, 2022. The increase is mainly due to one-time expenses related to the build out of the organization driven by the updated Company strategy.
- Total number of full-time employees at the end of June 2023 was 34, with most of the hires currently taking place to strengthen the Abivax presence in the U.S.
- Net loss amounted to EUR -52.0M as of June 30, 2023, an increase of EUR -30.8M compared to EUR -21.2M as of June 30, 2022. Net loss for the six months ended June 30, 2023, includes EUR -12.9M of non-cash expenses related to changes in fair value of our royalty certificates and derivative liabilities. Net loss for the six months ended June 30, 2022, includes EUR 7.2M of non-cash financial income related to changes in fair value of our derivative liabilities. These non-cash related items are driven by IFRS accounting standards.
- Cash at the end of June 2023 was EUR +114.4M, compared to EUR +27.0M at the end of 2022.
- A EUR 130M gross equity financing (EUR 123M net proceeds) was concluded in February 2023, and two additional structured debt agreements (EUR 27M net proceeds from the first tranches) were signed in August 2023. As of August 2023, Abivax had EUR 118M cash on hand (unaudited) and expects its current cash runway to finance its operations through Q2 2024. With an additional EUR 90M financing that can be accessed by leveraging the existing debt agreements beyond the recent draw downs (subject to certain conditions precedent being met), Abivax could extend its cash runway into Q4 2024.
Note that, out of the EUR 90M additional debt which can be accessed by leveraging the existing debt agreements beyond the recent draw downs, EUR 25M is conditional on Abivax raising a minimum of USD 125,000,000 in gross proceeds through a listing on Nasdaq before June 30, 2024. Please refer to Sections 5.2.1 and 7.2 of this Amendment for additional information on the Company's cash runway.
- The new strategic pre-clinical and clinical initiatives, as well as the expansion of Abivax's clinical, medical and commercial capabilities, will require additional capital. In August 2023, the Company announced its plans to conduct a registered public offering in the United States.

Further, Abivax announced the appointment of Dr. Paolo Rampulla as new member of the Abivax Board of Directors. Dr. Rampulla replaced Dr. Antonino Ligresti, M.D., as representative of Santé Holdings SRL, who retired from his position as member of the Board of Directors.

4. OVERVIEW OF ACTIVITIES

4.1 Main Activities

Section 5.1. "Main Activities" of the 2023 Universal Registration Document, is updated as follows:

5.1.1 Overview

The Company is a clinical-stage biotechnology company focused on developing therapeutics that harness the body's natural regulatory mechanisms to modulate the inflammatory response in patients with chronic inflammatory diseases. The Company is currently evaluating its lead drug candidate, obefazimod, in Phase 3 clinical trials for the treatment of adults with moderately to severely active ulcerative colitis ("UC"). The Company is also in the planning stages of initiating a Phase 2a clinical trial of obefazimod in patients with Crohn's disease ("CD"), as well as evaluating other potential inflammatory indications.

The Company focuses on indications where existing treatments have left patients with significant unmet needs, and where the Company believes its investigational agents have the potential to be meaningfully differentiated from currently available therapies. The indications the Company targets have substantial populations and represent large commercial opportunities, pending regulatory approvals and successful commercialization. Its initial focus is on inflammatory bowel diseases ("IBD"), chronic conditions involving inflammation of the gastrointestinal ("GI") tract, of which the two most common forms are UC and CD. As of 2022, an aggregate of approximately 2.9 million patients across the United States, EU4 (France, Germany, Italy and Spain), the United Kingdom and Japan suffered from IBD, with 1.5 million of these patients in the United States alone.

One of the primary goals of IBD therapy is to achieve durable clinical remission while simultaneously taking into consideration a patient's quality of life and concerns regarding potential side effects. Despite a number of different therapies approved for UC and CD, the vast majority of these therapies require chronic administration via injections or intravenous infusions, and may come with serious and concerning warnings, including, but not limited to, risks of serious infections leading to hospitalizations or death and increased risks of various malignancies. A vast majority of IBD patients do not achieve clinical remission with existing therapies, and a significant number of patients will lose response over time, especially those patients on TNF- α inhibitor therapy where anti-drug antibodies are very common. Further, despite the increased number of biosimilars, such as TNF- α inhibitor therapies, becoming available for the treatment of IBD, biosimilars unfortunately do not alleviate any of the potential side effect concerns that often cause patients to delay, or avoid altogether, stepping up to more advanced therapies. In addition, although a small number of oral therapies have more recently been approved for the treatment of IBD, these therapies also come with concerning potential side effects, which can discourage patients from initiating treatment with advanced therapies. Therefore, there continues to be significant unmet need for novel oral therapies with durable efficacy, improved safety profiles and minimal preinitiation requirements for patients with moderately to severely active IBD. Moreover, the Company believes the IBD market has significant growth potential driven by growing diagnosis of these diseases and increased penetration of oral treatments with improved benefit/risk profiles.

The Company believes its lead drug candidate, obefazimod, is differentiated from competing approaches for the treatment of IBD via its novel mechanism of action. Obefazimod was demonstrated to specifically enhance the expression of a single micro-RNA, miR-124, which plays a critical role in the regulation of the inflammatory response.

In the context of inflammation, miR-124 is a natural regulator of the inflammatory response, controlling progression of inflammation and restoring homeostasis of the immune system, without

causing broader immunosuppression. In contrast to currently available advanced therapies, prescribed post-conventional therapies, some of which target only a single cytokine or pathway, miR-124 modulates the expression of several key cytokines and pathways. Modulating multiple inflammatory pathways simultaneously may lead to more durability of efficacy results over the long-term, which is critical in lifelong conditions such as IBD, potentially differentiating obefazimod from currently available IBD treatments.

In its Phase 2 clinical trials for the treatment of moderately to severely active UC, consistent with the pharmacological effects observed in its preclinical studies, obefazimod demonstrated an onset of symptom relief by day 8 of dosing, with meaningful reductions in rectal bleeding and stool frequency scores. In its induction Phase 2b clinical trial, which included 252 patients, obefazimod met the primary endpoint of a statistically significant reduction in Modified Mayo Score, a measure of disease activity relative to placebo. In addition, the Company observed high rates of sustained and newly achieved clinical remission in the subsequent open-label maintenance extension trial of up to two years of treatment, of which approximately 45% of patients were previously exposed to biologics or Janus kinase (“JAK”) inhibitors. Greater than 90% of patients previously exposed to advanced therapy prior to enrollment were highly refractory, having failed at least two advanced therapies.

In April 2023, the Company reported the results from the final analysis of its Phase 2b open-label maintenance trial, including 217 patients of which 164 patients (76%) completed the second year of once-daily oral treatment with 50 mg obefazimod. At the conclusion of the second year of treatment, 114 of the 217 patients enrolled (53%) achieved clinical remission and 158 patients (73%) achieved clinical response. Among the 98 bio-refractory patients, 66 patients (67%) had a clinical response, 38 patients (39%) were in clinical remission, 46 patients (47%) had endoscopic improvement and 20 patients (20%) had endoscopic remission at week 96. Among the 124 patients that achieved clinical response at the end of the 8-week induction period of the double-blind study, 82 patients (66%) achieved clinical remission at week 48, mimicking the re-randomization of responders approach typically utilized in Phase 3 maintenance trials. At week 96, of the 124 patients in clinical response at week 8, 74 patients (60%) achieved clinical remission, 95 patients (77%) had clinical response, 79 patients (64%) achieved endoscopic improvement and 52 patients (42%) achieved endoscopic remission at week 96.

In September 2023, the Company reported an interim analysis of step-down dosing from 50 mg to 25 mg for the third and fifth year of open-label maintenance treatment with obefazimod in UC patients. These patients were treated with 50 mg of oral, once-daily obefazimod for approximately four years in the Phase 2a clinical trial and approximately two years in the Phase 2b clinical trial. Patients were eligible to enroll in the trial if they had a Mayo endoscopic subscore of 0 or 1. Eligible patients were switched to 25 mg, and an interim analysis was performed at week 48 with a cut-off date of July 31, 2023. Of the 71 eligible patients, 63 completed their 48-week visit. Among these patients, 53 out of 63 patients (84%) demonstrated disease control (stable or improved Modified Mayo Score). No new safety signals were detected in UC patients treated up to five years with oral, once-daily obefazimod.

Obefazimod’s tolerability profile indicates potentially important clinical differentiation. As of November 30, 2022 (the last safety data cut-off date), 1,074 patients and volunteers had been treated with obefazimod, of which 209 patients were treated with 50 mg obefazimod for one year or more with no change in the observed tolerability profile underscored by 76% of patients that remained on therapy throughout the two-year open-label maintenance trial period. No new adverse safety signals were observed.

The Company initiated its pivotal Phase 3 clinical trials of obefazimod for the treatment of moderately to severely active UC in October 2022, which consist of two induction trials (ABTECT-1 and ABTECT-2) and one ABTECT maintenance trial. Top-line data from the ABTECT-1 and ABTECT-2 induction trials is

expected to be announced in the first quarter of 2025, and top-line data from the ABTECT maintenance trial is expected to be announced in the first quarter of 2026. The Company intends to (i) file an Investigational New Drug Application (“IND”) in the fourth quarter of 2023, (ii) initiate a Phase 2 clinical trial in patients with CD in the first quarter of 2024 and (iii) announce top-line results in the second half of 2025 with the objective to demonstrate clinical response and tolerability profile consistent with that already observed in its clinical trials for moderately to severely active UC. Based on the results from this Phase 2 clinical trial, the Company intends to proceed directly to a Phase 3 clinical trial.

Its team is comprised of industry leaders in the fields of biology, data analytics and drug development, as well as scientific experts in chronic inflammatory diseases, including IBD. The Company is led by Marc de Garidel, its Chief Executive Officer, who has more than 40 years of experience in the pharmaceutical and biotechnology sector. Collectively, its team has decades of experience and a proven track record of advancing compounds into and through clinical development and commercialization, including at the following organizations: Amgen, Arena Pharmaceuticals, AstraZeneca, BioNTech, Boehringer Ingelheim, Eli Lilly, Genentech/Roche, Guerbet, Ipsen Pharmaceuticals, J&J, Pfizer, Sanofi, Sanofi-Pasteur and Shire/Takeda.

5.1.1.1 The Company's Pipeline

The Company's lead drug candidate, obefazimod, is in clinical development for the treatment of moderately to severely active UC. The Company is continuing to develop obefazimod for the treatment of CD and are evaluating additional potential inflammatory indications to pursue, subject to the availability of necessary resources and funding. In parallel, the Company is in the process of generating follow-on compounds based on the miR-124 platform.

The chart below sets forth details relating to the current stages of development of its lead drug candidate:

Drug Candidate	Regimen	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones	
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT) Initiated First Patient Enrolled in the US on Oct. 11, 2022						<ul style="list-style-type: none"> Induction trial topline data readout in Q1 2025 Maintenance trial topline data readout in Q1 2026
	Monotherapy	Crohn's Disease (CD)	Phase 2a Trial Planned						<ul style="list-style-type: none"> IND filing expected in Q4 2023 Initiate Phase 2a trial in Q1 2024 (first patient in) Phase 2a induction topline results expected in 2H 2025
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)							<ul style="list-style-type: none"> Decision on combination agent expected in 2025¹
	Monotherapy	Other Inflammatory Indications							<ul style="list-style-type: none"> Declare indication for PoC trial in 2024

¹ Decision subject to results of the Phase 3 monotherapy induction trials

5.1.1.2 IBD Overview and Limitations of Existing Treatments

IBD, such as UC and CD, is a chronic life-long immune-mediated inflammatory condition of the GI tract with many contributing factors, including genetic, environmental and immunologic. UC and CD are the two most common forms of IBD and are characterized by dysregulation of lymphocytes contributing to inflammation. Both UC and CD are chronic, relapsing, remitting, inflammatory conditions of the GI tract that begin most commonly during adolescence and young adulthood. UC involves the innermost lining of the large intestine, and symptoms include abdominal pain and diarrhea, frequently with blood and mucus. CD can affect the entire thickness of the bowel wall and all parts of the GI tract from mouth

to anus. CD symptoms include abdominal pain, diarrhea and other more systemic symptoms, such as weight loss, nutritional deficiencies and fever.

IBD, as of 2022, affected approximately 1.5 million patients in the United States alone. As of 2022, the prevalence of UC and CD in the United States were estimated at approximately 0.9 million and 0.6 million patients, respectively. The prevalence of IBD in the EU4 and the United Kingdom is estimated at 1.2 million with approximately 0.7 million patients with UC and 0.5 million patients with CD. As of 2022, an aggregate of approximately 2.9 million patients across the United States, EU4, the United Kingdom and Japan suffered from IBD. This figure is expected to grow to approximately 3.0 million patients by 2028.

One of the primary goals of IBD therapy is to achieve durable clinical remission while simultaneously taking into consideration a patient's quality of life and concerns regarding potential side effects. Despite a number of different therapies approved for UC and CD, the vast majority of these therapies require chronic administration via injections or intravenous infusions, and may come with serious and concerning warnings, including, but not limited to, risks of serious infections leading to hospitalizations or death and increased risks of various malignancies. A vast majority of IBD patients do not achieve clinical remission with existing therapies, and a significant number of patients will lose response over time, especially those patients on TNF- α inhibitor therapy where anti-drug antibodies are very common. Further, despite the increased number of biosimilars, such as TNF- α inhibitor therapies, becoming available for the treatment of IBD, biosimilars unfortunately do not alleviate any of the potential side effect concerns that often cause patients to delay, or avoid altogether, stepping up to more advanced therapies. In addition, although a small number of oral therapies have more recently been approved for the treatment of IBD, these therapies also come with concerning potential side effects, which can also discourage patients from initiating treatment with advanced therapies. Therefore, there continues to be significant unmet need for novel oral therapies with durable efficacy, improved safety profiles and minimal preinitiation requirements for patients with moderately to severely active IBD. Moreover, the Company believes the IBD market has significant growth potential driven by growing diagnosis of these diseases and increased penetration of oral treatments with improved benefit/risk profiles.

In 2022, pharmaceutical sales in IBD were \$16.3 billion in the United States and \$7.4 billion in the rest of the world, totaling \$23.7 billion worldwide. In 2028, pharmaceutical sales in IBD are estimated to be \$17.5 billion and \$26.8 billion in the United States and worldwide, respectively. Worldwide sales in the UC market were \$7.4 billion in 2022 and are estimated to be \$10.2 billion in 2028, while in the CD market worldwide sales reached \$16.3 billion in 2022 and are estimated to be \$16.6 billion in 2028. The Company believes the IBD market has significant growth potential driven by growing diagnosis of these diseases and increased penetration of oral treatments with improved benefit/risk profiles. The Company believes the potential for oral agents to gain significant market share is supported by physician and patient preference for the convenience of oral administration over injectable agents, increasing demand for therapies with long-term efficacy profiles and the opportunity for potent and well-tolerated oral agents to expand the overall segment of the moderately to severely active UC population undergoing treatment.

Medical treatment of IBD is typically divided into two types of therapy: induction and maintenance. Induction therapy is used to reduce inflammation quickly (in three months or less) and maintenance therapy is used to sustain that reduction. Patients with IBD are classified by the activity of their disease as either mild to moderately active or moderately to severely active based on the level of symptoms experienced, inflammatory biomarkers and severity of disease on endoscopy. The current standard of care for the treatment of patients with moderately to severely active IBD is to reduce inflammation with anti-inflammatory agents. Patients with mild to moderately active IBD are treated with so-called "conventional therapies" which are anti-inflammatory treatments that include: aminosalicylates (e.g.,

5-ASAs), immunosuppressants or immunomodulators (e.g., 6-mercaptopurine, methotrexate and azathioprine) and corticosteroids.

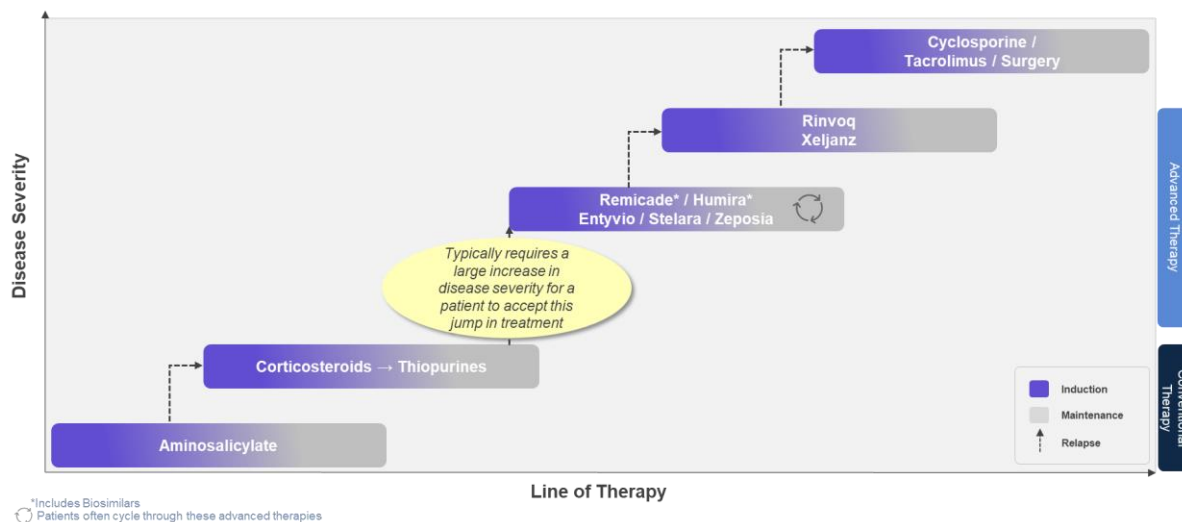
Despite the widespread use of conventional therapies to treat mild to moderately active IBD, due to the progressive and lifelong nature of both UC and CD, for many patients the severity of their disease progresses in activity and are considered moderately to severely active. This requires patients and their physicians to consider using more targeted therapies typically termed “advanced therapies.” The majority of advanced therapies require chronic parenteral administration including TNF- α inhibitors (e.g., infliximab, adalimumab and golimumab), Interleukin (“IL”)-12/23 inhibitor (ustekinumab), anti-integrin antibodies (vedolizumab), or IL-23 inhibitors (mirikizumab). There are also two classes of oral treatments including JAK inhibitors (e.g., tofacitinib, filgotinib and upadacitinib) and sphingosine-1-phosphate (“S1P”) receptor agonists (ozanimod). Although these therapies have demonstrated efficacy in UC and/or CD, the majority of IBD patients do not achieve clinical remission, and a significant number of patients lose response over time, especially those treated with TNF- α inhibitor therapies where anti-drug antibodies are common. Due to mechanisms of action that are poorly understood, with each line of advanced therapy that is exhausted, patients become less likely to respond to the next advanced therapy utilized in the sequence of care.

Each of the advanced therapy classes are associated with notable side effect and safety tradeoffs that must be considered before initiating treatment. For instance:

- TNF- α inhibitors: Boxed warnings for increased risk of serious infections leading to hospitalizations or death and various forms of malignancies are noted in the United States prescribing information with similar warnings in the European Medicines Agency (“EMA”) summary of product characteristics (“SmPCs”).
- IL-12/23 inhibitors: Warnings in label for serious infections, tuberculosis, malignancies and posterior reversible encephalopathy syndrome (PRES).
- Anti-integrin antibodies: Warnings in label for potential risk of Progressive Multifocal Leukoencephalopathy (“PML”), gut specificity of vedolizumab may be connected with exacerbating or causing extraintestinal manifestations.
- IL-23 inhibitors: Warnings in the EU for severe infections and risk of hepatic enzyme elevations (mirikizumab not approved in the United States).
- JAK inhibitors: Boxed warnings for increased risk of serious infections leading to hospitalization or death, higher rates of all-cause mortality, malignancies, cardiovascular death, myocardial infarction, stroke and thrombosis appear in the United States prescribing information with similar warnings in the EU.
- S1P receptor agonists: Warnings in label for infections, bradyarrhythmia and atrioventricular conduction delays, liver injury and macular edema. These warnings result in multiple preinitiation requirements prior to initiating therapy. Risk of PML also exists.

Patients and physicians must take into consideration the lifelong burden of chronic parenteral administration for injectable agents and the potential safety warnings for all therapies when deciding which treatment, if any, to initiate.

The following chart depicts the current UC treatment landscape:



For patients who do not or no longer respond to treatment, or experience complications, surgical treatment may be necessary. Approximately 50% to 80% of CD patients and 10% to 30% of UC patients require surgery over their lifetime. In light of the above, the Company believes that there is significant unmet medical need in the UC treatment paradigm due to imperfect existing therapies with unfavorable clinical characteristics and limited efficacy that frequently wanes over time. A general patient preference for oral agents over injectables suggests a potential untapped market opportunity available for efficacious, well-tolerated oral therapies.

5.1.2 The Company's Strengths

The Company believes the following strengths will allow the Company to advance its proprietary drug candidates through clinical trials, while building upon its advanced position in the development of therapeutics for IBD and other chronic inflammatory diseases:

- **The Company's focus on indications of high unmet need and substantial commercial potential, with an initial focus on IBD.**

The Company focuses on indications where existing treatments have left patients with significant unmet needs, and where the Company believes its investigational agents have the potential to be meaningfully differentiated from currently available therapies. The indications the Company targets have substantial populations and represent large commercial opportunities, pending regulatory approvals and successful commercialization. Its initial focus is on IBD, chronic conditions involving inflammation of the GI tract, of which the two most common forms are UC and CD.

The Company believes the IBD market has significant growth potential driven by growing diagnosis of these diseases and increased penetration of oral treatments with improved benefit/risk profiles. The Company believes the need for differentiated treatment options is high, in particular for patients with moderate and severe forms of IBD, for whom available therapies often have limited efficacy and durability while carrying significant safety and tolerability challenges.

- **The Company believes it is market leader in leveraging micro-RNA biology to target inflammation.**

The Company believes its lead drug candidate, obefazimod, is differentiated from competing approaches for the treatment of IBD via its novel mechanism of action. Obefazimod was

demonstrated to specifically enhance the expression of a single micro-RNA, miR-124, which plays a critical role in the regulation of the inflammatory response. In the context of inflammation, miR-124 is a natural regulator of the inflammatory response, controlling progression of inflammation and restoring homeostasis of the immune system, without causing broader immunosuppression. In contrast to currently available advanced therapies, prescribed post-conventional therapies, some of which target only a single cytokine or pathway, miR-124 modulates the expression of several key cytokines and pathways. Modulating multiple inflammatory pathways simultaneously may lead to more durability of efficacy results over the long-term, which is critical in lifelong conditions such as IBD, potentially differentiating obefazimod from currently available IBD treatments.

- **Robust data generated from its Phase 2 clinical trials of obefazimod for the treatment of moderately to severely active UC.**

In its Phase 2 clinical trials for the treatment of moderately to severely active UC, consistent with the pharmacological effects observed in its preclinical studies, obefazimod demonstrated an onset of symptom relief by day 8 of dosing, with meaningful reductions in rectal bleeding and stool frequency scores. In its induction Phase 2b clinical trial, which included 252 patients, obefazimod met the primary endpoint of a statistically significant reduction in Modified Mayo Score, a measure of disease activity relative to placebo. In addition, the Company observed high rates of sustained and newly achieved clinical remission in the subsequent open-label maintenance extension trial of up to two years of treatment, of which approximately 45% of patients were previously exposed to biologics or JAK inhibitors. Greater than 90% of patients previously exposed to advanced therapy prior to enrollment were highly refractory, having failed at least two advanced therapies.

- **The Company's lead drug candidate, obefazimod, has been well-tolerated in its clinical trials to date.**

Obefazimod's tolerability profile indicates potentially important clinical differentiation. Many existing therapies for IBD have been limited by safety and tolerability concerns, including increased risks of serious infections or various malignancies, sometimes requiring warning labels. By contrast, as of November 30, 2022 (the last safety data cut-off date), the tolerability profile of obefazimod is supported by more than 1,074 patients and volunteers that had been treated with obefazimod, of which 209 patients were treated with 50 mg obefazimod for one year or more with no change in the observed tolerability profile. In addition, to date, the entire obefazimod safety database presents no death or malignancies and no reported clinically significant changes in laboratory parameters, such as liver function, hemoglobin levels and white blood cell counts. The most common treatment emergent adverse event ("TEAE") reported has been mild to moderate headache, which has been transient and manageable with or without over-the-counter medications. Furthermore, at present, no increased rate of opportunistic infections or malignancies compared with placebo have been observed across all clinical trials. The Company conducts an annual analysis of clinical safety data from its ongoing clinical trials using an annual cut-off date of November 30 with the intention to provide additional safety data in January of the following year.

- **Compelling and differentiating clinical characteristics position obefazimod as a potential first-line therapy for moderately to severely active UC.**

Therapies currently available to patients with UC in the first-line setting are limited to older, broad immunosuppressive agents with safety, tolerability and efficacy challenges. Advanced therapies, which include biologic agents such as TNF- α inhibitors, IL-12/23 inhibitors or IL-23

inhibitors, carry significant safety and tolerability challenges and their administration, as injectable agents, is not convenient to patients. Newer oral molecules, such as JAK inhibitors and S1P receptor agonists, while addressing convenient route of administration for patients, also present safety and tolerability challenges. Comparatively, obefazimod is being developed as a once-daily, oral medication which, combined with its observed tolerability to date, would represent a meaningfully differentiated clinical profile from existing therapies. The Company believes this may position obefazimod as a potential first-line advanced therapy choice for both prescribers and patients, if approved.

- **The Company’s experienced team is comprised of global industry leaders in the development of therapeutics for chronic inflammatory diseases.**

The Company believes that the breadth of experience and accomplishments of its management team, board of directors and scientific advisory board, combined with its broad network of established relationships with leaders in the industry and medical community, provide the Company with fresh insights into drug development and commercialization, and have allowed the Company to bring together top researchers to build interdisciplinary research and development teams. The Company is led by Marc de Garidel, its Chief Executive Officer, who has more than 40 years of experience in the pharmaceutical and biotechnology sector and successfully led the sales of CinCor Pharma to AstraZeneca in 2023 and Corvidia Therapeutics to Novo Nordisk in 2020. Collectively, its team has decades of experience and a proven track record of advancing compounds into and through clinical development and commercialization, including at the following organizations: Amgen, Arena Pharmaceuticals, AstraZeneca, BioNTech, Boehringer Ingelheim, Eli Lilly, Genentech/Roche, Guerbet, Ipsen Pharmaceuticals, J&J, Pfizer, Sanofi, Sanofi-Pasteur and Shire/Takeda.

5.1.3 The Company's Programs

The Company's lead drug candidate, obefazimod, is in clinical development for the treatment of moderately to severely active UC. The Company are continuing to develop obefazimod for the treatment of CD and are evaluating additional potential inflammatory indications to pursue, subject to the availability of necessary resources and funding. In parallel, the Company is in the process of generating follow-on compounds based on the miR-124 platform.

The chart below sets forth details relating to the current stages of development of the Company's lead drug candidate:

Drug Candidate	Regimen	Indication	Research	Nonclinical	Phase 1	Phase 2	Phase 3	Anticipated Milestones	
Obefazimod	Monotherapy	Moderately to Severely Active Ulcerative Colitis (UC)	Pivotal Phase 3 Program (ABTECT) Initiated First Patient Enrolled in the US on Oct. 11, 2022						<ul style="list-style-type: none"> • Induction trial topline data readout in Q1 2025 • Maintenance trial topline data readout in Q1 2026
	Monotherapy	Crohn's Disease (CD)	Phase 2a Trial Planned						<ul style="list-style-type: none"> • IND filing expected in Q4 2023 • Initiate Phase 2a trial in Q1 2024 (first patient in) • Phase 2a induction topline results expected in 2H 2025
	Combination Therapy	Moderately to Severely Active Ulcerative Colitis (UC)							<ul style="list-style-type: none"> • Decision on combination agent expected in 2025¹
	Monotherapy	Other Inflammatory Indications							<ul style="list-style-type: none"> • Declare indication for PoC trial in 2024

1. Decision subject to results of the Phase 3 monotherapy induction trials

5.1.3.1 The Company's Lead Drug Candidate for the Treatment of Inflammatory Diseases: Obefazimod

Obefazimod is an oral small molecule drug candidate in clinical development for the treatment of moderately to severely active UC. The Company believes that obefazimod is the only small molecule drug candidate in clinical development with a mechanism of action that was demonstrated to specifically enhance the expression of a single micro-RNA, miR-124, which plays a critical role in the regulation of the inflammatory response.

In its induction Phase 2b clinical trial, which included 252 patients, obefazimod met the primary endpoint of a statistically significant reduction in Modified Mayo Score, a measure of disease activity relative to placebo. The Company has observed an onset of symptom relief by day 8 of dosing, with meaningful reductions in rectal bleeding and stool frequency scores, consistent with the pharmacological effects observed in its preclinical studies, and high rates of sustained and newly achieved clinical remission in the subsequent open-label maintenance extension trial of up to two years of treatment, of which approximately 45% of patients were previously exposed to biologics or JAK inhibitors. In April 2023, the Company reported the results from the final analysis of its Phase 2b open-label maintenance trial, including 217 patients of which 164 patients (76%) completed the second year of once-daily oral treatment with 50 mg obefazimod. At the conclusion of the second year of treatment, 114 of the 217 patients enrolled (53%) achieved clinical remission and 158 patients (73%) achieved clinical response. Among the 98 bio-refractory patients, 66 patients (67%) had a clinical response, 38 patients (39%) were in clinical remission, 46 patients (47%) had endoscopic improvement and 20 patients (20%) had endoscopic remission at week 96. Among the 124 patients that achieved clinical response at the end of the 8-week induction period of the double-blind study, 82 patients (66%) achieved clinical remission at week 48, mimicking the re-randomization of responders approach typically utilized in Phase 3 maintenance trials. At week 96, of the 124 patients in clinical response at week 8, 74 patients (60%) achieved clinical remission, 95 patients (77%) had clinical response, 79 patients (64%) achieved endoscopic improvement and 52 patients (42%) achieved endoscopic remission at week 96.

In September 2023, the Company reported an interim analysis of step-down dosing from 50 mg to 25 mg for the third and fifth year of open-label maintenance treatment with obefazimod in UC patients. These patients were treated with 50 mg of oral, once-daily obefazimod for approximately four years in the Phase 2a clinical trial and approximately two years in the Phase 2b clinical trial. Patients were eligible to enroll in the trial if they had a Mayo endoscopic subscore of 0 or 1. Eligible patients were switched to 25 mg, and an interim analysis was performed at week 48 with a cut-off date of July 31, 2023. Of the 71 eligible patients, 63 completed their 48-week visit. Among these patients, 53 out of 63 patients (84%) demonstrated disease control (stable or improved Modified Mayo Score). No new safety signals were detected in UC patients treated up to five years with oral, once-daily obefazimod.

Furthermore, obefazimod's tolerability profile indicates potentially important clinical differentiation. As of November 30, 2022 (the last safety data cut-off date), 1,074 patients and volunteers had been treated with obefazimod, of which 209 patients were treated with 50 mg obefazimod for one year or more with no change in the observed tolerability profile underscored by 76% of patients that remained on therapy throughout the two-year open-label maintenance trial period. No new adverse safety signals were observed.

The Company initiated its pivotal Phase 3 clinical trials of obefazimod for the treatment of moderately to severely active UC in consultation with international regulators, including the U.S. Food and Drug Administration (the "FDA"), the EMA, the Pharmaceuticals and Medical Devices Agency ("PMDA") and the China Center for Drug Evaluation ("CDE"). These pivotal Phase 3 clinical trials consist of two induction trials (ABTECT-1 and ABTECT-2) and one ABTECT maintenance trial in doses of 25 mg and 50

mg across 36 countries in North America, Latin America, Europe and Asia Pacific, involving 1,200 moderately to severely active UC patients in over 600 sites. Each of the trials will be randomized, double-blind and placebo-controlled, using independent and central review of video-taped endoscopies with the primary endpoint of clinical remission according to the Modified Mayo Score assessed at week 8 (induction) and at week 44 (maintenance), as recommended by the FDA. Enrollment of the first patient under this program occurred on October 11, 2022. Top-line data from the ABTECT-1 and ABTECT-2 induction trials is expected to be announced in the first quarter of 2025, and top-line data from the ABTECT maintenance trial is expected to be announced in the first quarter of 2026.

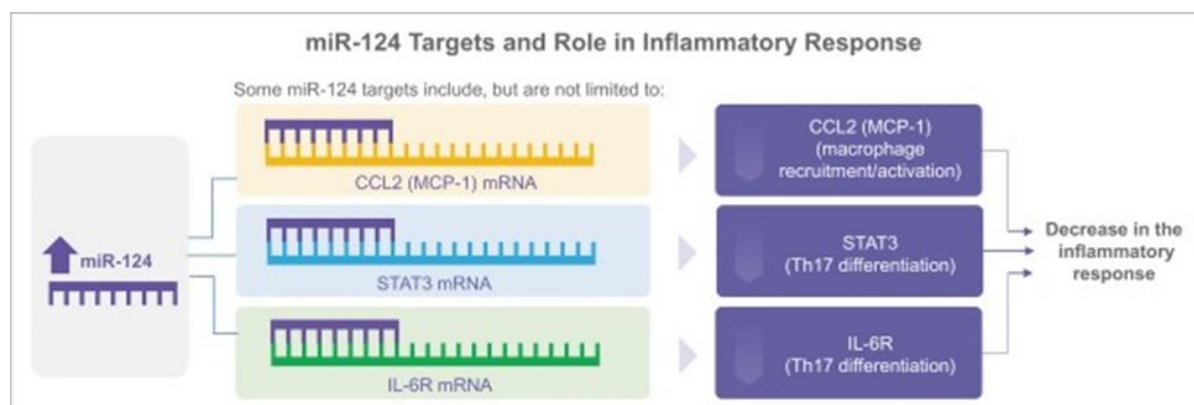
Currently, the obefazimod safety database is supported by more than 1,000 subjects treated with obefazimod across different indications, including UC patients, some of whom are in their fifth year of continuous daily dosing.

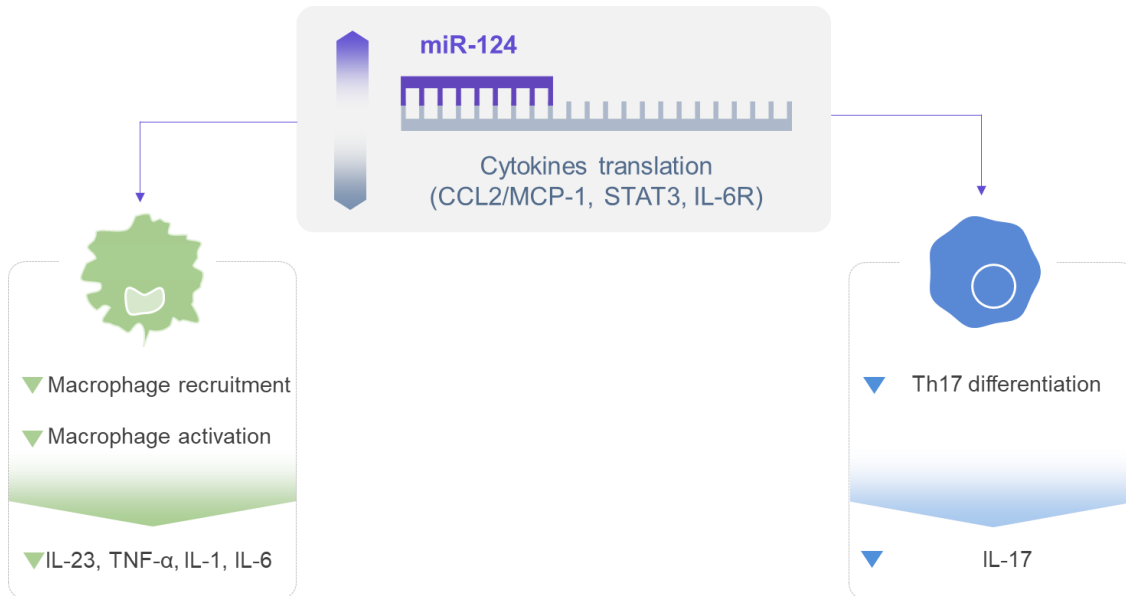
5.1.3.2 Summary of Obefazimod's Mechanism of Action

The Company believes its lead drug candidate, obefazimod, is differentiated from competing approaches for the treatment of IBD via its novel mechanism of action. Obefazimod was demonstrated to specifically enhance the expression of a single micro-RNA, miR-124, which plays a critical role in the regulation of the inflammatory response. In the context of inflammation, miR-124 is a natural regulator of the inflammatory response, controlling progression of inflammation and restoring homeostasis of the immune system, without causing broader immunosuppression. Once expressed, micro-RNA interact with specific mRNA targets and decrease their translation into proteins to regulate specific pathways. By binding to the cap binding complex, a complex playing a role in cellular RNA biogenesis, obefazimod enhances the selective splicing of a single long non-coding RNA to generate the anti-inflammatory micro-RNA, miR-124, in immune cells. Importantly, obefazimod does not impact the splicing of cellular messenger RNA.

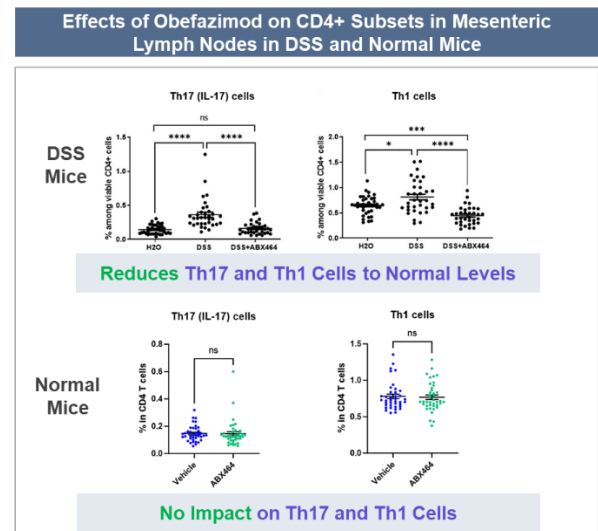
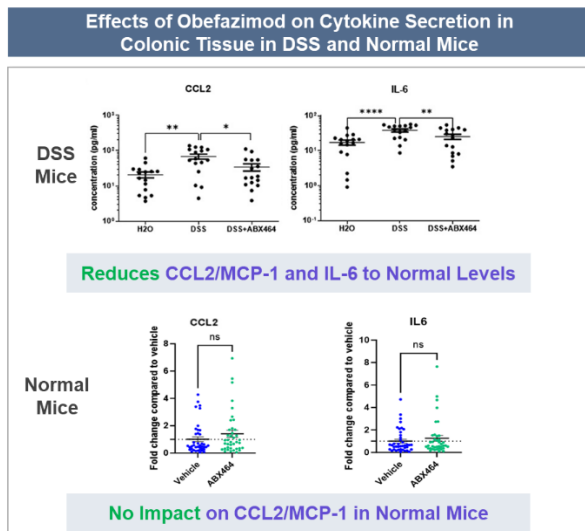
By targeting key inflammatory mRNA players such as STAT3 and MCP1, miR-124, a known anti-inflammatory micro-RNA, regulates inflammation by decreasing macrophages and downregulating the translation of pro-inflammatory cytokines and chemokines, such as TNF- α , IL-6, MCP-1 and IL-17, as well as Th17+ cells, to control overactive immune stimulation seen in chronic inflammatory diseases. This downregulation thereby regulates the inflammatory process and suggests broad potential as a novel anti-inflammatory therapeutic agent.

The following charts provide schematics of obefazimod's mechanism of action at both a protein-level (direct downregulation) and cellular-level (indirect downregulation):



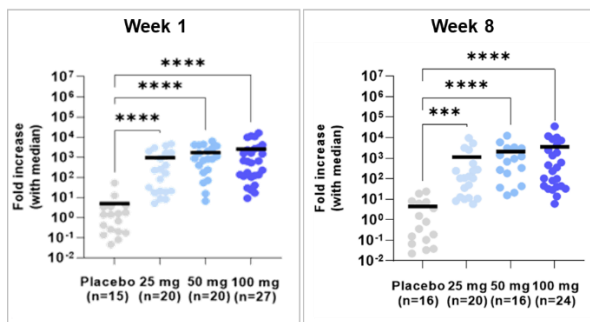


In a DSS mouse model, the Company observed that administration of DSS enhances the expression of pro-inflammatory cytokines in colonic tissue and Th17 cells in lymph nodes and that the treatment of these mice with obefazimod reduced the level of pro-inflammatory cytokines and Th17 cells back to their normal level. Interestingly, when the Company treated healthy mice with obefazimod, the Company did not observe any effect on Th17 cells in the lymph node and on cytokine levels in the colonic tissue, which the Company believes illustrates that regulation via enhanced expression of miR-124 has an effect only when these pathways are dysregulated, as shown below:



Laboratory analysis of the Phase 2b clinical trial at week 8 showed a highly statistically significant enhancement of expression of miR-124 in rectal tissue in patients treated with obefazimod, compared to baseline. The median increases were 13-fold for the 25 mg group, 25-fold for the 50 mg group and 25-fold for the 100 mg group, while no enhanced expression was observed in the placebo group (1.02-fold increase), indicative of the positive pharmacological effect of obefazimod. Downstream effects of enhancement of expression of miR-124 have been demonstrated by the reduction in IL-17 and IL-23 levels in the blood and rectal biopsies of patients treated with obefazimod. The following charts depict those results:

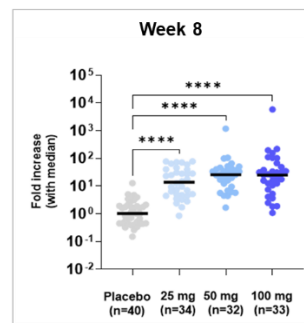
miR-124 Levels in Blood at Weeks 1 & 8



miR-124 expression in the blood is statistically higher with obefazimod compared with placebo after 1 week and 8 weeks

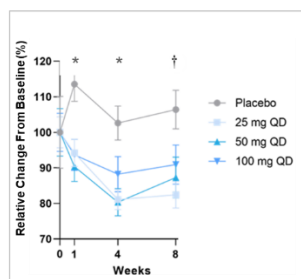
***p<0.001 vs placebo
****p<0.0001 vs placebo

miR-124 Levels in Rectal Tissue at Week 8



miR-124 expression in the rectal tissue is statistically higher with obefazimod compared with placebo after 8 weeks

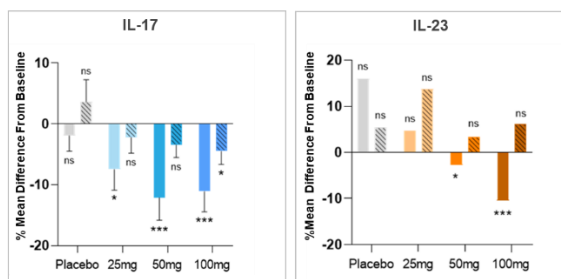
IL-17 Levels in Blood at Weeks 1, 4 & 8 (relative change from baseline, %)



IL-17 is statistically lower in obefazimod treated subjects at week 1, 4, and 8

*p-value <0.01 for all 3 doses
†p-value <0.01 for 25mg and 50mg only

IL-17 & IL-23 Levels in Rectal Tissues at Week 8 (mean difference from baseline, %)



Change from baseline in IL-17 is statistically significant with obefazimod 25 and 50 mg and in IL-23 with obefazimod 50 mg

Solid Bars: Patients with a clinical response at week 8
Shaded Bars: Patients without a clinical response at week 8
*p<0.05; **p<0.01; ***p<0.001

In contrast to currently available advanced therapies, prescribed post-conventional therapies, some of which target only a single cytokine or pathway, miR-124 modulates the expression of several key cytokines and pathways. Modulating multiple inflammatory pathways simultaneously may lead to more durability of efficacy results over the long-term, which is critical in lifelong conditions such as IBD, potentially differentiating obefazimod from currently available IBD treatments.

5.1.4 Obefazimod in UC

5.1.4.1 UC Overview

UC, one of the most common forms of IBD, is a chronic inflammatory disease of the large intestine or colon, that affects the lining of the colon and causes small sores or ulcers. UC is the result of several factors that are not yet well understood. Abnormal inflammatory response, genetics, microbiome and environmental factors all contribute to UC. UC can occur at any age, though most people are diagnosed aged 20 to 30, and men and women are equally likely to be affected. UC can affect people of any racial or ethnic group. UC symptoms can vary, depending on the severity of inflammation and where it occurs. Signs and symptoms may include diarrhea, rectal bleeding, abdominal pain and cramping, weight loss, fatigue and fever, substantially impacting the quality of life of patients with this debilitating disease. There were an estimated 4.1 million prevalent cases of UC globally in 2022.

During the 12 months ended May 2023, the Company estimates that there were approximately 776,000 patients treated for UC in the United States. Of those patients, approximately 594,000 patients received conventional therapies; approximately 285,000 patients were maintained on

conventional therapy, approximately 193,000 patients received steroids only and approximately 116,000 patients could not be controlled with conventional therapies. The remaining 182,000 patients received some form of advanced therapies, which the Company believes represented approximately \$5.3 billion of sales in the United States; approximately 43,000 patients were new to advanced therapy, approximately 51,000 patients received suboptimal results or recently switched from other forms of therapy and approximately 88,000 patients were maintained on advanced therapy.

5.1.4.2 Existing Therapies and Their Limitations

The current UC treatment approach is influenced by multiple factors, including disease severity, previous response to treatment, side effects and co-morbidities. Both existing conventional therapies as well as advanced therapies, including approved products and drug candidates in development, face significant room for improvement in efficacy, safety and tolerability, and convenience from dosing and route of administration standpoints as discussed below.

Conventional Therapies for UC

Aminosalicylates (5-ASAs) are used as a first-line therapy in mildly to moderately active UC. Corticosteroids are used primarily during induction therapy and are effective for reducing symptoms, but do not address mucosal healing which limit their ability to modify and improve the underlying cause of disease. In addition, there are safety considerations with extended corticosteroid use, including lowered quality of life, bone loss, weight gain and cardiovascular complications. As a result, corticosteroids are used primarily as a bridge to manage symptoms until immunomodulators or biologic agents become effective and enable mucosal healing. Oral immunosuppressants (e.g., azathioprine, 6-mercaptopurine and methotrexate) have not been effective as induction agents and are generally used for steroid-sparing or as an adjunctive therapy for reducing immunogenicity against biologic agents. Oral immunosuppressants are also associated with known toxicities such as drops in white blood cell counts and increased risk for infection.

Given the above insufficiencies of these conventional therapies, patients suffering from mild UC may evolve towards moderate and severe forms requiring the use of advanced therapies.

Advanced Therapies for UC

Advanced therapies for UC include biological agents as well as emerging oral molecules. Biological agents such as TNF- α inhibitors (including infliximab, adalimumab and golimumab), IL-12/23 inhibitors (such as ustekinumab) or IL-23 inhibitors, which specifically block certain inflammatory factors involved in UC. Biological agents also include gut-specific anti-integrin antibodies (such as vedolizumab and natalizumab). New oral molecules acting on certain pathways of the inflammation include JAK inhibitors (including tofacitinib and upadacitinib) – or, on the trafficking of inflammatory cells such as S1P receptor agonists (e.g., ozanimod).

However, these therapies often only have moderate efficacy that may wane over time, as patients stop responding or do not respond at all to these treatments and thus require new therapeutic management options. For patients who do not or no longer respond to treatment, or experience complications, surgical treatment may be necessary. Approximately 10% to 30% of UC patients require surgery over their lifetime.

In addition, while TNF- α inhibitors and JAK inhibitors and newer biological agents, including anti-integrin antibodies, IL-12/23 inhibitors and IL-23 inhibitors, have generally improved the care of moderate to severely active IBD (JAK inhibitors specifically in UC), these are all anti-inflammatory agents with safety and tolerability concerns. These include increased risks for cancers, infections and blood clots due to their systemic impact and resulting effects on the immune system outside of the GI

tract. In addition, prolonged treatment with biological therapies can lead to anti-drug antibody development by patients' immune systems which may lead to gradual waning of therapeutic efficacy and patients needing to switch to other biological agents. Furthermore, biological agents require injections or intravenous infusions, resulting in patient inconvenience and burden, which often negatively impacts patient compliance. Injections can also lead to injection-related events such as sciatica, neuralgia, neuropathic pain and peripheral neuropathy.

In September 2021, the FDA published strict warnings about increased risk of serious heart-related events, cancer, blood clots and death for JAK inhibitors that treat certain chronic inflammatory conditions (including UC). In January 2023, the EMA stated recommendations to minimize the risk of serious side effects with JAK inhibitors used to treat several chronic inflammatory disorders, noting that these side effects include cardiovascular conditions, blood clots, cancer and serious infections which were adopted by the European Commission in March 2023.

Recently, there have been efforts to develop drug candidates targeting novel mechanisms, such as S1P receptor agonists and TL1A inhibitors. S1P agonists, while offering convenient oral dosing, have not achieved meaningful commercial adoption. Ozanimod and other S1P agonists work by blocking capacity of lymphocytes to egress from lymph nodes, thereby reducing the number of lymphocytes in peripheral blood, which can lead to increased susceptibility to infections. Furthermore, Ozanimod, in its UC Study 1 which assessed efficacy during the induction period, achieved 18% clinical remission in all patients at week 10, with only 10% of patients with prior exposure to TNF- α inhibitors showing clinical remission. TL1A inhibitors have garnered interest from those seeking newer targets and agents with differentiated clinical profile. While Merck-Prometheus and Pfizer-Roivant have generated promising early Phase 2 data in both biologics-experienced and biologics-naïve patients, neither have initiated Phase 3 clinical trials and do not have long-term safety and efficacy data beyond 56 weeks.

In summary, the Company believes that there is significant unmet medical need in the UC treatment paradigm due to imperfect existing therapies with unfavorable clinical characteristics and limited efficacy that frequently wanes over time.

Obefazimod is being developed as a once-daily, oral medication which, combined with its observed tolerability to date, would represent a meaningfully differentiated clinical profile from existing therapies. The Company believes this may position obefazimod as a potential first-line advanced therapy choice for both prescribers and patients, if approved.

5.1.4.3 Market Opportunity: UC

The estimated market opportunity for UC was approximately \$7.4 billion in worldwide sales in 2022 and is expected to reach \$10.2 billion in worldwide sales in 2028. In 2022, there were 4.1 million prevalent cases of UC worldwide. In the United States, EU4, the United Kingdom and Japan, there were 2.0 million prevalent cases of UC, of which 1.3 million of these cases in G7 countries were treated with 5-ASAs or advanced therapies. In addition, approximately 76% of patients suffering from UC in the United States were covered by commercial insurance, with approximately 20% and 3% covered by Medicare and Medicaid, respectively. The UC market has significant growth potential driven by increasing incidence of the disease as well as the development of innovative oral therapeutics. The Company believes the potential for oral agents to gain significant market share is supported by physician and patient preference for the convenience of oral administration over injectable agents, increasing demand for therapies with long-term efficacy profiles and the opportunity for potent and well-tolerated oral agents to expand the overall segment of the moderately to severely active UC population undergoing treatment.

5.1.5 Clinical Trial Results of Obefazimod in Moderately to Severely Active UC

As of November 30, 2022 (the last safety data cut-off date), 1,074 patients and volunteers had been treated with obefazimod, of which 209 patients were treated with 50 mg obefazimod for one year or more with no change in the observed tolerability profile. At present, no increased rate of opportunistic infections or malignancies compared with placebo have been observed across all clinical trials. The Company is conducting Phase 3 clinical trials in moderately to severely active UC in the United States, Europe, Asia Pacific and Latin America.

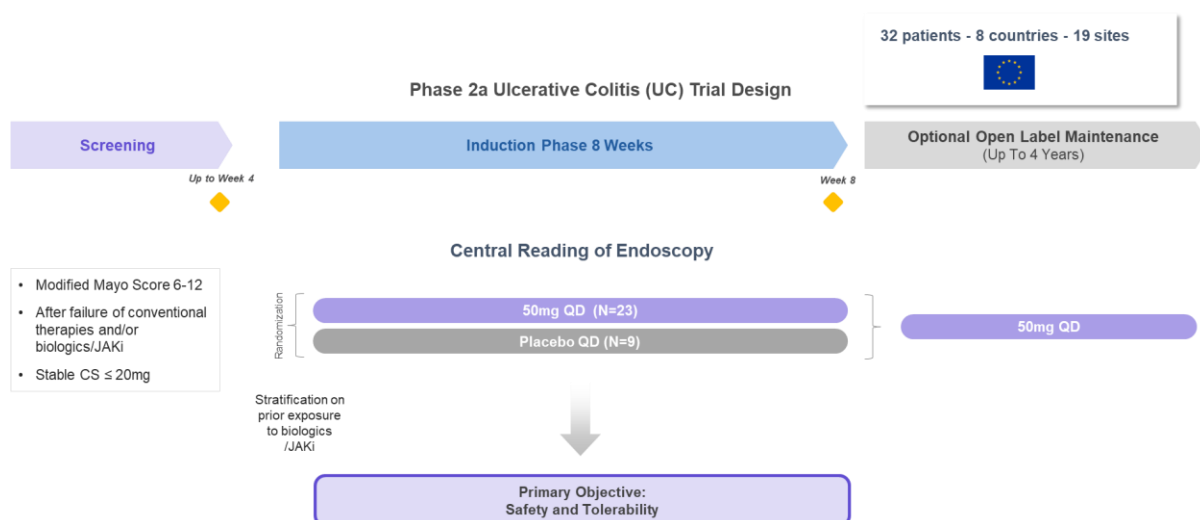
5.1.5.1 Phase 2a Clinical Trial with Obefazimod for the Treatment of Moderately to Severely Active UC

The induction Phase 2a clinical trial was a randomized trial of an 8-week placebo-controlled, double-blind induction phase followed by an open-label long term extension trial. It was completed in September 2018. This proof-of-concept trial enrolled 32 adult patients who had been diagnosed with moderately to severely active UC for at least 12 weeks and who failed or were intolerant to conventional treatments (50%) or biologics (50%). Patients who completed the induction phase were eligible to continue in the open-label extension trial.

In the induction phase, patients were randomized two-to-one to a once-daily orally-administered 50 mg dose of obefazimod or placebo for eight weeks. In the long-term extension, all patients received a once-daily orally-administered 50 mg dose of obefazimod.

This double-blind, placebo-controlled trial follows a standard study design in this indication for which a dose response as well as placebo effect can be frequently observed. The 50 mg daily dose was selected on the basis of the safety data accumulated for this dose.

The trial design of its Phase 2a clinical trial for obefazimod in patients with moderately to severely active UC is depicted below:



Overview of Primary Endpoints of Induction Phase 2a Clinical Trial with Obefazimod for the Treatment of UC

The primary endpoint in the induction Phase 2a clinical trial was safety, assessed as the rate of TEAEs. The primary endpoint in the induction phase, evaluation of safety and tolerability of obefazimod, was

met. The most frequently reported adverse events reported in the 50 mg group were GI disorders and headaches. GI disorders were experienced by 35% of subjects in the obefazimod group and 22% of subjects in the placebo group. These included abdominal pain, abdominal pain upper, anal fissure, anorectal discomfort, dyspepsia and nausea for the obefazimod group and abdominal pain and diarrhea for the placebo group. Headaches was experienced by 17% of subjects in the obefazimod group and 0% in the placebo group. Headaches occurred early and were transient (lasting only a few days), mainly mild or moderate (grade 1 or 2) and manageable with or without over-the-counter medications. No serious adverse events related to treatment were observed.

The following table provides an overall summary of TEAEs by treatment group:

	Placebo N=9 n (%)	Obefazimod 50 mg N=23 n (%)	Total N=32 n (%)
AE	5 (55.6)	18 (78.3)	23 (71.9)
TEAE	5 (55.6)	18 (78.3)	23 (71.9)
Related TEAE	0	5 (21.7)	5 (15.6)
TEAE leading to discontinuation	0	1 (4.3)	1 (3.1)
Severe TEAE	1 (11.1)	3 (13.0)	4 (12.5)
Serious TEAE	1 (11.1)	1 (4.3)	2 (6.3)
Related serious TEAE	0	0	0

AE = adverse event; TEAE = treatment-emergent adverse event

Overview of Secondary Endpoints of Induction Phase 2a Clinical Trial with Obefazimod for the Treatment of UC

The following table depicts secondary efficacy endpoints of its Phase 2a clinical trial with obefazimod in moderately to severely active UC at week 8:

	Placebo n=9/9 ITT PP	Obefazimod n=23/20 ITT PP	p value ¹ (PP)
Clinical remission	11% 11%	30% 35%	0.160
Endoscopic improvement	11% 11%	43% 50%	0.030
Clinical response	33% 33%	61% 70%	0.060
miR-124 expression in rectal biopsies (fold increase)	1.46	7.69	0.004

1. POC Study was not powered for efficacy
ITT = Intent-to-treat; PP = Per Protocol

The secondary endpoints in the induction Phase 2a clinical trial included the proportion of patients achieving clinical remission at week 8 as compared to placebo, change from baseline to week 8 in total Modified Mayo Score (which is based on stool frequency, rectal bleeding, physician global assessment and endoscopic subscore), rate of endoscopic improvement, clinical response rate, as well as miR-124 expression in the rectal tissue of the patients.

Overview of Additional Follow-Up Data from Long Term Extension Portion of Phase 2a Clinical Trial with Obefazimod for the Treatment of Moderately to Severely Active UC

For the long-term extension, the primary objective was long term safety of obefazimod. Additional efficacy endpoints included clinical and endoscopic rates of response and remission. Overall, 32 patients were enrolled in the induction phase, 23 patients were randomized to obefazimod, and nine patients were randomized to placebo.

Of the 29 patients who completed the induction phase (20 patients for obefazimod and nine patients for placebo), 22 patients continued their treatment into the long-term extension.

In October 2019, the Company announced the 12-month data from this Phase 2a proof-of-concept trial. This open-label maintenance trial was conducted in 22 patients, of which 19 completed the first year of treatment. At 12 months, an endoscopy was performed in 16 of the 19 patients to evaluate the rate of clinical remission, and 12 of the 16 evaluable patients (75%) were observed to achieve clinical remission. Obefazimod was also observed to maintain enhanced expression of miR-124 throughout the 12 months of the trial. At month 12, mean change in Mayo Score was observed at -2.6 points compared to the maintenance baseline. Median fecal calprotectin decreased from 153.1 µg/g (baseline) to 27.9 µg/g and 31.6 µg/g at week 52 and month 24, respectively.

The following table depicts secondary efficacy endpoints of its Phase 2a clinical trial with obefazimod in moderately to severely active UC at 24 and 48 months:

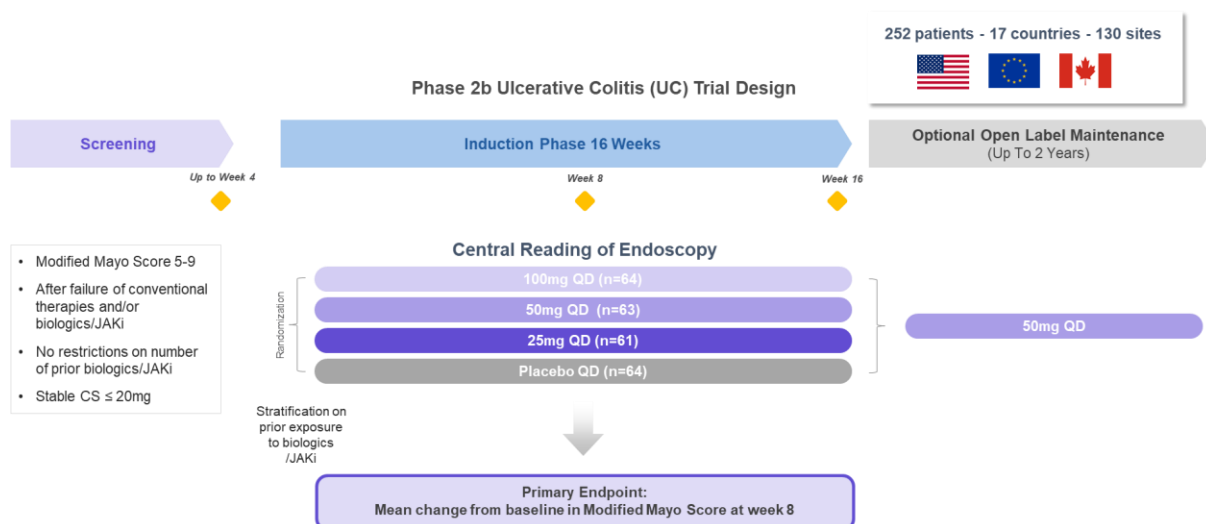
	M24 N=22 n (%)	M48 N=22 n (%)
Clinical remission	10 (45.4)	9 (40.9)
Endoscopic improvement	10 (45.4)	9 (40.9)
Clinical response	13 (59.1)	11 (50.0)

5.1.5.2 Phase 2b Clinical Trial with Obefazimod for the Treatment of UC

Overview of Induction Phase 2b Clinical Trial with Obefazimod for the Treatment of UC

The induction Phase 2b clinical trial for the treatment of moderately to severely active UC was conducted in 252 patients enrolled at 130 trial sites across 15 European countries, Canada and the United States. It was completed in April 2021. The trial was a randomized, double-blind and placebo-controlled 16-week induction trial with a primary efficacy endpoint at week 8 involving four treatment groups (receiving an oral once-daily 25 mg, 50 mg or 100 mg dose of obefazimod or placebo). Endoscopies were read centrally and blinded, by independent reviewers. Electronic patient diaries were used to enhance the reliability of the collection of stool frequency, rectal bleedings, and other patient reported outcomes-all efficacy endpoints were set according to FDA guidance.

The following chart depicts the design of its Phase 2b clinical trial with obefazimod in moderately to severely active UC:



Between August 13, 2019 and April 16, 2021, 252 patients were randomly allocated to obefazimod 100 mg (n=64), obefazimod 50 mg (n=63), obefazimod 25 mg (n=61) or placebo (n=64).

Baseline characteristics were well-balanced among the treatment groups, indicating a moderately to severely active UC population. At screening, 49% of patients had an inadequate response, loss of response, or intolerance to TNF- α inhibitors, vedolizumab, other biologics and/or JAK inhibitors treatments, while the other patients were refractory to conventional treatments only. Enrolled patients suffered from longstanding UC with an overall mean disease duration of 8.05 years and 71% of the patients had a severe disease profile (baseline Modified Mayo Score of 7 to 9 points).

The following table depicts the baseline characteristics of its Phase 2b clinical trial:

		Placebo (n=64)	25mg (n=61)	50mg (n=63)	100mg (n=64)
Modified Mayo Score (MMS)	Mean (SD)	7.0 (1.20)	7.1 (1.09)	7.1 (0.96)	7.0 (1.07)
7 to 9	n (%)	42 (65.6)	44 (72.1)	47 (74.6)	47 (73.4)
Endoscopic Sub-Score = 3	%	75%	67%	75%	66%
Duration of Disease (years)	Mean (SD)	8.8 (6.8)	7.4 (6.8)	8.2 (7.8)	7.8 (7.3)
Fecal Calprotectin ($\mu\text{g/g}$)	Median	1558	1743	1671	1623
Previous Exposure to Biologics/JAKi	n (%)	31 (48.4)	30 (49.2)	30 (47.6)	32 (50.0)
Previous Exposure to 2 or More Biologics/JAKi*	n (%)	28 (90.3)	27 (90.0)	29 (96.7)	31 (96.9)
Primary Non-Response to Biologic/JAKi*	n (%)	15 (48.4)	14 (46.7)	18 (60.0)	19 (59.4)
Concomitant UC Medication					
Corticosteroids	n (%)	29 (45.3)	32 (52.5)	33 (52.4)	37 (57.8)

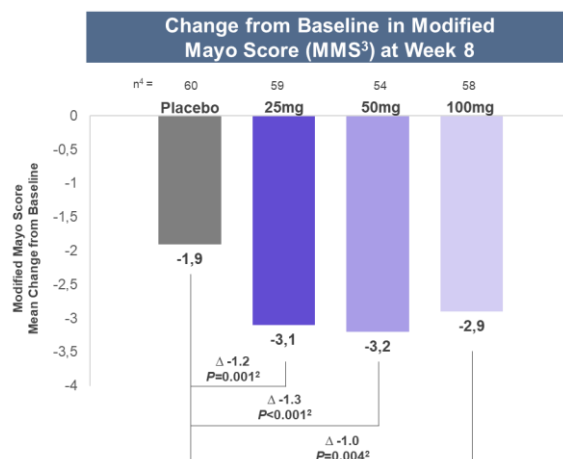
*Percentages based on number of patients with previous exposure to biologics/JAK inhibitors

Overview of Primary Endpoints of Induction Phase 2b Clinical Trial with Obebazimod for the Treatment of UC

Modified Mayo Score: In the full analysis set ("FAS"), corresponding to an ITT analysis, the primary endpoint was met at week 8 (statistically significant reduction of Modified Mayo Score) with -2.9 (95% CI -3.4 to -2.5) for the obefazimod 100 mg group, -3.2 (-3.7 to -2.7) for the obefazimod 50 mg group, -3.1 (-3.6 to -2.6) for the obefazimod 25 mg group, and -1.9 (-2.4 to -1.5) for placebo group. The magnitude of the difference in Modified Mayo Score from baseline was significantly greater in all three obefazimod groups compared with placebo (p=0.0039 for obefazimod 100 mg vs placebo, p=0.0003 for obefazimod 50 mg vs placebo, and p=0.0010 for obefazimod 25 mg vs placebo).

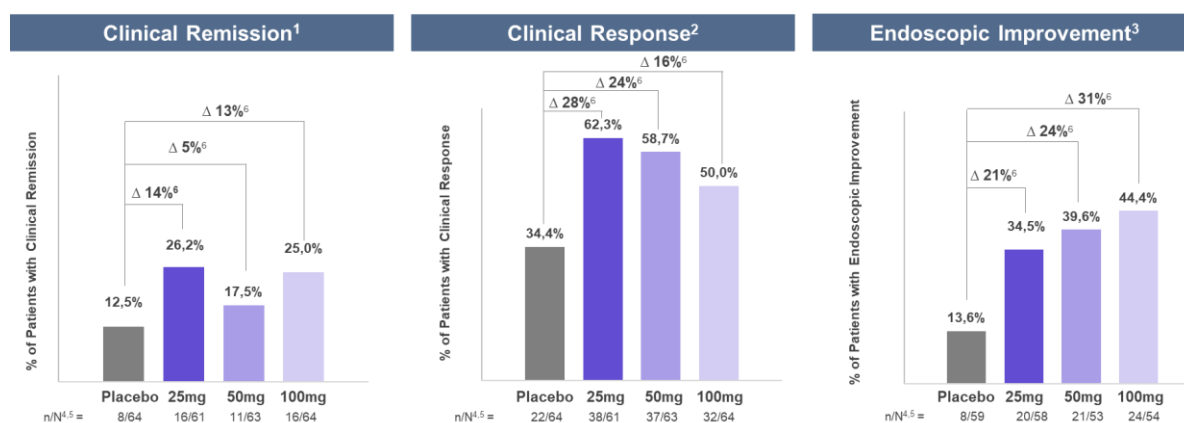
Clinical Response, Clinical Remission and Endoscopic Improvement: Furthermore, rates of clinical response and clinical remission at week 8 in the FAS were higher in the three obefazimod dosage groups than with placebo. The subgroup of patients who were refractory to one or more second line therapies showed results that were consistent with the overall analysis for clinical response and clinical remission at week 8. Rates of endoscopic improvement at week 8 were also higher in the obefazimod dosage groups than in the placebo group in the FAS. Change in fecal calprotectin from baseline in the FAS was greater in all obefazimod groups than with placebo.

The following tables depict the changes of the primary endpoint from baseline in Modified Mayo Score at week 8:



- (1) ANCOVA model for change from baseline MMS at week 8 which includes baseline MMS as a covariate and treatment, previous exposure to biological drugs or JAK inhibitors as fixed effects and a random error term.
- (2) p-values are based on nonparametric ANCOVA using ranked data.
- (3) MMS is the sum of assessment scores (0-3) of mucosal appearance on endoscopy, stool frequency, and rectal bleeding.
- (4) n = number of patients in the category with data available for baseline and week 8 visit.

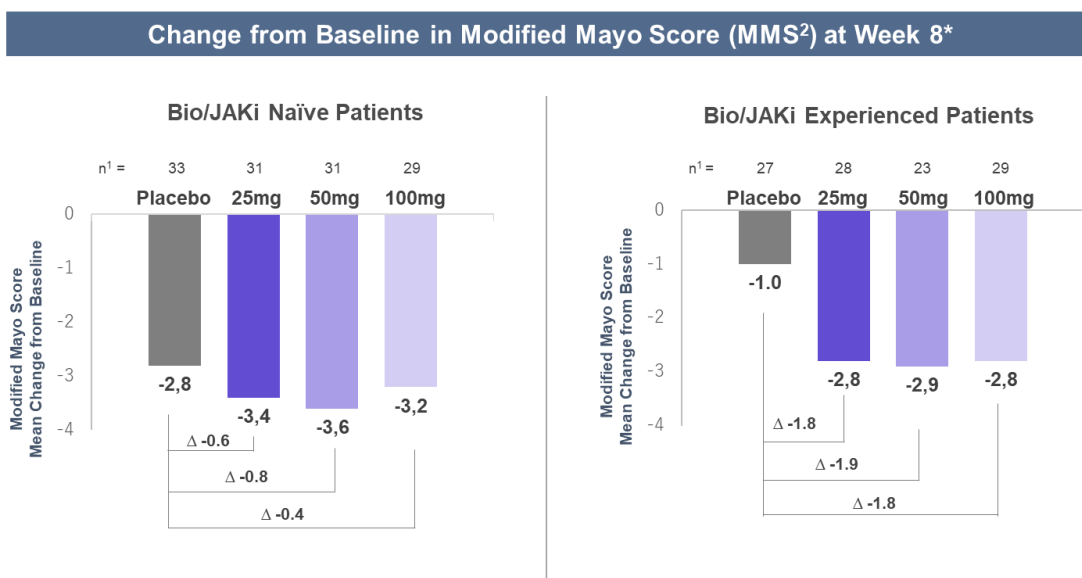
The following tables depict the secondary efficacy endpoint results at week 8:



- (1) Clinical remission (per Modified Mayo Score) is defined as stool frequency subscore (SFS) ≤1, rectal bleeding subscore (RBS) of 0 and endoscopic subscore ≤1.

- (2) Clinical response (per Adapted Mayo Score) is defined as a decrease from baseline in the Modified Mayo Score ≥ 2 points and ≥ 30 percent from baseline, plus a decrease in RBS ≥ 1 or an absolute RBS ≤ 1 .
- (3) Endoscopic improvement is defined as endoscopic subscore ≤ 1 without friability.
- (4) n = number of patients that met the respective endpoint.
- (5) N = number of patients in the relevant analysis set.
- (6) Delta = arithmetic difference rounded to nearest full percentage.

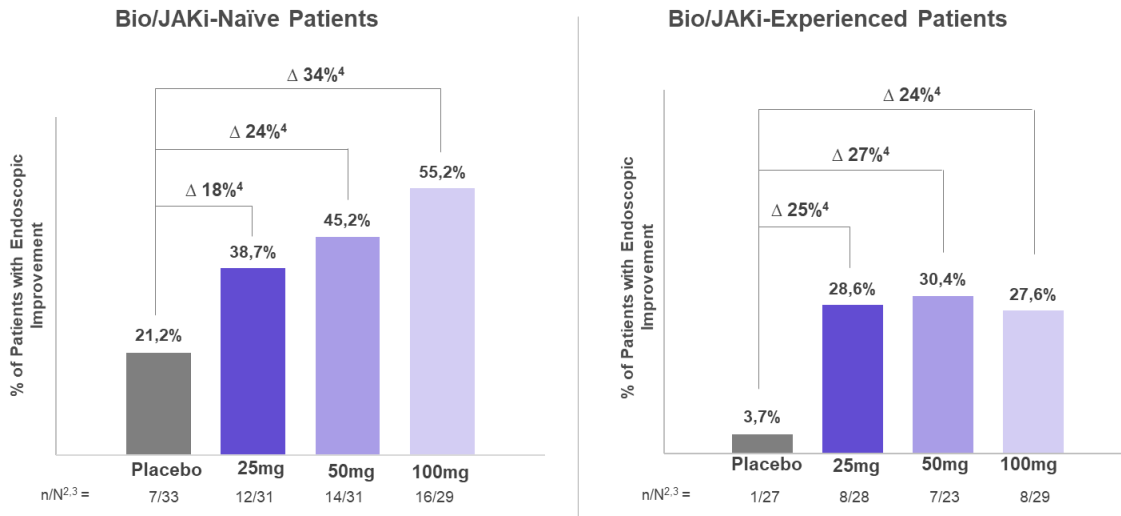
The Company also conducted sub-group analyses of biologics / JAK-naïve and biologics / JAK-experienced patients, the results of which are displayed below:



* Trial not powered for statistical significance for sub-group analysis.

- (1) n = Number of patients in the category with data available for baseline and week 8 visit.
- (2) MMS is the sum of assessment scores (0-3) of mucosal appearance on endoscopy, stool frequency, and rectal bleeding.

Endoscopic Improvement¹ at Week 8*



* Trial not powered for statistical significance for sub-group analysis.

(1) Endoscopic improvement is defined as endoscopic subscore ≤ 1 without friability.

(2) n = number of patients that met the respective endpoint.

(3) N = number of patients in the relevant analysis set.

(4) Delta = arithmetic difference rounded to nearest full percentage.

Overview of Maintenance Phase 2b Clinical Trial with Obefazimod for the Treatment of UC

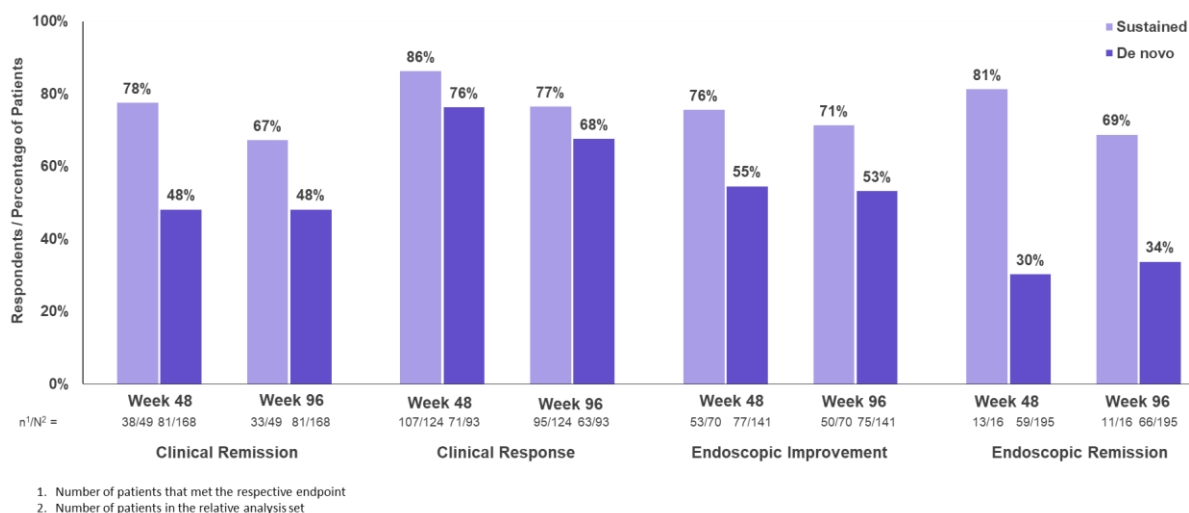
Of the 222 patients who completed the 16-week Phase 2b induction trial, 217 patients (98%) enrolled in the subsequent open-label maintenance trial to evaluate the induction Phase 2b clinical trial long-term safety and efficacy profile of obefazimod for up to two years, irrespective of treatments or treatment outcome during the induction phase.

At week 48, of those 217 patients who received a 50 mg once-daily oral dosing with obefazimod, 178 patients (82%) had clinical response, 119 patients (55%) were in clinical remission, 133 patients (61%) had endoscopic improvement and 72 patients (33%) had endoscopic remission. Moreover, 38 patients were in sustained clinical remission and 107 patients showed sustained clinical response. A total of 71 patients exhibited de novo clinical response and 81 patients exhibited de novo clinical remission. Among the 98 bio-refractory patients, 66 patients (67%) had a clinical response, 38 patients (39%) were in clinical remission, 46 patients (47%) had endoscopic improvement and 20 patients (20%) had endoscopic remission at week 96. These results demonstrate the long-term clinical response of obefazimod in patients who were refractory to conventional treatments, as well as patients who were previously exposed to treatment with biologics and/or JAK inhibitors.

At week 96, of the 49 patients who were in clinical remission at the end of the induction phase, 33 patients (67%) remained in clinical remission. Of the 168 patients who were not in clinical remission at the end of the induction phase, 81 patients (48%) exhibited de novo clinical remission. Furthermore, the clinical remission rate for patients who did not show at least a clinical response at the end of the 8-week induction phase was 43% (40 patients). Of the patients included in the maintenance trial, 164 patients (75%) completed two years of once-daily oral dosing with 50 mg obefazimod. Thirty patients dropped out during the first year of treatment. Six patients did not qualify for the second year due to

non-response after the first year of treatment, and 17 patients dropped out during the second year. These patients were all considered as treatment failures in the intent-to-treat analysis.

The following chart depicts clinical results of its long-term extension Phase 2b clinical trial at weeks 48 and 96:



Sustained clinical remission/response or endoscopic remission/improvement means a clinical remission or clinical response or endoscopic remission or endoscopic improvement in the subpopulation of patients with clinical remission or clinical response or endoscopic remission or endoscopic improvement at maintenance trial entry (i.e., at week 8 of induction trial).

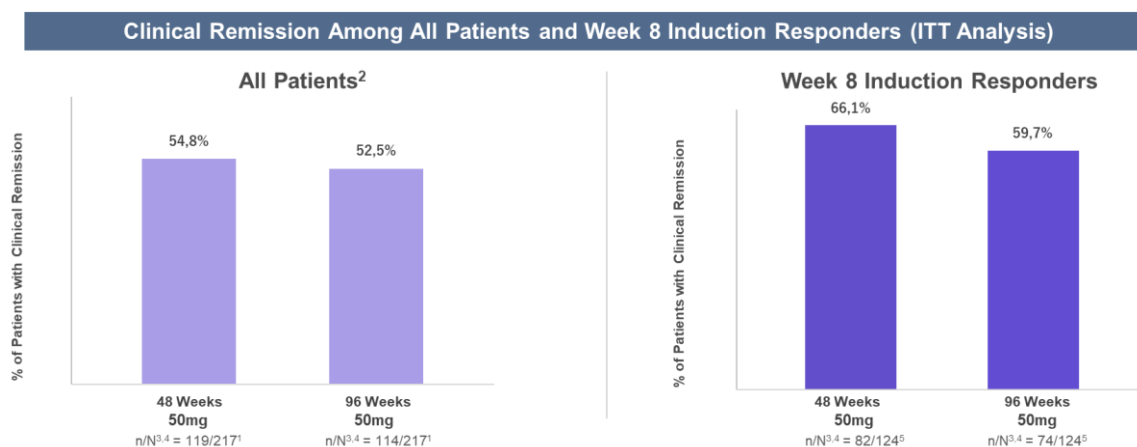
De novo clinical remission/response or endoscopic remission/improvement means a clinical remission or clinical response or endoscopic remission or endoscopic improvement in the subpopulation of patients without clinical remission or clinical response or endoscopic remission or endoscopic improvement at maintenance trial entry (i.e. at week 8 of induction trial).

* For week 48, with respect to six subjects, endoscopic data were missing at week 8 of the induction trial and were not included in this analysis.

* For week 96, drop outs were considered as treatment failures in the intent-to-treat analysis (30 patients dropped out during the first year; six patients did not qualify for the second year of treatment due to non-response after the first year and 17 patients dropped out during the second year).

Of all 217 patients who entered the Phase 2b open-label maintenance trial, regardless of their status at the end of the 8-week induction period, 119 patients (55%) achieved clinical remission at week 48 and 114 patients (53%) achieved clinical remission at week 96. Among the 124 patients who achieved clinical response at the end of the 8-week induction period of the double-blind study, 82 patients (66%) achieved clinical remission at week 48, mimicking the re-randomization of responders approach

typically utilized in Phase 3 maintenance trials, and 74 patients (60%) achieved clinical remission at week 96. This comparison is shown below:



- (1) 217/222 eligible patients enrolled into open label maintenance study.
- (2) Irrespective of patient outcome at the end of the 8-week induction phase.
- (3) n = Number of patients that met the respective endpoint.
- (4) N = Number of patients in the relevant analysis set.
- (5) 124 patients achieved clinical response at end of 8-week induction phase.
- (6) From week 48 to week 96, 19 patients began experiencing symptoms of UC again (i.e., were not in clinical remission anymore), and 14 patients achieved clinical remission.

The below table depicts the types of adverse events observed from its Phase 2b clinical trial:

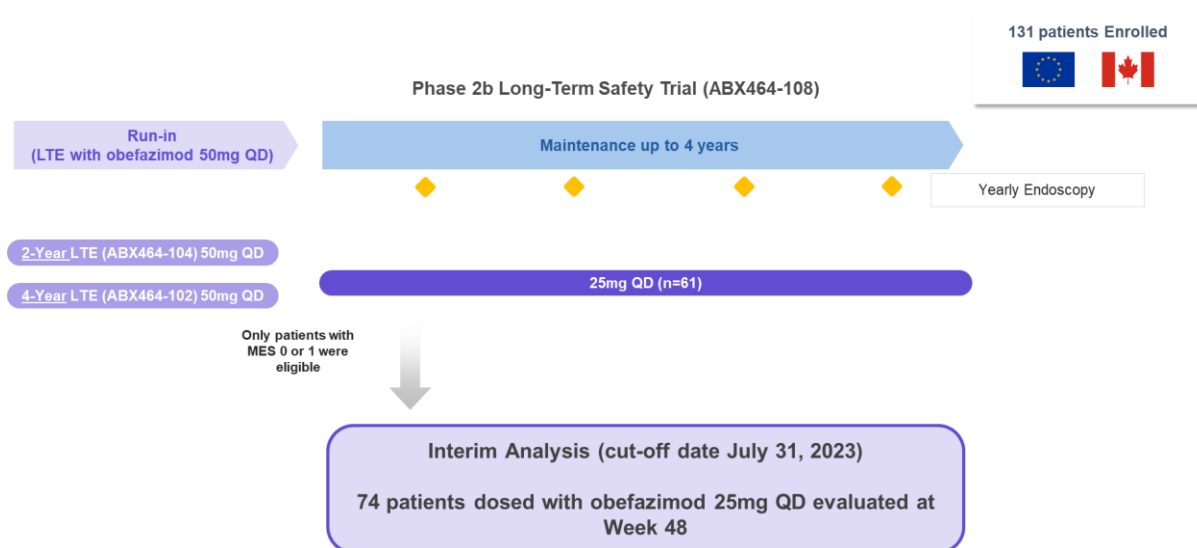
	Placebo (N=64)	Obefazimod 25 mg (N=62)	Obefazimod 50 mg (N=63)	Obefazimod 100 mg (N=64)
TEAE Leading to Study Discontinuation	5 (7.8%)	4 (6.5%)	9 (14.3%)	8 (12.5%)
Discontinuation Due to Headache	0 (0%)	1 (1.6%)	3 (4.8%)	4 (6.3%)
SAEs	4 (6.3%)	1 (1.6%)	4 (6.3%)	4 (6.3%)
Serious Infections	0	0	1 (1.6%)	0
AEs Reported in ≥ 5% of patients in any treatment group				
Headache	5 (7.8%)	13 (21.0%)	19 (30.2%)	27 (42.2%)
Nausea	4 (6.3%)	5 (8.1%)	4 (6.3%)	9 (14.1%)
Infections	6 (9.4%)	3 (4.8%)	8 (12.7%)	5 (7.8%)
Colitis Ulcerative	4 (6.3%)	0	4 (6.3%)	1 (1.6%)
Arthralgia	3 (4.7%)	1 (1.6%)	1 (1.6%)	5 (7.8%)
Vomiting	1 (1.6%)	1 (1.6%)	2 (3.2%)	5 (7.8%)
Abdominal Pain Upper	0	3 (4.8%)	3 (4.8%)	4 (6.3%)
Myalgia	0	0	0	5 (7.8%)

Only 100 mg AEs ≥5% below this line ↓

During the induction and the maintenance treatments of the Phase 2b clinical trial, the safety and tolerability profile observed was consistent with previous findings and no new adverse safety signals were observed. As of November 30, 2022 (the last safety data cut-off date), 1,074 patients and volunteers had been treated with obefazimod, of which 209 patients were treated with 50 mg obefazimod for one year or more with no change in the observed tolerability profile. At present, no increased rate of opportunistic infections or malignancies compared with placebo have been observed across all clinical trials.

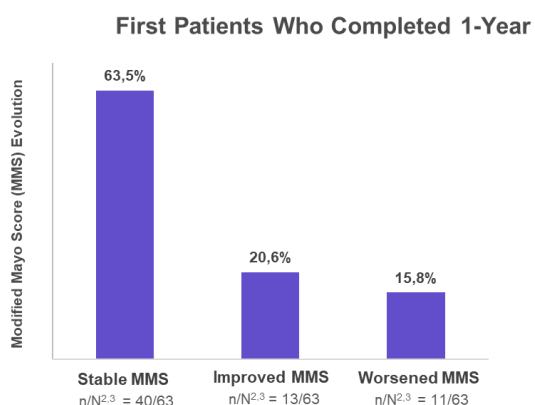
Overview of Phase 2 Open-Label Trial to Evaluate Long-Term Safety and Efficacy of Obefazimod at 25

In September 2023, the Company reported an interim analysis of step-down dosing from 50 mg to 25 mg for the third and fifth year of open-label maintenance treatment with obefazimod in UC patients.



These patients were treated with 50 mg of oral, once-daily obefazimod for approximately four years in the Phase 2a clinical trial and approximately two years in the Phase 2b clinical trial. Patients were eligible to enroll in the trial if they had a Mayo endoscopic subscore of 0 or 1. Eligible patients were switched to 25 mg, and an interim analysis was performed at week 48 with a cut-off date of July 31, 2023.

Change from ABX464-108 Baseline in MMS at Week 48¹



- 74 patients at Week 48 - 10 pts coming from the 102 LTE (4Y) & 64 pts from the 104 LTE (2Y)
 - 11 patients withdrew prior to 1 year
 - 3 due to no eligibility (MES > 1 at study baseline)
 - 2 AEs
 - 1 pregnancy
 - 5 due to consent withdrawal or investigator decision
- 63 performed their 1-year visit
 - **Disease control Rate (Stable + improved MMS) = 84.1% (45/63)**
 - Levels of Fecal Calprotectin consistent with the level of the disease control (93% < 250 microgram/gm)

No new safety signals in UC patients treated with obefazimod for up to 5 years

- (1) ABX464-108 Interim Analysis Outputs as of July 31, 2023.
- (2) n = Number of patients that met the respective endpoint.
- (3) N = Number of patients in the relevant analysis set.

Of the 71 eligible patients, 63 completed their 48-week visit. Among these patients, 53 out of 63 patients (84%) demonstrated disease control (stable or improved Modified Mayo Score). No new safety signals were detected in UC patients treated up to five years with oral, once-daily obefazimod.

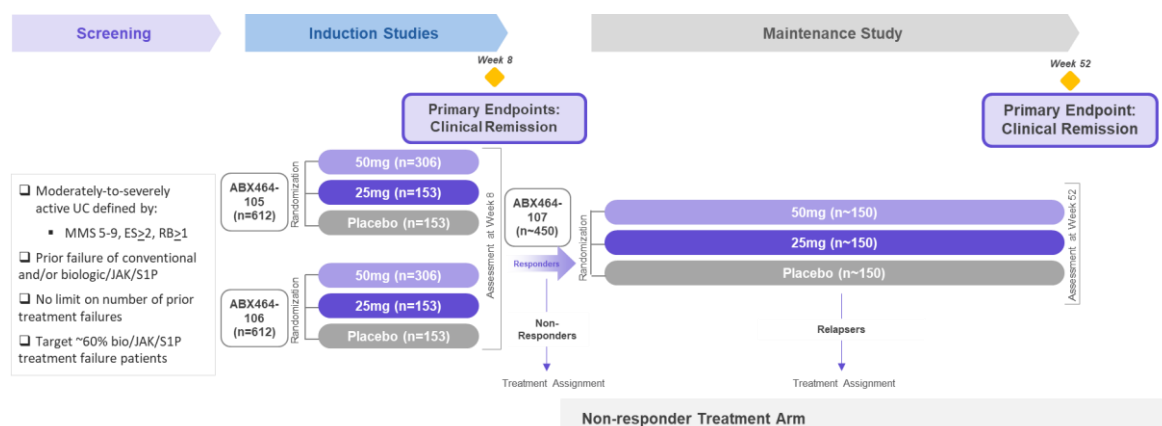
Phase 3 Clinical Trials and Regulatory Pathway in UC

The Company is working with IQVIA, a global premier contract research organization, to conduct the Phase 3 clinical trials with obefazimod in moderately to severely active UC, following consultations with regulatory agencies, including FDA, EMA, CDE and PMDA.

These pivotal Phase 3 clinical trials consist of two induction trials (ABTECT-1 and ABTECT-2) and the subsequent ABTECT maintenance trial investigating obefazimod at doses of 25 mg and 50 mg across 36 countries in North America, Latin America, Europe and Asia Pacific, involving 1,200 moderately to severely active UC patients in over 600 sites. Each of the trials will be randomized, double-blind and placebo-controlled, using independent and central review of the video-taped endoscopies with the primary endpoint of clinical remission according to the Modified Mayo Score assessed at week 8 (induction) and at the end of the 44-week maintenance trial (total 52 weeks), as recommended by the FDA.

The Modified Mayo Score evaluates UC disease activity, based on three parameters: stool frequency, rectal bleeding and endoscopic evaluation. Each parameter of the score ranges from zero (normal or inactive disease) to three (severe activity). The patient rates stool frequency score (“SFS”) and rectal bleeding score (“RBS”) daily. The endoscopy subscore is evaluated by a central reader (who is blinded to any clinical information about the patient) from an endoscopy that is performed at the trial site. The inclusion criteria based on FDA guidance for moderately to severely active UC is active disease defined by a Modified Mayo Score ≥ 5 with (RBS) ≥ 1 and endoscopy subscore of 2 or 3 (confirmed by central reader). The primary endpoint for induction and maintenance is clinical remission defined as SFS of 0 or 1 and not greater than baseline and RBS = 0 and endoscopy subscore of 0 or 1. At week 8, secondary endpoints include endoscopic improvement, clinical response, symptomatic remission and histologic-endoscopic mucosal improvement (“HEMI”). At week 44 of the maintenance trial, secondary endpoints include endoscopic improvement, symptomatic remission, corticosteroid-free clinical remission, sustained clinical remission, HEMI and endoscopic remission.

The following chart depicts the design of its Phase 3 clinical trial with obefazimod in moderately to severely active UC:



Enrollment of the first patient under this program in the United States occurred on October 11, 2022. Top-line data from the ABTECT-1 and ABTECT-2 induction trials is expected to be announced in the first quarter of 2025, and top-line data from the ABTECT maintenance trial is expected to be announced in the first quarter of 2026.

The following chart depicts its recently completed and expected upcoming milestones for its Phase 3 clinical trials of obefazimod for moderately to severely active UC:



Additional Clinical Trials Completed with Obefazimod

In addition, four Phase 1 clinical trials have recently been completed to assess the tolerability and safety profile of obefazimod: (i) a Phase 1 heart rhythm (QT interval) trial, for which the Company enrolled 120 healthy volunteers; (ii) a Phase 1 clinical trial of drug-drug interactions, for the purposes of providing further information on any possible interactions of obefazimod with other drugs, for which the Company enrolled 60 healthy volunteers; (iii) a Phase 1 absorption, distribution, metabolism and excretion trial for the purposes of generating additional data to further evaluate the safety profile of obefazimod, for which the Company enrolled 12 healthy volunteers; and (iv) a Phase 1 clinical trial conducted in Japanese subjects to further evaluate pharmacokinetics and tolerability of obefazimod in this population, for which the Company enrolled 48 healthy volunteers. The results of these Phase 1 clinical trials provide supportive data for its further clinical development and New Drug Application (“NDA”) submission. Furthermore, additional Phase 1 clinical trials to support NDA submission are planned. While the Company has decided not to pursue additional clinical work in RA at this point, the Company has completed a Phase 2a clinical trial in patients with RA, where the Company saw encouraging proof-of-concept data supporting obefazimod’s potential role in addressing inflammatory conditions beyond IBD.

5.1.6 Obefazimod in CD

5.1.6.1 CD Overview

CD is a chronic inflammatory condition that can affect the GI tract from mouth to anus but typically affects the colon and last section of the ileum (terminal ileum). Although considered in the same category of IBD as UC, the inflammation occurs across the bowel wall which leads to different complications including stricture and fistula formation. CD affects about 3.2 per 1,000 people in Europe, North America and the United Kingdom. Collectively, the Company estimates there are approximately 1.1 million CD patients in G7 countries. Of these patients, approximately 0.5 million patients (or approximately 44%) are estimated to be diagnosed with moderately to severely active CD, with approximately 0.6 million patients (or approximately 56%) diagnosed with mildly to moderately active CD. While this disease is diagnosed at any age, onset is more common among adolescents and young adults. Patients typically present with abdominal pain, diarrhea, fatigue and weight loss. In cases of bowel obstruction, patients will also experience bloating and vomiting. The likelihood of having surgery mostly due to bowel obstruction within the lifetime of a CD patient is approximately 80%. Besides bowel complications, patients can experience extra-intestinal manifestations (“EIMs”), which impact the skin, eye and joints primarily. The prevalence rate of EIMs is approximately 24% in all IBD patients, 27% in UC patients, but as high as 35% in CD patients.

5.1.6.2 Existing Therapies and Their Limitations

Similar to existing UC treatments, patients may receive oral immunosuppressants, such as azathioprine and methotrexate as well as short courses of corticosteroids. In cases of moderately to severely active CD, the options for advanced therapy include very commonly prescribed TNF- α inhibitors, anti-integrin antibodies, IL-12/23 inhibitors, IL-23 inhibitors and JAK inhibitors. Therapies such as TNF- α inhibitors, IL-12/23 inhibitors or IL-23 inhibitors are injectable agents, representing a significant commercial disadvantage due to patients' and prescribers' preference for the convenience of oral therapies. JAK inhibitors are accompanied by safety warnings due to increased risk of adverse events such as infection, cancer or blood clots.

Induction remission rates for these existing therapies are less than 50% and maintenance remission rates often decrease over time. There remains unmet needs for more effective and durable therapy, including those with more convenient delivery methods (as there are no approved oral therapies for first-line use in the United States), durable efficacy, treatment of patients who have failed biologic agents, improved mucosal healing, improved treatment for fistulizing CD and improved corticosteroid free remission. The Company believes obefazimod's differentiated clinical profile, including dosing as a once-daily, oral therapy as well as its demonstrated tolerability and durability to date, position it favorably as a potential first-line advanced therapy option for patients and prescribers, if approved.

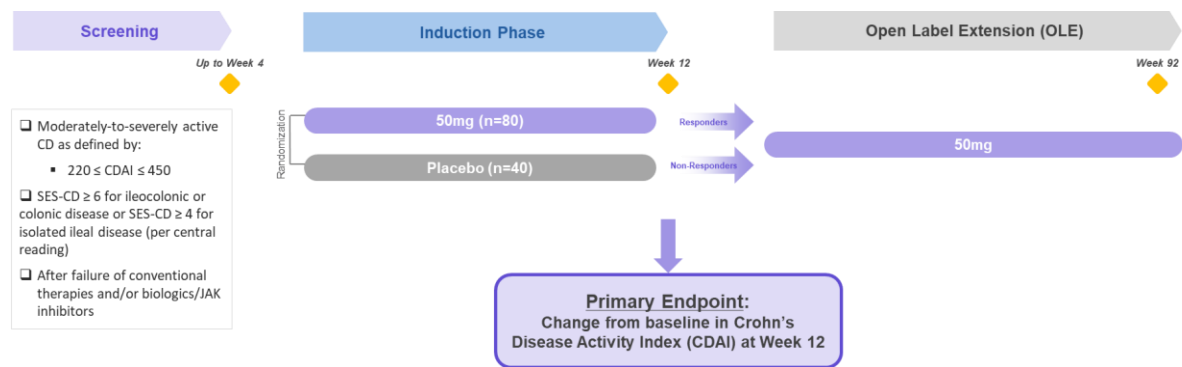
5.1.6.3 Market Opportunity: CD

The estimated market opportunity for CD was approximately \$16.3 billion in worldwide sales in 2022 and is expected to reach \$16.6 billion in worldwide sales in 2028. In 2022, approximately \$11.4 billion of sales came from the United States and all moderately to severely active CD sales came exclusively from injectable products. Similar to the UC market, the Company believes oral agents represent a significant commercial opportunity, particularly if such therapeutics can provide long-term safety and efficacy profiles comparable to injectable agents.

5.1.6.4 Proposed Obefazimod CD Development Program

Due to the pathophysiological and clinical similarities of CD and UC, the Company plans to initiate a Phase 2a clinical trial in patients with CD in the first quarter of 2024 to potentially demonstrate outcomes consistent with those observed in its Phase 2 clinical trials for moderately to severely active UC. The Company believes the preclinical and Phase 1 data generated in its UC clinical trials are sufficient for completion of these equivalent trials in CD. The Company intends to (i) file an IND in the fourth quarter of 2023, (ii) initiate a Phase 2 clinical trial in patients with CD in the first quarter of 2024 and (iii) announce top-line results in the second half of 2025 with the objective to demonstrate clinical response and tolerability profile consistent with that already observed in its clinical trials for moderately to severely active UC. Based on the results from this Phase 2 clinical trial, the Company intends to proceed directly to a Phase 3 clinical trial.

The following chart depicts the design of its Phase 2a clinical trial with obefazimod in CD:



5.1.7 Potential Combination Therapy for the Treatment of IBD with Obefazimod as the Cornerstone

Despite the development of various advanced targeted therapies for IBD over the past 20 years, a single agent with transformational efficacy remains elusive. Although cross-trial efficacy comparisons must be interpreted with caution, induction of clinical remission rates have currently reached a placebo-adjusted therapeutic ceiling up to 30%. Improved efficacy of combination therapy with thiopurines and TNF- α inhibitors has been well described (SONIC and UC-SUCCESS) but did not breach the aforementioned efficacy ceiling. Emerging data utilizing dual advanced targeted therapy affecting complementary mechanisms of action indicate a potential path to higher efficacy rates. The first trial utilizing this strategy (VEGA) randomized patients to three parallel treatment groups: (1) dual combination therapy with guselkumab (IL-23 inhibitor) plus golimumab (TNF- α inhibitor); (2) guselkumab alone; or (3) golimumab alone. At the end of the 12-week induction period, a greater proportion of patients randomized to dual combination therapy achieved clinical remission (approximately 47%) compared to either monotherapy treatment arms (guselkumab at approximately 25%; golimumab at approximately 24%). Importantly, adverse events, serious adverse events and infection rates were comparable among treatment groups.

The Company believes synergistic improvements that may be achieved with advanced combination therapy should be balanced with patient adherence to multiple biologic injections and safety considerations associated with immune suppression. Several of obefazimod's attributes make it a potentially attractive candidate to pair with other advanced treatments. First, the oral route of administration is preferred by a majority of patients, potentially resulting in higher levels of medication adherence. Further, obefazimod's proposed mechanism of action harnesses the body's natural regulatory mechanisms to modulate the inflammatory response in patients with chronic inflammatory diseases. The novel mechanism of action of obefazimod potentially lends itself as complementary to other oral or injectable agents with the potential of improving the induction and remission efficacy over monotherapy. The Company believes the current clinical results the Company has observed with obefazimod including a lack of signals for malignancy, opportunistic or serious infection risk up to 96 weeks of treatment support development as an agent to be used in potential combination therapy.

5.1.8 Follow-On Compounds Program

Based on the mechanistic concept of obefazimod, a research and development program is currently ongoing to generate new potential drug candidates to strengthen its intellectual property portfolio on the miR-124 platform. The first follow-on drug candidate is expected to be selected and enter preclinical development in 2024.

5.1.9 Manufacturing and Supply

5.1.9.1 Obefazimod

Its lead compound, obefazimod, is manufactured using commercially available, widely used raw materials and common chemical engineering and synthetic processes. Obefazimod is formulated as an oral solid capsule. The Company has successfully scaled-up active pharmaceutical ingredients and drug product processes, and the Company has a large supply of active pharmaceutical ingredients and capsules available for clinical trials.

The Company outsources all manufacturing operations and rely on European third-party contract manufacturing organizations (“CMOs”) to supply clinical trials and finalize the development of obefazimod. These operations are designed to be in compliance with the standards imposed by Good Manufacturing Practice (“GMP”). The Company believes its outsourcing strategy and internal organization allow the Company to focus its resources on the development of different drug candidates and the management of third parties, without investing in expensive manufacturing facilities and equipment. All third parties are assessed under its quality system and agreements are in place to compel compliance and the Company maintains agreements with manufacturers which include confidentiality and intellectual property provisions to protect proprietary rights.

The Company is in the process of further optimizing and scaling up its supply chain for obefazimod to ensure capacity for its expected commercial supply, if the FDA or foreign regulatory authority approved.

5.1.10 Research and Development

Since its incorporation in 2013, the majority of its resources have been allocated to research and development activities. The Company is conducting development activities to expand the commercial potential of its drug candidates, in particular obefazimod. In the years ended December 31, 2021 and 2022, the Company incurred EUR 47.8 million and EUR 48.3 million, respectively, of research and development expenses, or 89.5% and 69.6% respectively, of its total operating expenses. Its research and development expenses consist primarily of the following items:

- personnel expenses, including salaries, benefits, and share-based compensation expenses, for employees engaged in research and development activities;
- sub-contracting, collaboration and consultant expenses that primarily include the cost of third-party contractors such as CROs who conduct its preclinical studies and clinical trials, and research related to its proprietary platforms, as well as investigative sites and consultants that conduct its preclinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- expenses relating to preclinical studies and clinical trials;
- expenses relating to regulatory affairs; and
- expenses relating to the implementation of its quality assurance system.

For the year ended December 31, 2022, its total operating expenses were EUR 69.4 million, as compared to EUR 53.4 million for the year ended December 31, 2021, an increase of EUR 16.1 million,

or 30%. This increase was primarily due to an increase in goodwill impairment loss and in general and administrative expenses while research and development expenses remained at a consistent level.

4.2 Strategy and objectives

Section 5.4. "Strategy and objectives" of the 2023 Universal Registration Document, is updated as follows:

5.4 The Company's Strategy

The Company's primary goal is to develop and commercialize obefazimod for the treatment of inflammatory diseases, starting with moderately to severely active UC. The Company has already generated compelling data in moderately to severely active UC from its Phase 2a and 2b clinical trials, which the Company believes provides it with potential readthrough into broader set of inflammatory diseases. The Company focuses on indications with high unmet needs with substantial commercial potential. To achieve its goal, the Company is pursuing the following key elements of its strategy:

- Advance obefazimod through pivotal clinical trials and establish obefazimod as a potential first-line advanced therapy for IBD.

The Company believes that the strength of the data the Company has generated in its Phase 2 clinical trials, specifically the potential to demonstrate rapid onset of action and durability of safety and efficacy results (as evidenced by a clinical remission rate of 53%, clinical response rate of 73% and no new adverse safety signals observed from its two-year Phase 2b open-label maintenance trial), if supported by the results of its Phase 3 clinical trials, uniquely positions obefazimod as a potential first-line advanced therapy choice for moderately to severely active UC, if approved.

Based on the positive clinical data generated in its UC trials, preclinical studies in dextran sulfate sodium mouse model which provide support for pursuing further development in CD, and underlying biological and mechanistic rationale, the Company plans to initiate a Phase 2a clinical trial in patients with CD in the first quarter of 2024 to potentially demonstrate outcomes consistent with those observed in its Phase 2 clinical trials for moderately to severely active UC. CD shares many of the underlying pathophysiological processes and clinical manifestations of UC, and, as a result, the current treatment paradigm of CD is similar to UC. In addition, the Company believes that obefazimod's clinical profile observed to-date lends itself to potential combinations with existing or new therapies, which the Company is exploring.

- Disrupt the IBD landscape in the near-term with its Phase 3 data beginning in 2025.

Currently available therapies have limited efficacy and durability that wanes over time, have extensive pre-initiation requirements, carry significant safety and tolerability challenges (such as black box safety warnings), and most of them are injectable biologics. The Company believes the potential for oral agents to gain significant market share is supported by physician and patient preference for the convenience of oral administration over injectable agents, increasing demand for therapies with long-term efficacy profiles and the opportunity for potent and well-tolerated oral agents to expand the overall segment of the moderately to severely active UC population undergoing treatment. The Company believes obefazimod's novel mechanism of action that modulates multiple inflammatory pathways simultaneously offers a potentially differentiated oral treatment option that may lead to more durability of efficacy results as the Company observed in its Phase 2 clinical trials.

- Leverage library of miR-124 enhancers to expand its pipeline.

Based on the mechanistic concept of obefazimod, the Company has launched a research and development program to generate new potential drug candidates to strengthen its intellectual property portfolio on the miR-124 platform and to identify additional drug candidates from its proprietary small molecule library that includes additional miR-124 enhancers. Its strategy is to conduct proof-of-concept studies with obefazimod to show that enhanced expression of miR-124 demonstrates disease-modifying effects in other inflammatory conditions where there is unmet medical need. To further its strategy, its first follow-on drug candidate is expected to be selected and enter preclinical development in 2024.

- Opportunistically evaluate strategic partnerships to maximize the value of obefazimod and its therapeutic pipeline.

The Company currently holds and intend to retain worldwide development and commercialization rights for obefazimod. For certain geographies, the Company may opportunistically enter into strategic partnerships to accelerate development activities in order to realize the commercial potential of obefazimod as well as other assets in its pipeline.

4.3 Intellectual Property Protection Policy

Paragraph 5.5.1.1 "Intellectual Property Protection Policy" of the 2023 Universal Registration Document, is updated as follows:

Intellectual Property

The Company's success will depend upon its ability to obtain and maintain patents and other intellectual property for its drug candidates in the United States and internationally, including composition-of-matter, pharmaceutical composition, synthesis process, method of manufacture and method of treatment, as well as patent and other intellectual property and proprietary protection for its novel discoveries and other important technology inventions and know-how.

One of its strategies is also to file new patents that could extend obefazimod's intellectual property protection in the United States to 2039 and to generate new intellectual property through the protection of potential follow-on compounds.

In addition to patents, the Company relies upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain its competitive position. The Company protects its proprietary information, in part, using confidentiality agreements with its commercial partners, collaborators, employees and consultants and invention assignment agreements with its employees. The Company also has confidentiality agreements or invention assignment agreements with its commercial partners and selected consultants. Despite these measures, any of its intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit the Company to take advantage of current market trends or otherwise to provide competitive advantages. In addition, such confidentiality agreements and invention assignment agreements can be breached and the Company may not have adequate remedies for any such breach. For more information, please refer to chapter 3 "Risk factor" of the 2023 Universal Registration Document.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which the Company is seeking patent protection for its drug candidates, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be lengthened by a patent term

adjustment, which provides for term extension in the case of administrative delays at the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent with an earlier expiration date. Furthermore, in the United States, the term of a patent covering an FDA approved drug may be eligible for patent term extension (“PTE”) under the Hatch-Waxman Amendments as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent but cannot extend the term of a patent beyond a total of 14 years from the date of product approval. Only one patent covering a single FDA-approved product among those eligible for an extension may be extended. In the future, if any of its drug candidates receives FDA approval, the Company expects to apply for a PTE, if available, to extend the term of a patent covering such approved drug product. The Company also expects to seek PTEs in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with its assessment of whether such an extension should be granted, and even if granted, the length of such an extension. See “Risk Factors—Risks Related to its Intellectual Property — Its ability to commercialize its drug candidates may decrease if the Company is unable to protect its intellectual property rights or if these rights are insufficient for its purposes.

4.4 Trademarks

Paragraph 5.5.3.1 "Trademarks" of the 2023 Universal Registration Document, is updated as follows:

5.5.3.1 Trademarks

The Company has the following trademarks:

Trademark	Number	Status	Filing date	Territory	Class
Abivax	1 732 388	Registered	16/6/2015	Canada	5
Abivax	013957212	Registered	16/4/2015	EU	5
Abivax	913957212	Registered	16/4/2015	UK	5
Abivax	13 4 043 749	Registered	30/10/2013	France	5
Abivax	1 260 622	Registered	7/5/2015	Cuba	5
Abivax	2984677	Registered	12/6/2015	India	5
Abivax	2015-15483	Registered	29/7/2019	South Africa	5
Abivax	72273485	Registered	31/10/2022	China	5

The Company did not consider it appropriate to file trademarks protecting the names of its technology platforms or products under clinical development.

At the date of this Amendment, a trademark opposition proceeding has been brought in Australia against a trademark of the Company by a third party.

4.5 Competitive Environment

Section 5.6 "The competitive environment" of the 2023 Universal Registration Document, is updated as follows:

5.6 Competition

The Company competes with companies that have drugs on the market or are developing drug candidates for chronic inflammatory disease. The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change, as researchers learn more about chronic inflammatory diseases and develop new technologies and treatments.

Significant competitive factors in its industry include: (i) product efficacy and safety; (ii) quality and breadth of an organization's technology; (iii) skill of an organization's employees and its ability to recruit and retain key employees; (iv) timing and scope of regulatory approvals; (v) government reimbursement rates for, and the average selling price of, pharmaceutical products; (vi) the availability of raw materials and qualified manufacturing capacity; (vii) manufacturing costs; intellectual property and patent rights and their protection; and (viii) sales and marketing capabilities. Given the intense competition in its industry, the Company cannot assure you that even if the Company is able to successfully develop any products, that they will have a higher benefit-risk profile or better cost effectiveness compared to products developed or introduced by its competitors. Its competitors in the chronic inflammatory disease field are primarily large pharmaceuticals companies including, but not limited to, AbbVie, Pfizer, Eli Lilly, Takeda and Johnson & Johnson. Several lines of research are being developed to improve the treatment of IBD. Many companies are working to develop new, more effective and better tolerated treatments with more practical formulations, especially small molecules administered orally, better accepted than monoclonal antibodies that require administration by injection or intravenous infusions.

The molecules in development have various mechanisms of action and are primarily: (i) TNF- α inhibitors; (ii) IL-12/23 inhibitors; (iii) anti-integrin anti-bodies; (iv) IL-23 inhibitors; (v) JAK inhibitors; (vi) S1P receptor agonists; or (vii) TL1A inhibitors.

In the TNF- α treatment class, Remicade[®] (Janssen) was first approved by the FDA in 1998. In 2012, the European Commission approved AbbVie's Humira[®] for the treatment of pediatric patients aged six to 17 years with severe active CD who have an inadequate response, are intolerant or have contraindications to conventional therapy.

IL-12/23 inhibitors entered the UC market in 2019 as ustekinumab (Johnson & Johnson's Stelara[®]). In 2021, AbbVie filed an authorization application with FDA and EMA for Risankizumab (Anti-IL-23—Skyrizi[®]) for the treatment of moderately to severely active CD and a Phase 3 clinical trial in patients with UC is underway.

Etolizumab, a selective anti-alpha-4/beta-7 monoclonal antibody developed by Roche/Genentech, recently failed in Phase 3 for CD after failing in Phase 3 in UC in 2020. The anti-integrin class is currently represented by vedolizumab/Entyvio[®] and natalizumab/Tysabri[®]. The Company is also aware of Morphic Therapeutic's MORF-057 and Protagonist Therapeutics/Johnson & Johnson's PN-943 currently in development. The anti-integrin drugs work by preventing the leukocytes to move from the blood vessels to sites of inflammation. They block the action of integrin on the surface of circulating immune cells and endothelial cell adhesion molecules, thereby inhibiting the interactions between leukocytes and intestinal blood vessels. Natalizumab and vedolizumab block α 4-integrin and α 4 β 7-integrin respectively. These drugs are injectable (Humanized mAb).

In 2021, Eli Lilly reported that mirikizumab (Anti-IL-23) generated data in a Phase 3 maintenance trial in patients with UC that led to the submission of an authorization request to regulatory agencies. Phase 3 clinical trials in CD are also underway with mirikizumab. All these drugs are injectable (Humanized mAb). IL-23 is a regulator of T-helper (Th)-17 cell. IL-23 prevents regulatory T-cell response in the intestine, and therefore increases inflammation in the gut. Anti-interleukins targeting the IL-23 have been shown to be effective for induction and maintenance of remission in patients with moderate-severe UC.

The JAK correspond to four intracellular tyrosine kinases: JAK1, JAK2, JAK3 and tyrosine kinase 2. Inhibition of the JAK-STAT signal channel makes it possible to block the production of pro-inflammatory cytokines, including TNF- α , to block other pathways of inflammation and to regulate innate and adaptive immunity. Thus, several cytokines and several inflammation pathways are blocked simultaneously, unlike TNF- α inhibitors, which only have a single target. In September 2021, FDA published a black box warning, requiring pharmaceutical companies to provide a warning for increased risk of serious cardiac events, cancer, blood clots and death linked to JAK inhibitor treatments used for the treatment of certain IBD, including UC. Consequently, these treatments are only accessible to patients who do not respond to any other available treatment and who have certain well-defined conditions. In the JAK inhibitor class, to its knowledge the following products are authorized or in advanced development:

- Pfizer's tofacitinib (Xeljanz[®]) is a non-selective JAK inhibitor. It obtained marketing approval in UC in June 2018. In September 2021, the FDA concluded that there was a high risk of serious side effects following a randomized clinical trial conducted to assess the safety of tofacitinib. Consequently, the molecule will be used as a third line treatment in patients who meet specific criteria.
- Gilead and Galapagos' filgotinib (Jyseleca[®]) is a selective JAK1 inhibitor. Since November 2021, filgotinib has been approved for the treatment of UC in the European Union (the "EU"). Authorization requests have also been submitted to the UK Medicines and Healthcare products Regulatory Agency ("MHRA") and the Japanese PMDA for the treatment of moderately to severely active UC. A Phase 3 clinical trial in patients with CD is also underway.
- AbbVie's upadacitinib (Rinvoq[®]), which is also a selective JAK1 inhibitor, was approved by the FDA in March 2022 for the treatment of moderately to severely active UC. EMA authorization for the treatment of moderately to severely active UC was granted in July 2022. A Phase 3 clinical trial in patients with CD is currently underway.

S1P receptor agonists allow sequestration of activated lymphocytes in lymph nodes and thus reduce their circulation in the GI tract. Ozanimod (Zeposia[®]) is a S1P receptor modulator that is selective for the S1P1 and S1P5 receptors. It was approved by the FDA and EMA for the treatment of moderately to severely active UC in 2021. Phase 3 clinical trials are currently being conducted to assess the efficacy of ozanimod in CD. Top-line results of a Phase 3 induction trial of ARENA Pharmaceuticals' Etrasimod for the treatment of UC were announced in March 2022 and the primary endpoint, as well as the key secondary endpoints were reached; a Phase 2/3 clinical trial is currently being conducted in CD. In addition, in June 2023, Ventyx Biosciences announced completion of enrollment of its Phase 2 clinical trial of VTX002 in UC.

The Company is also aware of other types of treatments currently under various stages of development, such as NImmune Biopharma's omilancor (a Lanthionine Synthetase C-Like 2 activator) as well as tyrosine kinase 2 inhibitors from Bristol Myers Squibb's Sotyktu (deucravacitinib – approved in the EU) and Ventyx Biosciences' VTX 958.

Furthermore, TL1A inhibitors have garnered interest from those seeking newer targets and agents with differentiated clinical profile. While PRA023 (Merck-Prometheus) and RVT-3101 (Pfizer-Roivant) have generated promising early Phase 2 data in both biologics-experienced and biologics-naïve patients, neither have initiated Phase 3 clinical trials and do not have long-term safety and efficacy data beyond 56 weeks.

Its competitors may also succeed in obtaining European Commission, FDA or other regulatory approvals for their drug candidates more rapidly than the Company, which could place the Company at a significant competitive disadvantage. Market acceptance of its drug candidates will depend on a number of factors, including: (i) potential advantages over existing or alternative therapies or tests; (ii) the actual or perceived safety of similar classes of products; (iii) the effectiveness of its sales, marketing, and distribution capabilities; and (iv) the scope of any approval provided by the FDA or foreign regulatory authorities.

The Company anticipates that the Company will face intense and increasing competition as new drugs and therapies enter the market and advanced technologies become available.

5. RISKS FACTORS

The Company does not anticipate any significant evolution of the Group's risk factors as described in Chapter 3 of the Universal Registration Document. This Chapter presents updates for specific risks, to take into account the Company's updated strategy and perspectives.

Accordingly, the table ranking the risk factors in Chapter 3 of the Universal Registration Document is replaced by the following and the Sections of Chapter 3 of the Universal Registration Document are renumbered accordingly:

Title of the risk	Probability of occurrence <i>High</i> <i>Medium</i> <i>Low</i>	Impact of risk <i>Significant</i> <i>Moderate</i> <i>Negligible</i>	Criticality level <i>High: ***</i> <i>Medium: **</i> <i>Low: *</i>
1. Risks related to the Company's business			
<i>3.1.1 Risks related to the clinical development of the Company's drug candidates</i>	High	Significant	***
<i>3.1.2 Risks related to obtaining marketing authorisation and other pre-marketing certifications</i>	High	Significant	***
<i>3.1.3 Risks related to the Company's commercial and strategic development</i>	High	Significant	***
<i>3.1.4 Risks related to the Company's competition</i>	High	Significant	***
<i>3.1.5 Risks related to the technologies belonging to the Company and partners with whom it has entered into licensing agreements</i>	Medium	Moderate	*
<i>3.1.6 Risks related to reimbursement and delisting of drugs and treatments</i>	Medium	Moderate	*
<i>3.1.7 Risks related to the armed conflict between Ukraine and Russia</i>	Medium	Moderate	*
2. The Company's financial and market risks			
<i>3.2.1 Uncertainty of capital resources and liquidity risk</i>	High	Significant	***
<i>3.2.2 Risks related to the fluctuations in currency exchange rate</i>	High	Significant	***
<i>3.2.3 Risks related to the commitments associated with the Company's debt financing and repayable advances</i>	High	Significant	***
<i>3.2.4 Risks related to historic and future losses</i>	High	Significant	***
<i>3.2.5 Risk of dilution</i>	High	Significant	***
<i>3.2.6 Risks related to the French Research Tax Credit (CIR)</i>	Medium	Moderate	*

Title of the risk	Probability of occurrence <i>High</i> <i>Medium</i> <i>Low</i>	Impact of risk <i>Significant</i> <i>Moderate</i> <i>Negligible</i>	Criticality level <i>High: ***</i> <i>Medium: **</i> <i>Low: *</i>
3.2.7 Risks related to the future use of tax loss carry forwards	Medium	Moderate	*
3.2.8 Risks related to the impairment of goodwill	Medium	Moderate	*
3.2.9 Risk related to internal control	Low	Moderate	*
3. The Company's regulatory and legal risks			
3.3.1 Risks related to a restrictive and changing regulatory framework	High	Significant	***
3.3.2 Risks related to intellectual property	High	Significant	***
3.3.3 Risks related to product liability claims	Medium	Significant	**
3.3.4 Risks related to restrictive regulations governing the cross-border collection, use, processing and transfer of personal information	Medium	Moderate	*
4. Risks related to the Company's organisation			
3.4.1 Risks related to managing the Company's growth	High	Significant	***
3.4.2 Risks of dependency on third parties	High	Significant	***
3.4.3 Risk related to the Company losing key employees and not being able to attract new qualified individuals	High	Significant	***

5.1 Risks related to the Company's business

5.1.1 Risks related to the clinical development of the Company's drug candidates

The following additional paragraphs are added at the end of Section 3.1.1 "Risks related to the clinical development of the Company's drug candidates" of the 2023 Universal Registration Document:

"The Company may find it difficult to enroll patients in its clinical trials. If the Company encounters difficulties enrolling patients in its clinical trials, its clinical development activities could be delayed or otherwise adversely affected."

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of the clinical trials of the Company will depend, in part, on the speed at which the Company can recruit patients to participate in its trials, as well as completion of required follow-up periods. The Company may not be able to initiate or continue clinical trials for its drug candidates if the Company is unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by applicable regulatory authorities. The eligibility criteria of its clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the drug candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any products that may be approved for, or any drug candidates under investigation for, the indications the Company is investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. The Company also relies on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of its clinical trials and preclinical studies. Though the Company has entered into agreements governing their services, the Company will have limited influence over their actual performance. The Company's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays or may require it to abandon one or more clinical trials altogether. Enrollment delays in its clinical trials may result in increased development costs for its drug candidates and jeopardize its ability to obtain regulatory approval for the sale of its drug candidates. Furthermore, even if the Company is able to enroll a sufficient number of patients for its clinical trials, the Company may have difficulty maintaining enrollment of such patients in its clinical trials.

The Company may conduct clinical trials for its drug candidates outside of the U.S., and the FDA may not accept data from such trials, in which case its development plans may be delayed, which could materially harm its business.

The Company has in the past conducted clinical trials or a portion of its clinical trials for its drug candidates outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., for example, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the

sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the relevant jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it may result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future drug candidates that the Company may develop not receiving approval for commercialization in the applicable jurisdiction.

Interim, "top-line" and preliminary data from its clinical trials and preclinical studies that the Company announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, the Company may publicly disclose interim, top-line, or preliminary data from its clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. The Company also makes assumptions, estimations, calculations and conclusions as part of its analyses of data, and it may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, or preliminary results that the Company reports may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data the Company previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that the Company may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, top-line, or preliminary data and final data could significantly harm the Company's business prospects. Further, disclosure of such data by the Company or by its competitors could result in volatility in the price of the Company's securities.

Further, others, including regulatory agencies, may not accept or agree with the Company's assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or product and the Company in general. In addition, the information the Company chooses to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and investors or others may not agree with what the Company determines is material or otherwise appropriate information to include in its disclosure, and any information the Company determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug candidate or its business. If the interim, top-line, or preliminary data that the Company reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, the Company's ability to obtain approval for, and commercialize, its drug candidates may be harmed, which could harm its business, operating results, prospects or financial condition."

5.1.2 Risks related to obtaining marketing authorization and other pre-marketing certifications

The following additional paragraphs are added at the end of Section 3.1.2 "Risks related to obtaining marketing authorization and other pre-marketing certifications" of the 2023 Universal Registration Document:

"The Company may not be able to conduct, or contract others to conduct, animal testing in the future, which could harm its research and development activities.

Certain laws and regulations relating to drug development require the Company to test its drug candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, the Company's research and development activities may be interrupted or delayed."

5.1.3 Risks related to the war between Ukraine and Russia

Section 3.1.8 "Risks related to the war between Ukraine and Russia" of the 2023 Universal Registration Document, is renumbered and updated as follows:

"3.1.7 Risks related to the war between Ukraine and Russia

In February 2022, Russia invaded Ukraine. The conflict has already had major implications for the global economy and the rate of inflation, particularly in relation to the supply of energy, raw materials and food products. It has also caused intense volatility on the financial markets, something that is still ongoing at the reporting date and has pushed down stock market prices around the world.

Given these developments, the Company has decided not to include Russia and Belarus in its global Phase 3 program for obefazimod in UC. However, the global scale of this conflict cannot be predicted at this stage. The Company, therefore, cannot rule out an adverse impact of this conflict on its business, including in terms of access to raw materials, logistics, the performance of clinical trials and in relation to any future financing the Company may seek.

The Phase 2b maintenance trial of obefazimod in moderately to severely active UC is the Company's only clinical trial currently in progress in Ukraine. The Company has, however, terminated a few trial sites since the Russia/Ukraine war began. The 12-month assessment was carried out in all the Ukrainian patients before the war broke out and these patients are therefore included in the one-year maintenance results that were reported on April 6, 2022. Ukrainian patients who completed the two-year Phase 2b maintenance trial have been transitioned to the long-term safety and efficacy trial that is still on-going. None of these sites are located in the Crimea Region of Ukraine, the so-called Donetsk People's Republic, or the so-called Luhansk People's Republic. The Company is also evaluating the possibility to include a few Ukrainian sites in the western part of Ukraine in the ABTECT Phase 3 clinical trials."

5.2 The Company's financial and market risks

5.2.1 Uncertainty of capital resources and additional funding

Section 3.2.1 "Uncertainty of capital resources and additional funding" and Section 3.2.2 "Liquidity risks" of the 2023 Universal Registration Document, are replaced as follows:

"3.2.1 Uncertainty of capital resources and liquidity risk

The Company's operations have consumed substantial amounts of cash since inception. The Company is currently advancing obefazimod through clinical development and conducting preclinical studies with respect to other programs. Developing drug candidates is expensive, lengthy and risky, and the Company expects its research and development expenses to increase substantially in connection with its ongoing activities, particularly as the Company seeks to advance obefazimod toward commercialization. If the Company's clinical trials are successful and the Company obtains regulatory approval for drug candidates that it develops, the Company will incur commercialization expenses before these drug candidates are marketed and sold.

As a result of (a) existing cash and cash equivalents of EUR 114.4 million as of June 30, 2023, (b) the net proceeds of the August 2023 drawdown of the first tranches of the Kreos / Claret Financing and the Heights Financing, collectively amounting to EUR 27.2 million (net of repayments of all outstanding amounts that remained due under the pre-existing Kreos loans and the OCEANE bonds), (c) the available drawdowns of the second tranches of the Kreos / Claret Financing and the Heights Financing (which tranches are not conditional on amount raised in the planned registered public offering in the United States), collectively amounting to EUR 65 million in gross proceeds, and (d) the expected reimbursement of the 2022 Research Tax Credit in the second half of 2023 amounting to EUR 4.5 million, the Company expects to be able to fund its forecasted operating cash flow requirements through the third quarter of 2024.

This takes into account the Company's assumption that R&D expenditure will be substantially increased in 2023 driven by the progression of the Phase 3 clinical trials of obefazimod, which started enrollment of patients with moderately to severely active UC in October 2022.

The Company's expected spendings over the next twelve months will be overwhelmingly allocated to the conduct of the Company's Phase 3 clinical trials in UC and the payment of the Company's general and administrative costs. The development of obefazimod in CD will only represent a limited portion of its expenses.

However, the Company's operating plans may change as a result of a variety of factors, and it may need to seek additional funds sooner than planned. In any event, the Company will require additional capital to pursue preclinical and clinical activities, obtain regulatory approval for and commercialize its drug candidates. More specifically, the Company will require additional funding to further advance its Phase 3 clinical trials in UC.

In addition, the development of obefazimod in other indication beyond UC, in particular in CD, and, more generally, the expansion of the size of the Company's team and organization, may result in additional costs for the Company.

The table below illustrates the liquidity risk on the Company's commitments under its existing financial indebtedness as at August 31, 2023 and reflecting the impact of the above refinancing Transaction.

In thousands of euros	Balance at 31/08/2023	01/09/2023 to 31/12/2023	2024	2025	2026	2027	2028
CARENA (Subsidies)	1 187	210					
CARENA (Conditional Advances)	2 187	1 343	-500	-750	-1 100	-1 747	0
RNP-VIR (Subsidies)	1 123	510	479	0	0	0	0
RNP-VIR (Conditional Advances)	4 032	-323	-699	-1 644	-1 644		0
EBOLA (Conditional Advances)	110	-55	-55	0	0	0	0
COVID-19 (Subsidies)	11 214	0	0	0	0	0	0
COVID-19 (Conditional Advances)	0	0	0	0	0	0	0
Total BPI	19 853	1 684	-775	-2 394	-2 744	-1 747	0
Kreos & Claret (Tranche A)	25 000				-18 682	-6 318	
PGE (State Guaranteed Loan)	3 761		-1 246	-1 254	-1 261		
OC (Heights, Tranche A)	35 000	-2 188	-8 750	-8 750	-8 750	-6 563	
Royalty Certificates	2 931					-2 931	
Total	86 545	-503	-10 771	-12 398	-31 437	-17 558	0

Until the Company can generate sufficient product or royalty revenue to finance its cash requirements, which it may never do, the Company may seek additional financing in the form of public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and collaborations, strategic alliances and licensing arrangements or a combination of these sources.

The amount and timing of its funding needs will depend on factors that are largely outside of its control, such as:

- higher costs and slower-than-expected progress on its research and development programs and clinical trials;
- costs related to preparing, filing, enforcing and maintaining its patents and other intellectual property rights;
- the scope of the research required and time needed to sign licensing agreements with industrial partners;
- the expenses needed to respond to technological and market developments;

- higher costs and longer-than-expected lead times obtaining regulatory authorizations, including time for preparing application dossiers for the relevant authorities; and
- new opportunities for developing new products or acquiring technologies, products or companies.

Any additional fundraising efforts may divert the Company's management from their day-to-day activities, which may adversely affect its ability to develop and, if approved, commercialize its drug candidates. In addition, the Company cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to it, if at all. Under French law, its share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting on the basis of a report from the board of directors. In addition, the French Commercial Code imposes certain limitations on its ability to price certain offerings of its share capital without preferential subscription rights (*droit préférentiel de souscription*), which limitation may prevent it from successfully completing any such offering. To the extent that the Company raises additional capital, the terms of any financing may adversely affect the holdings or the rights of its shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of its ordinary shares to decline. The sale of additional equity or convertible securities will dilute its shareholders ownership interest. The incurrence of indebtedness would result in increased fixed payment obligations and the Company may be required to agree to certain restrictive covenants, such as limitations on its ability to incur additional debt, limitations on its ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact its ability to conduct its business. To the extent that the Company raises additional funds through arrangements with research and development partners or otherwise, it may be required to relinquish some of its technologies, drug candidates or revenue streams, license its technologies or drug candidates on unfavorable terms, or otherwise agree to terms unfavorable for the Company. If the Company is unable to obtain adequate financing, it may be required to delay, reduce or eliminate the number or scope of its projects and drug candidates (including its preclinical studies and clinical trial programs). In order to obtain financing, it may be required to relinquish rights to some of its technologies or drug candidates or otherwise agree to terms unfavorable to the Company. If the Company is unable to obtain funding on a timely basis, the Company may be required to significantly curtail, delay or discontinue one or more of its research or development programs or the commercialization of any drug candidate or be unable to expand its operations or otherwise capitalize on its business opportunities, as desired, which could impair its prospects.

The Company's financial statements contain a footnote describing management's assumption regarding its ability to continue as a going concern, which could prevent the Company from obtaining new financing on reasonable terms or at all.

The Company's independent registered public accounting firm included an emphasis of matter in its report that its financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred net losses of EUR 60.7 million and EUR 42.5 million for the years ended December 31, 2022 and 2021, respectively. As of June 30, 2023, the Company carried forward accumulated tax losses of EUR 355.4 million. Recurring losses may cast significant doubt or raise substantial doubt about its ability to continue as a going concern.

There cannot be any assurance that the Company will be successful in obtaining necessary financing in the future to continue as a going concern or achieve profitability. The Company expects that it will need to raise additional capital following the completion of this equity offering in order to complete the necessary trials to achieve commercial viability of some or all of its drug candidates. If funds are not available, the Company may be required to delay, reduce the scope of, or eliminate research or development plans for, or commercialization efforts with respect to the Company's products. The sale

of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding ordinary shares. Issued debt securities may contain covenants and limit its ability to pay dividends or make other distributions to the Company's shareholders. If the Company is unable to obtain such additional financing, future operations (such as its clinical development programs) would need to be scaled back or discontinued. These factors may raise substantial doubt about its ability to continue as a going concern."

5.2.2 Risks related to the commitments under the Company's debt financing and repayable advances

Section 3.2.4 "Risks related to the commitments set out in the framework of the bond loans taken out from Kreos Capital", Section 3.2.5 "Risks related to the commitments associated with the OCEANE bonds", Section 3.2.6 "Risks related to commitments set out in the framework of a State Guaranteed Loan (PGE) taken out from Société Générale" and Section 3.2.8 "Risks related to access to grants and repayable advances" of the 2023 Universal Registration Document, are replaced as follows.

The reorganization of the presentation of these risks follows the reimbursement in full of the 2018 and 2020 Kreos Capital financings and of the 2021 OCEANE bonds and the entering by the Company into new financings in August 2023.

"3.2.3 Risks related to the commitments under the Company's debt financing and repayable advances

The Company has significant debt commitments, which require the Company to meet certain operating covenants, and if it fails to comply with those covenants the bondholders would be able to accelerate its repayment obligations. Additionally, the conversion of some or all of its bonds into ordinary shares would dilute the ownership interests of existing shareholders.

Reimbursement of previous financings

Prior Kreos Agreements

On July 24, 2018, the Company entered into a EUR 20 million venture loan agreement with Kreos (the "First KC Agreement"). The financing consisted of two tranches of structured debt financing: (i) a total principal amount of First Tranche A Notes of EUR 10 million, comprised of (x) EUR 8 million in non-convertible bonds issued in July 2018 and (y) EUR 2 million in convertible bonds issued in August 2018 and (ii) a total principal amount of First Tranche B Notes of EUR 10 million, comprised of (x) EUR 8 million in non-convertible bonds and (y) EUR 2 million in convertible bonds, each issued in May 2019.

On October 12, 2020, the Company entered into a bonds issue agreement with Kreos (the "Second KC Agreement"), pursuant to which the Company issued bonds in a total principal amount of Second Tranche A Notes of EUR 15 million, comprised of (i) a EUR 10 million tranche and Second Tranche B Notes of EUR 5 million.

On August 21, 2023, the Company repaid all outstanding amounts that remained due under the First KC Agreement and the Second KC Agreement.

OCEANE Bonds

On July 30, 2021, the Company issued EUR 25 million 6% convertible senior unsecured and unsubordinated bonds due July 30, 2026 corresponding to 654,621 OCEANE bonds. The OCEANE bonds were exchangeable, at the option of the bondholders, for new or existing shares and bear interest at a rate of 6% per annum, payable semi-annually on January 30 and July 30 of each year, beginning January 30, 2022.

On August 24, 2023, the Company repaid all amounts due under the OCEANE bonds.

2023 Kreos / Claret Financing

On August 20, 2023, the Company entered into a framework subscription agreement (the “Framework Subscription Agreement”) with Kreos and Claret (together, the “Secured Lenders”). Under this Framework Subscription Agreement, the Company may draw up to EUR 75 million in structured debt financing (the “Kreos / Claret Financing”), in three tranches of EUR 25 million in aggregate principal amount each. The Kreos / Claret Financing provides for certain restrictive covenants (subject to customary exceptions), which include, among other things, restrictions on the incurrence of indebtedness, cross-default, the distribution of dividends and the grant of security interests.

On August 21, 2023, the Company drew the first tranche of the Kreos/ Claret Financing consisting in senior secured convertible bonds with warrants attached with an aggregate principal amount of EUR 25 million (the “Kreos / Claret OCABSA”).

Interest on the Kreos / Claret OCABSA accrues at a 9.00% annual fixed interest rate, payable in quarterly installments. The Kreos / Claret OCABSA’s maturity date is March 31, 2027, it being specified that the scheduled date of final repayment is January 1, 2027.

The Kreos / Claret OCABSA are convertible into 1,178,084 ordinary shares at any time from their issuance at the request of the holders at a fixed conversion price of EUR 21.2209, subject to standard adjustments, including anti-dilution and dividend protections.

The Company is allowed to pre-pay the amounts due under the Kreos / Claret OCABSA at any time. In such case, the Company will be required to pay a sum equal to (i) the principal outstanding at the time of the pre-payment (plus accrued interests), plus (ii) an aggregate of all remaining interest payments that would have been paid throughout the remainder of the term of the tranche, discounted to present value by applying a discount rate of 4%, plus (iii) an end-of-loan exit fee equal to 8.0% of the amounts drawn thereunder. In case of prepayment, the holders of the Kreos / Claret OCABSA will have the option to request a conversion of their Kreos / Claret OCABSA instead of a cash repayment, in which case, the end-of-loan exit fee is not payable by the Company.

The Kreos / Claret Financing includes certain restrictive covenants (subject to customary exceptions) including, inter alia, restrictions on the incurrence of indebtedness, cross-default, the distribution of dividends and the grant of security interests.

As security for the Kreos / Claret Financing, the Secured Lenders benefit from the grant of first-ranking collateral on its principal tangible and intangible assets, including pledges over its business (fonds de commerce) as a going concern and intellectual property rights in its lead drug candidate, as well as pledges over its bank accounts and receivables. Such securities apply to all tranches of the Kreos / Claret Financing.

It is specified that the securities granted by the Company under the Kreos / Claret Financing are similar in nature and scope to the securities granted by the Company under the 2018 and 2020 Kreos financings which have been repaid in full in August 2023.

There is no guarantee that the Company will have sufficient cash to pay the bonds issued to Kreos and Claret. If a breach or event of default occurs, there can be no assurance that the Company will be able to cure the breach within the time permitted. In the event of any failure to pay its obligations when due, any breach or default of its covenants or other obligations, or any other event that causes an acceleration of payment at a time when the Company does not have sufficient resources to meet these obligations, the Secured Lenders could foreclose on the collateral. If the Secured Lenders were to be successful, the Company would lose its intellectual property rights in its lead drug candidate and be unable to commercialize its lead drug candidate and conduct its business. Any of these consequences would have a material adverse effect on the Company's business, financial condition and share price.

2023 Heights Financing

On August 20, 2023, the Company entered into a subscription agreement (the "Heights Subscription Agreement") with Heights. Under the Heights Subscription Agreement, the Company may draw up to EUR 75 million in amortizing senior convertible notes (the "Heights Convertible Notes"), in two tranches of EUR 35 million and EUR 40 million, respectively, as further described below (the "Heights Financing").

On August 24, 2023, the Company drew the first tranche of the Heights Financing consisting in amortizing senior convertible notes with an aggregate principal amount of EUR 35 million (the "Heights Convertible Notes").

The Heights Convertible Notes are convertible into 1,472,606 ordinary shares at any time from their issuance at the request of the holder at a fixed conversion price set at EUR 23.7674, subject to standard adjustments, including anti-dilution and dividend protections.

Interest on the Heights Convertible Notes accrues at a 6.00% annual fixed interest rate payable in quarterly installments in cash or, at the option of the Company, in ordinary shares.

The Heights Convertible Notes will be repaid through sixteen quarterly installment payments, beginning three months after their issuance date (corresponding, for the first tranche, to a final repayment date on August 24, 2027). Installments are payable in cash or, at the option of the Company, in ordinary shares.

Any interest or installment payments in shares will be made on the basis of a share price equal to 90% of the Market Price of the ordinary shares at the time of payment, where "Market Price" refers to the arithmetic average of the daily volume weighted average price ("VWAP") for the ordinary shares on the two (2) days with the lowest daily VWAPs out of the five (5) trading days immediately preceding the applicable date, but in no event greater than the VWAP of the ordinary shares on the applicable date. The Market Price may not be higher than the applicable conversion price. Issuances of ordinary shares may not be made at a price lower than EUR 14.4303 per ordinary share.

Upon the occurrence of certain events (including a change of control of the Company, a free float event or a delisting of the ordinary shares on Euronext Paris), any noteholder will have the option to require the Company to redeem all, but not in part, of its Heights Convertible Notes at par plus accrued but unpaid interests. In the event that the ordinary shares are targeted by a public offer (in cash or in securities, in cash and securities, etc.) which may result in a change of control or filed following a change of control, upon conversion of the Heights Convertible Notes, the Company shall (i) deliver

new ordinary shares at the conversion price and (ii) pay a cash amount equal to the sum of the remaining coupons scheduled until the maturity date, and any accrued interest.

The terms and conditions of the Heights Convertible Notes include a standard negative pledge providing that any security granted in favor of other borrowed debt or debt instruments should also be granted in favor of the Heights Convertible Notes on an equal basis (with the exception of the securities issued pursuant to the Kreos / Claret Financing).

To the extent the Company exercises its option for the repayment in shares of all or part of the principal or interests due under the Heights Convertible Notes, up to 2,830,201 new Ordinary Shares could be issued, representing 6.65% of the Company's current share capital (on the basis of 42,547,568 ordinary shares composing the share capital of the Company on August 31, 2023 and an assumed conversion price equal to the Price Limit of EUR 14.4303 per ordinary share).

Any failure to make scheduled payments or trigger for early repayment of the Heights Convertible Notes could have a material adverse effect on the Company's business, financial position, income, growth and outlook. There is no guarantee that the Company would have the necessary resources to fund an advance repayment of the Heights Convertible Notes.

2020 State-guaranteed Loan

In June 2020, the Company obtained a non-dilutive financing in the form of a State-guaranteed loan of EUR 5.0 million. The loan was structured with an initial maturity of 12 months at 0.25% and a five-year extension option. In March 2021, the Company exercised the five-year extension option with a one-year deferral of principal repayment, with the following conditions: (i) a revised interest rate of 0.58% per annum, excluding insurance and State-guaranteed premium; and (ii) a State-guaranteed premium of EUR 0.1 million to be paid by instalments over the contract period starting in June 2021.

The loan includes certain customary covenants and prepayment provisions. The negative covenants include an undertaking not to dispose of all or part of its assets for more than 50% of the gross value of the Company's fixed assets.

Risk of cross-default

There is also no guarantee that the Company will have sufficient cash to make the scheduled payments on the Kreos / Claret Financing, the Heights Financing or the State-guaranteed loan, which could have a material adverse effect on its business, financial position and results of operations. If the Company breaches its obligations under any of these agreements, it could result in default and trigger an early repayment of the other debt financings of the Company and there is no guarantee that the Company would have the necessary resources to fund an advance repayment of such debt financings.

The Company relies on grants and subsidies, which may not continue to be available and it may be forced to repay conditional advances prematurely if it fails to comply with its contractual obligations under certain innovation grant agreements.

The Company has received various grants and conditional advances from Bpifrance under various development programs, in a total amount of EUR 20.1 million as of December 31, 2022. In the event that the Company does not comply with the contractual conditions stipulated in the aid agreements it has entered into, the Company may have to repay the sums advanced early. Such premature repayment could deprive the Company of the necessary financial resources for its research and development projects and the Company cannot guarantee that the Company will find necessary additional financial resources, the timeline for or the possibility of replacing these financial resources with others. The Company cannot guarantee that it will have the necessary resources to cope with an

early repayment. A material repayment would result in a material adverse effect on its business, operations, financial position, income, growth, and outlook.

In addition, the amount and date of payment of current and future grants and subsidies depend on many factors that are not in the Company's control, including possible non-distribution decisions or the freezing of funds, as well as the achievement of key milestones previously agreed on with Bpifrance. Delays or failure in obtaining or replacing these grants and subsidies in the future could have a material adverse effect on its business, financial position, income, growth and outlook."

5.2.3 Risks related to historic and future losses

Section 3.2.7 "Risks related to historic and future losses" of the 2023 Universal Registration Document, is renumbered and updated as follows:

"3.2.4 Risks related to historic and future losses

Since the Company's inception, the Company has incurred net losses. For the years ended December 31, 2022 and 2021, the Company incurred net losses of EUR 60.7 million and EUR 42.5 million, respectively. As of June 30, 2023, the Company carried forward accumulated losses of EUR 355.4 million.

The Company has devoted most of its financial resources to research and development, including its clinical and preclinical development activities. Even if the Company obtains regulatory approval to market a drug candidate, its future revenues will depend upon the size of any markets in which its drug candidates have received approval and its ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for its drug candidates in those markets. There can be no assurance that the Company will ever earn any revenues or revenues sufficient to offset past, current and future losses or achieve profitability, which would impair the Company's ability to sustain its operations. Moreover, even if the Company achieves profitability, such profitability may not be sustainable. Any inability to generate sustained profits could have a material adverse effect on its business, prospects, financial condition, cash flows and results of operations.

The Company expects to continue to incur significant expenses and operating losses for the foreseeable future. The Company does not anticipate achieving profitability in the future unless it obtains the regulatory approvals necessary to commercialize obefazimod and any additional drug candidates that the Company may pursue in the future. The Company anticipates that its expenses will increase substantially if, and as, the Company:

- timely and successfully completes clinical development of obefazimod, its clinical-stage drug candidate;
- seeks and maintains regulatory and marketing approvals for obefazimod and any future drug candidates for which the Company successfully completes clinical trials;
- continues the preclinical and clinical development of its drug candidates;
- expands the scope of its current clinical trials for its drug candidates;
- begins new clinical trials for its drug candidates;
- develops, scales and validates its commercial manufacturing capabilities for its drug candidates;

- establishes a sales, marketing and distribution infrastructure to commercialize any drugs for which the Company may obtain marketing approval for which it has not entered into a collaboration with a third-party;
- seeks to discover, identify and validate additional drug candidates;
- acquires or in-licenses other drug candidates and technologies;
- makes milestone, royalty or other payments under in-license or collaboration agreements;
- obtains, maintains, protects, enforces and expands its intellectual property portfolio;
- attracts new and retains existing skilled personnel; and
- creates additional infrastructure to support its operations as a U.S. public company.

In addition, following the issuance of royalty certificates in September 2022 and other royalties that may become payable under its royalty agreements, the payment of royalties in the event of commercialization of obefazimod will result in a decrease in cash flows generated by sales of the product, which could have an unfavorable impact on its financial position, particularly at the beginning of the commercialization phase.

The net losses the Company incurs may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of its results of operations may not be a good indication of its future performance. In any particular period or periods, its operating results could be below the expectations of securities analysts or investors, which could cause the price of the ordinary shares to decline. An increase in operational losses would have a material adverse effect on its business, financial position, income, growth and outlook."

5.2.4 Risk of Dilution

Section 3.2.9 "Risks of dilution" of the 2023 Universal Registration Document, is renumbered updated as follows:

"3.2.5 Risk of dilution

Current equity agreements and convertible debt instruments may dilute the Company's equity resulting in dilution to its shareholders.

Since its incorporation, the Company has issued and granted founder warrants ("BCEs") and stock subscription warrants ("BSAs") and granted free bonus shares ("AGAs") to persons linked to the Company and financing entities. The Company has also issued convertible bonds.

The theoretical exercise and/or vesting of all the free shares, founder warrants and stock subscription warrant instruments giving access to its capital issued and outstanding as of August 31, 2023, excluding securities held by financing entities, would allow for the subscription of 2,177,189 potential new ordinary shares, resulting in a hypothetical dilution equal to 5.1% based on its existing share capital as of August 31, 2023.

In addition, the Company issued in August 2023 the following securities in connection with the Kreos / Claret Financing and the Heights Financing:

- 25,000,000 convertible bonds with warrants attached with an individual nominal value of EUR 1.00 issued to Kreos and Claret, which allow for the subscription of up to 1,178,084 new ordinary shares at a conversion price of EUR 21.2209 per ordinary share;
- 214,198 share warrants (BSA) issued to Kreos and Claret, which allow for the subscription of up to 214,198 new ordinary shares at an exercise price of EUR 18.6744 per ordinary share; and
- 350 convertible notes due 2027 with an individual nominal value of EUR 100,000 issued to Heights, which allow for the subscription of up to 1,472,606 new shares at a conversion price of EUR 23.7674 per ordinary share. In case the Company opts to repay the principal and accrued interest of such notes entirely in shares, the Company may issue up to 2,830,201 new ordinary shares in connection with such repayment.

The theoretical exercise, conversion and/or vesting of all instruments giving access to its capital issued and outstanding as of August 31, 2023, including securities held by financing entities, would allow for the subscription of 5,042,077 potential new ordinary shares, resulting in a hypothetical dilution equal to 10.59% on a fully diluted basis as of August 31, 2023, i.e. 47,589,645 total shares.

Furthermore, its general meeting of June 5, 2023 delegated authority to the board of directors (the "Board") to carry out one or more capital increases and/or issues of securities giving access to its capital subject to the following limitations:

- a total maximum nominal amount of the capital increases set at EUR 500,000 (or the equivalent value of that amount in the event of an issue in another currency) with a total maximum nominal amount of the debt securities that may be issued set at EUR 150,000,000 (or the equivalent value of that amount in the event of an issue in another currency); and
- the shares that may be issued or allotted in the context of equity incentive plans (BSAs, stock options and/or AGA) may not exceed 10% of the share capital on a fully diluted basis recorded as of June 5, 2023."

5.2.5 Risks related to the French Research Tax Credit (CIR)

Section 3.2.10 "Risks related to the French Research Tax Credit (CIR)" of the 2023 Universal Registration Document, is renumbered and updated as follows:

"3.2.6 Risks related to the French Research Tax Credit (CIR)

As a French biopharmaceutical company, the Company has benefited from certain tax advantages, including, for example, the Research and Development Tax Credit (*crédit impôt recherche*) ("Research Tax Credit"), which is a French tax credit aimed at stimulating research and development. The Research Tax Credit can be offset against French corporate income tax due and the portion in excess, if any, may be refunded. The Research Tax Credit is calculated based on its claimed amount of eligible research and development expenditures in France and represents EUR 4.5 million for 2022 and EUR 2.2 million for the six-month period ended June 30, 2023. The French tax authorities, with the assistance of the Higher Education and Research Ministry, may audit each research and development program in respect of which a Research Tax Credit benefit has been claimed and assess whether such program qualifies in its view for the Research Tax Credit benefit. The French tax authorities may challenge its eligibility for, or its calculation of, certain tax reductions or deductions in respect of its research and development activities and, should the French tax authorities be successful, its credits may be reduced, which would have a negative impact on its results of operations and future cash flows. Furthermore, the French Parliament may decide to eliminate, or to reduce the scope or the rate

of, the Research Tax Credit benefit, either of which it could decide to do at any time. If the Company fails to receive future Research Tax Credit amounts, its business, prospects, financial condition, cash flows or results of operations could be adversely affected."

5.2.6 Risks related to the future use of tax loss carryforwards

Section 3.2.11 "Risks related to the future use of tax loss carryforwards" of the 2023 Universal Registration Document, is renumbered and updated as follows:

"3.2.7 Risks related to the future use of tax loss carryforwards

As of June 30, 2023, the Company's tax losses carried forward amounted to EUR 355.4 million. In 2014, the Company acquired the companies Splicos, Wittycell and Zophis by means of a universal transfer of assets and liabilities. The tax losses carried forward of the three companies combined (Splicos, Wittycell and Zophis) amounted to EUR 26.0 million on the date of the mergers and transfer of remaining assets. The transfer to the Company of these losses was subject to a post-merger approval by the French tax authorities, which approved the transfer of a total amount of EUR 22.5 million. As a result of the transfer of these tax losses to us, its tax losses carried forward amounted to EUR 308.8 million as at the end of 2022. To the extent the Company has continued conducting the business that led to these losses for a minimum period of three years, without making significant changes during this period, the transfer of such tax losses should be definitive. In France, the maximum amount of carried forward tax losses that can be written off against the tax profits of a given financial year is limited to EUR 1 million plus 50% of the amount of taxable profits for the financial year exceeding EUR 1 million. The outstanding tax losses remain valid and can be carried forward to be written off against tax profits of subsequent financial years subject to the same limit, for an unlimited period of time (subject to any "significant change of activity" at its level). It cannot be ruled out that regulatory or legislative changes in corporate taxation may suppress or limit all or part of the ability to use carried forward tax losses, or limit how long they can be used, to offset future profits. Changes in corporate taxation regarding the use of carried forward tax losses to offset future tax profits could have a material adverse effect on its financial position and results of operations."

5.2.7 Risks related to the impairment of goodwill

An additional Section 3.2.8 "Risks related to the impairment of goodwill" is inserted in the 2023 Universal Registration Document as follows:

"3.2.8 Risks related to the impairment of goodwill

The Company carries a goodwill balance, which is allocated to obefazimod and ABX196 cash generating units, on its balance sheet as a result of past business acquisitions, including with respect to obefazimod and ABX196. The Company is required to review its goodwill for impairment on an annual basis or more frequently if events or changes in circumstances indicate evidence of impairment. For the year ended December 31, 2022, the Company recorded a goodwill impairment loss of EUR 13.6 million.

The goodwill impairment loss was related to an impairment test conducted with respect to the ABX196 cash-generating unit as a result of significant external changes in the hepatocellular carcinoma treatment landscape, which are expected to require a new, lengthy, heavy and risky internal development process (use of a combination of compounds). As such, due to the lack of progress made in the negotiation of a development partnership, the Company made the decision to freeze the development program for ABX196 in the treatment of hepatocellular cancer, which led to full impairment of ABX196 goodwill. In July 2023, the Company has decided to completely stop its ABX196 program, which will be reflected in its next financial statements.

After full impairment of the goodwill allocated to ABX196, the Company continues to carry a goodwill balance allocated to obefazimod amounting to EUR 18.4 million in aggregate as of June 30, 2023. As at the date of this Amendment, the Company has not identified reasons to impair the goodwill allocated to obefazimod.

However, there can be no assurance that, based on the results of its annual goodwill impairment tests, the Company will not be required to identify further goodwill impairment losses, which could have a material adverse effect on its results of operations."

5.3 The Company's regulatory and legal risks

The risks described in Section 3.3.1 "Specific risks related to the preclinical studies and clinical trials necessary to obtain marketing authorisations for the Company's therapeutic products" of the 2023 Universal Registration Document are covered in Section 3.1.1 "Risks related to the clinical development of the Company's drug candidates", Section 3.1.2 "Risks related to obtaining marketing authorisation and other pre-marketing certifications" and Section 3.4.2 "Risks of dependency on third-parties" as amended by this Amendment.

Accordingly, Section 3.3.1 "Specific risks related to the preclinical studies and clinical trials necessary to obtain marketing authorisations for the Company's therapeutic products" of the 2023 Universal Registration Document is deleted.

5.4 Risks related to the Company's organisation

Section 3.4.2 "Risks of dependency on third-parties" of the 2023 Universal Registration Document is updated as follows:

"3.4.2 Risks of dependency on third-parties

The Company relies on a small number of third-party suppliers and manufacturers, and in certain cases a single-source supplier, and the Company may be in a position of dependence with respect to these third parties.

The Company does not own or operate manufacturing facilities and has no current plans to develop its own clinical or commercial-scale manufacturing capabilities. The Company currently relies, and expects to continue to rely, on a small number of third-party suppliers, and in certain cases a single-source supplier, for the supply of various raw materials and chemical products and clinical batches needed for its preclinical studies and clinical trials, such as Acobiom, Eurofins, Cerba, Evotec, Delpharm, Seqens, Creapharm, Charles River or Histalim. In the case of certain manufactured and clinical supplies, the Company relies on single-source suppliers. The supply of specific raw materials and products required for conducting clinical trials and manufacturing its products cannot be guaranteed.

The Company is dependent on third parties for the supply of various materials, including chemical or biological products that are necessary to produce drug candidates for its clinical trials and, ultimately, commercial supply for any of its drug candidates that may receive approval.

The facilities used by its third-party manufacturers must be approved for the manufacture of its drug candidates by the FDA and the EMA, and comparable foreign regulatory authorities in other jurisdictions, pursuant to inspections that will be conducted after the Company submits an NDA to the FDA, MAA to the EMA, or submits a comparable marketing application to a comparable regulatory authority. The Company does not control the manufacturing process of, and is completely dependent on, third-party manufacturers for compliance with GMP requirements for manufacture of its drug

candidates. If these third-party manufacturers cannot successfully manufacture material that conforms to its specifications and the strict regulatory requirements of any applicable regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities.

In addition, the Company has no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If any regulatory authority does not approve these facilities for the manufacture its drug candidates, or if such authorities withdraw any such approval in the future, the Company may be required to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain regulatory approval for or market its drug candidates, if approved. The Company's failure, or the failure of its third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on the Company, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect the Company's financial position.

The Company's or a third party's failure to execute on its manufacturing requirements on commercially reasonable terms and in compliance with GMP or other regulatory requirements could adversely affect its business in a number of ways, including:

- an inability to initiate or complete clinical trials of its drug candidates in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for its drug candidates;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of its drug candidates; and
- in the event of approval to market and commercialize any drug candidate, an inability to meet commercial demands.

In addition, the Company does not have any long-term commitments or supply agreements with any third-party manufacturers. The Company may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of its drug candidates or such quantities at an acceptable cost. Any performance failure on the part of its existing or future manufacturers or suppliers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. The Company does not currently have second source for all required raw materials used in the manufacture of its drug candidates. If its existing or future third-party manufacturers cannot perform as agreed, the Company may be required to replace such manufacturers and the Company may be unable to replace them on a timely basis or at all, which would have a material adverse impact on its financial position.

The Company relies on third parties to conduct its preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company may not be able to obtain regulatory approval for or commercialize its drug candidates and its business could be substantially harmed.

The Company is dependent on third parties to conduct its clinical trials and preclinical studies. Specifically, the Company relies on, and will continue to rely on, medical institutions, clinical investigators, CROs such as IQVIA (in charge of conducting the ABTECT Phase 3 program) or Simbec Orion, and consultants to conduct preclinical studies and clinical trials, in each case in accordance with

trial protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though the Company expects to carefully manage its relationships with such CROs, investigators and other third parties, there can be no assurance that the Company will not encounter challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects. Further, while the Company has and will have agreements governing the activities of its third-party contractors, the Company has limited influence over its actual performance. Nevertheless, the Company is responsible for ensuring that each of its clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and its reliance on its CROs and other third parties does not relieve the Company of its regulatory responsibilities.

In addition, the Company and its CROs are required to comply with stringent standards governing the conduct of preclinical studies and clinical trials, including Good Laboratory Practice (“GLP”) and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities, for its drug candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If the Company or any of its CROs or trial sites fails to comply with applicable GLP, GCP or other requirements, the data generated in its clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require the Company to perform additional clinical trials before approving its marketing applications, if ever. Furthermore, its clinical trials must be conducted with materials manufactured in accordance with GMP regulations. Failure to comply with these regulations may require the Company to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of the Company’s CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to its clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, its clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom the Company contracts may also have relationships with other commercial entities, including its competitors, for whom they may also be conducting clinical trials or other activities that could harm its competitive position. In addition, principal investigators for the Company’s clinical trials may be asked to serve as scientific advisors or consultants to the Company 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 the FDA concludes that the financial relationship may have affected the interpretation of the study, 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 by the FDA of any NDA the Company submits. Any such delay or rejection could prevent the Company from commercializing its drug candidates.

In addition, its CROs have the right to terminate their agreements with the Company in the event of an uncured material breach and under other specified circumstances. If any of the Company’s relationships with these third parties terminate, the Company may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires its management’s time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact its ability to meet its desired clinical development timelines. Though the Company works to carefully manage its relationships with its CROs, investigators and other third parties, there can be no assurance that the Company will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects.

If any of its relationships with these third parties terminate, the Company may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires the Company's management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact the Company's ability to meet its desired clinical development timelines. Though the Company works to carefully manage its relationships with its CROs, investigators and other third parties, there can be no assurance that the Company will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on the Company's business, financial condition and prospects."

6. INFORMATION ABOUT THE COMPANY

An additional Section 4.5 "Facilities" is inserted in the 2023 Universal Registration Document, as follows:

"4.5 Facilities

The Company subleases approximately 765 m² of office space and three parking spaces at 7-11 boulevard Haussmann, 75009 Paris, France, for its headquarters and other administrative functions. The sublease agreement has been entered into for a period of three years expiring on June 21, 2025. Unless terminated by either party, it will be automatically renewed for additional successive periods of one year. The sublease of these facilities may, subject to certain restrictions provided by law, be terminated by the Company or by the lessor from June 30, 2024, subject to nine months' prior written notice. Furthermore, the sublease will automatically terminate in the event of the early termination of the head lease (which expires on June 30, 2027). The Company believes that its facilities are sufficient to meet its current needs and that suitable additional space will be available in the future on commercially reasonable terms, if required."

7. COMPANY FINANCIAL INFORMATION

7.1 Incorporation by reference of the 2023 Half-Year Financial Report

The 2023 Half-Year Financial Report is incorporated by reference to this Amendment and is available in the Investor/Investor Documents section on the Company's website which can be accessed using the following link:

<https://www.abivax.com/investors/investor-documents/>

7.2 Update relating to the financing needs and financing structure

Section 8.3 "Financing Needs and Financing Structure" of the 2023 Universal Registration Document is updated with the following information:

On August 20, 2023, the Company entered into a framework subscription agreement (the "Framework Subscription Agreement") with certain entities affiliated to Kreos Capital ("Kreos") and Claret European Growth Capital ("Claret"). Under this Framework Subscription Agreement, the Company may draw up to EUR 75 million in structured debt financing (the "Kreos/Claret Financing"), in three tranches of EUR 25 million in aggregate principal amount each.

On the same date, i.e., August 20, 2023, the Company also entered into a subscription agreement (the "Heights Subscription Agreement") with CVI Investments, Inc. ("Heights"). Under the Heights Subscription Agreement, the Company may draw up to EUR 75 million in amortizing senior convertible notes (the "Heights Convertible Notes"), in two tranches of EUR 35 million and EUR 40 million respectively (the "Heights Financing" and together with the "Kreos/Claret Financing", the "Transaction").

On August 21, 2023, the Company has drawn the first tranche of the Kreos/ Claret Financing consisting in senior secured convertible bonds with warrants attached with an aggregate principal amount of EUR 25 million.

On August 24, 2023, the Company has drawn the first tranche of the Heights Financing consisting in amortizing senior convertible notes with an aggregate principal amount of EUR 35 million.

As part of the Kreos/Claret Financing, security interests have been granted on the Company's principal tangible and intangible assets: in particular, on its goodwill, intellectual property rights relating to its lead drug candidates, as well as a pledge of its bank accounts and receivables.

Please refer to Sections 3.8 and 5.2.2 of this Amendment for additional details on the Kreos/Claret Financing and the Heights Financing.

As part of the Transaction, the Company also repaid in full a total outstanding amount of EUR 32.7 million under (i) the pre-existing debt agreements with Kreos for a total amount of EUR 7.7 million, and (ii) the pre-existing OCEANE bonds for a total amount of EUR 25.1 million by way of set-off with the Heights Financing, thereby fully repaying such pre-existing indebtedness.

After giving effect to the repayment of EUR 32.7 million of existing indebtedness, the net proceeds to the Company from the first tranches of the Kreos / Claret Financing and the Heights Financing (once drawn on) amounted to EUR 27.2 million.

The maximum proceeds from the Transaction (if all the tranches are drawn on), net of the refinancing of the existing indebtedness, are expected to be EUR 117.2 million in total.

The table below shows the balance of the Company's repayment commitments under its existing financial indebtedness as at August 31, 2023, taking into account the impact of the above refinancing Transaction.

In thousands of euros	Balance at 31/08/2023	01/09/2023 to 31/12/2023	2024	2025	2026	2027	2028
CARENA (Subsidies)	1 187	210					
CARENA (Conditional Advances)	2 187	1 343	-500	-750	-1 100	-1 747	0
RNP-VIR (Subsidies)	1 123	510	479	0	0	0	0
RNP-VIR (Conditional Advances)	4 032	-323	-699	-1 644	-1 644		0
EBOLA (Conditional Advances)	110	-55	-55	0	0	0	0
COVID-19 (Subsidies)	11 214	0	0	0	0	0	0
COVID-19 (Conditional Advances)	0	0	0	0	0	0	0
Total BPI	19 853	1 684	-775	-2 394	-2 744	-1 747	0
Kreos & Claret (Tranche A)	25 000				-18 682	-6 318	
PGE (State Guaranteed Loan)	3 761		-1 246	-1 254	-1 261		
OC (Heights, Tranche A)	35 000	-2 188	-8 750	-8 750	-8 750	-6 563	
Royalty Certificates	2 931					-2 931	
Total	86 545	-503	-10 771	-12 398	-31 437	-17 558	0

As a result of (a) existing cash and cash equivalents of EUR 114.4 million as of June 30, 2023, (b) the net proceeds of the August 2023 drawdown of the first tranches of the Kreos / Claret Financing and the Heights Financing, collectively amounting to EUR 27.2 million (net of repayments of all outstanding amounts that remained due under the pre-existing Kreos loans and the OCEANE bonds), (c) the available drawdowns of the second tranches of the Kreos / Claret Financing and the Heights Financing (which tranches are not conditional on amount raised in the planned registered public offering in the United States), collectively amounting to EUR 65 million in gross proceeds, and (d) the expected reimbursement of the 2022 Research Tax Credit in the second half of 2023 amounting to EUR 4.5 million, the Company expects to be able to fund its forecasted operating cash flow requirements through the third quarter of 2024.

This takes into account the Company's assumption that R&D expenditure will be substantially increased in 2023 driven by the progression of the Phase 3 clinical trials of obefazimod, which started enrollment of patients with moderately to severely active UC in October 2022.

The Company expects that it will be able to extend its financing horizon beyond the third quarter of 2024 through additional dilutive and non-dilutive financing, which could include a combination of capital increase, venture loans and convertible bonds.

8. REGULATORY ENVIRONMENT

Chapter 9 “Regulatory Environment” of the 2023 Universal Registration Document is updated as follows:

“9.1 Government Regulation

Companies operating in the pharmaceutical industry are subject to increased scrutiny by the competent authorities and must deal with an ever-changing and increasingly restrictive legal and regulatory environment.

The development of drugs involves several stages: research and development, preclinical tests, clinical trials, authorization, manufacturing and commercialization.

All of these stages are subject to specific requirements that impose substantial and onerous constraints, compliance with which is ensured by various national, regional (in the EU, the EMA) or federal (in the United States, the FDA) authorities.

Failure to comply with these regulations may be subject to fines, to the suspension or withdrawal of the authorizations and certifications required to perform pharmaceutical activities, to the seizure or withdrawal of products from the market, or to partial or total suspension of their manufacturing. Regulatory authorities may also withdraw marketing authorizations (“MAs”) previously granted or reject MA applications (“MAAs”) and initiate legal proceedings, and their outcome remains uncertain.

Although the regulatory constraints may differ from a country to another, development of therapeutic products for human use must comply with requirements shared by all developed countries. The steps to be completed before obtaining an MA in the EU and in the United States are generally as follows:

- conduct of preclinical laboratory tests and studies in animals, in accordance with Good Laboratory Practice (“GLP”);
- conduct of clinical trials in humans to demonstrate the safety and efficacy of the product for each considered indication, in accordance with Good Clinical Practice (“GCP”), if necessary after authorization by a competent authority and an ethics committee;
- preparation and submission of an MAA to the competent authority, in order to market the product;
- inspection by the competent authority of the manufacturing facilities in which the product and/or its ingredients are manufactured to assess compliance with Good Manufacturing Practices (“GMP”);
- inspection by the competent authority of establishments distributing medicinal products in order to assess their compliance with Good Distribution Practice (“GDP”); and
- if needed, commitment by the applicant to comply with post-MA requirements.

Due to these regulatory constraints, the development and approval process of a drug candidate for commercialization, which varies according to its nature, complexity and novelty, usually extends over several years.

9.2 EU Regulation

9.2.1 Preclinical Studies

Within all EU Member States, preclinical studies include laboratory evaluation of the composition, purity and stability of the active pharmaceutical ingredient and the formulated product, as well as studies to evaluate the tolerance (toxicological studies), activity and behavior of the product candidate in vitro and in animals (in vivo).

The conduct of preclinical studies is subject to legal and regulatory provisions. Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labelling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Preclinical studies are a prerequisite for the initiation of clinical trials in humans: all the results of these trials are submitted to the regulatory authorities at the same time as the application to initiate clinical trials. However, while preclinical tests must be performed prior to conducting clinical trials in humans, certain long-term preclinical tests, such as tests on reproductive toxicity and carcinogenicity, may continue after the submission of an application to initiate clinical trials.

9.2.2 Clinical Trials in Humans

The various phases of clinical trials in the EU are subject to significant regulatory controls. They must be conducted in accordance with EU and national regulations, the standards adopted by the International Conference on Harmonization (“ICH”) and GCP.

Directive no. 2001/20/EC on the conduct of clinical trials sought to harmonize the regulatory framework for clinical trials in the EU, setting out common rules for the monitoring and authorization of clinical trials in the EU. To reduce disparities between the transpositions by the Member States, Regulation 536/2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, was adopted on April 16, 2014. This regulation aims to further harmonize and streamline the clinical trial authorization process, simplify adverse event reporting procedures, improve the supervision of clinical trials, and increase the transparency of clinical trials. This regulation became applicable on January 31, 2022. However, it provides for a three-year transition period (i.e., clinical trials for which an application was submitted in accordance with Directive no. 2001/20/EC before January 31, 2022, will continue to be subject to the Directive provisions for a period of three years). Furthermore, sponsors having submitted a clinical trial under the Directive until January 31, 2023 may remain governed by the Directive until January 31, 2025. By that date, all ongoing trials will become fully subject to the provisions of the Regulation 536/2014.

Under the clinical trials regulation, the sponsor may submit its application for a clinical trial authorization to one or several Member States, in which case the evaluation of Part I of the dossier (scientific part) is carried out according to a coordinated procedure. In this framework, the sponsor must submit a single application for authorization via the portal associated with the EU database (“CTIS”), comprising a common scientific part evaluated jointly by all the EU Member States in which the trial will be carried out (with one of the Member States concerned acting as rapporteur Member State) and a national part covering the ethical aspects of the trial, evaluated independently by each Member State.

The conclusion of the rapporteur Member State with regard to Part I of the assessment report is deemed to be the conclusion of all Member States concerned. However, the Member States concerned may disagree with this conclusion for a number of limited reasons, for example when they consider that participation in the clinical trial would lead to a subject receiving a treatment inferior to that of normal clinical practice on their territory. The Member State concerned may then refuse the clinical trial on its territory.

A “single” decision covering the conclusions of the Part I and Part II evaluations is issued by each of the Member States concerned and is notified to the sponsor on the dedicated European portal.

The sponsor of a clinical trial conducted in the EU notifies through the EudraVigilance database without delay and at the latest within the deadlines set by the clinical trials regulation, of all relevant information on suspected serious and unexpected adverse reactions to the investigational medicinal product. If the competent bodies concerned consider that the adverse effects outweigh the benefits for the participants, they may require the immediate suspension or early termination of the trial at any time.

In addition, the sponsor must submit through CTIS once a year, for the duration of the clinical trial, an Annual Safety Report (ASR) for each investigational drug used in the clinical trial.

Finally, the EU framework applicable to clinical trials has also been significantly strengthened with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, “GDPR”), which entered into force on May 25, 2018. This regulation has significantly increased EU citizens’ rights by giving them more control over their personal data. Thus, depending on the type of personal data processing carried out during clinical trials and the nature of such trials, it might be necessary to carry out formalities by the local Data Protection Authority, in addition to seeking formal informed consent which must be obtained from each clinical trial subject.

9.2.3 Responsibility of the Sponsor and Insurance Obligation of the Sponsor

In the EU, the sponsor shall indemnify the subject of the trial in case of damage arising as a consequence of the research, unless he proves that the damage does not result from his fault or the fault of any other person intervening in the trial. In the EU, Member States generally require a sponsor to have an insurance covering its civil liability and the liability of any person intervening in the research. In addition, any breach to the provisions concerning clinical trials may lead to significant administrative, criminal and/or reputational penalties.

9.2.4 Marketing Approval

Within the EU, marketing of medicinal products is governed by EU regulations (including but not limited to Directive 2001/83/EC and Regulation 726/2004/EU).

On April 26, 2023, the European Commission issued proposals for a revision of the current legal framework. Although the proposal is subject to adoption by EU institutions, which become effective upon adoption, this new framework, which in particular aims at granting timely access to patients for safe, effective and affordable medicines and at enhancing supply of medicines, may significantly amend general principles described above, notably timelines and market exclusivity periods.

In the EU, medicinal product candidates can only be commercialized after obtaining an MA. To obtain regulatory approval of a product candidate under EU regulatory systems, the Company must submit

an MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- “Centralized MAs” are granted by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use (“CHMP”) of the EMA. The MA issued under this procedure is valid in all EU Member States.
- The centralized procedure is compulsory for some types of medicinal products such as biotechnology products, designated orphan medicinal products, products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes or autoimmune and viral diseases, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products). The centralized procedure is optional for products containing a new active substance that has not yet been authorized in the EU or for products which present a significant therapeutic, scientific or technical innovation or are of interest for the public health in the EU.
- “National MAs” are issued at a national level by the competent authorities of the concerned Member States. They are valid only on their territory. National MAs can be issued for products that do not fall within the mandatory scope of the centralized procedure. Medicinal products which have not received a national MA in any of the Member States, may be authorized through the decentralized procedure. This procedure enables the simultaneous issuance of national MAs in several EU countries. Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which an MA is sought. One of these Member States is designated by the applicant to act as the Reference Member State (“RMS”). The competent authority of the RMS drafts an assessment report and prepares an SmPC, a package leaflet and a draft labelling, which are sent to the other Member States involved in the procedure, known as the Concerned Member States (“CMS”), for approval. If the CMS do not raise any objections based on a potential serious risk to public health, regarding the assessment, the SmPC, the labelling or the packaging proposed by the RMS, a national MA is granted for the product in all Member States involved in the procedure (i.e., in the RMS and the CMS). Where a product has already been authorized for marketing in an EU Member State, this national MA can be recognized in another member state through the mutual recognition procedure. In this procedure, the Member State which issued the initial MA, known as the RMS, must prepare an assessment report on the medicinal product or update any existing report. This report is sent to the CMS, together with the approved SmPC and the labelling and package leaflet. Unless an objection based on a potential serious risk to public health is raised, the CMS issue(s) a national MA for the product, the terms of which are identical to the MA granted by the RMS.

Depending on the procedure used, the EMA or the national competent authority(ies) must, before granting a MA, make an assessment of the benefit/risk ratio of the product based on scientific criteria of quality, safety of use and efficacy. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops. In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines (“PRIME”) scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA’s support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME

designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a conditional MA may be granted by the European Commission for a period of one year and is renewable annually.

A conditional MA is granted in the absence of sufficient clinical data to obtain an ordinary MA if the following requirements are met: (i) the medicinal product is intended to treat, prevent or diagnose a fatal or seriously debilitating disease, (ii) it fulfils to an unmet medical need, (iii) its benefit/risk ratio is, on the basis of the available data, positive, (iv) it is likely that the applicant will be able to provide the required comprehensive post-MA clinical data and (v) in terms of public health, the benefits of the product's immediate availability to patients outweigh the risks inherent to the lack of sufficient clinical data.

The granting of a conditional MA is accompanied by specific obligations, in particular relating to the completion of clinical trials, the performance of new studies and the collection of pharmacovigilance data in order to confirm the benefit/risk ratio of the product. Once the pending studies are provided, it can become a "standard" MA.

MAAs may also be granted under exceptional circumstances to medicinal products for which a complete evaluation file cannot be provided when the product's indication is too rarely encountered and reasonably prevents the provision of comprehensive evidence, when the current state of scientific knowledge prevents the provision of such data or when the collection of the necessary data would be unethical. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

However, despite the granting of a MA, both the MA holder and the competent authorities may decide to withdraw (voluntarily or compulsorily) a product from the market or a MA, when it appears that the product presents more risks than benefits for the patients.

9.2.5 Data and Marketing Exclusivity

In the EU, new products authorized for marketing (*i.e.*, reference products) generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications, which, during the scientific evaluation

prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical or biological entity, and products may not qualify for data exclusivity.

9.2.6 Pediatric Development

In the EU, MAAs for new medicinal products must include the results of studies conducted in the pediatric population, in compliance with a Pediatric Investigation Plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all the EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two-year extension of the orphan market exclusivity is granted.

9.2.7 Manufacturing and Distribution-related Requirements

To ensure patients' safety, the manufacturing, distribution and import of active pharmaceutical ingredients and finished products into the EU are also subject to extensive requirements and both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the Member States.

Medicines (including their active substances) must be manufactured in accordance with GMP requirements. These regulations govern manufacturing processes and procedures, and notably provide for requirements relating to the implementation of quality systems to control and ensure the quality of materials and products. Manufacturing activities must be performed only within companies holding valid licenses from the competent regulatory authorities of the Member States which is issued following an inspection of the concerned facilities. In addition, routine inspections are conducted on a regularly basis to ensure that compliance is maintained.

Distributors must also comply with very strict requirements, including good distribution practices ("GDP"). These regulations provide for strict requirements including the implementation of an effective quality system and adequate procedures to ensure the quality of the products all over the distribution chain and efficiently respond to claims, recalls, and risks of falsification, or the use of appropriate facilities, equipment and personnel. Similarly to manufacturing, distribution activities are subject to a prior approval from the competent regulatory authorities of the Member States which is issued following an inspection of the concerned facilities which aims at ensuring that the establishment complies with the applicable regulations. Routine inspections are also conducted on a regularly basis.

Finally, the import of active pharmaceutical ingredients and medicines into the EU must also be authorized in advance, in order to ensure that the products are manufactured and distributed in accordance with standards at least equivalent to those existing for the EU market.

Failure to comply with the above requirements may be sanctioned by the suspension or withdrawal of the manufacturing/distribution/import authorization, civil, criminal or administrative penalties, or the withdrawal of the concerned active ingredients and finished products from the market.

9.2.8 Post-Approval Requirements

9.2.8.1 Pharmacovigilance Requirements

The MA holder must establish and maintain a pharmacovigilance system and designate a Qualified Person Responsible for Pharmacovigilance (“QPPV”) who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. The main obligations of the QPPV include prompt reporting of suspected serious adverse reactions and submission of periodic pharmacovigilance update reports (“PSURs”).

All new MAA must include a risk management plan (“RMP”) describing the risk management system that the company will put in place and setting out measures to prevent or minimize the risks associated with the medicinal product. The regulatory authorities may also issue an MA subject to the fulfillment of specific obligations. These risk reduction measures or post-authorization obligations may consist, in particular, of reinforced safety monitoring, more frequent submission of PSURs, the conduct of additional clinical trials or the performance of post- authorization safety studies.

9.2.8.2 Advertising Requirements

In the EU, the advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. The general principles applicable to the advertising of medicines, which is broadly defined as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, are established by EU directives.

Any advertising or promotion of a medicinal product must comply with its approved SmPC. Consequently, any promotion of off-label promotion is prohibited. Indeed, the advertising must encourage the rational use of medicines by presenting them objectively without exaggeration and thus, must not be misleading. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each Member State and can differ from one country to another.

Depending on the Member States, advertising-related regulatory requirements may be sanctioned notably by fines, suspension or withdrawal of regulatory authorizations, medicinal products recalls, medicinal products seizures, operating restrictions and even criminal and/or civil prosecution and significant fines.

The aforementioned EU rules are generally applicable in the European Economic Area (“EEA”) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

9.2.9 Coverage and Reimbursement

In the EU, pricing and reimbursement systems widely vary from one country to another and remain exclusively the responsibility of the Member States.

Thus, Member States may restrict the range of medicines for which their national health insurance system provides reimbursement and to control the price of medicines for human use, provided that

time limits for review of a reimbursement application provided in Directive 89/105/EEC of 21 December 1988 must be complied with.

Some Member States use a system of positive and negative lists, whereby medicines can only be marketed after a reimbursement price has been agreed. Others may require additional studies comparing the cost-effectiveness of a medicinal product to existing therapies in order to obtain approval for reimbursement or pricing. Finally, Member States can agree to a set price or, instead, allow companies to set their own prices while having their profits monitored and controlled (e.g., control of the quantity of prescriptions).

Over the last few years, many EU Member States have increased the amount of rebates applied to medicinal products, and these efforts may continue as Member States exercise greater control over their healthcare spending due to often large debts. The downward pressure on healthcare costs in general, including medicinal products subject to mandatory prescription, has become considerable. Changing political, economic and regulatory conditions can complicate price negotiations. This price negotiation can continue after reimbursement has been achieved and is generally subject to periodic reviews. Finally, reference prices used by various EU Member States and parallel trade (i.e., arbitrage by distributors between low and high price Member States) may also lead to further price reductions.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment (“HTA”) amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022 it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once the Regulation becomes applicable, it will have a phased implementation depending on the concerned products. This regulation intends to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

9.2.10 Other Healthcare Laws

Relationships between the pharmaceutical industry and healthcare professionals are subject to national restrictions and regulations in order to avoid any incentive to prescribe drugs that is not justified by the patient’s state of health and profile.

For example, in France, relations between companies producing and/or marketing health products or providing services associated with these products, regardless of their nationality and/or the location of their registered office, and healthcare professionals practicing in France are governed by the “anti-gift” and “transparency” laws.

The purpose is to ensure that healthcare professionals, in their choice of a medicinal product, equipment or service, are guided solely by medical information and considerations.

By way of principle, under the French anti-gift law, persons providing health services, manufacturing or marketing healthcare products are prohibited from promising or offering advantages, in cash or in kind, either directly or indirectly, to healthcare professionals practicing in France, students intending

to enter such professions or associations of these individuals, including learned societies and national professional councils.

The list of benefits that do not qualify as “advantages” under the anti-kickback regulation is very limited and includes, for example, benefits that relate to the exercise of the beneficiary’s profession and of negligible value, which may not exceed the amounts provided for by a Ministerial Order.

By way of exception, above-mentioned health stakeholders may provide advantages to the healthcare professionals/associations mentioned above, subject to the conclusion of a written agreement and to a prior declaration to or approval from the authority to which the concerned beneficiary belongs.

This exception is however limited to specific situations mainly including:

- The remuneration, compensation and expenses for research activities, research promotion, scientific evaluation, consultancy, provision of services or commercial promotion, provided that the remuneration is proportionate to the service provided and that the compensation or expenses do not exceed the costs actually incurred by the persons concerned;
- Donations and gifts, in cash or in kind, exclusively intended to finance research activities, the promotion of research or scientific evaluation; or
- Hospitality offered during events of an exclusively professional or scientific nature, or during events promoting healthcare products or services, provided that this hospitality is of a reasonable level, strictly limited to the main purpose of the event and to healthcare professionals (excluding students);

When failing to comply with these regulations, in addition to a significant risk to their reputation, the companies and professionals concerned may be subject to significant criminal penalties and, in the case of the latter, disciplinary penalties.

The French transparency provision, for its part, provides citizens with access to certain information on a website so that they can more objectively assess the relationships between health actors (i.e., a broad list including healthcare professionals, associations of healthcare professionals, students, associations of users of the health system, health establishments, academic institutions, foundations, learned societies and societies or advisory bodies involved in the health product or health services sector, etc.) and companies producing or marketing health products or providing services associated with these products. Under the terms of this regulation, the companies concerned must disclose the main information relating to their relationships with healthcare professionals, such as compensation or benefits paid, and agreements entered into. Companies that knowingly fails to disclose such information may be subject to criminal penalties.

9.3 UK Regulation

Since the end of the Brexit transition period on January 1, 2021, Great Britain (“GB”) (England, Scotland and Wales) has not been directly subject to EU laws. However, under the terms of the Ireland/Northern Ireland Protocol, EU laws have generally applied to Northern Ireland. On February 27, 2023, the UK government and the European Commission reached a political agreement on the so-called “Windsor Framework” which is intended to revise the Ireland/Northern Ireland Protocol in order to address some of the perceived shortcomings in its operation. The agreement was adopted at the Withdrawal Agreement Joint Committee on March 24, 2023. If the changes are adopted in the form proposed, medicinal products to be placed on the market in the UK will be authorized solely in accordance with UK laws. Northern Ireland would be reintegrated back into a UK-

only regulatory environment under the authority of the MHRA with respect to all medicinal products. The implementation of the Windsor Framework would occur in various stages, with new arrangements relating to the supply of medicines into Northern Ireland anticipated to take effect in 2025.

The EU laws that have been transposed into United Kingdom (“UK”) law through secondary legislation remain applicable in Great Britain. However, new EU legislation that was either adopted or entered into application after Brexit such as the EU CTR is not applicable in Great Britain. The UK regulatory framework in relation to clinical trials is derived from previously existing EU legislation (as implemented into UK law, through secondary legislation). On January 17, 2022, the UK MHRA launched an 8-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022, and aims to streamline clinical trial approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality and promote patient and public involvement in clinical trials. The outcome of the consultation is being closely watched and will determine whether the UK chooses to align with the (EU) CTR or diverge from it. Under the terms of the Ireland/Northern Ireland Protocol, provisions of the EU CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products currently apply in Northern Ireland.

Since January 1, 2021, the MHRA has been the sole regulatory of medicines and medical devices in GB and for medicinal products that are not authorized through the centralized procedure in Northern Ireland. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, including a 150-day assessment and a rolling review procedure. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder opted-out. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, since Brexit, companies established in the UK can no longer use the EU centralized procedure for authorization of medicinal products intended to be marketed in the UK. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures to obtain an MA to commercialize products in the UK. Until December 31, 2023, the MHRA may rely on a decision taken by the European Commission on the approval of a new (centralized procedure) MA when reviewing an application for authorization of a medicinal product to be supplied in GB. Depending on the nature and intended therapeutic purpose of the medicinal product, the MHRA may, alternatively, use its own decentralized or mutual recognition procedures which enable the MHRA to have regard to MAs approved in EU Member States, Iceland, Liechtenstein, Norway) when granting an MA in the UK or GB. From the first quarter of 2024, a new international recognition framework should be in place with an aim to extend the countries whose assessments the MHRA will take into account. The UK government will need to adopt new legislation to introduce this route.

There is no pre-MA orphan designation procedure. Applications for orphan designation are made at the same time as an application for MA and the MHRA will review applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market (i.e., the prevalence of the condition in GB, rather than the EU, must not be more than five in 10,000). Should an orphan designation be granted, the period of market exclusivity will be set from the date of first approval of the product in GB.

9.4 U.S. Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, (“FDCA”) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, and local statutes and regulations requires the

expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs, withdrawal of an approval, imposition of a clinical hold on a clinical trial, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- Completion of preclinical laboratory studies, animal studies and formulation studies in compliance with the FDA's GLP regulations, and other applicable regulations;
- Submission to the FDA of an IND which must become effective before human clinical trials may begin;
- Approval by the Institutional Review Board ("IRB") or ethics committee, at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials, in accordance with GCP requirements to establish the safety and effectiveness of the proposed drug product for each indication;
- Submission to the FDA of an NDA;
- Satisfactory completion of an FDA advisory committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice ("cGMP") requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA.

9.4.1 Preclinical Studies and INDs

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical studies may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

9.4.2 Clinical Trials

Clinical trials involve the administration of the investigational drug to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing for

their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the IRB(s) competent for the institution(s) participating in the clinical trial must review and approve the plan for any clinical trial before it commences. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their www.clinicaltrials.gov website.

While the IND is active, progress reports detailing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

For purposes of FDA approval, human clinical trials are generally conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The drug candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- *Phase 2:* The drug candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- *Phase 3:* The drug candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the drug candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to, among other things, gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with GMPs. The manufacturing process must be capable of consistently producing quality batches of the drug

candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

9.4.3 Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include Medication Guides (FDA approved patient labeling to be provided to patients when the drug is dispensed), physician communication plans, assessment plans, or Elements to Assure Safe Use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an Advisory Committee. 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 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.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the commercial product would be 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 may inspect one or more clinical trial sites to verify the clinical data submitted in the NDA, and to assure compliance with GCP requirements.

After evaluating the NDA and all related information, including the Advisory Committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, 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 will not be approved in its present form, and describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may at any time prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After initial approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

9.4.4 Post-Approval Requirements

Drugs manufactured or distributed 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, the submission of 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 program user fee requirements for any marketed products, as well as new application fees for certain supplemental applications.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require manufacturers to investigate and correct of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the 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 mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution 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, warning letters or holds on post-approval clinical trials;
- 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 labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved uses (“off-label” uses), and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested by the Company and approved by the FDA. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer’s communications on the subject of off-label use of their products.

9.4.5 Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (“ANDA”), or an NDA submitted under Section 505(b)(2) (“505(b)(2) NDA”) submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs

containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

9.4.6 Coverage and Reimbursement

Sales of its drug candidates, if approved, will depend, in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors determine which medications they will cover and establish reimbursement levels. In addition, these third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. In addition, the U.S. government and state legislatures have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. 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 the Company's products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of the Company's products. As a result, adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit its net revenue and results. Decreases in third-party reimbursement for its drug candidates or a decision by a third-party payor to not cover its drug candidates could reduce physician usage of its drug candidates, once approved, and have a material adverse effect on its sales, results of operations and financial condition. Additionally, the Company or its collaborators may develop companion diagnostic tests for use with its drug candidates. The Company or its collaborators will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement the Company seeks for its drug candidates, once approved. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

9.4.7 Other Healthcare Laws

The Company will also be subject to other healthcare regulation and enforcement by the U.S. federal government and the states in which the Company will conduct its business once its drug candidates are approved. Failure to comply with these laws, where applicable, can result in the imposition of significant administrative, civil, and criminal penalties. The laws that may affect its ability to operate in the United States include:

- The federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and wilfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- Federal false claims act laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- The federal health care fraud statutes, which created additional federal criminal statutes that impose criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters;
- The Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as and ownership and investment interests held by physicians and their immediate family members;
- The U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal statutes that impose criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or knowingly and willingly falsifying, concealing or covering up a material fact or making false statements relating to healthcare matters; and
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information.

In addition, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Further, certain states enacted laws that require: pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; the reporting of information related to drug pricing; the registration of pharmaceutical sales representatives. Certain states have also enacted legislation to govern the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Additionally, to the extent that its product is sold in a foreign country, the Company may be subject to similar foreign laws.

9.4.8 Healthcare Reform

The enactment of the Affordable Care Act (“ACA”) has substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The ACA, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in

Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. Most recently, on June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA"), into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law which among other things, led to aggregate reductions in Medicare payments to providers. These reductions went into effect on April 1, 2013, and, due to subsequent legislative amendments, will remain in effect until 2032, except for a temporary suspension from May 1, 2020, through March 31, 2022, due to the COVID-19 pandemic.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to litigation. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation ("CMMI") can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. In response, on February 14, 2023, HHS released a report outlining three new models for testing by the CMMI which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures are increasingly 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.

The Company expects that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for its drug candidates or additional pricing pressures."

9. INFORMATION ON TRENDS

Chapter 10 “Information on trends” of the 2023 Universal Registration Document is updated as follows:

“10.1 Main trends since the beginning of the current financial year

January 2023	Abivax publishes novel data with respect to obefazimod’s anti-inflammatory mechanism of action
February 2023	Abivax to present blood and rectal tissue data from UC patients treated with obefazimod at the 18 th Congress of ECCO Abivax appoints Dr. Sheldon Sloan, M.D., as Chief Medical Officer Abivax announces successful oversubscribed EUR 130 million cross-over financing at market price with top-tier US and European Biotech investors
March 2023	Abivax does not hold any cash or otherwise have any deposits at SVB or at any other U.S. financial institution Abivax adjusts its 2023 Financial Communication Calendar
April 2023	Abivax appoints Marc de Garidel as Chief Executive Officer and Interim Board Chair Abivax reports two-year efficacy and safety data of obefazimod phase 2b maintenance trial in ulcerative colitis Abivax appoints Michael Ferguson as Chief Commercial Officer Abivax reports 2022 financial results and operations update
May 2023	Abivax announces that its ordinary and extraordinary general meeting would be held on June 5, 2023
June 2023	Abivax announces the release of the results of its June 5, 2023 ordinary and extraordinary general meeting Abivax announces the appointment of Ida Hatoum as Chief People Officer Abivax announces that, as of June 1 st , the Abivax stock is represented in the MSCI Indexes Abivax announces that it has received the “Capital Market Transaction of the Year Award” at the European Mediscience Awards 2023
July 2023	Abivax announces the appointment of June Lee, M.D. and Troy Ignelzi as Members of the Board of Directors.
August 2023	Abivax announces its plans to conduct a registered public offering of its ordinary shares, in the form of American Depositary Shares, in the United States, subject to market and other conditions, and that it had confidentially submitted a draft registration statement on Form F-1 to the U.S. Abivax announces that it has concurrently signed two structured debt financing transactions for a total amount of up to EUR 150M consisting of (i) up to EUR 75M from Kreos and Claret together with the issuance of warrants (<i>bons de souscription d’actions</i>) exercisable to receive up to EUR 8M worth of ordinary shares of the Company, par value of EUR 0.01 per share , and (ii) up to EUR 75M from a fund advised by Heights Capital Management, Inc.

Abivax announces the appointment of Patrick Malloy as Senior Vice President Investor Relations

September 2023 Abivax provides business and operational update

Abivax presents first-half 2023 financial results

10.2 Trends, uncertainties, constraints, commitments or events likely to have a material impact on the Company's outlook

The Company intends to focus on the following objectives:

- **Advance Obefazimod—Establish obefazimod as a potential first-line advanced therapy for the treatment of IBD.** This goal is based on (i) robust Phase 2a and 2b clinical trial data in patients with moderately to severely active UC, as well as (ii) obefazimod's novel mechanism of action that was demonstrated to enhance the expression of miR-124, a natural regulator of the inflammatory response. Initiation of the Phase 2a clinical trial in Crohn's disease ("CD") is expected in the first quarter of 2024 to potentially demonstrate outcomes consistent with those observed in the ongoing Phase 2 clinical trials for moderately to severely active UC..
- **Optimize Opportunity in IBD in the Near Term with Phase 3 Data Beginning in 2025—**Overcome limitations of currently available treatments for UC to establish obefazimod as a differentiated treatment option with the goal of providing convenient oral administration, safety, tolerability, and durable efficacy.
- **Leverage Library of miR-124 Enhancers—**Explore and expand development options of obefazimod in other inflammatory conditions and continue R&D work to identify additional drug candidates from the Company's proprietary small molecule library that includes additional miR-124 enhancers. To further the Company's strategy, its first follow-on drug candidate is expected to be selected and enter preclinical development in 2024."

10. ADMINISTRATIVE, MANAGEMENT AND SUPERVISING BODIES AND GENERAL MANAGEMENT

10.1 Executives, directors and non-voting directors

Section 12.1.1 “Composition of the Board of Directors” of the 2023 Universal Registration Document is updated as follows:

“12.1.1 Composition of the Board of Directors

As at the date of this Amendment, the Company’s Board of Directors is composed of the following eight members:

Name	Office	Independent	Term of office start and end date	Committees
Marc de Garidel	Chairman of the Board of Directors	Yes	Appointed Chairman of the Board of Directors by the Board of Directors on April 4, 2023, effective as from May 5, 2023.	N/A
Corinna zur Bonsen-Thomas	Director	Yes	Appointed Director by the General Meeting of Shareholders held on June 23, 2017. Renewed by the Combined General Meeting held on June 4, 2021 for a term of four years expiring at the close of the General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2024. Appointed Chairman of the Board of Directors by the Board of Directors on August 15, 2022. Stepped down as acting Chair on April 4, 2023, effective as from May 5, 2023, and remained a board member.	- Member of the Audit Committee - Member of the Appointments and Compensation Committee
Troy Ignelzi	Director	Yes	Co-opted as Director by the Board of Directors on July 11, 2023 to replace Mr. Jean-Jacques Bertrand who resigned from his position as Director on July 5, 2023.	- Chairman of the Audit Committee
June Lee	Director	Yes	Co-opted as Director by the Board of Directors on July 11, 2023 to replace Joy Amundson who resigned from her position as Director on July 4, 2023.	- Chairman of the Appointments and Compensation Committee

Name	Office	Independent	Term of office start and end date	Committees
Santé Holdings SRL (permanent representative to the Board: Paolo Rampulla)	Director	No	Co-opted as Director by the Board of Directors on July 6, 2015 to replace Jérôme Gallot and confirmed by the Board of Directors on September 14, 2015. Renewed by the Combined General Meeting held on June 4, 2021 for a term of four years expiring at the close of the General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2024	
Truffle Capital (permanent representative to the Board: Philippe Pouletty)	Director	No	Appointed Director under the terms of the Company's Charter. Renewed by the Combined General Meeting held on June 4, 2021 for a term of four years expiring at the close of the General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2024	- Member of the Appointments and Compensation Committee
Carol L. Brosgart	Director	Yes	Co-opted as Director by the Board of Directors on January 22, 2018 to replace Christian Pierret. Renewed by the Combined General Meeting held on June 9, 2022 for a term of four years expiring at the close of the General Meeting of Shareholders called to approve the financial statements for the year ended 31 December 2025.	
Sofinnova Partners (permanent representative to the Board: Kinam Hong)	Director	No	Co-opted Director in place of resigning Claude Bertrand by the Board of Directors of September 17, 2019. Renewed by the Combined General Meeting held on June 9, 2022 for a term of four years expiring at the close of the General Meeting of Shareholders called to approve the financial statements for the year ended December 31, 2025.	- Member of the Audit Committee - Member of the Appointments and Compensation Committee

The term of office of Directors is four years and expires at the close of the Ordinary General Meeting of Shareholders called to approve the financial statements for the preceding year and held in the year during which the term of office of said Director expires. Directors are eligible for reappointment. They may be removed from office at any time.

The Management experience and expertise of these individuals are the result of various employee and Management positions they have previously held (see Section 12.1.5 “Biographies of the Directors and of the Chief Executive Officer”).

At the date of this Amendment, the Board of Directors has eight members, three of whom are women. The Company shall comply with the provisions of Article L. 225-18-1 and L. 22-10-3 of the French Commercial Code relating to the diversity policy applied to members of the Board of Directors with regard to criteria such as age, sex or qualifications and professional experience.

The business addresses of the Directors are as follows:

- Marc de Garidel: Seeblick 3 6452 Sisikon, Switzerland
- Corinna zur Bonsen-Thomas: Alte Holzgasse 6, 83666 Waakirchen, Germany
- June Lee: 4047 25th Street, SF CA 94114, United States
- Troy Ignelzi: 7702 Finnagen Drive, Mattawan, MI 49071, United States
- Paolo Rampulla (Santé Holdings SRL): Via Agnello 12, 20121 Milan, Italy
- Philippe Pouletty (Truffle Capital): 5, rue de la Baume, 75008 Paris, France
- Carol L. Brosgart: 3133 Lewiston Avenue, Berkeley, CA 94705, United States
- Kinam Hong (Sofinnova partners): 7-11 boulevard Haussmann, 75009 Paris, France

The evaluation of the independence of the directors currently on the Board is based on the criteria of the Middenext Code.

10.2 Statement regarding the members of the Board of Directors and the Chief Executive Officer

The statements regarding the members of the Board of Directors included in Section 12.1.3 “Statement regarding the members of the Board of Directors and the Chief Executive Officer” of the 2023 Universal Registration Document apply without amendments to the members of the Board of Directors who have joined the Board of Directors since the release of the 2023 Universal Registration Document.

10.3 Other corporate offices and duties

Section 12.1.4 “Other corporate offices and duties” of the 2023 Universal Registration Document is updated as follows:

12.1.4 Other corporate offices and duties

Other current directorships and positions held

At the date of this Amendment, the other offices held and duties performed by directors were as follows:

Name	Office	Company
Marc de Garidel	<ul style="list-style-type: none"> Chairman of the board of directors 	Ipsen
	<ul style="list-style-type: none"> Director 	Claris Bio
Corinna zur Bosen-Thomas	<ul style="list-style-type: none"> Managing Director 	RetInSight GmbH
June Lee	<ul style="list-style-type: none"> Venture partner Member of the board Director Director 	5AM Venture Management, LLC Johns Hopkins University Center for Therapeutic Translation’s Advisory Board Tenaya Therapeutics Inc Eledon Pharmaceuticals Inc. GenEdit
Troy Ignelzi	<ul style="list-style-type: none"> Director 	Vedanta Biosciences, Inc.
Carol L. Brosgart	<ul style="list-style-type: none"> Director and member of the Scientific Committee 	Hepatitis B Foundation
	<ul style="list-style-type: none"> Director 	Berkeley Community Scholars
	<ul style="list-style-type: none"> Director 	Galmed Pharmaceuticals
	<ul style="list-style-type: none"> Director 	Enochian Biosciences
	<ul style="list-style-type: none"> Director 	Merlin Biotech
	<ul style="list-style-type: none"> Director 	Eradivir
Kinam Hong (Permanent Representative of Sofinnova partners)	<ul style="list-style-type: none"> Director 	LimFlow SA CytolImmune
	<ul style="list-style-type: none"> Director 	CytolImmune Therapeutics, Inc.
Paolo Rampulla (Permanent Representative of Santé Holdings SRL)	<ul style="list-style-type: none"> Sole Director 	Immobiliare Cosio SRL
	<ul style="list-style-type: none"> Director 	Columbus Clinic Center SRL
	<ul style="list-style-type: none"> Permanent Representative of Santé Holdings SRL 	Carmat SA
Philippe Pouletty	Management positions:	
	<ul style="list-style-type: none"> Chief Executive Officer and Director 	Truffle Capital SAS
	<ul style="list-style-type: none"> General Manager 	Nakostech SARL
	<ul style="list-style-type: none"> Permanent Representative of Truffle Capital, Chairman 	Caranx SAS

Name	Office	Company
	<ul style="list-style-type: none"> • Permanent Representative of Truffle Capital, Chairman • Permanent Representative of Truffle Capital, Chairman 	Spiklmm SAS Diaccurate SA
	Directorships:	
	<ul style="list-style-type: none"> • Director – Chairman of the Board • Permanent Representative of Truffle Capital, Chairman • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director 	Carbios SA PKMed SAS Affluent Medical Holistick Medical SAS Artedrone SAS Skinosive SAS BariaTek SAS

Other corporate offices held by the directors over the past five financial years and not currently held

As of the date of this Amendment, the other corporate offices held by the directors during the last five years and ended to date are:

Name	Office	Company
Marc de Garidel	<ul style="list-style-type: none"> • Chief Executive Officer • Chief Executive Officer • Chief Executive Officer 	CinCor Pharma AZTherapies Corvidia Theurapeutics
June Lee	<ul style="list-style-type: none"> • Chief Executive Officer • Executive Vice President • Director 	Esker Therapeutics MyoKardia, Inc. CinCor Pharma
Troy Ignelzi	<ul style="list-style-type: none"> • Director 	CinCor Pharma
Corinna zur Bonsen-Thomas	None	None
Philippe Pouletty	<ul style="list-style-type: none"> • Director • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director • Permanent Representative of Truffle Capital, Director 	Deinove SA Vexim SA Carmat SA Pharnext SA
Paolo Rampulla (Permanent Representative of Santé Holdings SRL)	None	None

Name	Office	Company
Carol L. Brosgart	<ul style="list-style-type: none"> • Member of the Hepatitis B Group Management Committee • Member of the medical advisory committee • Chair of the Scientific Advisory Board • Director • Director • Director • Director • Member of the Scientific Committee 	<p>Forum for Collaborative Research, University of California, Berkeley, School of Public Health</p> <p>Liver Wellness Foundation</p> <p>Hepion Pharmaceuticals (formerly ContraVir)</p> <p>Juvaris</p> <p>Tobira Therapeutics</p> <p>Intrivo Diagnostics</p> <p>Mirum Pharma</p> <p>Pardes Biosciences</p>
Kinam Hong (Permanent Representative of Sofinnova partners)	None	None

10.4 Biographies of Directors and Chief Executive Officer

Section 12.1.5 “Biographies of Directors and Chief Executive Officer” of the 2023 Universal Registration Document is updated as follows:

12.1.5 Biographies of Directors and Chief Executive Officer

Marc de Garidel has been the Company’s Chief Executive Officer and Chairman of the Board since May 5, 2023 and has more than 40 years of experience in the pharmaceutical and biotechnology sector, including 12 years of experience as Chief Executive Officer of pharmaceutical and biotechnology companies. Between July 2021 and April 2023, he served as Chief Executive Officer of CinCor Pharma and led its successful sale for up to \$1.8 billion, subject to the achievement of certain milestones, to AstraZeneca in February 2023. Between September 2020 and May 2021, Mr. de Garidel served as Chief Executive Officer of AZTherapies. From April 2018 until August 2020, he was Chief Executive Officer of Corvidia Therapeutics and led its sale to Novo Nordisk for \$2.1 billion in total consideration. Mr. de Garidel was the Chief Executive Officer of Ipsen between November 2010 and July 2016, overseeing the development of its U.S. presence. Prior to that, he worked for Amgen and Eli Lilly in jobs of increasing responsibilities and in various markets, including the United States and Europe. Mr. de Garidel has served as chairman of the board of directors of Ipsen since 2010 and has been a member of the board of directors of Claris Bio since 2020. He holds a degree in Civil Engineering from the Ecole des Travaux Publics in Paris, a Master’s degree in International Management from Thunderbird Global School Management and an executive MBA from Harvard Business School. The Company believes that Mr. de Garidel is qualified to serve on the Company’s Board because of his experience as an executive and member of the boards of companies in the life sciences industry.

June Lee has been one of the Company’s independent directors since July 2023. Dr. Lee has served as a venture partner at 5AM Venture Management, LLC since July 2022. Dr. Lee was most recently Founder and Chief Executive Officer of Esker Therapeutics until September 2021. Dr. Lee previously served as the Executive Vice President and Chief Development Officer of MyoKardia, Inc. from January 2019 to June 2020, and was the Chief Operating Officer from February 2017 until January 2019, and the Chief Development Officer from October 2017 to January 2019. From April 2011 until February 2017, Dr. Lee served on the faculty of the University of California, San Francisco, or UCSF, where she

was director of the Catalyst program at the Clinical and Translational Science Institute and a professor in the School of Medicine, and was responsible for overall strategy and operations for enabling and supporting translational research at the university. Catalyst is an internal UCSF accelerator for therapeutics, devices, diagnostics, and digital health technologies. Prior to UCSF, Dr. Lee was a disease area lead, early clinical development, at Genentech, Inc. from 2006 to 2011, where she was responsible for all strategy and activities as well as management of staff, budget, and resource allocation in the early clinical development group in multiple therapeutic areas. Dr. Lee served as a Medical Director in the clinical development group at Genentech, Inc. from 2004 to 2006, where she was responsible for clinical activities for licensed product of the Company. She currently serves on Johns Hopkins University Center for Therapeutic Translation's Advisory Board, serves on the board of directors of Tenaya Therapeutics Inc, Eledon Pharmaceuticals Inc. and GenEdit, is a member of the Scientific Advisory Board for Foresite Labs, and previously served as a member of the board of directors of CinCor Pharma, Inc. Dr. Lee holds a B.A. in chemistry from Johns Hopkins University and an M.D. from the University of California, Davis. The Company believes that Dr. Lee is qualified to serve on the Company's Board because of her experience as an investor and member of the boards of companies in the life sciences industry.

Troy Ignelzi has been one of the Company's independent directors since July 2023. Mr. Ignelzi has served as the Chief Financial Officer of Karuna Therapeutics, Inc. since March 2019. Prior to that, Mr. Ignelzi was the Chief Financial Officer of scPharmaceuticals Inc. from March 2016 to February 2019, and provided consulting services to scPharmaceuticals Inc. in February and March 2016. Mr. Ignelzi previously served as Chief Financial Officer and as a member of the executive leadership teams at Juventas Therapeutics Inc., a privately held biotechnology company, from October 2014 to February 2016. From October 2013 to October 2014, Mr. Ignelzi served as Senior Vice President—Operations and Business Development of Pharmalex GmbH. Prior to Pharmalex, Mr. Ignelzi was Vice President—Business Development at Esperion Therapeutics, Inc., a public pharmaceutical company, from January 2009 to September 2013. Mr. Ignelzi served as Vice President, Business Development & Strategic Planning at Insys Therapeutics, Inc., a specialty pharmaceutical company, from February 2007 to February 2009. Previously, Mr. Ignelzi had served as a specialty senior sales representative at Eli Lilly from February 2002 to August 2005. Mr. Ignelzi currently serves as a member of the board of directors of Vedanta Biosciences, Inc. and previously served as a member of the board of directors of CinCor Pharma, Inc. Mr. Ignelzi has a B.S. in accounting from Ferris State University. The Company believes that Mr. Ignelzi is qualified to serve on the Company's Board because of his experience as an executive and member of the boards of companies in the life sciences industry.

Carol L. Brosgart has been one of the Company's independent directors since January 2018. She has held several executive management positions, notably those of Chief Medical Officer at Alios (now J&J), from February 2011 to August 2011, and Senior Vice President and Medical Director at the Children's Hospital and Research Center in Oakland, California from December 2009 to January 2011. She held several executive management positions at Gilead Sciences (Vice President Clinical Research, Vice President Medical Affairs, Vice President Public Health and Strategy) between 1998 and 2009. She has served as a member of the board of directors of Galmed Pharmaceuticals, a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases, since 2017, and Enochian Biosciences, a biotechnology company committed to developing advanced allogenic cell and gene therapies, since 2020. Dr. Brosgart also serves as a director on the board of Mirum Pharmaceuticals, a clinical stage drug development biopharmaceutical company for rare liver diseases, since 2021. Dr. Brosgart is the chair of the scientific advisory board at Hepion Pharmaceuticals, formerly ContraVir, a biotech company operating in the area of NASH, HBV, HCV and HDV in the field of HBV cures. She is also a consultant at Dynavax and several biotech companies working in the fields of liver diseases and infectious diseases. In addition, Dr. Brosgart currently sits on the board of the Hepatitis B Foundation, the Management Committee of the National Viral Hepatitis Roundtable, the Executive Committee of the Forum for Collaborative Research and the

Management Committee of the HBV Cure Forum. She is also a clinical professor of medicine, biostatistics and epidemiology in the Global Health Sciences Department of the University of California, San Francisco. Dr. Brosgart holds a degree in Community Medicine from UC Berkeley and earned a Doctor of Medicine from UC San Francisco. The Company believes that Dr. Brosgart is qualified to serve on the Company's Board because of her extensive experience as an executive and as a member of the boards of companies in the life sciences industry and her medical background.

Corinna zur Bensen-Thomas served as the Company's Chair between August 2022 and May 2023 and has been one of the Company's independent directors since June 2017. Since April 2020, Ms. zur Bensen-Thomas has held the position of Managing Director and Chief Executive Officer of RetInSight GmbH, a company which she co-founded in April 2020 and specializes in ophthalmic imaging. Ms. zur Bensen-Thomas was General Counsel for Smart Reporting GmbH from February 2017 to December 2022. From 1999 to 2015, she served as a member of the Supervisory Board of Baxter AG, an Austrian company. She has more than thirty years of international professional experience in the pharmaceutical, biopharmaceutical, medical and biotechnology industries. Ms. zur Bensen-Thomas received her First Law State Examination from Ludwig Maximilian Universitaet and her Second Law State Examination from the Bavarian Ministry of Justice. The Company believes that Ms. zur Bensen-Thomas is qualified to serve on the Company's Board because of her extensive professional experience in the life sciences industry.

Kinam Hong has served as the permanent representative of Sofinnova Partners on the Company's Board since September 2019. He has served as the partner responsible for Sofinnova's strategy of crossover and growth investment in late development stage companies at Sofinnova Partners since January 2017. He has served as the permanent representative of Sofinnova Partners on the board of directors of CytolImmune Therapeutics, Inc. since July 2021 and as an observer then board member of Limflow SA since April 2018. Prior to Sofinnova Partners, Dr. Hong spent ten years as an investor and research analyst covering the biotechnology sector. Dr. Hong co-led the Exane Equinox Fund, a global healthcare fund investing in public biotech companies. He also worked at Citigroup investment research where he focused on small- and midcap biotechnology companies. Before his investment career, Dr. Hong worked in new product development at Sanofi, a multinational pharmaceutical company, where he held positions in business development and strategic/new product marketing. Dr. Hong is a doctor and scientist who holds a Bachelor of Science degrees in molecular biology/biochemistry and a Doctor of Medicine from the University of Florida. He also holds a Chartered Financial Analyst and a Master of Business Administration from INSEAD, France. The Company believes that Dr. Hong is qualified to serve on the Company's Board because of his extensive experience as an investor and as a member of the boards of companies in the life sciences industry.

Paolo Rampulla has served as the permanent representative of Santé Holdings SRL on the Company's Board since September 2023. Dr. Rampulla is a trained economist, qualified tax advisor (*dottore commercialista*) and chartered auditor (*revisore legale*). Dr. Rampulla has served as a member of the board of Carmat SA since September 2023. Dr. Rampulla holds a Master in Tax Law from Ippsoa School of Economics, Milan, Italy, and a degree in Economics from the University Luigi Bocconi, Milan, Italy. Dr. Rampulla is a partner at ADVANT-NCTM, where he has practiced law since 2003 and regularly advises clients in M&A and international tax matters in the healthcare and med-tech industries. We believe that Dr. Rampulla is qualified to serve on our Board because of his experience as an advisor to companies in the life sciences industry.

Philippe Pouletty, MD has served as a director since December 2013 and is the Company's founder, as well as founder or co-founder of Carbios, Carmat, Vexim, Symetis, Affluent Medical, SpikImm and more than a dozen other biotechnology and medical technology companies of Truffle Capital, several being listed or were acquired. He was the Chairman of France Biotech from 2001 to 2006 and from 2007 to 2009, the French association of biotech companies and Vice-Chairman of Europabio from 2002

to 2006, the European federation of biotechnologies. Dr. Pouletty is a member of the board of directors or the chairman of several biotechnology and medical device companies in Europe. Dr. Pouletty, acting as permanent representative of Truffle Capital, has served as director of Pharnext SA, from April 2016 to October 2021, Carmat SA, from April 2021 to July 2021, and Deinove SA, from 2009 to 2021. Dr. Pouletty holds a Doctor of Medicine from Université Paris VI and was a Post-doctoral fellow at Stanford University and is a permanent member of the hall of fame of inventors of Stanford University. The Company believes that Dr. Pouletty is qualified to serve on the Company's Board because of his extensive experience as founder and member of the boards of companies in the life sciences industry, his medical background and his experience as an executive of several biotechnology organizations."

11. COMPENSATION AND BENEFITS

As an update to Chapter 13 "Compensation and Benefits" of the 2023 Universal Registration Document, it is specified that the annual ordinary and extraordinary general meeting of shareholders held on June 5, 2023, approved the compensation policy set forth in Chapter 13 of the 2023 Universal Registration Document and applicable to the Chairman, the Chief Executive Officer and the directors.

12. FUNCTIONING OF ADMINISTRATIVE AND MANAGEMENT BODIES

12.1 Information on the agreements between the executives and/or the directors and the Company

Section 14.2 "Information on the agreements between the executives and/or the directors and the Company" of the 2023 Universal Registration Document is updated as follows:

"14.2 Information on the agreements between the executives and/or the directors and the Company

The Company has not entered into agreements with its directors or chief executive officer during the financial year 2022.

In February 2023, the Company entered into an offer letter with Dr. Sloan, its Chief Medical Officer. Dr. Sloan may terminate his employment with Abivax without good reason (as defined in his offer letter), and Abivax may terminate his employment without cause (as defined in his offer letter) upon four months of notice. If Dr. Sloan's employment is terminated by Abivax without cause or Dr. Sloan resigns with good reason (as defined in his offer letter), then he will be entitled to receive severance pay in an amount equal to (i) six months of his then-current base compensation, (ii) prorated portion of the variable compensation and (iii) any premiums for healthcare plans provided by the Company (including any eligible COBRA coverage) for the earlier of a period of six months from the date of termination and the date on which Dr. Sloan becomes eligible to receive such benefits with a new employer. The offer letter also includes a non-competition provision lasting during and for six months following his employment with Abivax.

In April 2023, the Company entered into a transition protocol with Mr. Hartmut Ehrlich and in a management agreement with Mr. Marc de Garidel.

Under his management agreement, Mr. Marc de Garidel is entitled, in case of termination of the Chief Executive Officer as a result of (i) non-renewal, (ii) revocation except for gross negligence or willful misconduct and/or (iii) resignation justified by invalidity or health issues or Mr. de Garidel's definitive retirement (a "Qualifying Departure"), to a severance payment equal to 12 months of the higher of either (i) the monthly average fixed remuneration and variable remuneration received by Mr. de Garidel during the 12-month period preceding the effective date of the Qualifying Departure, or (ii) the monthly average fixed remuneration received by Mr. de Garidel during the 12-month period preceding the effective date of the Qualifying Departure plus 1/12th of the variable remuneration for the financial year immediately preceding the date of the Qualifying Departure, irrespective of the date of payment of that variable remuneration.

The main financial conditions of the transition protocol with Mr. Hartmut Ehrlich and the management agreement with Mr. Marc de Garidel are further described in Section 13.1 of the 2023 Universal Registration Document.

In April 2023, the Company also entered into an offer letter with Mr. Ferguson, its Chief Commercial Officer. Mr. Ferguson may terminate his employment with Abivax without good reason (as defined in his offer letter), and Abivax may terminate his employment without cause (as defined in his offer letter) upon four months of notice. If Mr. Ferguson's employment is terminated by the Company without cause or Mr. Ferguson resigns with good reason (as defined in his offer letter), then he will be entitled to receive severance pay in an amount equal to (i) six months of his then-current base compensation, (ii) prorated portion of the variable compensation and (iii) any premiums for healthcare plans provided by the Company (including any eligible COBRA coverage) for the earlier of a period of six months from the date of termination and the date on which Mr. Ferguson becomes

eligible to receive such benefits with a new employer. The offer letter also includes a non-competition provision lasting during and for six months following his employment with Abivax.”

12.2 Information on the Audit Committee, the Compensation Committee and the Scientific Committee

Section 14.3 "Information on the Audit Committee, the Compensation Committee and the Scientific Committee" of the 2023 Universal Registration Document is updated as follows:

“14.3 Information on the Audit Committee, the Compensation Committee and the Scientific Committee

At the date of this Amendment, the Board of Directors had three committees in place: an Appointments and Compensation Committee, an Audit Committee and a Scientific Committee.

14.3.1 Audit Committee

Mission and Responsibilities

The audit committee monitors issues relating to the elaboration and control of accounting and financial information as provided for by French law and by its by-laws and by the rules of procedure of the board of directors. It then formulates recommendations to the board of directors in its task of permanent control of the Management of the Company. It also issues recommendations in relation to the proposed statutory auditors.

The audit committee is responsible for:

- monitoring the preparation and development of accounting and financial information and, where appropriate, formulating recommendations in this respect to ensure its accuracy;
- reviewing the efficiency of the internal control and risk management systems;
- ensuring proper legal oversight of the preparation of the annual financial statements and financial statements by the statutory auditors; and
- selecting and ensuring the independence of the statutory auditors.

The audit committee is also responsible for approving:

- non-audit services provided by the statutory auditors (including the permitted level of fees); and
- all budgets for statutory audits and other engagements provided by the statutory auditors.

The audit committee further controls the services provided by the auditors in relation to what is permitted by law or regulation.

The audit committee is responsible for formulating recommendations regarding the statutory auditors proposed for nomination by the General Meeting of Shareholders and/or during the renewal of their term.

Within this context, the audit committee may examine its annual financial statements in the form that they are presented to the board of directors, hear the opinions of the statutory auditors and the finance director and receive communications in relation to their analysis work and their conclusions.

The audit committee may use external experts at its expense, after approval of the chairperson of the board of directors or the audit committee or of the Chief Executive Officer, and render any expert reports to the board of directors.

The audit committee may hear any director and carry out any internal or external audit on any subject it considers relevant to its mission. The chairperson of the audit committee shall inform the board in

advance. In particular, the audit committee has the power to interview the persons involved in the preparation of the accounts or in their control (administrative and financial director and the main managers of the financial department).

Composition and Compensation

The audit committee and chairperson of the audit committee are appointed by the board of directors from members of the board of directors, excluding executive directors, with finance or accounting skills and at least one member must be independent in accordance with the provisions of the Middenext Code. Members of the audit committee are appointed for a fixed period of time, which may not exceed the duration of their terms of office as director and may be revoked by the board of directors at any time and without reason. Appointments are renewable without limitation. The audit committee is composed of at least two members and members receive no compensation other than attendance fees. Their duties on the audit committee may be taken into account in determining the allocation of such attendance fees.

The current members of the audit committee are Troy Ignelzi, Corinna zur Bonsen-Thomas and Kinam Hong (representing Sofinnova Partners). The current chairperson of the audit committee is Mr. Ignelzi.

The committee may invite any person, internal or external to the Company, to take part in its meetings and its work.

Conditions of Functioning

The audit committee meets when the chairperson of the audit committee, at least two members of the audit committee, the chairperson of the board of directors or the Chief Executive Officer deems useful and at least twice per year, particularly before publication of the financial statements. The committee may be convened by any means 24 hours before the meeting by the chairperson of the audit committee or of the board of directors or any individual to whom one of them shall have delegated the necessary authority. The committee meets at the registered office or in any other place specified in the notice of the meeting. It may also meet by video conference or by any means of telecommunication as specified in the internal regulation of the board of directors.

To deliberate validly, at least half of the members of the committee must be present. At meetings, one member of the audit committee may be represented by another audit committee member and the audit committee's recommendations are adopted by simple majority. Upon completion of each meeting, if the members deem it necessary, meeting minutes may be prepared. The chairperson of the audit committee regularly reports to the board of directors on the committee's work and immediately report any difficulty encountered.

14.3.2 Appointments and Compensation Committee

Mission and Responsibilities

The appointments and compensation committee makes recommendations to the board of directors in relation to the nomination of, and compensation for, executive directors and the operational and functional management, and with regard to appointments and compensation policy and internal profit sharing. In particular, the appointments and compensation committee:

- provides recommendations and proposals to the board of directors concerning the appointment, in particular in the research of a balanced representation of men and women on the board of directors, compensation, retirement and provident scheme, supplementary pension benefits, benefits in kind, various financial rights of its managers and executive officers, the allocation of founder warrants, bonus shares, share subscription warrants, share subscription or share purchase options, for the benefit of its employees, managers or consultants and, where applicable, its subsidiaries, in accordance with legal provisions;

- defines the methods for determining the variable portion of the compensation of corporate officers and monitors its application;
- proposes a general policy for awarding founder warrants, free or performance shares, and options to subscribe or purchase shares, and determines the frequency thereof, depending on the categories of beneficiaries;
- examines the system of for the allocation of directors' fees among the members of the board of directors, particularly according to their participation in its committees; and
- expresses its opinion to senior management about the compensation of the principal senior executives.

The appointments and compensation committee is also involved in discussing each independent director's qualifications upon his or her nomination and during the exercise of his or her term of office, as applicable.

Composition and Compensation

The appointments and compensation committee is composed of at least two members. The chairperson of the compensation committee and the committee's members are appointed by the board of directors from members of the board of directors. Members are appointed for a fixed period of time, which may not exceed, as applicable, the duration of their term of office as director and may be revoked by the board of directors at any time and without reason. Their appointments shall be renewable without limitation.

The chairperson of the board, if not a member of the appointments and compensation committee, may be invited to participate in the appointments and compensation committee's meetings. The appointments and compensation committee shall invite him/her to present its proposals. He/she shall not have the right to vote and shall not be present during the deliberations relating to his/her own situation.

The current members of the appointments and compensation committee are June Lee, Philippe Pouletty (representing Truffle Capital), Corinna zur Bonsen-Thomas and Kinam Hong (representing Sofinnova Partners). The current chairperson of the compensation committee is Dr. Lee.

The appointments and compensation committee may invite any person, internal or external to us, to take part in its meetings and its work.

Appointments and compensation committee members shall receive no compensation other than attendance fees. Their duties on the compensation committee may be taken into consideration in determining the allocation of such attendance fees.

Conditions of Functioning

The appointments and compensation committee meets when the chairperson of the appointments and compensation committee, at least two members of the appointments and compensation committee, the chairperson of the board of directors or the Chief Executive Officer deems useful and at least once a year. The appointments and compensation committee may be convened by any means, 24 hours before the meeting, by the chairperson of the appointments and compensation committee or of the board of directors, or any individual to whom one of them shall have delegated the authority necessary for the convocation.

The committee meets at the registered office or in any other place specified in the notice of the meeting. It may also meet by video conference or by any means of telecommunication, as specified in the internal regulation of the board of directors.

To deliberate validly, at least half of the members of the committee must be present. A member of the appointments and compensation committee may be represented by another appointments and

compensation committee member and the appointments and compensation committee's recommendations are adopted by simple majority. Upon completion of each meeting, if the members deem it necessary, meeting minutes may be prepared.

The appointments and compensation committee chairperson reports regularly to the board of directors on the appointments and compensation committee's work and shall immediately report any difficulty encountered.

14.3.3 Scientific Committee

Mission and Responsibilities

The scientific committee was created by a decision by the board of directors on September 27, 2018.

The role of the scientific committee is to:

- examine specific scientific questions submitted to it;
- make recommendations for determining the general guidelines to be adopted in the scientific field; and
- make recommendations for defining its priorities in the field of research and development and the means for achieving such objectives.

The committee meets at least once a year.

It works in collaboration with the Chief Executive Officer, who may request its opinion on subjects related to its mission. At the request of the board of directors, the chairperson of the scientific committee reports on the committee's work to the board of directors.

Composition and Compensation

The scientific committee is composed of at least four members appointed by the board of directors upon proposal of the Chief Executive Officer. The members of the scientific committee do not have to be members of the board.

The current members of the scientific committee are Prof. Ian McGowan, MD, PhD, (Chairman); Prof. Christian Bréchet; Prof. Christoph Huber; Prof. Jürgen Rockstroh; Prof. Christian Trepo; Prof. Lawrence R. Stanberry; Prof. Luc Teyton; and Claude Bertrand.

The composition of the scientific committee is currently under review in light of the Company's needs for the continued development of its clinical programs."

13. EMPLOYEES

13.1 The Company's Team

Section 15.1.1 "Organisational chart as at the date of filing of this Universal Registration Document" of the 2023 Universal Registration Document is updated as follows:

"15.1.1 The Company's Team

The Company's team is comprised of industry leaders in the fields of biology, data analytics, and drug development, as well as scientific experts in chronic inflammatory diseases including IBD, with 34 full-time employees as of June 30, 2023. Collectively, its team has decades of experience and a proven track record of advancing compounds into and through clinical development and commercialization.

- Marc de Garidel, its Chief Executive Officer, has more than 40 years of experience in the pharmaceutical and biotechnology sector, including 12 years of experience as Chief Executive Officer of pharmaceutical and biotechnology companies. Between July 2021 and April 2023, he served as Chief Executive Officer of CinCor Pharma and led its successful sale for up to \$1.8 billion, subject to the achievement of certain milestones, to AstraZeneca in February 2023. From April 2018 until August 2020, he was Chief Executive Officer of Corvidia Therapeutics and led its sale to Novo Nordisk for \$2.1 billion in total consideration.
- Didier Blondel, its Chief Financial Officer and Board Secretary, was previously Chief Financial Officer at Sanofi Pasteur MSD, a Lyon-based joint venture between Sanofi and Merck. Over the past 20 years, he has held a wide variety of senior finance positions at Sanofi in both Commercial Operations and Research and Development, including as Global Research and Development Chief Financial Officer.
- Sheldon Sloan, MD, M Bioethics, its Chief Medical Officer, has over 30 years of experience in academia and the biopharmaceutical industry, with an extensive track record in the field of gastroenterology and IBD. Prior to joining the Company, Dr. Sloan worked for Arena Pharmaceuticals and, after its acquisition, for Pfizer, where he was Program Lead for Etrasimod. Before joining Arena Pharmaceuticals, he held different leadership positions at Johnson and Johnson in Medical Affairs, Research and Development, and Science Policy, including Global Medical Affairs Leader for IBD, leading the global launch strategy and execution for CD and UC for Stelara.
- Michael Ferguson, MBA, its Chief Commercial Officer, has over 22 years of experience in the biopharmaceutical industry, with an extensive track record in the field of gastroenterology and IBD. He has spent the last 16 years of his career in large pharmaceutical and biotech companies, including 13 years in leading commercial positions at Shire/Takeda, followed by Arena Pharmaceuticals, where he served as Vice President Global Commercial Marketing and Planning and specifically as Global Commercial Lead for Etrasimod across all GI Indications.
- Pierre Courteille, Pharmacist, MBA, its Chief Business Officer, has more than 25 years of experience in marketing, sales and business development within the pharmaceutical industry. He has extensive commercial launch and marketing experience from prior roles as Senior Vice President of Sales and Marketing for Guerbet and Chief Executive Officer of MEDEX, a medical device company owned by Guerbet, and Marketing Manager at Sanofi Pasteur Japan's joint-venture with Daiichi Sankyo.
- Didier Scherrer, Ph.D., Chief Scientific Officer, has extensive experience in the development of a portfolio of therapeutics in oncology, viral diseases and autoimmune / inflammatory

diseases. Prior to joining the Company in March 2009, he performed a combined role of Chief Executive Officer and Scientific Director at Splicis. He also has experience from prior roles as Associate Director (Capability Pathways—Discovery Enabling Capabilities and Sciences) of the Research Department of AstraZeneca and as Head of Research at LFB Biotechnologies.

- The Company's management team also consists of other top industry veterans such as Paul Gineste, PharmD, its VP of Clinical Operations and formerly International Clinical Trials Manager at Boehringer Ingelheim; Jérôme Denis, Ph.D., its VP of Process Development & Manufacturing and formerly Executive Head of Development & Associate Director of Vaccine Development at Imaxio; and Mary Mantock, MSc, its VP of Regulatory Affairs and formerly Executive Director, RA, Global Development for immune-oncology at Astellas.

The Company relies on skilled, experienced and innovative employees to conduct the operations of its company. The Company is committed to building an outstanding, committed team and the Company focuses on a culture that values a focus on scientific innovation, inclusion, collaboration and equity. The Company focuses on recruiting, retaining and developing employees from a diverse range of backgrounds to conduct its research, development, clinical, commercial, marketing and market access activities. The Company recognizes that recruiting, motivating and retaining talented employees is vital to its success. The principal purposes of its equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase shareholder value and the success of its company by motivating such individuals to perform to the best of their abilities and achieve its objectives. The Company aims to create an equitable, inclusive and empowering environment in which its employees can grow and advance their careers, with the overall goal of developing, expanding and retaining its workforce to support its current pipeline and future business goals. Employees are encouraged to attend scientific, clinical and technological meetings and conferences and have access to broad resources they need to be successful."

13.2 Staff numbers and breakdown

Section 15.1.2 "Staff numbers and breakdown" of the 2023 Universal Registration Document is updated as follows:

"15.1.2 Staff numbers and breakdown

As of June 30, 2023, the Company's had 34 full-time employees, consisting of 18 within the research and development department, 6 employees within the commercial, marketing and market access department and 10 within the general administrative department. The Company's employees based in France are subject to the national collective bargaining agreement for the pharmaceutical industry (the *convention collective nationale de l'industrie pharmaceutique*). The Company believes that it maintains good relations with its employees. A majority of its future planned hires are expected to be residing in the United States. As of June 30, 2023, 25 full-time employees were based in France and nine full-time employees were based in the United States."

13.3 Agreement providing for shareholdings of employees

Section 15.3 "Agreement providing for shareholdings of employees" of the 2023 Universal Registration Document is updated as follows:

"15.3 Agreement providing for shareholdings of employees

As of August 31, 2023, some employees and executive officers already held shares of the Company.

Some employees and executive officers are also holders of BCEs and BSAs and/or have been granted AGAs, with a total potential shareholding of 4.10% of the Company's capital in the event that (i) all the BCEs and BSAs held by these employees as at August 31, 2023 are fully exercised, and that (ii) all the AGAs allocated to these employees as at August 31, 2023 become fully vested, based on the fully diluted capital (i.e. 47,589,645 shares).

Details of the BCEs, BSAs and AGAs as at August 31, 2023 are set out in Paragraph 19.1.4 "Securities conferring rights to share capital" of the 2023 Universal Registration Document, as amended by this Amendment."

14. MAJOR SHAREHOLDERS

14.1 Breakdown of capital and voting rights

Section 16.1.1 "Breakdown of share capital and voting rights" of the 2023 Universal Registration Document is updated as follows:

"16.1.1 Breakdown of share capital and voting rights

As at August 31, 2023, the breakdown of the Company's share capital and voting rights is as follows.

Shareholders	Number of shares (undiluted capital)	% of capital (undiluted)	% of voting rights (undiluted)	% of capital (diluted)	% of voting rights (diluted)
TCG Crossover	4,956,596	11.65%	9.99%	10.42%	9.07%
Truffle Capital	4,677,069	10.99%	17.80%	9.83%	16.16%
Sofinnova Partners	4,064,739	9.55%	11.59%	8.54%	10.52%
Invus	4,034,364	9.48%	8.13%	8.48%	7.38%
Deeptrack	2,675,238	6.29%	5.39%	5.62%	4.89%
Venrock	2,613,000	6.14%	5.27%	5.49%	4.78%
Sante Holding	741,541	1.74%	2.71%	1.76%	2.64%
Holding Incubatrice	210,970	0.50%	0.68%	0.44%	0.62%
Management	112,133	0.26%	0.34%	3.81%	3.42%
Board of Directors (1)	275,000	0.65%	1.11%	0.65%	1.07%
Employees	162,235	0.38%	0.45%	0.87%	0.87%
Consultants	400	0.00%	0.00%	0.10%	0.09%
Other (2)	283,462	0.67%	0.80%	6.72%	6.06%
Treasury shares	11,017	0.03%	0.00%	0.02%	0.00%
Floating	17,729,804	41.67%	35.74%	37.26%	32.44%
Total	42,547,568	100.00%	100.00%	100.00%	100.00%

(1) Excluding Truffle, Sofinnova Partners, Sante Holding and Marc de Garidel.

(2) Others: lenders (including Kreos, Claret and Heights), historical minority shareholders or holders of BSA/BCE/AGA, Kepler Cheuvreux (on the basis of the declaration of threshold crossing dated July 3, 2019), as well as former employees of the Company, former members of the Board or certain committee members."

14.2 Recent transactions involving the Company's capital

Section 16.1.3 "Recent transactions involving the Company's capital" of the 2023 Universal Registration Document is updated as follows:

"16.1.3 Recent transactions involving the Company's capital

During fiscal year 2022, various transactions were conducted involving the Company's capital:

- On March 8, 2022, 334 shares of the Company were subscribed by the exercise of 334 BCE-2018-5.
- On May 30, 2022, 18,800 shares of the Company were subscribed via the exercise of 188 BSA-2014-3.

- On September 2, 2022, the Company announced a capital increase via the issuance of 5,530,000 new shares of the Company, said issuance having taken place on September 7, 2022.

During fiscal year 2023, the following transactions were completed:

- On January 20, 2023, 18,400 shares of the Company were subscribed via the exercise of 184 BCE-2014-4, as acknowledged by the Board of Directors on February 7, 2023.
- On February 22, 2023, the Company announced a capital increase via the issuance of 20,000,000 new shares of the Company, said issuance having taken place on March 1st, 2023.
- On May 10, 2023, 16,400 shares of the Company were subscribed via the exercise of 16,400 BSA-2014-3.
- On May 24, 2023, 67,887 shares of the Company were subscribed via the exercise of 67,887 BSA-2018-KREOS-A, said issuance taken place on June 6, 2023.
- On May 24, 2023, 31,696 shares of the Company were subscribed via the exercise of 31,969 BSA-2018-KREOS-B, said issuance taken place on June 6, 2023.
- On June 19, 2023, 100,000 shares of the Company were subscribed via the exercise of 100,000 BCE-2014-2.”

14.3 Direct or indirect control of the Company

Section 16.3 "Direct or indirect control of the Company " of the 2023 Universal Registration Document is updated as follows:

“16.3 Direct or indirect control of the Company

As at August 31, 2023, funds controlled by Truffle Capital hold the largest number of votes within the Company share capital. However, the Company is not controlled by such funds within the meaning of Article L. 233-3 of the French Commercial Code. These funds jointly hold 4,667,069 shares representing 10.99 % of the share capital and 17.80 % of the voting rights of the Company based on undiluted capital at August 31, 2023 (9.83 % of share capital and 16.16 % of voting rights based on fully diluted capital).

To the best of the Company’s knowledge, there are no shareholders acting in concert.”

14.4 Summary of transactions by persons mentioned in Article L. 621-18-2 of the French Monetary and Financial Code carried out on Company securities by executives

Section 16.5.1 "Summary of transactions by persons mentioned in Article L. 621-18-2 of the French Monetary and Financial Code carried out on Company securities by executives" of the 2023 Universal Registration Document is updated as follows:

16.5.1 Summary of transactions by persons mentioned in Article L. 621-18-2 of the French Monetary and Financial Code carried out on Company securities by executives

Below, the Company indicates the transactions conducted by the Company's corporate officers (directors and CEO) and their relatives in the Company's securities during the 2022 financial year, and the current financial year as declared by these persons in application of the provisions of Article 223-26 of the AMF General Regulation:

Transactions as from 1st January 2022	
02/09/2022	Purchase by Sofinnova Partners SAS of 584,000 shares for a unit price of EUR 8.36
02/09/2022	Purchase by Truffle Capital of 197,000 shares for a unit price of EUR 8.36
02/09/2022	Purchase by Santé Holdings SRL of 101,000 shares for a unit price of EUR 8.36
07/09/2022	Purchase by Sofinnova Partners SAS of 1 royalty certificate for a unit price of EUR 309,520
07/09/2022	Purchase by Santé Holdings SRL of 1 royalty certificate for a unit price of EUR 53,530
06/12/2022	Sale by Truffle Capital of 215,000 shares for a unit price of EUR 6.2302
27/02/2023	Subscription by Sofinnova Partners of 1,535,000 shares for a unit price of EUR 6.50
27/02/2023	Subscription by Santé Holdings SRL of 38,461 shares for a unit price of EUR 6.50
08/06/2023	Sale by Truffle Capital of 224,729 shares for a unit price of EUR 17.22
13/07/2023	Sale by Truffle Capital of 192,781 shares for a unit price of EUR 16.0881

15. ADDITIONAL INFORMATION

15.1 Amount of share capital

Section 19.1.1 "Total share capital" of the 2023 Universal Registration Document is updated as follows:

"19.1.1 Total share capital

As at the date of the Amendment, the share capital amounted to four hundred twenty-five thousand four hundred seventy-five euros and sixty-eight cents (EUR 425,475.68).

It is divided into forty-two million euros five hundred forty-seven thousand five hundred sixty-eight (42,547,568) fully paid-up shares of the same class, each with a par value of one (1) euro cent (EUR 0.01) each."

15.2 Securities granting entitlement to a share of the capital

Section 19.1.4 "Securities eligible for a share of capital" of the 2023 Universal Registration Document is updated as follows:

"19.1.4 Securities providing access to the share capital

As at the date of the Amendment, the Company had issued the following securities giving access to capital:

Founder warrants (BCEs)

As at August 31, 2023, the Company issued the following securities providing access to capital:

Category	BCE-2014-1	BCE-2014-2	BCE-2014-3	BCE-2014-4	BCE-2014-5	BCE-2014-6	BCE-2014-7	BCE-2015-9 (G)	BCE-2015-9 (S)	BCE-2015-9 (D)	BCE-2015-9 (C)	BCE-2016-1	BCE-2017-1	BCE-2017-2	BCE-2017-3	BCE-2017-4	BCE-2017-5
Expiry date	11/03/2024	11/03/2024	11/03/2024	11/03/2024	11/03/2024	11/03/2024	Expired	Expired	Expired	Expired	Expired	7/11/2026	23/01/2027	20/11/2027	20/11/2027	20/11/2027	20/11/2027
Subscription or purchase price	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Strike price per share	0.01	0.01	0.01	0.01	0.01	0.01	12.5	17.79	17.79	17.79	17.79	7.44	6.39	11.14	11.14	11.14	11.14
Exercise conditions	Achievement of objectives Note (1)	Note (2)		Achievement of objectives Note (3)	Achievement of objectives	Achievement of objectives Note (4)	Achievement of objectives Note (5)	Achievement of objectives	Achievement of objectives	Achievement of objectives	Achievement of objectives	Note (6)	Achievement of objectives Note (7)	Achievement of objectives Note (8)	Achievement of objectives Note (9)	Achievement of objectives Note (10)	Achievement of objectives Note (11)
Number of shares subscribed	275,000	275,000	76,300	98,400	2,800	19,700	0	0	0	0	0	40,006	374	0	48,426	1	3,000
Beneficiaries (number of shares that may be subscribed)																	
Corinna zur Bonsen-Thomas																	
Marc de Garidel																	
Other				0								22,495	67,000			67,373	64,374
Cumulative number of cancelled or expired BCEs	0	0	626	0	169	328	1,650	33,687	67,374	33,687	67,374	21,499	0	37,500	52,635	0	0
BCEs as at 31/08/2023	0	0	0	0	0	0	0	0	0	0	0	22,495	67,000	112,500	0	67,373	64,374
BCEs exercisable as at 31/08/2023	0	0	0	0	0	0	0	0	0	0	0	22,495	67,000	112,500	0	67,373	64,374

Category	BCE-2018-1	BCE-2018-2	BCE-2018-3	BCE-2018-4	BCE-2018-5
Expiry date	15/03/2028	21/05/2028	20/11/2028	14/05/2028	14/05/2028
Subscription or purchase price	0	0	0	0	0
Strike price per share	8.96	8.96	7.33	7.33	7.33
Exercise conditions	Note (12)	Achievement of objectives Note (13)	Achievement of objectives Note (14)	Achievement of objectives Note (15)	Note (16)
Number of shares subscribed	6,930	44,916	16,843	0	5,750
Beneficiaries (number of shares that may be subscribed)					
Corinna zur Bonsen-Thomas					
Marc de Garidel					
Other					
Cumulative number of cancelled or expired BCEs	3,090	22,458	0	0	10,250
BCEs as at 31/08/2023	11,980	0	16,844	16,843	6,000
BCEs exercisable as at 31/08/2023	11,980	0	16,844	16,843	6,000

Note (1): up to a maximum quantity X per full monthly period, calculated as follows: $X = 2,750$ multiplied by (number of months since the Company's date of incorporation/48) from the 1st day after the 18th month following the Company's date of incorporation (it being understood that the beneficiary must, from the 1st day after the 18th month following the Company's date of incorporation up to and including the 48th month following the Company's date of incorporation, devote more than 33% of his/her professional time to the Company).

Note (2): Up to a maximum quantity X per full monthly period, calculated as follows: $X = 2,750$ multiplied by (number of months since December 9, 2014/48).

Note (3): 246 BCE-2014-4 warrants may be exercised at any time from 11 March 2014. 369 BCE-2014-4 warrants may be exercised up to a maximum quantity X per full monthly period, calculated as follows: $X = 369$ multiplied by (number of months since the Company's date of incorporation/48) from the first anniversary of the Company's incorporation. 369 BCE-2014-4 warrants may be exercised if qualitative and/or quantitative objectives are achieved, as determined by the Board of Directors on September 8, 2014.

Note (4): 197 BCE-2014-6 warrants may be exercised up to a maximum quantity X per full monthly period, calculated as follows: $X = 197$ multiplied by (number of months since the Company's date of incorporation/48) from the first anniversary of the Company's incorporation. 328 BCE-2014-6 warrants may be exercised if qualitative and/or quantitative objectives are achieved, as determined by the Board of Directors on September 8, 2014 and revised on November 20, 2017.

Note (5): 50% of the BCE-2014-7 warrants allocated to each beneficiary up to a maximum quantity X per full monthly period, calculated as follows: $X = 50\%$ multiplied by (number of months since the Company's date of incorporation/48), which may be exercised for the first time after the first anniversary of the Company's incorporation. 50% of the BCE-2014-7 warrants may be exercised if qualitative and/or quantitative objectives are achieved, as determined by the Board of Directors on September 8, 2014.

Note (6): Up to the total number of BCE-2016-1 warrants in proportion to the number of months elapsed since November 7, 2016 over a total term of forty-eight (48) months, i.e. a quantity X of BCE-2016-1 warrants calculated as follows, it being specified that the beneficiary may only exercise his/her BCE-2016-1 warrants after a period of one (1) year from their allocation date: $X = 100\%$ of the allocated BCE-2016-1 warrants multiplied by (number of months elapsed since November 7, 2016/48).

Note (7): Up to 33,687 BCE-2017-1 warrants in proportion to the number of months elapsed since January 23, 2017 over a total term of forty-eight (48) months, i.e. a quantity X of BCE-2017-1 warrants calculated as follows, it being specified that the beneficiary may only exercise his/her BCE-2017-1 warrants after a period of one (1) year from their allocation date:

- $X = 33,687$ of the allocated BCE-2017-1 warrants multiplied by (number of months since January 23, 2017/48);
- Up to 16,844 BCE-2017-1 warrants, only if the qualitative targets set by the Board of Directors are achieved,
- Up to 16,843 BCE-2017-1 warrants, only if the quantitative targets set by the Board of Directors are achieved.

Note (8):

- Up to 75,000 BCE-2017-2 warrants in proportion to the number of months elapsed since November 20, 2017 over a total term of forty-eight (48) months, i.e. a quantity of X BCE-2017-2 warrants calculated as follows:

X = 75,000 BCE-2017-2 warrants allocated multiplied by (number of months elapsed since November 20, 2017/48), it being specified that, in any event, the beneficiary may only exercise his/her BCE-2017-2 warrants at the end of a term of one (1) year from their allocation date,

- Up to 75,000 BCE-2017-2 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (9):

- Up to 16,844 BCE-2017-3 warrants, exercisable from May 31, 2018;
- Up to 33,687 BCE-2017-3 warrants, exercisable under the conditions below:
 - Up to 16,844 BCE-2017-3 warrants in proportion to the number of months elapsed since November 20, 2017 over a total term of twenty-four (24) months, i.e. a quantity of X BCE-2017-3 warrants calculated as follows:

X = 16,844 BCE-2017-3 warrants allocated multiplied by (number of months elapsed since November 20, 2017/24);

- Up to 16,843 BCE-2017-3 warrants in proportion to the number of months elapsed since November 20, 2017 over a total term of forty-eight (48) months, i.e. a quantity of X BCE-2017-3 warrants calculated as follows:

X = 16,843 BCE-2017-3 warrants allocated multiplied by (number of months elapsed since November 20, 2017/48), it being specified that the beneficiary may only exercise his/her BCE-2017-3 warrants at the end of a term of one (1) year from their allocation date,

- Up to 50,530 BCE-2017-3 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (10):

- Up to 16,844 BCE-2017-4 warrants exercisable at the end of a term of one (1) year from their allocation date, i.e. from November 20, 2018;
- Up to 16,843 BCE-2017-4 warrants in proportion to the number of months elapsed since November 20, 2017 over a total term of twenty-four (24) months, i.e. a quantity of X BCE-2017-4 warrants calculated as follows:

X = 16,843 BCE-2017-4 warrants allocated multiplied by (number of months elapsed since November 20, 2017/24), it being specified that the beneficiary may only exercise his/her BCE-2017-4 warrants at the end of a term of one (1) year from their allocation date,

- Up to 33,687 BCE-2017-4 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (11):

- Up to 8,422 BCE-2017-5 warrants, exercisable from May 31, 2018;
- Up to 8,421 BCE-2017-5 warrants in proportion to the number of months elapsed since November 20, 2017 over a total term of twenty-four (24) months, i.e. a quantity of X BCE-2017-5 warrants calculated as follows:

X = 8,421 BCE-2017-5 warrants allocated multiplied by (number of months elapsed since November 20, 2017/24), it being specified that the beneficiary may only exercise his/her BCE-2017-5 warrants at the end of a term of one (1) year from their allocation date,

- Up to 16,844 BCE-2017-5 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (12):

- Up to the total number of BCE-2018-1 warrants in proportion to the number of months elapsed since March 15, 2018 over a total term of forty-eight (48) months, i.e. a quantity X of BCE-2018-1 warrants calculated as follows, it being specified that the beneficiary may only exercise his/her BCE-2018-1 warrants after a period of one (1) year from their allocation date:

X = 100% of the allocated BCE-2018-1 warrants multiplied by (number of months elapsed since March 15, 2018/48).

Note (13):

- Up to 33,686 BCE-2018-2 warrants in proportion to the number of months elapsed since May 21, 2018 over a total term of forty-eight (48) months, i.e. a quantity X of BCE-2018-2 warrants calculated as follows, it being specified that the beneficiary may only exercise his/her BCE-2018-2 warrants after a period of one (1) year from their allocation date:

X = 33,686 BCE-2018-2 warrants allocated multiplied by (number of months elapsed since May 21, 2018/48);

- Up to 33,686 BCE-2018-2 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (14):

- Up to 8,422 BCE-2018-3 warrants, exercisable from May 14, 2018;
- Up to 8,421 BCE-2018-3 warrants in proportion to the number of months elapsed since May 14, 2018 over a total term of twenty-four (24) months, i.e. a quantity of X BCE-2018-3 warrants calculated as follows:

X = 8,421 BCE-2018-3 warrants allocated multiplied by (number of months elapsed since May 14, 2018/24), it being specified that the beneficiary may only exercise his/her BCE-2018-3 warrants at the end of a term of one (1) year from their allocation date,

- Up to 16,844 BCE-2018-3 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (15):

- Up to 4,211 BCE-2018-4 warrants, exercisable from May 14, 2018;
- Up to 4,211 BCE-2018-4 warrants in proportion to the number of months elapsed since May 14, 2018 over a total term of twenty-four (24) months, i.e. a quantity of X BCE-2018-4 warrants calculated as follows:

X = 4,211 BCE-2018-4 warrants allocated multiplied by (number of months elapsed since May 14, 2018/24), it being specified that the beneficiary may only exercise his/her BCE-2018-4 warrants at the end of a term of one (1) year from their allocation date,

- Up to 8,421 BCE-2018-4 warrants, only if the qualitative targets set by the Board of Directors are achieved.

Note (16):

- Up to the total number of BCE-2018-5 warrants in proportion to the number of months elapsed since May 14, 2018 over a total term of forty-eight (48) months, i.e. a quantity X of BCE-2018-5 warrants calculated as follows, it being specified that the beneficiary may only exercise his/her BCE-2018-5 warrants after a period of one (1) year from their allocation date:

X= 100% of the allocated BCE-2018-5 warrants multiplied by (number of months elapsed since May 14, 2018/48).

General note: all of the Company's BCE plans provide for specific cases of acceleration resulting in the exercise of said BCEs in the event of the occurrence of specific events and in particular in the event of a change of control of the Company.

Stock subscription warrants (BSAs)

As at August 31, 2023, the Company issued the following securities providing access to capital:

Category	BSA-2014-1	BSA-2014-2	BSA-2014-3	BSA-2014-4	BSA-2014-5	BSA-2014-6	BSA-2014-7	BSA-2015-9	BSA-2015-11- Santé Holdings SRL	BSA-2015-12	BSA-2017-1	BSA-2018-1	BSA-2018-2
Date of the General Meeting	11/03/2014	11/03/2014	11/03/2014	11/03/2014	11/03/2014	11/03/2014	11/03/2014	20/02/2015	20/02/2015	20/02/2015	23/06/2017	23/06/2017	23/06/2017
Date of the Board of Directors meeting	21/02/2014	21/02/2014	21/02/2014	21/02/2014	21/02/2014	21/02/2014	21/02/2014	14/09/2015	04/12/2015	04/12/2015	18/09/2017	22/01/2018	14/05/2018
Date of decisions of the Chief Executive Officer													
Total number of shares that may be subscribed or purchased (*):													
Marc de Garidel													
Santé Holdings SRL									96,924				
Corinna zur Bonsen-Thomas											16,400		
Carol L. Brosgart												16,400	
Other	0	0	32,800	84,160	45,900	0	0	0	0	16,400	0	0	0

(*) The number of shares resulting from the exercise of BSAs and BCEs was multiplied by 100 for all BSAs and BCEs issued prior to the division by 100 of the nominal value of the shares, decided by the Company's General Meeting on 20 February 2015.

(*) Under the exercise conditions provided for in the notes below and assuming that the objectives have been met.

Category	BSA-2014-1	BSA-2014-2	BSA-2014-3	BSA-2014-4	BSA-2014-5	BSA-2014-6	BSA-2014-7	BSA-2015-9	BSA-2015-11 – Santé Holdings SRL	BSA-2015-12	BSA-2017-1	BSA-2018-1	BSA-2018-2
Option exercise start date	According to the achievement of objectives (see Exercise conditions)	According to the achievement of objectives (see Exercise conditions)	According to the achievement of objectives (see Exercise conditions)	According to the achievement of objectives (see Exercise conditions)	According to the achievement of objectives (see Exercise conditions)	11/03/2014	11/03/2014	14/09/2015	10/12/2015	04/12/2016	18/09/2017	22/01/2018	14/05/2018
Expiry date	11/03/2024	11/03/2024	11/03/2024	11/03/2024	11/03/2024	11/03/2024	11/03/2024	14/09/2025	04/12/2025	04/12/2025	18/09/2027	22/01/2028	14/05/2028
	or after a period of 90 days following the date the beneficiary ceases working for the Company						or after a period of 90 days following the expiry of the beneficiary's term of office						
Subscription or purchase price	0.1	0.1	0.1	0.1	0.1	0.1	0.1	2.07	1.78	1.78	1.29	0.90	0.73
Strike price per share	0.01	0.01	0.01	0.01	0.01	0.01	0.01	20.73	17.79	17.79	11.57	8.05	6.60
Exercise conditions	Achievement of objectives		Achievement of objectives Note (17)	Achievement of objectives Note (18)	Achievement of objectives Note (19)				Achievement of objectives Note (20)	Achievement of objectives Note (21)	Note (22)	Note (23)	Note (24)
Number of shares subscribed	39,400	44,800	58,000	47,340	0	5,200	8,100	0	0	0	0	16,400	0
Cumulative number of cancelled or expired stock subscription warrants	0	229	264	0	328	0	0	122,274	0	65,600	0	16,400	32,800
BSAs as at 31/08/2023	0	0	328	842	459	0	0	0	96,924	16,400	16,400	16,400	0
BSAs potentially exercisable at 31/08/2023*	0	0	328	842	459	0	0	0	96,924	16,400	16,400	16,400	0

Note (17): May be exercised per full monthly period according to the following rule: $X = (\text{number of BSA 2014-3 warrants allocated to the beneficiary}) \times (\text{number of months elapsed since the Company's date of incorporation}/48)$.

Note (18): Out of the total of 1,315 BSA-2014-4: (i) 263 BSA-2014-4 warrants may be exercised at any time from March 11, 2014, and (ii) 1,052 BSA-2014-4 warrants may be exercised if qualitative and/or quantitative objectives are achieved, as determined by the Board of Directors on September 8, 2014.

Note (19): May be exercised by their beneficiaries according to the exercise conditions set out by the Board of Directors on September 8, 2014.

Note (20): the BSA-2015-11 SANTE HOLDINGS SRL warrants allocated to Santé Holdings SRL may be exercised per full monthly period of continuous participation by Santé Holdings SRL, represented by Paolo Rampulla, on the Board of Directors of the Company, up to a quantity of X BSA-2015-11 SANTE HOLDINGS SRL warrants, calculated as follows:

$X = 96.924 \times (\text{number of months since July 6, 2015}/36)$.

Note (21): the BSA-2015-12 warrants may be exercised in proportion to the number of months of continuous participation on the Scientific Committee or the Board of Directors of the Company over a total period of 48 months, i.e. a quantity X of stock subscription warrants calculated as follows:

$X = 16,400 \times (\text{number of months elapsed since December 4, 2015}/48)$, it being specified that each beneficiary may not exercise his/her stock subscription warrants until one year has passed since their allocation date.

Note (22): the BSA-2017-1 warrants may be exercised under the following conditions: 1/3 of BSA-2017-1 warrants from September 18, 2017, 1/3 of the BSA-2017-1 warrants from March 18, 2018 and 1/3 of the BSA-2017-1 warrants from September 18, 2019.

Note (23): the BSA-2018-1 warrants may be exercised under the following conditions: 1/3 of the BSA-2018-1 warrants from January 22, 2018, 1/3 of the BSA-2018-1 warrants from July 22, 2018 and 1/3 of the BSA-2018-1 warrants exercisable from January 22, 2019.

Note (24): the BSA-2018-2 warrants may be exercised under the following conditions: 1/3 of BSA-2018-2 warrants from May 14, 2018, 1/3 of the BSA-2018-2 warrants from November 14, 2018 and 1/3 of the BSA-2018-2 warrants from May 14, 2019.

Information on free bonus share (“AGAs”) grants

As at August 31, 2023, the following AGAs had been allocated:

Category	AGA-2021-1	AGA-2023-1	AGA-2023-2
Date of the General Meeting	04/06/2021	05/06/2023	05/06/2023
Date of the Board of Directors meeting	21/09/2021	11/07/2023	11/07/2023
Total number of bonus shares granted:			
Marc de Garidel	0	1,382,796	0
Other	155,000	0	100,000
Expiry of the rights vesting period	21/09/2022	11/07/2027 (1)	11/07/2024 (2)
Date of end of lock-up period	21/09/2023	11/07/2027 (1)	11/07/2025 (2)
Number of shares vested at August 31, 2023	0	0	0
Cumulative number of cancelled or expired bonus shares at August 31, 2023	155,000	0	0
Number of bonus shares remaining at August 31, 2023	0	1,382,796	100,000

Note (1):

- Up to 212,738 AGA-2023-1, are acquired on July 11, 2024 and are subject to a lock-up until July 11, 2025;
- Up to 638,214 AGA-2023-1 are acquired as from July 11, 2024 in proportion to the number of months elapsed since July 11, 2024 over a total term of thirty-six (36) months. AGA-2023-1 acquired prior to July 11, 2025 are subject to a lock-up until July 11, 2024. AGA-2023-1 acquired on or after July 11, 2025 are not subject to a lock-up.
- Up to 531,844 AGA-2023-1 are acquired subject to performance conditions. AGA-2023-1 acquired prior to July 11, 2025 are subject to a lock-up until July 11, 2024. AGA-2023-1 acquired on or after July 11, 2025 are not subject to a lock-up.

Note (2):

- Up to 25,000 AGA-2023-2, are acquired on July 11, 2024 and are subject to a lock-up until July 11, 2025;
- Up to 75,000 AGA-2023-2 are acquired subject to performance conditions. AGA-2023-2 acquired prior to July 11, 2025 are subject to a lock-up until July 11, 2024. AGA-2023-2 acquired on or after July 11, 2025 are not subject to a lock-up.

Summary of dilutive instruments as at August 31, 2023

Category	BSAs	BCEs	AGAs
Total number of BSAs/BCEs issued or AGAs allocated	404,076	911,454	1,637,796
Total number of BSAs/BCEs subscribed	183,238	911,454	N/A
Total number of BSAs/BCEs/AGAs cancelled or expired	237,895	352,327	155,000
Total number of BSAs/BCEs exercised or AGAs vested	18,428	173,718	0
Total number of BSAs/BCEs/AGAs remaining	147,753	385,409	1,482,796
Total number of shares that may be subscribed based on the remaining BSAs/BCEs* or issued in connection with AGA allocations	308,984	385,409	1,482,796

(*) The number of shares resulting from the exercise of BSAs and BCEs was multiplied by 100 for all BSAs and BCEs issued prior to the division by 100 of the nominal value of the shares, decided by the Company's General Meeting on February 20, 2015.

In addition, the Company issued in August 2023 the following securities in connection with the Kreos / Claret Financing and the Heights Financing:

- 25,000,000 convertible bonds with warrants attached with an individual nominal value of EUR 1.00 issued to Kreos and Claret, which allow for the subscription of up to 1,178,084 new ordinary shares at a conversion price of EUR 21.2209 per ordinary share;
- 214,198 share warrants (BSA) issued to Kreos and Claret, which allow for the subscription of up to 214,198 new ordinary shares at an exercise price of EUR 18.6744 per ordinary share; and
- 350 convertible notes due 2027 with an individual nominal value of EUR 100,000 issued to Heights, which allow for the subscription of up to 1,472,606 new shares at a conversion price of EUR 23.7674 per ordinary share. In case the Company opts to repay the principal and accrued interest of such notes entirely in shares, the Company may issue up to 2,830,201 new ordinary shares in connection with such repayment.

As at August 31, 2023, the total dilution that may result from the potential exercise of all financial instruments entitling their holders to the Company's capital, which would result in the issue of 5,042,077 Company shares, corresponds to a potential dilution of 10.59% on a fully diluted basis, i.e. 47,589,645 total shares."

15.3 Unissued authorized capital

Section 19.1.5 "Unissued authorized capital" of the 2023 Universal Registration Document is updated as follows:

"19.1.5 Unissued authorized capital

The resolutions for the issuance of capital approved by the General Meeting of the Company held on June 5, 2023 are summarized below.

Purpose of resolution	Date	Period	Use of resolution	Maximum
Authorization to reduce the Company's share capital through the cancellation of treasury shares (thirteenth resolution of the General Meeting of 5 June 2023)	05/06/2023	18 months – 05/12/2024		Up to 10% of the share capital per year
Delegation of authority granted to the Board of Directors to increase the capital by issuing, with preferential subscription rights, shares and/or securities giving immediate and/or future access to the Company's capital (fourteenth resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		500,000€ (1)
Delegation of authority granted to the Board of Directors to increase the capital by issuing shares and/or securities giving immediate and/or future access to the Company's capital, without preferential subscription rights, through a public offering, with the option of granting a priority right (fifteenth resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		500,000€ (1)

			<p>€11,780.84 corresponding to up to 1,178,084 shares which may be issued in case of exercise or conversion of OCABSA issued on August 21, 2023</p>	
<p>Delegation of authority to the Board of Directors to increase the capital by issuing shares, equity securities giving access to other equity securities or giving entitlement to the allotment of debt securities and/or securities giving access to equity securities, without preferential subscription rights in favor of a category of persons (sixteenth resolution of the General Meeting of 5 June 2023)</p>	<p>05/06/2023</p>	<p>18 months – 05/12/2024</p>	<p>€2,141.98 corresponding to up to 214,198 shares which may be issued in case of exercise of share warrants (BSA) issued on August 21, 2023</p>	<p>500,000 € (1)</p>
			<p>€28,302.01 corresponding to up to 2,830,201 shares which may be issued in case of conversion of the Convertible</p>	

			Notes issued on August 24, 2023	
Delegation of authority to the Board of Directors to increase the share capital, immediately or in the future, by issuing ordinary shares or any other securities giving access to the share capital, up to a maximum of 20% of the share capital per year without preferential subscription rights, through an offer to qualified investors or to a limited circle of investors within the meaning of paragraph II of Article L. 411-2 of the French Monetary and Financial Code (private placement) (seventeenth resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		€84,663 and up to 20% of the share capital as at the date of the transaction and per year (1)
Authorization for the Board of Directors, in the event of the issue of shares or any other securities giving access to the capital, without preferential subscription rights, to set the issue price within the limit of 10% of the share capital and within the limits provided for by the General Meeting (eighteenth resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		Up to 10% of the share capital per year
Delegation of authority to the Board of Directors to increase the number of shares to be issued in the event of a capital increase with or without preferential subscription rights (nineteenth resolution of the of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		15% of the initial issuance
Delegation of authority granted to the Board of Directors to increase the share capital through the capitalization of premiums, reserves, profits or other funds (twentieth resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		€500,000

Delegation of authority granted to the Board of Directors to increase the share capital, up to 10% of the share capital, in consideration for contributions in kind of equity or securities providing access to the share capital of third-party companies outside a public exchange offer (twenty-first resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		Up to 10% of the share capital per year (1)
Delegation of authority granted to the Board of Directors to increase the capital by issuing ordinary shares or securities giving access to the capital to remunerate contributions of securities in the event of a public offer including an exchange component initiated by the Company (twenty-second resolution of the General Meeting of 5 June 2023)	05/06/2023	26 months – 05/08/2025		€500,000 (1)
Authorization to be given to the Board of Directors to grant subscription or purchase options for Company shares, without preferential subscription rights reserved for a certain category of individuals (twenty-fourth resolution of the General Meeting of 5 June 2023)	05/06/2023	38 months – 05/08/2026		up to 10% of the share capital on a fully diluted basis as of the date of the General Meeting (2)
Delegation of authority granted to the Board of Directors to increase the capital by issuing warrants with cancellation of preferential subscription rights in favor of a category of persons (twenty-fifth resolution of the General Meeting of 5 June 2023)	05/06/2023	18 months – 05/12/2024		up to 10% of the share capital on a fully diluted basis as of the date of the General Meeting (2)
Authorization to be given to the Board of Directors to proceed with the free allocation of existing shares or shares to be issued (twenty-sixth resolution of the General Meeting of 5 June 2023)	05/06/2023	38 months – 05/08/2026	Allocation of 1,482,796 free shares on July 11, 2023	up to 10% of the share capital on a fully diluted basis as of the date of the General Meeting (2)
Delegation of authority granted to the Board of Directors to increase the share capital, the subscription of which would be reserved for members of a company savings plan established pursuant to Articles L. 3332-1 et seq. of the French Labor Code, with cancellation of preferential subscription rights in favor of the latter (thirty-first resolution of the General Meeting of 5 June 2023)	05/06/2023	18 months – 05/12/2024		N/A (resolution rejected)

- (1) These amounts are not cumulative. The cumulative maximum for nominal increases in the Company's share capital authorised by the General Meeting is EUR 500,000. The total nominal amount of issues of debt securities by the Company providing access to the Company's share capital may not exceed EUR 150,000,000.
- (2) 10% of the Company's share capital, on a fully diluted basis (i.e. assuming that all outstanding marketable securities and other rights providing access to the Company's share capital have been exercised) as at June 5, 2023."

15.4 Capital history

Section 19.1.7 "Changes in share capital " of the 2023 Universal Registration Document is updated as follows:

"19.1.7 Changes in share capital

Historical changes:

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
25/04/2014	Capital increase through contributions in kind and capital increase by issuing new shares	40,000	32,467,755	25,995	65,995	€1	65,995	€1.250
21/05/2014	Exercise of BCE-2014-3	65,995	0	555	66,550	€1	66,550	€1
30/07/2014	Capital increase through issue of new shares	66,550	3,247,400	2,600	69,150	€1	69,150	€1.250
20/02/2015	Stock split				6,915,000	€0.01	69,150	-
24/03/2015	Exercise of BCE-2014-5	69,150	0	2,800	6,917,800	€0.01	69,178	€0.01
06/07/2015	Capital increase through issue of new shares	69,178	57,633,924	2,707,089	9,624,889	€0.01	96,248.89	€21.30
25/09/2015	Exercise of BSA-2014-3	96,248.89	0	6,400	9,631,289	€0.01	96,312.89	€0.01
26/09/2015	Exercise of BSA-2014-2	96,312.89	0	44,800	9,676,089	€0.01	96,760.89	€0.01
22/12/2015	Exercise of BCE-2014-3	96,760.89	0	20,800	9,696,889	€0.01	96,968.89	€0.01
11/04/2016	Exercise of BSA-2014-6	96,968.89	0	5,200	9,702,089	€0.01	97,020.89	€0.01
17/03/2017	Exercise of BSA-2014-1	97,020.89	0	39,400	9,741,489	€0.01	97,414.89	€0.01

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
01/08/2017	Exercise of BSA-2014-4	97,414.89	0	47,340	9,788,829	€0.01	97,988.29	€0.01
01/08/2017	Exercise of BCE-2014-4	97,988.29	0	10,000	9,798,829	€0.01	97,988.29	€0.01
28/09/2017	Exercise of BCE-2014-2	97,988.29	0	40,000	9,838,829	€0.01	98,388.29	€0.01
09/2017 10/2017	Exercise of Kepler BSAs	98,388.29	0	60,000	9,898,829	€0.01	98,988.29	€0.01
30/10/2017	Exercise of BSA-2014-7	98,988.29	0	2,900	9,901,729	€0.01	99,017.29	€0.01
20/12/2017	Exercise of BCE-2016-1	99,017.29	0	2,500	9,904,229	€0.01	99,042.29	€0.01
14/02/2018	Exercise of BCE-2016-1	99,042.29	0	1	9,904,230	€0.01	99,042.30	€0.01
20/03/2018	Exercise of BCE-2014-2	99,042.30	0	40,000	9,944,230	€0.01	99,442.30	€0.01
20/03/2018	Exercise of BCE-2016-1	99,442.30	0	1	9,944,231	€0.01	99,442.31	€0.01
13/06/2018	Exercise of BCE-2014-4	99,442.31	0	69,950	10,014,181	€0.01	100,141.81	€0.01
13/06/2018	Exercise of BCE-2016-1	100,141.81	0	1	10,014,182	€0.01	100,141.82	€0.01
03/07/2018	Exercise of Kepler BSAs	100,141.82	0	10,000	10,024,182	€0.01	100,241.82	€0.01
23/07/2018	Exercise of BCE-2014-2	100,241.82	0	95,000	10,119,182	€0.01	101,191.82	€0.01
04/09/2018	Exercise of Kepler BSAs	101,191.82	0	50,000	10,169,182	€0.01	101,691.82	€0.01
07/09/2018	Exercise of Kepler BSAs	101,691.82	0	30,000	10,199,182	€0.01	101,991.82	€0.01
04/12/2018	Exercise of BCE-2016-1	101,991.82	0	5	10,199,187	€0.01	101,991.87	€0.01
18/12/2018	Exercise of BCE-2016-1	101,991.87	0	1	10,199,188	€0.01	101,991.88	€0.01

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
16/01/2019	Exercise of BCE-2014-6	101,991.88	0	100	10,199,288	€0.01	101,992.88	€0.01
17/01/2019	Exercise of BCE-2014-6	101,992.88	0	19,600	10,218,888	€0.01	102,188.88	€0.01
15/05/2019	Exercise of Kepler BSAs	102,188.88	93,400	10,000	10,228,888	€0.01	102,288.88	€9.35
21/05/2019	Exercise of BCE-2016-1	102,288.88	7,43	1	10,228,889	€0.01	102,288.89	€7.44
05/06/2019	Exercise of Kepler BSAs	102,288.89	82,500	10,000	10,238,889	€0.01	102,388.89	€8.26
06/06/2019	Exercise of BCE-2014-4	102,388.89	0	50	10,238,939	€0.01	102,389.39	€0.01
10/06/2019	Exercise of Kepler BSAs	102,389.39	82,800	10,000	10,248,939	€0.01	102,489.39	€8.29
19/06/2019	Exercise of Kepler BSAs	102,489.39	78,200	10,000	10,258,939	€0.01	102,589.39	€7.83
25/06/2019	Exercise of Kepler BSAs	102,589.39	73,600	10,000	10,268,939	€0.01	102,689.39	€7.37
01/07/2019	Exercise of Kepler BSAs	102,689.39	139,800	20,000	10,288,939	€0.01	102,889.39	€7.00
02/07/2019	Exercise of Kepler BSAs	102,889.39	139,800	20,000	10,308,939	€0.01	103,089.39	€7.00
15/07/2019	Capital increase through issue of new shares	103,089.39	11,985,000	1,500,000	11,808,939	€0.01	118,089.39	€8.00
14/10/2019	Exercise of Kepler BSAs	118,089.39	37,150	5,000	11,813,939	€0.01	118,139.39	€7.44
17/10/2019	Exercise of Kepler BSAs	118,139.39	37,150	5,000	11,818,939	€0.01	118,189.39	€7.44
21/10/2019	Exercise of Kepler BSAs	118,189.39	178,800	30,000	11,848,939	€0.01	118,489.39	€5.97
22/10/2019	Exercise of Kepler BSAs	118,489.39	63,120	8,000	11,856,939	€0.01	118,569.39	€7.90
07/11/2019	Exercise of Kepler BSAs	118,569.39	178,800	20,000	11,876,939	€0.01	118,769.39	€8.95

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
13/11/2019	Exercise of BCE-2014-1	118,769.39	0	275,000	12,151,939	€0.01	121,519.39	€0.01
21/11/2019	Exercise of BCE-2018-1	121,519.39	89,50	10	12,151,949	€0.01	121,519.49	€8.96
22/11/2019	Exercise of BCE-2018-1	121,519.49	89,50	10	12,151,959	€0.01	121,519.59	€8.96
28/11/2019	Exercise of Kepler BSAs	121,519.59	258,000	25,000	12,176,959	€0.01	121,769.59	€10.33
03/12/2019	Exercise of Kepler BSAs	121,769.59	274,750	25,000	12,201,959	€0.01	122,019.59	€11.00
07/01/2020	Exercise of BCE-2016-1	122,019.59	9,659	1,300	12,203,259	€0.01	122,032.59	€7.44
11/01/2020	Exercise of BSA-2014-3	122,032.59	0	16,400	12,219,659	€0.01	122,196.59	€0.01
16/01/2020	Exercise of BCE-2016-1	122,196.59	22,290	3,000	12,222,659	€0.01	122,226.59	€7.44
17/01/2020	Exercise of BCE-2018-1	122,226.59	89,50	10	12,222,669	€0.01	122,226.69	€8.96
22/01/2020	Exercise of BCE-2016-1	122,226.69	10,402	1,400	12,224,069	€0.01	122,240.69	€7.44
11/02/2020	Exercise of BCE-2016-1	122,240.69	11,888	1,600	12,225,669	€0.01	122,256.69	€7.44
17/03/2020	Exercise of BSA-2014-7	122,256.69	0	2,600	12,228,269	€0.01	122,282.69	€0.01
29/07/2020	Exercise of BSA-2014-7	122,282.69	0	2,600	12,230,869	€0.01	122,308.69	€0.01
30/10/2020	Conversion of convertible bonds	122,308.69	3,995,356.91	464,309	12,695,178	€0.01	126,951.78	€8.61
02/11/2020	Capital increase through issue of new shares	126,951.78	27,983,789.90	1,620,370	14,315,548	€0.01	143,155.48	€17.28
09/11/2020	Exercise of BCE-2017-1	143,155.48	2,386.12	374	14,315,922	€0.01	143,159.22	€6.39
30/11/2020	Exercise of BCE-2018-5	143,159.22	5,490	750	14,316,672	€0.01	143,166.72	€7.33

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
02/12/2020	Exercise of BCE-2016-1	143,166.72	12,623.57	1,699	14,318,371	€0.01	143,183.71	€7.44
08/12/2020	Exercise of BCE-2018-1	143,183.71	17,005	1,900	14,320,271	€0.01	143,202.71	€8.96
04/01/2021	Exercise of BCE-2018-1	143,202.71	8,950	1,000	14,321,271	€0.01	143,212.71	€8.96
05/01/2021	Exercise of BCE-2016-1	143,212.71	5,944	800	14,322,071	€0.01	143,220.71	€7.44
05/01/2021	Exercise of BCE-2018-1	143,220.71	17,900	2,000	14,324,071	€0.01	143,240.71	€8.96
05/01/2021	Exercise of BCE-2018-5	143,240.71	9,150	1,250	14,325,321	€0.01	143,253.21	€7.33
07/01/2021	Exercise of BCE-2016-1	143,253.21	14,860	2,000	14,327,321	€0.01	143,273.21	€7.44
08/01/2021	Exercise of BSA-2017-3	143,273.21	131,856	16,400	14,343,721	€0.01	143,437.21	€8.05
11/01/2021	Exercise of BCE-2017-3	143,437.21	11,13	1	14,343,722	€0.01	143,437.22	€11.14
12/01/2021	Exercise of BCE-2018-3	143,437.22	7,320	1,000	14,344,722	€0.01	143,447.22	€7.33
22/01/2021	Exercise of BCE-2016-1	143,447.22	11,145	1,500	14,346,222	€0.01	143,462.22	€7.44
28/01/2021	Exercise of BCE-2018-3	143,462.22	7,320	1,000	14,347,222	€0.01	143,472.22	€7.33
28/01/2021	Exercise of BCE-2017-3	143,472.22	523,343.73	47,021	14,394,243	€0.01	143,942.43	€11.14
01/02/2021	Exercise of BCE-2018-3	143,942.43	21,960	3,000	14,397,243	€0.01	143,972.43	€7.33
02/02/2021	Exercise of BCE-2018-3	143,972.43	21,960	3,000	14,400,243	€0.01	144,000.43	€7.33
09/02/2021	Exercise of BCE-2018-3	144,000.43	29,280	4,000	14,404,243	€0.01	144,032.43	€7.33
22/02/2021	Exercise of BCE-2018-3	144,032.43	14,640	2,000	14,406,243	€0.01	144,062.43	€7.33
02/03/2021	Exercise of BCE-2016-1	144,062.43	17,089	2,300	14,408,543	€0.01	144,085.43	€7.44

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
02/03/2021	Exercise of BCE-2018-3	144,085.43	20,810.76	2,843	14,411,386	€0.01	144,113.86	€7.33
03/03/2021	Exercise of BCE-2017-3	144,113.86	3,895.5	350	14,411,736	€0.01	144,117.36	€11.14
25/05/2021	Exercise of Kepler BSAs	144,117.36	2,998,800	120,000	14,531,736	€0.01	145,317.36	€25.00
26/05/2021	Exercise of Kepler BSAs	145,317.36	1,249,500	50,000	14,581,736	€0.01	145,817.36	€25.00
31/05/2021	Exercise of Kepler BSAs	145,817.36	519,800	20,000	14,601,736	€0.01	146,017.36	€26.00
02/06/2021	Exercise of BCE-2017-4	146,017.36	11,13	1	14,601,737	€0.01	146,017.37	€11.14
03/06/2021	Exercise of Kepler BSAs	146,017.37	573,980	22,000	14,623,737	€0.01	146,237.37	€26.00
15/06/2021	Exercise of BCE-2016-1	146,237.37	18,575	2,500	14,626,237	€0.01	146,262.37	€7.44
24/06/2021	Exercise of Kepler BSAs	146,262.37	549,800	20,000	14,646,237	€0.01	146,462.37	€27.50
25/06/2021	Exercise of Kepler BSAs	146,462.37	146,450	5,000	14,651,237	€0.01	146,512.37	€29.30
29/06/2021	Exercise of Kepler BSAs	146,512.37	288,100	10,000	14,661,237	€0.01	146,612.37	28.82 €
30/06/2021	Exercise of Kepler BSAs	146,612.37	282,800	10,000	14,671,237	€0.01	146,712.37	€28.29
01/07/2021	Exercise of BCE-2017-5	146,712.37	22,260	2,000	14,673,237	€0.01	146,732.37	€11.14
02/07/2021	Exercise of Kepler BSAs	146,732.37	539,800	20,000	14,693,237	€0.01	146,932.37	€27.00
05/07/2021	Exercise of Kepler BSAs	146,932.37	944,650	35,000	14,728,237	€0.01	147,282.37	€27.00
22/07/2021	Capital increase through issue of new shares	147,282.37	59,981,506.74	1,964,031	16,692,268	€0.01	166,922.68	€30.55
06/09/2021	Exercise of BCE-2017-3	166,922.68	11,731.02	1,054	14,729,291	€0.01	166,933.22	€11.14

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
09/09/2021	Exercise of BCE-2016-1	166,933.22	22,327.15	3,005	14,732,296	€0.01	166,963.27	€7.44
09/09/2021	Exercise of BCE-2016-1	166,963.27	2,972	400	14,732,696	€0.01	166,967.27	€7.44
10/09/2021	Exercise of BCE-2016-1	166,967.27	74,292.57	9,999	14,742,695	€0.01	167,067.26	€7.44
20/09/2021	Exercise of BCE-2016-1	167,067.26	22,282.57	2,999	14,745,694	€0.01	167,097.25	€7.44
18/10/2021	Exercise of BCE-2018-1	167,097.25	8,950	1,000	14,746,694	€0.01	167,107.25	€8.96
20/10/2021	Exercise of BCE-2016-1	167,107.25	22,245.42	2,994	14,749,688	€0.01	167,137.19	€7.44
20/10/2021	Exercise of BCE-2018-5	167,137.19	25,005.12	3,416	14,753,104	€0.01	167,171.35	€7.33
25/10/2021	Exercise of BCE-2018-1	167,171.35	8,950	1,000	14,754,104	€0.01	167,181.35	€8.96
25/10/2021	Exercise of BCE-2017-5	167,181.35	11,130	1,000	14,755,104	€0.01	167,191.35	€11.14
30/11/2021	Exercise of BCE-2018-2	167,191.35	187,950	21,000	14,776,104	€0.01	167,401.35	€8.96
21/12/2021	Exercise of BCE-2018-2	167,401.35	214,048.20	23,916	14,800,020	€0.01	167,640.51	€8.96
08/03/2022	Exercise of BCE-2018-5	167,640.51	2,448.88	334	14 800 354	€0.01	167,643.85	€7.33
30/05/2022	Exercise of BSA-2014-3	167,643.85	0	18 800	14,819,154	€0.01	167,831.85	€0.01
07/09/2022	Capital increase through issue of new shares	167,831.85	46,175,500.00	5,530,000	22 313 185	€0.01	223,131.85	€8.36
20/01/2023	Exercise of BCE-2014-4	223,131.85	0	18 400	22,331,585	€0.01	223,315.85	€0.01
01/03/2023	Capital increase through issue of new shares	223,315.85	129,800,000	20 000 000	42,331,585	€0.01	423,315.85	€6.50

Date of issue	Type of transaction	Capital	Issue premium	Number of shares created	Cumulative number of shares forming the share capital after the transaction	Par value	Share capital	Issue price per share
10/05/2023	Exercise of BSA-2014-3	423,315.85	0	16,400	42,347,985	€0.01	423,479.85	€0.01
06/06/2023	Exercise of BSA-2018-KREOS-A	423,479.85	488,786.40	67,887	42,415,872	€0.01	424,158.72	€7.21
06/06/2023	Exercise of BSA-2018-KREOS-B	424,158.72	338,830.24	31,696	42,447,568	€0.01	424,475.68	€10.70
19/06/2023	Exercise of BCE-2014-2	424,475.68	0	100,000	42,547,568	€0.01	425,475.68	€0.01
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16. MAJOR CONTRACTS

Chapter 20 “Major Contracts” of the 2023 Universal Registration Document is updated as follows:

“20.1 Collaboration Research and Development Agreements

IQVIA Master Services Agreement

On December 17, 2018, the Company entered into a master services agreement with IQVIA Ltd (“IQVIA”) for the provision of clinical trial services, research and other services for individual clinical trials on human beings (the “IQVIA Master Services Agreement”), as amended on September 9, 2022.

Pursuant to the IQVIA Master Services Agreement and underlying Work Order, IQVIA agreed to perform certain services on its behalf as the Company requests, subject to IQVIA’s acceptance of the services and related budget in the applicable Work Order, including, but not limited to, strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, project management, pharmacovigilance, central laboratory services, clinical pharmacology services, electrocardiogram services and device services. In consideration therefore, the Company agreed to pay IQVIA an agreed set of fees based on its requests, as set forth in the applicable Work Order. The Company has the right to terminate the IQVIA Master Services Agreement or requested work without cause and at any time upon 45 days’ written notice. The Company and IQVIA each have the right to terminate the IQVIA Master Services Agreement in the event of a breach by the other party, if such breach has not been substantially cured within the 30-day period.

Pursuant to the IQVIA Master Services Agreement and a study specific Work Order executed with IQVIA, IQVIA is responsible for coordinating its Phase 3 clinical trial for obefazimod in moderately to severely active UC.

As of June 30, 2023, EUR 13.8 million in undiscounted advance payments to IQVIA had been paid in connection with the IQVIA agreement.

Evotec Drug Discovery Services Agreement

On September 1, 2017, the Company entered into a drug discovery services agreement with Evotec International GmbH (“Evotec”), pursuant to which Evotec provides drug discovery services to the Company, in order to have optimized leads obtained for various viral indications for further developments within the context of a global collaborative program and to any further development programs under which the Company would require the assistance of Evotec in the provision of services (the “Evotec Drug Discovery Services Agreement”). Under the Evotec Drug Discovery Services Agreement, Evotec must provide its services in accordance with common industry standard of current established practices by suitably qualified staff, using equipment in an agreed premises, under allocated timelines agreed between the parties and in compliance with all relevant legislation. Evotec may not subcontract its obligations to the Company other than to an affiliate without its express prior written consent.

In consideration for services provided, the Company are required to pay Evotec an agreed set of fees as agreed in the relevant project description relating to such services. As of June 30, 2023, the Company has paid EUR 7.6 million to Evotec, and no amounts were received as of such date. The total maximum amount that could be payable by the Company to Evotec under work orders in effect as of end of August 2023 is EUR 0.9 million. To the extent additional projects are completed under the agreement, additional amounts may be payable to Evotec, but they are not determinable as of the date of this prospectus. The Company owns, and Evotec assigns to the Company to the extent

permissible under applicable law, all intellectual property rights conceived, discovered, invented or made by Evotec in connection with the provision of drug discovery services. No milestone payments or royalties are payable pursuant to the Evotec Drug Discovery Services Agreement. No drug candidate has currently been discovered pursuant to this agreement.

The Company has the right to terminate Evotec Drug Discovery Services Agreement or any project without cause at any time upon 60 days' written notice. The Company and Evotec each have the right to terminate any ongoing project upon 20 days' written notice for a breach by the other party, if such breach has not been remedied within the 20-day period.

Delpharm Agreement

On November 24, 2016, the Company entered into a manufacturing agreement with Delpharm Lille S.A.S. ("Delpharm"), pursuant to which Delpharm produces batches of capsules containing obefazimod required to carry out clinical trials (the "Delpharm Agreement"). The Delpharm Agreement renews automatically for successive periods of one year until either party notifies the other of its intention not to renew the agreement. The agreement is still in effect on the date hereof. Either party may terminate the agreement upon serious breach or a serious non-execution of the agreement by the other party. Abivax may also terminate the Delpharm Agreement at any time, subject to certain reimbursement obligations to Delpharm.

Seqens Agreement

On March 11, 2016, the Company entered into a clinical batch development and production agreement with "Produits Chimiques Auxiliaires et de Synthèse" ("Seqens"), under which Seqens provides services relating to the development and production of active ingredients, including obefazimod (the "Seqens Agreement"). The Seqens Agreement was amended on March 2, 2021, in connection with its UC Phase 3 clinical trials. In accordance with the Seqens Agreement, in consideration for services provided, the Company is required to pay Seqens an agreed set of fees as agreed in the relevant Work Order.

The Seqens Agreement remains in full force and effect until the earlier of (i) the execution of an agreement for the commercial manufacturing by Seqens of obefazimod under Phase IV, such agreement to be negotiated between Seqens and the Company in good faith, (ii) the failure to reach such a Phase IV agreement or (iii) the failure to obtain all marketing approval by the FDA and other relevant regulators in Europe.

According to the Seqens Agreement, either party may terminate the agreement in the event of the other party's failure to perform one or more of its obligations. This termination shall only become effective one month after the issuance by the complaining party of a registered letter with acknowledgement of receipt setting out the reasons for the complaint, unless within this period the defaulting party has fulfilled its obligations or has provided proof of an impediment due to force majeure. The termination may take effect without delay by simple written notification in case of fraud or intentional fault by the party in default.

According to the Seqens Agreement, the Company has the right to postpone or terminate any pending work at any time upon 30 days prior written notice, subject to payment to Seqens of the sums due in proportion to the actual progress of the work on the day of receipt by Seqens of its notification, as well as any costs incurred prior to such receipt by Seqens that would be non-revocable and not subject to reallocation within a reasonable time.

Royalties Agreement

On December 18, 2008, the Company entered into an agreement with (i) the CNRS, (ii) the University of Montpellier, and (iii) the Institut Curie, which sets out financial conditions under which the Company can use any intellectual property rights and research results derived from certain research collaboration programs the Company had with the CNRS, the University of Montpellier, and the Institut Curie and which have now been terminated (the “Royalties Agreement”).

Pursuant to the Royalties Agreement, the CNRS and the Institut Curie are entitled to receive milestone payments, as well as royalty payments on global net sales of products using the intellectual property rights and research results jointly developed with them (including obefazimod) (each, a “Qualifying Product”). The amounts of the milestone payments for each Qualifying Product are limited and not material compared to the amount of the expected royalties.

In case the Company commercializes directly a Qualifying Product (either (i) implementing the jointly developed patents and the jointly developed know-how or (ii) only implementing the jointly developed know-how), royalties due under the Royalties Agreement are in the low single-digit percentages subject to an annual minimum.

In the event the Company commercializes a Qualifying Product by way of a license granted to a third-party, the Company may elect (i) to pay royalties calculated in the same manner as if the Company was commercializing the Qualifying Product directly, or (ii) to pay royalties (high single-digit to low double-digit percentages) calculated based on the revenues the Company receives under the license granted to the third-party. The Company must notify the CNRS regarding which royalty amount the Company elects to pay at the same time that the third-party grants the license.

For the avoidance of doubt, the Royalties Agreement does not include any cap on the total payments which may be due by the Company under such Royalties Agreement.

The Royalties Agreement survives until the expiration of the underlying intellectual property rights (without any termination rights to either party).

20.2 Financial agreements

Kreos/Claret Financing Agreements

On August 20, 2023, the Company entered into a framework subscription agreement (the “Framework Subscription Agreement”) with certain entities affiliated to Kreos Capital (“Kreos”) and Claret European Growth Capital (“Claret” and, together with Kreos, the “Secured Lenders”). Under this Framework Subscription Agreement, the Company may draw up to EUR 75 million in structured debt financing (the “Kreos/Claret Financing”), in three tranches of EUR 25 million in aggregate principal amount each, as further described below.

The first tranche with an aggregate principal amount of EUR 25 million takes the form of senior secured convertible bonds with warrants attached, which the Company refers to as the Kreos / Claret OCABSA. The Company drew the first tranche on August 21, 2023. On the same date, the Company repaid all outstanding amounts that remained due under the First KC Agreement and the Second KC Agreement (each as defined below). The Kreos / Claret OCABSA are convertible into ordinary shares at any time from their issuance at the request of their holders at a fixed conversion price of EUR 21.2209, subject to standard adjustments, including anti-dilution and dividend protections.

The second tranche, with an aggregate principal amount of EUR 25 million takes the form of senior secured non-convertible bonds and may be drawn before March 31, 2024, subject to satisfaction of

customary closing conditions. The drawdown of the second tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown. The “Debt-To-Market Capitalization Ratio” is calculated, on any relevant date, by dividing (i) its indebtedness (including amounts due under the Kreos / Claret Financing but excluding amounts due under the Heights Financing (as defined below)), by (ii) its market capitalization calculated by multiplying the number of its outstanding ordinary shares by the closing price of its ordinary shares on such relevant date.

The third tranche with an aggregate principal amount of EUR 25 million takes the form of senior secured non-convertible bonds and may be drawn before July 31, 2024, subject to satisfaction of customary closing conditions. The drawdown of the third tranche is subject to a maximum 10% Debt-To-Market Capitalization Ratio at the time of drawdown and is conditional on its raising of a minimum of \$125 million in gross proceeds through a listing on Nasdaq before June 30, 2024.

Interest on the Kreos / Claret OCABSA accrues annually at a rate of 9%, payable in quarterly installments. The Kreos / Claret OCABSA’s maturity date is March 31, 2027, and the final repayment date is January 1, 2027.

A variable interest rate of 7.5% plus European Central Bank Base Rate (subject to a minimum interest rate of 2.5% and a maximum interest rate of 4%) applies to each of the second and third tranches. These two tranches will be repaid monthly through March 31, 2027, after a deferred repayment of the principal (i) until October 1, 2024, for the second tranche, or February 1, 2025, if the conditions to draw the third tranche are met, and (ii) until February 1, 2025, for the third tranche.

The Kreos / Claret Financing provides for certain restrictive covenants (subject to customary exceptions) which include, among other things, restrictions on the incurrence of indebtedness, cross-default, the distribution of dividends and the grant of security interests. As security for the Kreos / Claret Financing, the Secured Lenders benefit from the grant of first-ranking collateral on its principal tangible and intangible assets, including pledges over its business (*fonds de commerce*) as a going concern and intellectual property rights in its lead drug candidate, as well as pledges over its bank accounts and receivables. Such securities apply to all tranches of the Kreos / Claret Financing.

As part of the Kreos / Claret Financing, the Company has issued warrants to the Secured Lenders for a global subscription price of EUR 1.00, giving them the right to subscribe to up to 214,198 new ordinary shares at an exercise price of EUR 18.6744.

If the conditions for the drawdown of the third tranche of the Kreos / Claret Financing are met, the Company will issue additional warrants to Kreos and Claret for a global subscription price of EUR 1.00 unless the Company expressly declines the third tranche within 14 days of the conditions being met. The exercise price of the additional warrants to be issued will be equal to 110% of the 15-day volume weighted average price (“VWAP”) of its ordinary shares prior to the date on which their issuance is decided. The number of warrants to be issued will be calculated by dividing EUR 4 million by the aforementioned exercise price. Of these additional warrants, 50% will be exercisable upon issuance and the remaining 50% shall only be exercisable if the Company draws the third tranche of the Kreos / Claret Financing.

The warrants issued to the Secured Lenders can be exercised over a period of seven years from their issuance date or up until the date of the successful closing of a tender offer for its ordinary shares, whichever is earlier. At the time of exercise of the warrants, the holders of the warrants are eligible to sell part of their warrants to the Company in accordance with a put option agreement to allow for a cashless exercise of the warrants.

The Kreos / Claret OCABSA, the non-convertible bonds and the warrants issued in the framework of the Kreos / Claret Financing will not be listed on any market. The agreements relating to the Kreos / Claret Financing are governed by French law.

Heights Convertible Notes

On August 20, 2023, the Company entered into a subscription agreement (the “Heights Subscription Agreement”) with CVI Investments, Inc. (“Heights”). Under the Heights Subscription Agreement, the Company may draw up to EUR 75 million in amortizing senior convertible notes (the “Heights Convertible Notes”), in two tranches of EUR 35 million and EUR 40 million respectively, as further described below (the “Heights Financing”).

The first tranche in aggregate principal amount of EUR 35 million was drawn on August 24, 2023. On the same date, the Company repaid all amounts due under the OCEANE bonds. The Heights Convertible Notes are convertible into ordinary shares at any time from their issuance at the request of the holder at a fixed conversion price set at EUR 23.7674, subject to standard adjustments, including anti-dilution and dividend protections.

The second tranche in aggregate principal amount of up to EUR 40 million may be drawn during the period from the date immediately following the three (3) month anniversary of the issuance of the first tranche to the first-year anniversary of the issuance of the first tranche. It may be drawn in up to two separate closings.

The amount available for drawdown under the second tranche will be determined based on its market capitalization (based on seven (7) of the ten (10) trading days immediately preceding such drawdown) (“Average Market Capitalization”) and the average daily valued traded of its ordinary shares (“ADVT”) over the three (3) month period preceding the drawdown, as follows:

Average Market Capitalization	ADVT	Maximum Cumulated Amount Outstanding Under Both First and Second Tranches of the Heights Financing
At least €700,000,000	At least €900,000	€45,000,000
At least €850,000,000	At least €1,250,000	€55,000,000
At least €1,000,000,000	At least €1,500,000	€65,000,000

Interest on the Heights Convertible Notes accrues annually at a rate of 6% payable in quarterly installments in cash or, at its option, in ordinary shares.

The Heights Convertible Notes will be repaid through sixteen quarterly installment payments, beginning three months after their issuance date (corresponding, for the first tranche, to a final repayment date on August 24, 2027). Installments are payable in cash or, at its option, in ordinary shares.

Any interest or installment payments in shares will be made on the basis of a share price equal to 90% of the Market Price of its ordinary shares at the time of payment. “Market Price” refers to the arithmetic average of the VWAP for its ordinary shares on the two (2) days with the lowest daily VWAPs out of the five (5) trading days immediately preceding the applicable date, but in no event greater than the VWAP of its ordinary shares on the applicable date. The Market Price may not be higher than the applicable conversion price. Issuances of ordinary shares may not be made at a price

lower than a 15% discount to the 15-day VWAP at the time of the decision to issue the Heights Convertible Notes (i.e., EUR 14.4303 per ordinary share for the first tranche).

Upon the occurrence of certain events (including a change of control of Abivax, a free float event or a delisting of its ordinary shares on Euronext Paris), any noteholder will have the option to require the Company to redeem all, and no less than all, of its Heights Convertible Notes at par plus accrued but unpaid interest. In the event that its ordinary shares are targeted by a public offer (in cash or in securities, in cash and securities, etc.) which may result in a change of control or filed following a change of control, upon conversion of the Heights Convertible Notes, the Company shall (i) deliver new ordinary shares at the conversion price, and (ii) pay a cash amount equal to the sum of the remaining coupons scheduled until the maturity date, and any accrued interest.

The terms and conditions of the Heights Convertible Notes include a standard negative pledge providing that any security granted in favor of other borrowed debt or debt instruments should also be granted in favor of the Heights Convertible Notes on an equal basis (with the exception of the securities issued pursuant to the Kreos / Claret Financing, as described above).

The Heights Financing is a senior, unsecured financing. The convertible bonds of the Heights Financing will not be listed on any market. The agreements relating to the Heights Financing are governed by French law.

State-Guaranteed Loan

On June 11, 2020, the Company obtained non-dilutive financing from Société Générale in the form of a EUR 5 million State-guaranteed loan (the “State-guaranteed loan”). The State-guaranteed loan had an initial duration of 12 months (subject to a five-year extension option) and accrues interest at a rate of 0.25% with repayment of principal falling due in June 2021. The State-guaranteed loan was immediately made available to the Company in June 2020. In March 2021, the Company entered into an amendment to the State-guaranteed loan, which extended the repayment date of the State-guaranteed loan by five years until June 2026 with a one-year deferral of principal repayment, with the following conditions: (i) a revised interest rate of 0.58% per annum, excluding insurance and State-guaranteed premium; and (ii) a State-guaranteed premium of EUR 0.1 million to be paid by instalments over the contract period starting in June 2021. The State-guaranteed loan includes certain customary covenants and prepayment provisions, as well as a negative covenant restricting the disposal of assets representing more than 50% of the gross value of its fixed assets.

Prior Kreos Agreements

On July 24, 2018, the Company entered into a EUR 20 million venture loan agreement with Kreos (the “First KC Agreement”). The financing consists of two tranches of structured debt financing: (i) a total principal amount of First Tranche A Notes of EUR 10 million, comprised of (x) EUR 8 million in non-convertible bonds issued in July 2018 and (y) EUR 2 million in convertible bonds issued in August 2018 and (ii) a total principal amount of First Tranche B Notes of EUR 10 million, comprised of (x) EUR 8 million in non-convertible bonds and (y) EUR 2 million in convertible bonds, each issued in May 2019.

On October 12, 2020, the Company entered into a bonds issue agreement with Kreos (the “Second KC Agreement”), pursuant to which the Company issued bonds in a total principal amount of Second Tranche A Notes of EUR 15 million, comprised of (i) a EUR 10 million tranche and Second Tranche B Notes of EUR 5 million, with an option to issue Second Tranche C Notes of an additional EUR 5 million.

On August 21, 2023, the Company repaid all outstanding amounts that remained due under the First KC Agreement and the Second KC Agreement.

OCEANE Bonds

On July 30, 2021, the Company issued EUR 25 million 6% convertible senior unsecured and unsubordinated bonds due July 30, 2026, corresponding to 654,621 OCEANE bonds. The OCEANE bonds were exchangeable, at the option of the bondholders, for new or existing shares and bear interest at a rate of 6% per annum, payable semi-annually on January 30 and July 30 of each year, beginning January 30, 2022. On August 24, 2023, the Company repaid all amounts due under the OCEANE bonds.

Royalty Certificates

On August 31, 2022, the Company issued EUR 2.9 million in royalty certificates (the "Royalty Certificates").

The terms and conditions of the Royalty Certificates provide holders with the right to royalties equal to 2% of the future net sales of obefazimod (worldwide and for all indications) following its commercialization. The amount of royalties that may be paid under the Royalty Certificates is capped at EUR 172 million (the "Royalty Cap"). The Royalty Certificates do not provide for any dividend rights, coupon payments or any other additional financial rights other than the right to royalties. In particular, the Royalty Certificates do not grant any financial rights in respect of any other products that may be developed by the Company beyond obefazimod.

The Royalty Certificates have a term of 15 years and do not provide for an accelerated repayment in case of a change of control. The Company may at any time repay the Royalty Certificates in full by paying an amount equal to the Royalty Cap minus any royalties paid prior to such reimbursement. The Royalty Certificates are subject to a one-year lock-up, after which they will become freely transferable by each holder thereof in whole, but not in part. The Royalty Certificates are not listed nor assigned an ISIN.

20.3 BPI France aid contracts (grants and/or repayable advances)

Bpifrance CARENA contract

As part of the development of therapeutic and diagnostic solutions targeting alternative splicing and RNA interference in the fields of virology (HIV-AIDS, HTLV-1) and metabolism (obesity), SPLICOS (absorbed by the Company on October 31, 2014) has entered into a Master Support Agreement with Bpifrance as well as a conditional advance contract in the name of the "CARENA" Strategic Industrial Innovation Project dated December 16, 2013. The Company, acting as project leader for the CARENA project, is associated as part of a consortium contract with Theradiag, a company specializing in in vitro diagnostics and the development of theranostic tests for monitoring biotherapies, as well as at the CNRS and the University of Montpellier.

The CARENA project aims to develop the anti-HIV-AIDS therapeutic program with the compound ABX464 up to the Phase 2b study, as well as a companion test set up by Theradiag simultaneously with the clinical development. Beyond the anti-HIV-AIDS program, the CARENA project should extend its pharmacological investigations to another retrovirus that could be combated by the same approach: HTLV-1.

The Company is committed to reimbursing the received conditional advances up to EUR 3,840 thousand. The Company will also have to pay an annuity of 50% of the proceeds from the sale of the intellectual property rights resulting from the project, as well as the sale of the prototypes, preproduction and models produced under the project; The sum due to BPI under this provision will be deducted from the repayment of the conditional advances. In addition, if the advance is repaid

under the conditions outlined above, the Company will pay to Bpifrance, over a period of five consecutive years after the date on which the repayment schedule ends and provided that the Company has reached cumulative pre-tax revenue greater than or equal to EUR 50 million, an amount equal to 1.20% of the annual revenue generated from the sale of the products developed as part of the project. This supplementary payment amount is capped at EUR 6,800 thousand. The total period, including fixed payments and incentive payments, is limited to 15 years.

Bpifrance RNP-VIR contract

In pursuit of the CARENA project, focused on the clinical development of a drug molecule and demonstrating the validity of an innovative therapeutic approach targeting viral RNPs, the Company has entered into a Master Support Agreement with Bpifrance as well as a beneficiary agreement with conditional advance for the “RNP-VIR” structuring research and development project for competitiveness dated December 16, 2016.

The RNP-VIR project will further the discovery of new molecules aimed at the treatment of multiple infectious diseases by the development of the antiviral technology platform. The Company, acting as project leader of the RNP-VIR project, is associated in a consortium contract with the CNRS and the University of Montpellier.

The Company is committed to reimburse the received conditional advances up to EUR 6,576 thousand. If applicable, the Company will also have to pay an annuity of 50% of the proceeds from the sale of the intellectual property rights resulting from the project, as well as the sale of the prototypes, preproduction and models produced under the project. The sum due to Bpifrance under this provision will be deducted from the last payment (and if needed from the previous payments).

If the advance is repaid under the conditions outlined above, the Company will pay to Bpifrance, over a period of five consecutive years following the date on which the repayment schedule ends and provided that the company has reached cumulative pre-tax revenue greater than or equal to EUR 25 million, an amount equal to 3% of the annual revenue generated from the sale of products developed as part of the project. The supplementary payments amount is capped at EUR 5,500 thousand. The total period, including fixed payments and incentive payments, is limited to 15 years.

Bpifrance Ebola

The Bpifrance and Occitanie Region joint support agreement granted on June 2, 2017 consists of conditional advances to the Company for a total amount of up to EUR 390 thousand, based on the success of the program (respectively EUR 130 thousand from the Languedoc Roussillon Midi Pyrénées Region and EUR 260 thousand from Bpifrance). In September 2019, the Company decided to terminate this program, due to the existence of a vaccine in the process of being licensed for this indication as well as changes in the macroeconomic climate for public funding.

The reimbursement of the conditional advance is spread until June 2024.”

17. CONCORDANCE TABLE

The table of concordance below indicates the chapters or sections of the Company's 2023 Universal Registration Document ("URD") being updated in this amendment, with direct links to the sections of the corresponding update. This table of contents is drawn up in accordance with Annexes 1 and 2 of Commission Delegated Regulation (EU) 2019/980 of March 14, 2019.

	Annexes 1 and 2 of delegated regulation (EU) n°2019/980	URD Chapters/Sections	Update carried out
1	Persons responsible, third-party information, experts' reports and competent authority approval	1	
1.1	Identity of Responsible Person	1.1	
1.2	Statement by Responsible Person	1.2	
1.3	Experts' reports	N/A	
1.4	Information from third parties	N/A	
1.5	Competent authority approval	1.5	
2	Statutory auditors	2	
2.1	Statutory Auditors	2.1	The section 2.1 has been updated by the present chapter 2
2.2	Statutory Auditors who have resigned or been dismissed	2.2 (N/A)	
3	Risk factors	3	
3.1	Risks related to the Company's business	3.1	The section 3.1 has been updated by the present section 5.1
3.2	The Company's financial and market risks	3.2	The section 3.2 has been updated by the present section 5.2
3.3	The Company's regulatory and legal risks	3.3	The section 3.3 has been updated by the present section 5.3
3.4	Risks related to the Company's organisation	3.4	The section 3.4 has been updated by the present section 5.4
4	Information about the issuer	4	The chapter 4 has been updated by the present chapter 6
4.1	Legal and commercial name	4.1	

	Annexes 1 and 2 of delegated regulation (EU) n°2019/980	URD Chapters/Sections	Update carried out
4.2	Location, registration number and LEI of issuer	4.2	
4.3	Date of incorporation and duration of issuer	4.3	
4.4	Company headquarters, legal form, applicable legislation, website and other information	4.4	
5	Business overview	5	
5.1	Main activities	5.1	The section 5.1 has been updated by the present section 4.1
5.2	Main markets	5.2	
5.3	Significant events in the growth of the Company's business since 2020	5.3	
5.4	Strategy and objectives	5.4	The section 5.4 has been updated by the present section 4.2
5.5	Patents, licences, trademarks, names and domain names	N/A	The section 5.5 has been updated by the present section 4.3
5.6	The competitive environment	5.6	The section 5.6 has been updated by the present section 4.4
5.7	Investments	5.7	
6	Organizational structure	6	
6.1	Brief description of the group	N/A	
6.2	List of major subsidiaries	6.2	
7	Review of financial position and results	7	The Chapter 7 has been updated by the present section 7.1
7.1	Financial situation	7.1	
7.2	Results of operations	7.2	
8	Cash and Capital		
8.1	Information on the Company's capital	8.1	

	Annexes 1 and 2 of delegated regulation (EU) n°2019/980	URD Chapters/Sections	Update carried out
8.2	Issuer's cash flow	8.2	
8.3	Issuer's financing requirements and structure	8.3	The section 8.3 has been updated by the present section 7.2
8.4	Restrictions on the use of the issuer's capital resources	8.4	
8.5	Expected sources of financing	8.5	
9	Regulatory environment	9	The chapter 9 has been updated by the present chapter 8
10	Trend information	10	
10.1	Main trends Significant change in financial performance	10.1	The section 10.1 has been updated by the present chapter 9
10.2	Factors likely to have a material impact on the outlook	10.2	The section 10.1 has been updated by the present chapter 9
11	Profit forecasts or estimates	11	
12	Administrative, management and supervising bodies and general management	12	
12.1	Executives, directors and non-voting directors	12.1	The section 12.1 has been updated by the present sections 10.1 to 10.4
12.2	Conflicts of interest of administrative and executive bodies	12.2	
13	Compensation and benefits	13	
13.1	Compensation and benefits	13.1	The section 13.1 has been updated by the present chapter 11
13.2	Total amounts set aside to pay pensions, retirement or other benefits	13.2	
14	Operation of administrative and management bodies	14	
14.1	Term of office	14.1	

	Annexes 1 and 2 of delegated regulation (EU) n°2019/980	URD Chapters/Sections	Update carried out
14.2	Service contract	14.2	The section 14.2 has been updated by the present section 12.1
14.3	Committee information	14.3	The section 14.3 has been updated by the present section 12.2
14.4	Declaration on corporate governance	14.4	
14.5	Impact of future changes in the composition of governing bodies	14.5	
15	Employees	15	
15.1	Human resources	15.1	The section 15.1 has been updated by the present sections 13.1 and 13.2
15.2	Shareholdings and stock options of corporate officers	15.2	
15.3	Agreement providing for shareholdings of employees	15.3	The section 15.3 has been updated by the present section 13.3
16	Major shareholders	16	
16.1	Breakdown of capital and voting rights	16.1	The section 16.1 has been updated by the present sections 14.1 and 14.2
16.2	Major shareholders' voting rights	16.2	
16.3	Direct or indirect control of the Company	16.3	The section 16.3 has been updated by the present section 14.3
16.4	Agreements that, when implemented, could result in a change of control	16.4	
16.5	Changes in share price	16.5	The section 16.5 has been updated by the present section 14.4
17	Related-party transactions	17	
18	Financial information about the issuer's assets and liabilities, financial position and results	18	The Chapter 18 has been updated by the present section 7.1

	Annexes 1 and 2 of delegated regulation (EU) n°2019/980	URD Chapters/Sections	Update carried out
18.1	Historical financial information	18.1	
18.2	Interim and other financial information	18.2 (N/A)	
18.3	Audit of historical annual financial information	18.3	
18.4	Company financial statements prepared in accordance with IFRS for the years ended December 31, 2022 and December 31, 2021	18.4 (N/A)	
18.5	Dividend policy	18.5	
18.6	Administrative, legal and arbitration proceedings	18.6	
18.7	Significant changes in the financial or trading position	18.7	
19	Additional information	19	
19.1	Share capital	19.1	The section 19.1 has been updated by the present sections 15.1, 15.2, 15.3 and 15.4
19.2	Charter and Articles of Association	19.2	
20	Major contracts	20	The chapter 20 has been updated by the present chapter 16