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THE DOCUMENT IS NOT FOR DISTRIBUTION, DIRECTLY OR INDIRECTLY, IN OR INTO THE UNITED STATES OF AMERICA (THE "U.S."). IT DOES NOT CONSTITUTE OR FORM A PART OF ANY OFFER OR SOLICITATION TO PURCHASE OR SUBSCRIBE FOR THE SECURITIES REFERENCED IN THE DOCUMENT IN THE U.S.. THE SECURITIES REFERENCED IN THE DOCUMENT HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE U.S. SECURITIES ACT OF 1933, AS AMENDED (THE "U.S. SECURITIES ACT") AND MAY NOT BE OFFERED OR SOLD IN THE U.S. UNLESS REGISTERED UNDER THE U.S. SECURITIES ACT, OR AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE U.S. SECURITIES ACT IS AVAILABLE. THE COMPANY AND ITS AFFILIATES HAVE NOT REGISTERED, AND DO NOT INTEND TO REGISTER, THE SECURITIES REFERENCED IN THE DOCUMENT UNDER THE U.S. SECURITIES ACT, AND DO NOT INTEND TO CONDUCT A PUBLIC OFFERING OF THE SECURITIES REFERENCED IN THE DOCUMENT IN THE U.S..

NO ACTION HAS BEEN TAKEN BY THE COMPANY THAT WOULD PERMIT AN OFFER OF THE SECURITIES REFERENCED IN THE DOCUMENT OR THE POSSESSION OR DISTRIBUTION OF THESE MATERIALS OR ANY OTHER OFFERING OR PUBLICITY MATERIAL RELATING TO THE SECURITIES REFERENCED IN THE DOCUMENT IN ANY JURISDICTION WHERE ACTION FOR THAT PURPOSE IS REQUIRED. THE RELEASE, PUBLICATION OR DISTRIBUTION OF THESE MATERIALS IN CERTAIN JURISDICTIONS MAY BE RESTRICTED BY LAW AND THEREFORE PERSONS IN SUCH JURISDICTIONS INTO WHICH THEY ARE RELEASED, PUBLISHED OR DISTRIBUTED, SHOULD INFORM THEMSELVES ABOUT, AND OBSERVE, SUCH RESTRICTIONS. THE ISSUE, SALE, SUBSCRIPTION FOR, OR PURCHASE OF THE SECURITIES REFERENCED IN THE DOCUMENT CAN BE SUBJECT TO SPECIAL LEGAL OR STATUTORY RESTRICTIONS IN CERTAIN JURISDICTIONS. THE COMPANY IS NOT LIABLE IF THE AFOREMENTIONED RESTRICTIONS ARE NOT COMPLIED WITH BY ANY PERSON.

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Important regulatory disclaimers. The **alfa**pump® system is currently not approved in the United States or Canada. In the United States and Canada, the alfapump system is currently under clinical investigation (POSEIDON Trial) and is being studied in adult patients with refractory or recurrent ascites due to liver cirrhosis. DSR® therapy is still in development and it should be noted that any statements regarding safety and efficacy arise from ongoing pre-clinical and clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the alfapump system in Europe, the United States or Canada.

*Note: **alfa**pump® and DSR® are registered trademarks.*

Sequana Medical NV

LISTING AND ADMISSION TO TRADING ON EURONEXT BRUSSELS OF UP TO 3,280,307 NEW SHARES

This prospectus (the "**Prospectus**") relates to the admission to listing and trading on the regulated market of Euronext Brussels of 3,280,307 shares (the "**New Shares**", and together with any of the outstanding ordinary shares of the Company, each a "**Share**") of Sequana Medical NV (the "**Company**" and, together with its consolidated subsidiaries, "**Sequana Medical**"), a limited liability company organised under the laws of Belgium, registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866, with LEI number 8755009AN12Y4PEOII07, and with its registered office located at Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium.

The 3,280,307 New Shares consist of:

- 2,169,013 New Shares that were issued by the Company on 27 April 2023 and 10 May 2023 as part of an aggregate of 4,445,205 new Shares and 1,111,294 subscription rights (at a ratio of one 1 subscription right per 4 new Shares) (the "**Subscription Rights**") that were placed with institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable securities law exemptions, via a private placement through an accelerated bookbuilding procedure (the "**Private Placement**"). The 4,445,205 newly issued shares (including 2,169,013 New Shares) were issued pursuant to a capital increase in cash that was decided by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company. All of the newly issued Shares were issued at a (gross) issue price of EUR 3.55 per Share. Of the 4,445,205 new Shares, 2,276,192 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance, while 2,169,013 new Shares, being a portion of the New Shares, were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance.
- up to 1,111,294 New Shares that are to be issued by the Company upon exercise of 1,111,294 Subscription Rights issued in the framework of the Private Placement (each Subscription Right is exercisable as from 30 October 2023 and gives the holder the right to subscribe for one new ordinary Share at an exercise price per underlying share of EUR 5.10). The 1,111,294 Subscription Rights were issued pursuant to a decision by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company.

Certain investors in the Private Placement agreed to accept newly issued Shares that would not be immediately admitted to listing and trading upon their issuance, provided that the Company undertakes as soon as practicable after their admission to apply to Euronext Brussels for the admission to listing and trading of such unlisted new Shares. Accordingly, all of the 2,169,013 New Shares issued in the Private Placement were allocated to, and subscribed for by, these investors.

The New Shares have not been and will not be registered under the US Securities Act of 1933, as amended from time to time (the "**Securities Act**"), or with any securities regulatory authority of any state or other jurisdiction of the United States. The 2,169,013 New Shares issued in the Private Placement were offered and sold outside the United States in reliance on Regulation S ("**Regulation S**") under the Securities Act and, unless New Shares are registered under the Securities Act or an exemption from the registration requirements of the Securities Act is available, New Shares may not be offered, sold or delivered within the United States (as that term is defined in Regulation S).

The Company has not authorised any offer of the New Shares to the public in any member state of the European Economic Area ("**EEA**") or elsewhere.

An investment in the Shares (including the New Shares) involves substantial risks and uncertainties. Prospective investors should read the entire Prospectus, and, in particular, should refer to the chapter "*Risk Factors*" beginning on page 8 for a discussion of certain factors that should be considered in connection with an investment in the New Shares, including the risks that (i) Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability, that (ii) Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump®, the DSR® product and/or any future products in target markets, that (iii) Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs and ensure its going concern, as well as (iv) current macroeconomic conditions generally, which could have an adverse effect on demand for the alfapump®, the DSR® product and/or any future products, and that (v) the Russian invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions. All of these factors should be considered before investing in the Shares (including the New Shares). Prospective investors must be able to bear the economic risk of an investment in the Shares (including the New Shares) and should be able to sustain a partial or total loss of their investment. Each decision to invest in the New Shares must be based on all information provided in this Prospectus.

An application has been made to admit the 2,169,013 New Shares issued in the framework of the Private Placement to listing and trading on the regulated market of Euronext Brussels under the symbol "SEQUA". Listing and trading of those New Shares on Euronext Brussels is expected to commence on or about 28 July 2023 (the "**Listing Date**"). An application to admit the other 1,111,294 New Shares to listing and trading on the regulated market of Euronext Brussels under the symbol "SEQUA" will be made when the relevant New Shares are issued (upon exercise of the relevant Subscription Rights).

The New Shares are all ordinary shares, are fully paid, and rank *pari passu* in all respects with all other existing and outstanding Shares of the Company. The Shares of the Company other than the 3,280,307 New Shares are already admitted to listing and trading on the regulated market of Euronext Brussels under the symbol "SEQUA". The closing price of the Shares on the regulated market of Euronext Brussels on 25 July 2023 was EUR 3.25 per Share.

No subscription rights of the Company (including the Subscription Rights) have been admitted to listing and trading on any regulated market and the Company has no intention to request such admission to listing and trading on any regulated market or any other trading platform or venue.

This Prospectus does not constitute, and the Company is not making, an offer to sell any of the Shares, including the New Shares, or a solicitation of an offer to purchase any of the Shares to any person in any jurisdiction where such an offer or solicitation is not permitted. The Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other listing related documents may be distributed or sent to any person or into any jurisdiction, except in circumstances that will result in the compliance with all applicable laws and regulations. Persons into whose possession this Prospectus may come are required to inform themselves about, and to observe all, such restrictions. The Company does not accept any responsibility for any violation by any person, whether or not it is a prospective purchaser of Shares, of any such restriction.

This Prospectus constitutes a listing prospectus for purposes of article 3 of Regulation 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC, as amended from time to time (the "**Prospectus Regulation**") and has been prepared in accordance with the provisions of the Prospectus Regulation and the Belgian Act of 11 July 2018 on the offering of investment instruments to the public and the admission of investment instruments to the trading on a regulated market, as amended from time to time (the "**Belgian Prospectus Act**"). Since the existing Shares of the Company, other than the New Shares, are already admitted to listing and trading on the regulated market of Euronext Brussels, this Prospectus has been drawn up as a simplified prospectus under the simplified disclosure regime in accordance with article 14 of the Prospectus Regulation. The English language version of this Prospectus was approved by the Belgian Financial Services and Markets Authority (the "**FSMA**") on 26 July 2023, as competent authority under the Prospectus Regulation.

Pursuant to articles 12(1) and 21(8) of the Prospectus Regulation, this Prospectus shall be valid until 26 July 2024, which is 12 months after its approval for admission of the New Shares to trading on the regulated market of Euronext Brussels, provided that it is completed by any supplement required pursuant to article 23 of the Prospectus Regulation and that not more than 3,280,307 New Shares are admitted to listing and trading on Euronext Brussels pursuant to this Prospectus. Any New Shares to be issued (upon exercise of Subscription Rights) after the expiration of the aforementioned 12 months' period (i.e., after 26 July 2024) will not be admissible to listing and trading on Euronext Brussels pursuant to this Prospectus. The obligation to supplement this Prospectus in the event of significant new factors, material mistakes or material inaccuracies does not apply when this Prospectus is no longer valid.

PROSPECTUS DATED 26 JULY 2023

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SUMMARY OF THE PROSPECTUS

Introduction and warnings

Unless determined otherwise in this summary, the terms used herein with a capital letter have the same meaning as defined in the Prospectus.

Disclosure requirement
Name and international securities identification number (ISIN) of the New Shares • **Name:** Sequana Medical NV (the "**Company**" and, together with its consolidated subsidiaries, "**Sequana Medical**"). • **ISIN:** The international securities identification number (ISIN) of the New Shares is BE0974340722.
Identity and contact details of the issuer, including its legal entity identifier (LEI) • The issuer is Sequana Medical NV, a limited liability company organized under the laws of Belgium, registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866, with LEI number 8755009AN12Y4PEOII07, and with registered office located at Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium. • The Company can be contacted by phone (+32 (0) 498 05 35 79), email (IR@sequanamedical.com) or via the contact form available on Sequana Medical's website (https://www.sequanamedical.com/contacts/).
Identity and contact details of the competent authority that approved this Prospectus • The FSMA is the competent authority under the Prospectus Regulation. • The FSMA can be contacted by phone (+32 (0)2 220 52 11), email (info@fsma.be) or via the contact form available on the FSMA's website (www.fsma.be/).
Date of approval of this Prospectus As competent authority under the Prospectus Regulation, the FSMA approved the English language version of the Prospectus on 26 July 2023 in accordance with article 20 of the Prospectus Regulation.
Warnings This summary should be read as an introduction to the Prospectus. Any decision to invest in the New Shares should be based on a consideration of the Prospectus as a whole by the investor and not just the summary. An investor could lose all or part of the invested capital. Where a claim relating to the information contained in, or incorporated by reference into, the Prospectus is brought before a court, the plaintiff investor might, under national law of the member states of the European Economic Area (EEA), have to bear the costs of translating the Prospectus and any documents incorporated by reference in it before the legal proceedings can be initiated. Civil liability attaches only to those persons who have tabled the summary, including any translation thereof, but only where the summary is misleading, inaccurate or inconsistent, when read together with the other parts of the Prospectus, or where it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in the New Shares. Where a claim relating to this Prospectus is brought before a court in a member state of the EEA, the plaintiff may, under the national legislation of the member state of the EEA where the claim is brought, be required to bear the costs of translating this Prospectus before the legal proceedings are initiated.

Key information on the Company

Disclosure requirement
Who is the issuer of the New Shares? • **Identification:** The issuer is Sequana Medical NV, a limited liability company organized under the laws of Belgium, registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866, with LEI number 8755009AN12Y4PEOII07 and with registered office located at Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium. • **Principal activities:** The principal activity of Sequana Medical is to develop innovative treatments utilizing its proprietary **alfa**pump® and DSR® (Direct Sodium Removal) technologies for the management of fluid

overload in liver disease, malignant ascites and heart failure when diuretics are no longer effective. Its two pillars of growth are the commercialisation of the **alfa**pump® in North America, a large market driven by non-alcoholic steatohepatitis (NASH)-related cirrhosis, and the clinical development of Direct Sodium Removal, a potential therapy for patients suffering from congestive heart failure.

- **Major shareholders:** The Company has a relatively widely held shareholder base, and no single shareholder controls the Company. The table below provides an overview of the shareholders that notified the Company pursuant to applicable transparency disclosure rules, up to the date of this Prospectus. Although the applicable transparency disclosure rules require that a disclosure be made by each person passing or falling under one of the relevant thresholds (3%, 5% or a multiple of 5%), it is possible that the information below in relation to a shareholder is no longer up-to-date.

		On a non-diluted basis	On a fully diluted basis	On a fully diluted basis
	Date of Notification	% of the voting rights attached to Shares (1)	% of the voting rights attached to Shares(2) (taking into account Subscription Rights)	% of the voting rights attached to Shares(3) (not taking into account Subscription Rights)
Partners in Equity V B.V.	16 March 2022	15.31%	13.45%	13.93%
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance NV/SA	18 February 2020	12.70%	11.16%	11.56%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P. / Erik Amble	6 February 2023	12.09%	10.62%	11.00%
LSP Health Economics Fund Management B.V.	19 February 2021	9.25%	8.13%	8.42%
Rosetta Capital Ltd	6 February 2023	5.97%	5.24%	5.43%
Participatiemaatschappij Vlaanderen NV	11 May 2023	4.80%	4.21%	4.37%
Newton Biocapital I SA	15 March 2022	4.64%	4.08%	4.22%
GRAC Société Simple	22 March 2022	4.25%	3.73%	3.86%
Sensinnovat BV	15 March 2022	3.79%	3.33%	3.45%
Optiverder B.V.	10 May 2023	3.29%	2.89%	2.99%

Notes:
(1) The percentage of voting rights is calculated on the basis of the number of outstanding Shares at the date of the relevant transparency notifications.
(2) The percentage of voting rights is calculated on the basis of the Shares outstanding on the date of this Prospectus (i.e., 28,191,733 Shares) and the assumed issuance of 3,905,321 additional Shares, assuming that new Shares are issued upon exercise of conversion of certain dilutive instruments (including as a result of the exercise of Subscription Rights).
(3) The percentage of voting rights is calculated on the basis of the Shares outstanding on the date of this Prospectus (i.e., 28,191,733 Shares) and the issuance of 2,794,027 additional Shares, assuming that new Shares are issued upon exercise of conversion of certain dilutive instruments (excluding as a result of the exercise of Subscription Rights).

- **Board of directors:** On the date of this Prospectus, the board of directors of the Company is composed of Pierre Chauvineau, Ian Crosbie, Rudy Dekeyser, Wim Ottevaere (acting through WIOT BV), Jackie Fielding, Doug Kohrs, Alexandra Clyde and Kenneth Macleod. Pierre Chauvineau is the chairman of the board of directors of the Company and Ian Crosbie is the Chief Executive Officer of the Company.
- **Statutory auditor:** The Company's statutory auditor is PwC Bedrijfsrevisoren BV, a private company with limited liability organised and existing under the laws of Belgium, registered with the Belgian Institute of Registered Auditors (*Instituut van de Bedrijfsrevisoren/Institut des Réviseurs d'Entreprises*), with office address at Culliganlaan 5, 1831 Machelen, Belgium, represented by Mr. Peter D'hondt.

What is the key financial information regarding the issuer?

The summarised condensed consolidated financial information as at 31 December 2022 (with comparative figures for the financial year ended at 31 December 2021) set forth below has been extracted without material adjustment from the audited consolidated financial statements of the Company as of and for the financial year ended 31 December 2022 (the "**Annual Financial Statements**"). The Annual Financial Statements have been prepared in accordance with International Financial Reporting Standards, as adopted by the European Union ("**IFRS**").

The Annual Financial Statements have been audited by the Company's statutory auditor, PwC Bedrijfsrevisoren BV, a private company with limited liability organised and existing under the laws of Belgium, registered with the Belgian Institute of Registered Auditors (*Instituut van de Bedrijfsrevisoren/Institut des Réviseurs d'Entreprises*), with office address at Culliganlaan 5, 1831 Machelen, Belgium, represented by Mr. Peter D'hondt. The numbers below are expressed in thousands of euro (EUR) except for the earnings per share which are expressed in euro (EUR).

Consolidated income statement

	Year ended 31 December 2022	Year ended 31 December 2021
	(in EUR) *(Audited)*	
Revenue ('000)	922.7	370.5
Earnings before interest and taxes(EBIT) ('000)	(28,094.5)	(22,613.6)
Net loss for the period ('000)	(30,763.1)	(23,615.1)
Basic loss per share	(1.35)	(1.30)

Condensed consolidated balance sheet

	As at 31 December 2022	As at 31 December 2021
	(in EUR) *(Audited)*	
Total assets ('000)	26,025.2	14,705.2
Total equity ('000)	(2,153.3)	(786.9)
Total financial debts (including lease debts) ('000)	17,592.2	8,085.1

Condensed consolidated cash flow statement

	Year ended 31 December 2022	Year ended 31 December 2021
	(in EUR) *(Audited)*	
Cash flow from operating activities ('000)	(27,481.8)	(23,617.4)
Cash flow from investing activities ('000)	(653.1)	(338.2)
Cash from financing activities ('000)	37,324.3	22,435.5

No *pro forma* financial information is provided in the Prospectus.

The statutory auditor issued an unqualified opinion in the statutory auditor's report on the Annual Financial Statements, which should be read in conjunction with the Annual Financial Statements. The opinion included a note with regard to material uncertainty related to the Company's going concern, referring to the fact that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals, and that it is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability, and that the Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The opinion also clarified that the impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear.

What are the key risks that are specific to Sequana Medical?

Sequana Medical is subject to the following key risks in relation to Sequana Medical's business and industry:

Risks relating to global events

- The Russian invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions.

Risks relating to Sequana Medical's financial situation

- Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.
- Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs.

Risks relating to clinical development

- Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.
- If Sequana Medical experiences delays or difficulties in the recruitment of Investigators, obtaining necessary approvals from study sites or the enrolment of subjects in clinical studies, or study sites failure to adhere to trial protocols and good clinical practices (GCP) regulations or similar regulations, its receipt of necessary regulatory approvals could be delayed or prevented.
- Adverse events may result in delays to, or even prevent, the completion of clinical studies regarding the **alfa**pump® or the DSR® product.

Legal and regulatory risks

- Seeking and obtaining regulatory approval for medical devices and drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.
- Sequana Medical is and will be subject to certain post-approval regulatory obligations in relation to the **alfa**pump® and the DSR® product.
- Sequana Medical is developing DSR 2.0, a proprietary second-generation DSR product, which will require approval by the FDA and regulatory authorities in any jurisdiction in which the product will be commercialized.

Risks relating to the Sequana Medical's dependence on third parties

- Sequana Medical depends on third party suppliers for services, components and pharmaceutical ingredients used in the production and operation of the **alfa**pump® and DSR® product and some of those services, components and pharmaceutical ingredients are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the **alfa**pump® and DSR® product, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.
- Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide regulatory advice and other services that are crucial to its business. Any disruption in the ability of third parties to continue to perform these critical activities could materially adversely impact Sequana Medical's business and results of operations.

Risks relating to commercialization and reimbursement

- Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources and it could fail to achieve or maintain reimbursement levels sufficient to support commercialisation on a large scale.

Risks relating to intellectual property

- Any inability to fully protect and exploit Sequana Medical's intellectual property may adversely impact Sequana Medical's financial performance and prospects.

Key information on the New Shares

Disclosure requirement
What are the main features of the New Shares? • **Type, class and ISIN:** This Prospectus relates to the admission to listing and trading on the regulated market of Euronext Brussels of up to 3,280,307 New Shares, consisting of (i) 2,169,013 New Shares that were issued by the Company's board of directors on 27 April 2023 and 10 May 2023 in the framework of a private placement of new shares through an accelerated bookbuilding procedure with institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable securities law exemptions (the "**Private Placement**") and that were not immediately admitted to listing and trading upon their issuance; and (ii) up to 1,111,294 New Shares that are to be issued by the Company upon exercise of the 1,111,294 subscription rights that were issued by the Company on 27 April 2023 and 10 May 2023 in the framework of the Private Placement, it being noted that the relevant subscription rights are only exercisable as from 30 October 2023. The 2,169,013 New Shares issued in the Private Placement are all ordinary Shares, are fully paid, and rank pari passu in all respects with all other existing and outstanding Shares of the Company. The up to 1,111,294 New Shares to be issued upon exercise of the Subscription Rights will all be ordinary Shares and rank *pari passu* in all respects with all other existing and outstanding Shares of the Company at that time. All of the Shares belong to the same class of securities and are in registered or dematerialised form. Holders of New Shares may elect, at any time, to have their registered New Shares converted into dematerialised New Shares, and vice versa, at their own expense. The New Shares are expected to be listed under the symbol "SEQUA" with ISIN BE0974340722. • **Rights attached to the New Shares:** Each shareholder of the Company is entitled to one vote per Share. All of the New Shares issued in the Private Placement, entitle the holder thereof to an equal right to participate in dividends in respect of the financial year ending 31 December 2022 and future years. All of the New Shares to be issued upon exercise of the Subscription Rights will entitle the holder thereof to an equal right to participate in dividends (if any) in respect of the relevant financial year in which the New Shares are issued and future years. All of the Shares participate equally in the Company's profits (if any). Each shareholder has the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. Within the limits of article 7:139 of the Belgian Companies and Associations Code, holders of securities have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. In principle, changes to the share capital are decided by the shareholders, and the general shareholders' meeting may decide to increase or reduce the share capital of the Company. In the event of a capital increase for cash with the issue of new Shares, or in the event of an issue of convertible bonds or subscription rights, the existing shareholders in principle have a preferential right to subscribe, *pro rata*, to the new Shares, convertible bonds or subscription rights. If the Company is dissolved for any reason any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the Shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders. • **Ranking:** All Shares represent an equal share of the share capital and shall all rank junior to all debt (instruments) of the Company. • **Restrictions on the free transferability:** The New Shares issued in the Private Placement are freely transferable. The New Shares to be issued upon exercise of the Subscription Rights will be freely transferable. The aforementioned is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements. • **Dividend policy.** The Company has not declared or paid dividends on the Shares in the past. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the board of directors. Belgian law and the Company's articles of association do not require the Company to declare dividends. Currently, the board of directors of the Company expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future. Furthermore, at the date of this Prospectus, the loan agreements entered into with PMV-Standaardleningen NV (formerly known as PMV/z) in July 2020 and most recently amended in March 2023 include protective covenants, which may limit the Company's ability (and require the prior consent of PMV-Standaardleningen NV) to make distributions by way of dividends or otherwise so long as any monies or obligations, actual or contingent, are outstanding under the aforementioned loan agreements. Under the loan facility agreement entered into with Kreos Capital VII (UK) Limited on 19 July

2022 and most recently amended in April 2023, no distributions by way of dividend can be declared or made without consent of Kreos Capital VII (UK) Limited (other than the payment of a dividend to the Company by any of its directly or indirectly wholly owned subsidiaries).
Where will the New Shares be traded? An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of 2,169,013 New Shares (issued in the framework of the Private Placement). These New Shares are expected to be listed under the symbol "SEQUA" with ISIN BE0974340722. Trading for these New Shares is expected to commence on or about 28 July 2023. An application will be made for the listing and admission to trading on the regulated market of Euronext Brussels of 1,111,294 New Shares (to be issued upon exercise of the 1,111,294 Subscription Rights issued in the framework of the Private Placement). These New Shares are expected to be listed (when listed) under the symbol "SEQUA" with ISIN BE0974340722.
Is there a guarantee attached to the New Shares? There is no guarantee attached to the New Shares.
What are the key risks that are specific to the New Shares? The New Shares are meant for investors who are able to assess the risks based on their knowledge and financial experience. The New Shares are subject to the following key risks in relation to the New Shares: • An active market for the Company's shares may not be sustained. • The market price of the Shares may fluctuate widely in response to various factors and the market price of the Shares may be adversely affected by such factors.

Key information on the admission to trading on Euronext Brussels

Disclosure requirement
Under which conditions and timetable can I invest in the New Shares? The 3,280,307 New Shares consist of (i) 2,169,013 New Shares that were issued by the Company on 27 April 2023 and 10 May 2023 in the framework of a Private Placement and that were not immediately admitted to listing and trading upon their issuance; and (ii) up to 1,111,294 New Shares that are to be issued by the Company upon exercise of the 1,111,294 subscription rights that were issued by the Company on 27 April 2023 and 10 May 2023 in the framework of the Private Placement An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of 2,169,013 New Shares (issued in the framework of the Private Placement). These New Shares are expected to be listed under the symbol "SEQUA" with ISIN BE0974340722. Trading for these New Shares is expected to commence on or about 28 July 2023. An application will be made for the listing and admission to trading on the regulated market of Euronext Brussels of 1,111,294 New Shares (to be issued upon exercise of the 1,111,294 Subscription Rights issued in the framework of the Private Placement). These New Shares are expected to be listed (when listed) under the symbol "SEQUA" with ISIN BE0974340722. The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the listing (including but not limited to legal publications, printing and translation of the Prospectus and listing related documents) and the remuneration of the FSMA (which is estimated at EUR 15,000.00) and Euronext Brussels, is expected to amount to approximately EUR 0.15 million.
Who is the person asking for admission to trade? The person asking admission to trading of the New Shares is Sequana Medical NV, a limited liability company organized under the laws of Belgium, registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866, with LEI number 8755009AN12Y4PEOII07, and with registered office located at Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium.
Why is this Prospectus being produced? This Prospectus constitutes a listing prospectus for purposes of article 3 of the Prospectus Regulation and has been prepared in accordance with the provisions of the Belgian Prospectus Act. This Prospectus has been drawn up as a simplified prospectus under the simplified disclosure regime in accordance with article 14 of the Prospectus Regulation. It relates to the admission to listing and trading of 3,280,307 New Shares not yet

admitted to listing and trading on the regulated market of Euronext Brussels of the Company, which consist of:

- 2,169,013 New Shares that were issued by the Company on 27 April 2023 and 10 May 2023 as part of an aggregate of 4,445,205 new Shares and 1,111,294 Subscription Rights (at a ratio of one 1 subscription right per 4 new Shares) that were placed with institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable securities law exemptions, via a private placement through an accelerated bookbuilding procedure (*i.e.*, the Private Placement). The 4,445,205 newly issued shares (including the 2,169,013 New Shares) were issued pursuant to a capital increase in cash that was decided by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company. All of the newly issued Shares were issued at a (gross) issue price of EUR 3.55 per Share. Of the 4,445,205 Shares, 2,276,192 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance, while 2,169,013 Shares, being a portion of the New Shares, were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance. A portion of the New Shares was allocated to the three investors that committed to submit a subscription order in the Private Placement prior to its launch.
- up to 1,111,294 New Shares that are to be issued by the Company upon exercise of the 1,111,294 Subscription Rights issued in the framework of the Private Placement (each Subscription Right giving the holder the right to subscribe for one new ordinary Share at an exercise price per underlying share of EUR 5.10). The 1,111,294 Subscription Rights were issued pursuant to a decision by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company.

Sequana Medical anticipated using the net proceeds of the Private Placement, equal to EUR 14.7 million, for the following purposes:

1) **alfa**pump® (approximately 33% of the net proceeds can be allocated to these purposes):
   (i) Progressing the North American pivotal study in recurrent and refractory liver ascites (POSEIDON) towards secondary endpoint readout planned for Q2 2024. This includes the Patient Preference Study with top-line data expected in H2 2023, sponsorship of the NACSELD ascites registry and market access / reimbursement activities. The total cost is estimated at ca. EUR 15.2 million of which EUR 12.2 million has been spent up to YE 2022 with the remainder to be attributed over 2023/2024;
   (ii) Preparing the PMA (Pre-Market Approval) filing and review, with planned submission to the FDA in H2 2023. The total project cost is estimated at ca. EUR 9.9 million of which EUR 5.4 million has been spent up to YE 2022 with the remainder to be attributed over 2023/2024.
2) **DSR** (approximately 5.5% of the net proceeds can be allocated to these purposes):
   (i) Initiating a US randomized controlled multi-center Phase 1/2a study using DSR 2.0 (MOJAVE), planned for Q2 2023 with initial results expected in H2 2023. The total study cost is estimated at ca. EUR 6.7 million of which EUR 1.7 million has been spent up to YE 2022 with the remainder to be spent from 2023 until 2025;
   (ii) Completing DSR 2.0 development work which includes the development of a Quality Management System to be used in MOJAVE clinical study. The total project cost is estimated at ca. EUR 2.2 million of which EUR 0.7 million has been spent up to YE 2022 with the remainder to be spent from 2023 until 2025.
3) **Others** (approximately 61.5% of the net proceeds can be allocated to these purposes):
   (i) Interest expense and a partial repayment of the loan facility with Kreos Capital (total loan cost of EUR 2.4 million up to Q1 2024), resulting from amendments to the above loan agreement, subject to certain conditions;
   (ii) General corporate and working capital purposes.

To the knowledge of the Company, there are, on the date of this Prospectus, no potential conflicts of interest between any duties of the members of the board of directors and members of the executive management to the Company and their private interest and/or other duties.

RISK FACTORS

Risks relating to Sequana Medical's business and industry

1. Risks relating to global events

The Russian invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions.

On 24 February 2022, Russia launched a full-scale invasion of Ukraine. As at the date of this Prospectus, the conflict remains ongoing. While the Group does not have any operations in Russia or Ukraine, it previously conducted its SAHARA clinical study in Georgia, which borders Russia. Although no delays were experienced as a result of the conflict and Sequana Medical does not have any plans for further studies in the region, if this were to change, these studies could encounter difficulties. DSR® product production will also be based in Romania, which borders Ukraine. Moreover, the conflict has had and could continue to have an adverse impact on global macroeconomic conditions generally, including due to the increase in oil and gas prices resulting from the conflict. This could in turn result in suppressed demand for the alfapump®, the DSR® product and/or any future products, although Sequana Medical has not experienced any such impact to date. Finally, the conflict may in the longer term result in issues for Sequana Medical in procuring sub-components for the **alfa**pump®, particularly since neon and palladium are often sourced from Ukraine, although it has not experienced material issues thus far.

The Company notes that the impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Company's executive management and the board of directors. For more information about the Company's working capital and the need for additional funds, reference is made to the chapter "*Capitalisation and Indebtedness*", section "*Working capital statement*" and the risk factor "*Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs.*".

2. Risks relating to Sequana Medical's financial situation

Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability.

Sequana Medical has incurred operating losses and negative operating cash flows in each period since it was founded in 2006. Operating loss from continuing operations for the year ended 31 December 2022 was EUR 30.8 million. As of 31 December 2022, Sequana Medical has a loss brought forward of EUR 173.5 million. These losses have resulted principally from costs incurred in the development and commercialisation of the **alfa**pump® and DSR® product, as well as from general and administrative costs associated with Sequana Medical's operations and manufacturing scale-up. Sequana Medical intends to fund the continued development of the **alfa**pump®, and the DSR® product, to expand manufacturing capabilities, to seek further regulatory and marketing approvals for these products, to secure reimbursement by payers, to maintain, protect and expand Sequana Medical's intellectual property portfolio and to expand sales and marketing activities. Management initially expected that the POSEIDON clinical study would cost around EUR 11 million to complete. This was, however, based upon a timeline in which primary endpoint data would be reported mid-year 2021. Due to delays associated with the COVID-19 outbreak, enrolment for the study was completed in December 2021, with implantation of the **alfa**pump® device having been completed in the first quarter of 2022 and primary endpoint read-out was achieved in October 2022. These delays have resulted in further costs to complete the study, with management currently expecting that the study will ultimately cost EUR 15.2 million. By the end of December 2022, EUR 12.2 million had been spent in connection with the POSEIDON clinical study. Management initially expected that the RED DESERT clinical study would cost around EUR 2.2 million to complete. Interim results for the study were announced in October 2020 and topline data was announced in May 2021. By the end of December 2022 the study ended and EUR 1.6 million had been spent in connection with the RED DESERT study. Sequana Medical also commenced enrolment for its SAHARA feasibility study in June 2021 and completed enrolment with its first-generation DSR product, DSR 1.0, in the first half of 2022. Top-line results for SAHARA were reported in November 2022. The SAHARA study cost approximately EUR 2.2 million. In addition, Sequana Medical plans to start MOJAVE, a randomised controlled study in approximately 30 diuretic resistant

chronic heart failure patients using Short Term DSR 2.0, following submission and approval of the U.S. IND application, which was received in May 2023. Management estimates that this study will cost approximately EUR 6.7 million.

On the other hand, the revenues associated with these clinical development activities are not expected to materialise for a significant period of time. For example, Sequana Medical does not expect to receive revenues from the sale of the **alfa**pump® in North America until after its launch. Currently, the regulatory filing with the U.S. Food and Drug Administration (the "**FDA**") in connection with the **alfa**pump® is expected to be made during the fourth quarter of 2023. Meanwhile, Sequana Medical's revenues from the sale of the **alfa**pump® in Europe, which were EUR 0.92 million in 2022, are not sufficient to compensate for these clinical affairs expenses. For that reason, Sequana Medical will likely continue to incur further losses for at least the next few years.

Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs.

Sequana Medical announced on 24 April 2023 that it had successfully raised an amount of EUR 15.8 million in gross proceeds by means of a private placement of new shares and subscription rights via an accelerated bookbuild offering of 4,445,205 New Shares (being approximately 18.72% of Sequana Medical's outstanding shares at that time) at an issue price of EUR 3.55 per share and 1,111,294 new subscription rights (if exercised into 1,111,294 new shares, representing approximately 4.68% of the outstanding shares at that time) at an exercise price of EUR 5.10 per underlying new share. The net proceeds of the Private Placement were EUR 14.7 million and are being used for the following purposes:

1) **alfa**pump® (approximately 33% of the net proceeds can be allocated to these purposes):

   (i) Progressing the North American pivotal study in recurrent and refractory liver ascites (POSEIDON) towards secondary endpoint readout planned for Q2 2024. This includes the Patient Preference Study with top-line data expected in H2 2023, sponsorship of the NACSELD ascites registry and market access / reimbursement activities. The total cost is estimated at ca. EUR 15.2 million of which EUR 12.2 million has been spent up to YE 2022 with the remainder to be attributed over 2023/2024;
   (ii) Preparing the PMA (Pre-Market Approval) filing and review, with planned submission to the FDA in H2 2023. The total project cost is estimated at ca. EUR 9.9 million of which EUR 5.4 million has been spent up to YE 2022 with the remainder to be attributed over 2023/2024.

2) **DSR** (approximately 5.5% of the net proceeds can be allocated to these purposes):

   (i) Initiating a US randomized controlled multi-center Phase 1/2a study using DSR 2.0 (MOJAVE), planned for Q2 2023 with initial results expected in H2 2023. The total study cost is estimated at ca. EUR 6.7 million of which EUR 1.7 million has been spent up to YE 2022 with the remainder to be spent from 2023 until 2025;
   (ii) Completing DSR 2.0 development work which includes the development of a Quality Management System to be used in MOJAVE clinical study. The total project cost is estimated at ca. EUR 2.2 million of which EUR 0.7 million has been spent up to YE 2022 with the remainder to be spent from 2023 until 2025.

3) **Others** (approximately 61.5% of the net proceeds can be allocated to these purposes):

   (i) Interest expense and a partial repayment of the loan facility with Kreos Capital (total loan cost of EUR 2.4 million up to Q1 2024), resulting from amendments to the above loan agreement, subject to certain conditions;
   (ii) General corporate and working capital purposes.

In July 2020, the Company entered into subordinated loan agreements with PMV-Standaardleningen NV (formerly known as PMV/z) ("**PMV Standaardleningen**"), Sensinnovat BV ("**Sensinnovat**") and Belfius Insurance NV ("**Belfius Insurance**"), in the aggregate principal amount of EUR 7.3 million, of which loans in the principal amount of EUR 1.4 million may be converted into new shares in the event of an equity financing or sale of the Company (the "**Subordinated Loan Agreements**"). In March 2021, as a result of the equity raising

by the Company that took place on 15 February 2021, Sensinnovat and Belfius Insurance exercised their conversion rights in the aggregate amount of EUR 618,916.67 (representing principal and interests) into an aggregate of 97,084 new Shares in accordance with the terms of the Subordinated Loan Agreements, thereby settling the convertible portion of their loans through a contribution in kind of their payables due by the Company under the relevant loans. In December 2021, the Company entered into amendment agreements related to the outstanding Subordinated Loan Agreements with the lenders (under which a principal amount of EUR 6,700,000.00 is still outstanding, whereby a principal amount of EUR 800,000.00 can be settled by conversion into new shares of the Company (through a contribution in kind of payables due by the Company)), thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing payment by instalments. In March 2023, the Company entered into new amendment agreements, thereby (i) amending the repayments terms and (ii) further increasing the interest rates retroactively. Consequently, the loans have a term of 60 months and are repayable in four equal quarterly instalments of EUR 1,675,000 on 30 September 2024, 31 December 2024, 31 March 2025 and 30 June 2025. The Subordinated Loan Agreements bear an interest rate of 7.0% per annum, except that the convertible portion of the loan granted by PMV-Standaardleningen bears an interest rate of 6.0% per annum. The loans with PMV-Standaardleningen, Belfius Insurance and Sensinnovat allow the Company to prepay the relevant loans together with all accrued interest, provided that the Company pays a termination indemnity equal to six months of interest on the prepaid loan. The convertible portion of the loan granted by PMV-Standaardleningen can be converted in the event of an equity financing or sale of the Company, at a price per share that is equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale.

Furthermore, in July 2022, the Company entered into a secured loan facility agreement (the "**Kreos Loan Agreement**") with Kreos Capital VII (UK) Limited ("**Kreos Capital**") in the amount of EUR 10.0 million and pursuant to which the Company is permitted to request an increase of the facilities in the amount of a maximum of EUR 10.0 million on an uncommitted basis. On 9 September 2022, the Company made a first drawdown in the amount of EUR 10 million. The loan matures on 30 September 2025 and the loans under the facility accrue interest at a fixed rate of 9.75% per annum. In April 2023, the facility agreement has been amended as clarified below. The amendment in April 2023 aimed at reducing the repayment of principal amounts that would otherwise be due during a specified period of time (the "**Initial Restructuring Period**"). The Initial Restructuring Period is the period starting on 27 April 2023 until either (i) 31 December 2023 or (ii) 31 March 2024, if the Company initiates its first clinical trial site for its Phase 1/2a US study of proprietary DSR 2.0 product (a sodium-free dextrose / icodextrin solution for direct sodium removal) in the United States (MOJAVE) by no later than 31 December 2023. During the Initial Restructuring Period, each scheduled principal repayment will be reduced at a rate of 75%. If the Company raises additional equity for an aggregate gross amount of at least EUR 20,000,000 before 31 December 2023, each scheduled principal repayment will be reduced by 50% during a period of six months after the end of the Initial Restructuring Period (the "**Additional Restructuring Period**"). The final repayment date remains 30 September 2025, meaning that the scheduled principal repayments falling after the Initial Restructuring Period and Additional Restructuring Period will be increased. In the framework of the aforementioned amendments, the Company (i) paid an amendment fee of EUR 100,000 to Kreos Capital and (ii) agreed to increase the end of loan payment from 1.25% to 1.75% provided that the Initial Restructuring Period enters into effect (which occurred on 27 April 2023). For more information regarding the aforementioned loan agreements, see *"Business Overview"* and *"Material contracts"*, subsections "*Subordinated Loan Agreements*" and "*Kreos Loan Agreement*".

If Sequana Medical is unable to successfully refinance the abovementioned Subordinated Loan Agreements, as most recently amended in March 2023, and/or the Kreos Loan Agreement, it may not be able to achieve its strategic objectives, including commercialisation of the **alfa**pump® in North America or the commercialisation of the DSR® product.

The Subordinated Loan Agreements, as most recently amended in March 2023, and the Kreos Loan Agreement also contain events of default that are customary for loans of this type, including, but not limited to, the incorrectness or misleading nature of any representation made or deemed to be made by the Company, the non-payment of any sums due under the aforementioned agreements at the time specified therein, the failure to perform or comply with any other obligation expressed to be assumed by the Company (if such failure is not adequately remedied within a certain time period), events such as the inability to pay debts as they fall due and certain bankruptcy and liquidation events. Upon the occurrence of an event of default, the relevant loans shall (immediately or upon written notice from the relevant lenders) become due and payable together with accrued interest thereon and any other sums then owed by the Company thereunder. For more information regarding the aforementioned loan agreements, see *"Business Overview"* and *"Material contracts"*, subsections "*Subordinated Loan Agreements*" and "*Kreos Loan Agreement*".

Other than the Subordinated Loan Agreements and the Kreos Loan Agreement (under which the Company cannot make further drawings), the Company has no other outstanding debt facilities under which it can make additional drawings.

In addition, in April 2023, several measures have already been carried out in order to reduce costs and expenditures, and Sequana Medical intends to carry out further savings. These measures include:

- Heart Failure / DSR: Slowing down the further progression of the MOJAVE clinical study;
- US alfapump program: Delaying the establishment of a new production facility; and
- EU alfapump commercial strategy: Reducing Sequana Medical's European commercial team by moving to a "reactive" rather than "proactive" commercial stance (i.e., ready to act on clinician interest and maintaining dialogue with key centres, instead of actively promoting the therapy).

Notwithstanding the above, Sequana Medical is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus. The Company's 12 month working capital shortfall as of the date of this Prospectus is approximately EUR 11.7 million to mid July 2024.

Furthermore, over the longer term (in particular, following the abovementioned 12 months period), Sequana Medical's existing capital resources will be insufficient to fund, among other things, the completion of the clinical development of the DSR® product required to bring it to market in Europe and North America, including MOJAVE studies.

The Company continues to evaluate equity and debt financing options (including discussions with existing and/or new investors), as well as potential strategic collaboration and licensing arrangements, it being noted that on the date of this Prospectus no concrete (refinancing) options or proposals are under consideration by the Company. Such equity and/or debt financing might not be available when needed or, if available, might not be available on commercially favourable terms, particularly if the difficult market conditions arising from the banking crisis in the United States and Europe and the conflict in Ukraine persist. If the necessary equity and/or debt funds are not available, Sequana Medical may seek funds through collaboration and licensing arrangements, at an earlier stage than originally planned, at terms that are less favourable than those it might otherwise have obtained or at terms which may require it to reduce or relinquish significant rights to its programmes. If Sequana Medical is unable to obtain necessary financing or enter into other arrangements to sustain its operations, it may not be able to achieve its strategic objectives (including commercialisation of the **alfa**pump® in North America or the commercialisation of the DSR® product) or ensure its going concern (which is not ensured as Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs).

In view of the Company's working capital needs, the Company's statutory auditor, PwC Bedrijfsrevisoren BV, represented by Mr. Peter D'hondt, auditor, has included a note with regard to material uncertainty related to the Company's going concern, referring to the fact that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals, and that it is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability, and that the Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The opinion also clarified that the impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear (see also risk factor "*The Russian invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions.*").

Furthermore, at the occasion of the preparation of the statutory (non-consolidated) financial statements of the Company for the financial year ended 31 December 2022, the board of directors of the Company determined that the net assets had fallen below the thresholds of the articles 7:228 and 7:229 of the Belgian Companies and Associations Code and submitted this matter to the Company's annual general shareholders'

meeting that took place on 25 May 2023, at which the shareholders decided (i) to continue the operations of the Company (and not to dissolve the Company), and (ii) to approve the proposed measures to redress the financial situation of the Company. This process will be repeated if and to the extent required in accordance with applicable law. Pursuant to article 7:229 of the Belgian Companies and Associations Code, if the amount of the Company's net assets has dropped below EUR 61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium (*naamloze vennootschap/société anonyme*)), any interested party is entitled to petition the competent court to dissolve the Company. In that event, the court can order the dissolution of the Company or grant a grace period within which the Company is to remedy the situation.

For more information about the Company's working capital and the need for additional funds, reference is made to the chapter "*Capitalisation and Indebtedness*", section "*Working capital statement*".

Changes in currency exchange rates could have a material negative impact on the profitability of Sequana Medical.

Sequana Medical's functional currency is the euro, while the functional currency of certain of its subsidiaries is Swiss francs or U.S. Dollars. Most of its current revenue from the sale of the **alfa**pump® is recorded in euro, although in the future, it expects that an increasing proportion of its revenue will be denominated in U.S. Dollars as it commercialises the **alfa**pump® in the United States. On the other hand, the costs in connection with the manufacturing of the **alfa**pump® are incurred in Swiss francs and general and administrative expenses are mainly incurred in euro. A significant portion of clinical affairs expenses and quality and regulatory expenses are incurred in U.S. Dollars as a result of the POSEIDON clinical study and consulting activities in relation to the planned pre-market approval ("**PMA**") from the FDA, respectively. The costs associated with the MOJAVE clinical study will also be incurred in U.S. Dollars. As a result, it is and will in the future continue to be, exposed to exchange rate fluctuations, including fluctuations in the euro exchange rate against U.S. Dollars, Swiss francs, and pounds sterling. Fluctuations in exchange rates outside the anticipated range may affect revenues, expenses, or the ability to raise future capital if it is needed, and may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects. The exchange rates between different currencies may be volatile and vary based on a number of interrelated factors, including the supply and demand for each currency, political, economic, legal, financial, accounting and tax matters and other actions that Sequana Medical cannot control.

3. Risks relating to clinical development

Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. Clinical studies require approvals, carry substantial risks and may be costly and time consuming, with uncertain results.

Sequana Medical is required to conduct clinical studies for regulatory approvals and other purposes. For example, for approval to market active implantable medical devices ("**AIMD**") in the United States, the FDA generally requires a prospective clinical study with results that meet pre-specified endpoints for safety and efficacy. Sequana Medical's studies are described in the Annual Report under the captions *"Our Business — Proof-of-concept studies of **alfa**pump in liver disease and cancer",* p. 46 and following, *" — Ongoing clinical studies of **alfa**pump in liver disease"*, p. 48 and following, *" — DSR in heart failure — Pre-clinical and clinical studies of DSR 1.0",* p. 68 and following, *and " — Pre-clinical and clinical studies of DSR 2.0"*, p. 76 and following. In addition, in relation to the DSR® product, Sequana Medical is seeking approval from FDA and/or other regulatory authorities as a drug requiring the Company to conduct clinical trials under a different set of rules, which are generally perceived as more stringent than for medical devices. See " *— Legal and regulatory risks— Seeking and obtaining regulatory approval for medical devices and drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales".*

The clinical studies that Sequana Medical may conduct may be long, expensive and unpredictable processes that can be subject to extensive delays. For instance, Sequana Medical has experienced delays in its clinical studies due to the impact of the COVID-19 pandemic. Management initially expected that the POSEIDON clinical study would cost around EUR 11 million to complete. This was, however, based upon a timeline in which primary endpoint data would be reported mid-year 2021. Due to delays associated with the COVID-19 outbreak, enrolment for the study was completed in December 2021, with implantation of the **alfa**pump® device having been completed in the first quarter of 2022 and primary endpoint read-out in October 2022. These delays will result in further costs to complete the study, with management currently expecting that

the study will ultimately cost EUR 15.2 million. The 12-month delay in Sequana Medical's clinical studies ultimately resulted in EUR 18.6 million in overall running costs during the pendency of the delay.

Furthermore, Sequana Medical and the relevant regulatory authority may not agree on a clinical study design or, if a clinical study design is accepted, one or more clinical study endpoints may not be achieved, and that may undermine support for regulatory approval. Clinical studies remain subject to ongoing review and monitoring throughout the duration of the study, and with certain exceptions, changes made to the study protocols after approval is received must also be approved prior to implementation. Failure to obtain or maintain the approvals required to conduct a clinical study on the **alfa**pump®, the DSR® product and/or any future products could significantly delay or prevent the completion of such study, necessitate additional testing or a re-design of the clinical study, incur significant additional time and costs and/or prevent Sequana Medical from achieving or maintaining profitability.

Furthermore, clinical studies (including registries such as TOPMOST) may not produce the anticipated clinical efficacy outcomes, or may uncover previously unknown safety issues or risks. Interim results of clinical studies do not necessarily predict final results, and success in pre-clinical testing and early clinical studies does not ensure that later clinical studies will be successful. Further studies may uncover product design or other issues not yet discovered by previous pre-clinical or clinical testing, which could lead to delays or suspension of the clinical studies or market approval while unexpected issues are resolved. Even if Sequana Medical obtains final approval to market the **alfa**pump®, the DSR® product and/or any future products in target markets, future studies or clinical studies may uncover previously unknown safety issues or risks or suggest that the **alfa**pump®, the DSR® product and/or any future products do not significantly improve clinical outcomes. Such results would slow or possibly stop the adoption of the **alfa**pump®, the DSR® product and/or any future products.

Regulators may require Sequana Medical to amend ongoing trials or perform additional trials, which could result in significant delays and additional costs or may be unsuccessful. If our clinical trials are not successful, or we fail to address identified deficiencies adequately, we will not obtain required approvals to market the products in development or new products. We cannot predict with certainty how long it will take to complete necessary clinical trials or obtain regulatory approvals of our current or future products. The time needed to complete clinical trials and obtain regulatory approvals varies by product, indication, and country.

If Sequana Medical's clinical studies are delayed, or if they do not produce the anticipated clinical efficacy outcomes, this could prevent it from achieving the commercialisation of the **alfa**pump® in North America and the DSR® product in the expected timeframe, which would in turn delay the timing of expected revenues from these products or prevent Sequana Medical from ever earning revenues from the sale of the **alfa**pump® in North America or the DSR® product.

If Sequana Medical experiences delays or difficulties in the recruitment of Investigators, obtaining necessary approvals from study sites or the enrolment of subjects in clinical studies, or study sites failure to adhere to trial protocols and good clinical practices (GCP) regulations or similar regulations its receipt of necessary regulatory approvals could be delayed or prevented.

Performing clinical studies requires the engagement of many hospitals, clinics, and clinicians. In particular, Sequana Medical must engage a physician at each clinical study centre to maintain overall responsibility for conduct of the clinical study (the "**Investigator**"). Each Investigator may have additional physicians working under his or her direction to conduct a study. Furthermore, Sequana Medical is required to obtain necessary approvals from the study sites where it conducts its clinical studies, including approvals from institutional review boards ("**IRBs**"), which are required for clinical studies conducted in the United States such as the POSEIDON study. For details of the arrangements into which Sequana Medical has entered for the conduct of its clinical studies, see *"Business Overview — Material contracts — Contract research organisations - Consultants"* and *" — Cooperative Research and Development Agreement"*.

Sequana Medical may not be able to attract sufficient qualified Investigators to conduct clinical studies within an adequate timeframe, and those Investigators may not be able to attract or enrol sufficient subjects to meet Sequana Medical's clinical study objectives. This may particularly be the case given the fact that the **alfa**pump® is an implantable device requiring clinical study subjects to undergo surgery. Any difficulties in enrolling a sufficient number of subjects, failure to conduct the clinical trial in accordance with regulatory requirements or the approved trial protocols or difficulty obtaining approvals from study sites for any of its clinical studies could result in significant delays or suspension of the trial and could require Sequana Medical to abandon one or more clinical studies altogether. Any such delays may result in increased development costs

that may exceed the resources available to Sequana Medical and in delays to commercially launching the **alfa**pump®, the DSR® product and/or any future products in target markets, if approved.

If Sequana Medical is unable to enter into a partnership or strategic alliance for the further development and commercialisation of the DSR® product, as is currently contemplated, it may incur additional costs and/or the development of these products might be delayed.

It is currently contemplated that, while Sequana Medical financed the SAHARA study and will finance the MOJAVE study in connection with the DSR® product, it will enter into a partnership or strategic alliance for the further development and commercialisation of the DSR® product. This is largely because these products are expected to require a different and/or expanded sales force compared to the sales force required for the **alfa**pump®. These relationships or those like them may require Sequana Medical to incur additional expenses, increase its capital expenditures, issue securities that dilute its shareholders or disrupt its management and business. In addition, Sequana Medical faces significant competition in seeking appropriate strategic partners and the negotiation process can with such parties be time consuming and complex. Moreover, Sequana Medical may not be successful in its efforts to establish a partnership or other strategic alliance for the DSR® product because this product may be deemed to be at too early a stage of development for collaborative effort and third parties may not view it as having the requisite potential. Furthermore, Sequana Medical cannot be certain that, following any partnership or strategic alliance, it will achieve the level of revenues that would justify such an arrangement. Any delays in entering into new strategic partnership agreements related to the DSR® product could also delay their development and commercialisation and reduce their competitiveness even if they reach the market.

If Sequana Medical is unable to identify a partnership or strategic alliance, it would need to complete the clinical and manufacturing development, file the associated regulatory filings on its own and commercialise the DSR® product through its own sales force. In that event, Sequana Medical might need to invest significant financial and management resources. Furthermore, its sales force might not be well equipped to market these products, which could adversely affect the revenues Sequana Medical is able to earn from them.

Adverse events may result in delays to the completion of clinical studies regarding the alfapump® or the DSR® product or may prevent completion.

Adverse events, both anticipated and unanticipated, occur in clinical studies. Adverse events may be associated with the **alfa**pump®, the DSR® product and/or any future products, or may be incorrectly ascribed to the **alfa**pump®, the DSR® product and/or any future products. For example, patients with liver refractory ascites generally have significant co-occurring diseases or disorders and due to their ongoing disease progression experience a significant rate of adverse events such as acute kidney injury ("**AKI**") and infections. It can be difficult to determine whether these adverse events are the result of the **alfa**pump® or are instead due to the co-occurring diseases and disorders that are prevalent in liver refractory ascites patients, and as a result adverse events may be incorrectly ascribed to the **alfa**pump®. The percentage of **alfa**pump® implantations that have required reintervention has generally been approximately 15% to 20%. In the first half of 2023 (to date), the second half of 2022, the first half of 2022, the second half of 2021 and the first half of 2021, the reintervention rate was 0%, 12%, 13%, 18% and 0%, respectively. This level of reintervention is considered acceptable given the severity of disease being experienced by patients implanted with the **alfa**pump®.

Prior clinical studies involving treatment with the **alfa**pump® have resulted in patients experiencing serious adverse events, including renal dysfunction and infection. Although it did not affect overall survival at 6 months, in the European RCT on the **alfa**pump® versus large volume paracentesis ("**LVP**") for the treatment of liver refractory ascites, adverse events and serious adverse events were more common in the **alfa**pump® group versus the LVP standard of care group and there were significantly more AKI events in the **alfa**pump® group versus the LVP standard of care group. In addition, prior clinical studies have also resulted in technical complications with the **alfa**pump®, including blockages. While Sequana Medical has enhanced the design of the **alfa**pump® to improve its technical performance, further technical complications and adverse events may arise in the future. In addition, although Sequana Medical provides training, instructions for use (labelling), and oversight by Sequana Medical's personnel, adverse events resulting from the failure of a physician to follow the instructions for use which are out of Sequana Medical's control, have occurred in the past, and may occur again in the future.

Any technical complications and/or adverse events in Sequana Medical's clinical studies that are ascribed to the **alfa**pump®, the DSR® product and/or any future products could result in damage to Sequana Medical's reputation, lawsuits, enrolment difficulties, suspension or termination of clinical studies and/or failure

to obtain marketing approval, and/or prevent the **alfa**pump®, the DSR® product and/or any future products from achieving commercial market acceptance. For example, if the rates of serious adverse events such as AKI in the POSEIDON study are significantly higher in patients during treatment with the **alfa**pump® as compared to LVP standard of care, the **alfa**pump® could fail to receive regulatory approval in North America and could fail to gain and/or maintain commercial market acceptance in target markets in Europe, which could have a material adverse effect on Sequana Medical's business, financial condition, results of operations and prospects.

4. Legal and regulatory risks

Seeking and obtaining regulatory approval for medical devices and drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Sequana Medical's target markets may delay, prohibit or reduce potential sales.

The process of obtaining marketing approvals, both in the United States and in foreign jurisdictions, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Applications for regulatory approval may require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies. The regulations to which Sequana Medical is subject are complex and have tended to become more stringent over time. Sequana Medical may be adversely affected by changes in government marketing approval policy or legislation applying to AIMDs and/or drugs. Varying interpretations of the data obtained from nonclinical and clinical testing could delay, limit, or prevent marketing approval of a product. Any marketing approval Sequana Medical obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Sequana Medical is obliged to comply with regulatory requirements that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can market or sell its products in each market.

At the date of this Prospectus, the **alfa**pump® is the only product that has been commercialised by Sequana Medical. Furthermore, the **alfa**pump® has only received regulatory approval in Europe (through a CE Mark) which is valid in the EEA and recognized in Switzerland. The DSR® product for the treatment of fluid overload in heart failure patients is in the early stage of development and will require substantial technical, pre-clinical and clinical development and testing prior to receiving marketing approval. The DSR® product may not be deemed to be safe and efficacious and it may not receive regulatory approval in any market. The DSR® product will require approval as a drug by the US FDA and likely by equivalent regulatory authorities in other jurisdictions.

For details of the regulatory regime applicable to AIMDs and drugs in each of the jurisdictions in which Sequana Medical has commercialised or intends to commercialise **alfa**pump®, see *"Business Overview—Regulation"*. In the EU, Sequana Medical received its CE certificate issued under Regulation 2017/745 (the "**Medical Devices Regulation** or **"EU MDR"**") in February 2022. The Medical Devices Regulation, which was passed by the European Parliament on 5 April 2017 and became applicable from 26 May 2021, also contains further obligations with which Sequana Medical is required to comply, which are generally stricter than the requirements previously in place and contain increased evidence requirements for CE Marking. Also, because the mutual recognition agreement between the European Union and Switzerland does not cover the medical devices certified under the EU MDR, Switzerland opted to unilaterally recognize CE certificates from EU notified bodies issued under the EU MDR but requires Sequana Medical as an EEA based manufacturer of a medical device to designate a representative in Switzerland to be able to continue to market medical devices with CE mark in the country. Furthermore, the DSR® product is at early stage of development. If successful, it may be marketed as a drug, for which the applicable regulatory regime in the EU is generally perceived as more strict than for medical devices. Sequana Medical would need to obtain a marketing authorisation from the EMA or national competent authorities in relevant markets and comply with a body of regulatory requirements including Directive 2001/83/EC on the Community Code relating to Medicines for Human Use. For further detail of these obligations, see *"Business Overview — Regulation — Europe"*. Ensuring compliance with these regulations is an intensive process requiring substantial human and financial resources. The burden of compliance may become significant relative to revenue from the **alfa**pump® and the DSR® product. If Sequana Medical fails to comply with applicable medical devices and pharmaceutical regulations, it may be forced to withdraw its products from the relevant market. In addition, it may be exposed to administrative, civil and criminal sanctions and lawsuits.

In the United States, regulatory approval for the **alfa**pump® is obtained via PMA from the FDA, as described in further detail under *"Business Overview — Regulation — United States"*. Timing for regulatory approval of the **alfa**pump® via a PMA by the FDA is uncertain, as it depends on the design of the clinical studies agreed between Sequana Medical and the FDA, including parameters such as number of subjects and duration of follow-up. The process is expected to take significantly longer than obtaining a CE Mark and there is a risk that the **alfa**pump® may not receive a PMA at all. Once approved, the PMA does not have an expiry date, however regulatory approvals may be withdrawn if, for example, a new and unexpected risk emerges which would make continued marketing of the relevant product no longer acceptable. The Federal Communications Commission must also determine that wireless medical devices, such as the **alfa**pump®, are compatible with other uses of the spectrum on which the device operates, and that power levels and the frequency spectrum of the wireless energy transfer comply with applicable regulations. In addition, certain governmental policies in the United States may impact the medical device industry. There have been judicial and Congressional challenges to certain aspects of the Patient Protection and Affordable Care Act (the "**Affordable Care Act**"), as well as previous efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and such challenges and amendments may continue, particularly upon a change in government from the current administration. These actions may adversely affect the healthcare industry in the United States and around the world. Sequana Medical cannot predict the likelihood, nature or extent of government regulation that may arise in the United States.

Sequana Medical may on occasion request that the indications for use of the **alfa**pump®, the DSR® product and/or any future products be expanded, and that expansion of indications is likely to also require regulatory approval. Any change or modification to a device or drug may also require further approvals and must be made in compliance with appropriate regulations, including in relation to Good Manufacturing Practices and quality management system ("**QMS**") requirements. In November 2021, for example, Sequana Medical announced that it had received Medical Device Single Audit Program ("**MDSAP**") certification from its auditing organisation British Standards Institution ("**BSI**"), thereby expanding its QMS towards the United States and Canada. It incurred significant expenses in connection with this certification. Review of Sequana Medical's regulatory submissions by regulatory agencies may result in requests to perform additional or repeat testing, to redesign one or more aspects of the **alfa**pump®, the DSR® product or any future products, or to change materials. Moreover, regulations and laws regarding the manufacture and sale of AIMDs such as the **alfa**pump®, as well as in relation to products such as the DSR® product are subject to future changes, as are administrative interpretation and policies of regulatory agencies, and any such changes could result in longer regulatory approval processes. The regulatory approval process may delay or prevent the launch and/or commercialisation of the **alfa**pump®, the DSR® product or any future products in target markets, which would negatively impact or prevent Sequana Medical's ability to achieve its milestones. If Sequana Medical fails to obtain approval of the **alfa**pump®, the DSR® product or any future products in target markets, on a timely basis or at all, the marketing and sale of the **alfa**pump®, the DSR® product and/or any future products in certain markets may be delayed or may not be achieved, which would in turn delay the timing of expected revenues from these products.

Sequana Medical intends to develop a proprietary DSR 2.0 product, which will require approval as a drug by the FDA and likely by regulatory authorities in other jurisdictions where Sequana Medical intends to market the DSR® product.

Sequana Medical is developing DSR 2.0, a proprietary second-generation DSR product. Sequana Medical is engaging with the FDA to pursue approval of the DSR® product as a drug. Sequana Medical commenced enrolment for its SAHARA feasibility study in June 2021 and completed enrolment with its first-generation DSR product, DSR 1.0, in the first half of 2022. Top-line results for SAHARA, using DSR 1.0, were reported in November 2022. The MOJAVE study, a randomised controlled study in approximately 30 diuretic resistant chronic heart failure patients using Short Term DSR 2.0, will be initiated following submission and clearance of the U.S. IND., which was received in May 2023. Sequana Medical has no experience with the FDA approval process for drugs or combination products. Therefore, it will need to expand its capabilities either by hiring additional employees or engaging with contractors, consultants or other third parties, which will result in additional costs. Sequana Medical may also experience difficulties in receiving approval from the FDA for its DSR 2.0 product. The testing, submission, and approval process requires substantial time, effort, and financial resources, including substantial application user fees and annual product and establishment user fees. There can be no assurance that any approval will be granted for any product at any time, according to any schedule, or at all. The FDA may refuse to accept or approve an application if it determines that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy. Even if regulatory approval is granted, the approval will be limited to specific indications. There can be no assurance that DSR 2.0

or any other future product candidates will receive regulatory approvals for marketing or, if approved, that approval will be for any or all of the indications that Sequana Medical requests. Sequana Medical may incur higher than expected costs in connection with the approval of its DSR 2.0 or it may encounter difficulties in receiving approval, this could require it to raise additional capital and/or could distract management attention from other clinical studies and/or projects.

Sequana Medical is and will be subject to certain post-approval regulatory obligations in relation to the alfapump® and the DSR® product.

Even though Sequana Medical has obtained regulatory approval in Europe for the **alfa**pump® in liver refractory ascites and malignant ascites it must continue to follow up on its product and implement a post-market clinical follow up plan approved by its notified body which may contain further obligations for post-market studies to demonstrate the safety and performance of the device.

After regulatory approval, issues with product performance may subsequently be identified once a product is in the market. Under the EU MDR, Sequana Medical must comply with increased post-market surveillance and vigilance requirements and must establish a post-market surveillance system described in a post-market surveillance plan. As part of its vigilance activities Sequana Medical must report incidents to the relevant authorities of the Member States of the EEA, and may be required to take Field Safety Corrective Actions ("**FSCAs**") to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to, or might have led to, the death of a patient, user or other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. Furthermore, Sequana Medical will need to prepare periodic safety update reports ("**PSURs**") for each device or category of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan.

Once the **alfa**pump® is commercially launched in the United States, Sequana Medical will be subject to FDA requirements applicable to medical device manufacturers to monitor and report adverse events as part of the medical device reporting ("**MDR**") regulations so that safety issues can be identified and addressed quickly. When such issues are identified, the FDA may require corrective actions – such as modifying labelling or instructions for use, improving training, or removing the device from the market – to ensure proper use or patient safety. Any of these could result in significant time and expense to correct and may harm the reputation of Sequana Medical. Such issues may result in the need for the **alfa**pump® to be suspended from sale or withdrawn from the market. In these circumstances, the **alfa**pump® may require substantial redesign and/or re-engineering to address any identified issues. This may result in Sequana Medical needing to undertake further clinical studies to re-establish the safety and efficacy of the revised product, which would be costly and time consuming and may exceed the resources of Sequana Medical. Similar reporting requirements exist for devices approved within the regulatory frameworks of other countries.

Moreover, as part of or following the FDA grant of a PMA for the **alfa**pump® in the United States, the FDA may require Sequana Medical to conduct one or more post-approval studies ("**PAS**"), which could be extensive, expensive and take additional time, effort and capital to complete. The PAS may uncover problems with the **alfa**pump® and may result in a need to redesign certain aspects of the **alfa**pump®, a need to conduct additional studies and/or possible suspension from sale. The requirement for corrective actions in response to MDRs, as well as a PAS may delay or inhibit Sequana Medical's ability to market the **alfa**pump® in target markets.

The **alfa**pump® is subject to extensive testing to international technical standards. Testing may uncover problems or non-compliance with standards that may require a substantial product redesign, resulting in extensive delays and additional costs. Changes in standards may require re-testing of the **alfa**pump®, and compliance with an earlier standard may not necessarily mean compliance with a more recent version of such standard.

In addition, to the extent that the DSR® product or any other future products are approved as drugs, Sequana Medical will need to comply with applicable pharmacovigilance regulations, which includes setting up a pharmacovigilance system with qualified personnel, complying with adverse event and periodic safety reporting requirements and any post-authorisation conditions imposed by the regulatory authorities such as

post-authorisation safety studies. Pharmacovigilance requirements are different from medical devices vigilance and post market surveillance requirements and will require additional personnel and resources to comply with.

If Sequana Medical is unable to comply with post-approval obligations in the markets in which it has commercialised the **alfa**pump®, and the DSR® product, this could result in sanctions, additional costs in order to remediate the identified issues and/or the curtailment of its commercial activities, which could in turn limit its revenues in the relevant market.

Sequana Medical's manufacturing facility and those of its third party suppliers are subject to significant regulations and approvals. If Sequana Medical or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Sequana Medical's business will be materially harmed.

Sequana Medical currently manufactures the **alfa**pump® at its manufacturing facility in Switzerland, and has entered into agreements with third party suppliers to manufacture and supply certain components of the **alfa**pump®. The DSR® product will be manufactured in Romania. The manufacturing practices of Sequana Medical and its third-party suppliers are subject to ongoing regulation and periodic inspection. Any failure to follow and document the adherence to regulatory requirements (including having in place an adequate QMS in line with the most up-to-date standards and regulations) by Sequana Medical or its third party suppliers may lead to significant delays in the availability of the **alfa**pump®, the DSR® product and/or any future products for commercial sale or clinical studies, may result in the termination of or a hold on a clinical study, or may delay or prevent filing or approval or maintenance of marketing applications for the **alfa**pump®, the DSR® product and/or any future products.

Failure to comply with applicable regulations could also result in regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring Sequana Medical to suspend or put on hold one or more of Sequana Medical's clinical studies;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring Sequana Medical to suspend manufacturing activities, sales, imports or exports of the **alfa**pump®, the DSR® product and/or any future products;
- requiring Sequana Medical to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving the **alfa**pump®, the DSR® product and/or any future products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could have a financial impact on Sequana Medical or could be detrimental to Sequana Medical's reputation.

Sequana Medical is subject to the risk of product liability claims or claims of defectiveness, which could result in uninsured losses for Sequana Medical or recalls of the relevant product.

Sequana Medical is exposed to the risk of potential product liability claims arising from adverse reactions, product failures and malfunctions, product use and associated surgical procedures. Sequana Medical maintains product liability insurance at levels which management believes are in line with market practice. To

date, no product liability claim has been initiated against Sequana Medical. However, Sequana Medical may not be able to maintain sufficient insurance coverage on commercially acceptable terms in the future, and its insurance coverage may not provide adequate protection against any product liability claims or claims of product defectiveness. As a consequence, Sequana Medical might have to face liabilities for a claim that may not be covered by its insurance or its liabilities could exceed the limits of its insurance.

Moreover, product failures or safety issues discovered during the clinical study phase may also lead to the suspension or termination of the relevant study. In addition, product failures and malfunctions, quality issues may result in a recall of the product, which may relate to a specific manufacturing lot or may impact all products in the field. Recalls may occur at any time during the life cycle of a device once regulatory approval has been obtained for the commercial distribution of the device. Recalls of the **alfa**pump®, the DSR® product and/or any future products would divert managerial and financial resources, can result in damaged relationships with regulatory authorities such as the FDA, lead to loss of market share to competitors and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects. In addition, any product recall may result in irreparable harm to Sequana Medical's reputation. Any product liability claims or other claims of defectiveness or any product recalls could have a financial impact on Sequana Medical or could be detrimental to Sequana Medical's reputation.

Compliance with regulations and standards for quality systems for medical device and drug companies is complex, time consuming and costly. Sequana Medical may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.

Sequana Medical has developed and maintains a QMS to ensure the quality of Sequana Medical's products and activities. The system is ultimately intended to achieve compliance with regulations in different jurisdictions, including the Quality Systems Regulations (the "**QSR**") mandated by the FDA, and the requirements of the Medical Devices Regulation, including the international QMS standard for Medical Devices ISO13485 required by the countries in Europe that recognise the CE Mark and Israel. In some circumstances, the requirements of regulations and standards may be different.

In the past, medical devices marketed in Canada had to have their QMS assessed under the Canadian Medical Devices Conformity Assessment System ("**CMDCAS**"). This option has no longer been available since 1 January 2019. From 1 January 2019, Health Canada requires any manufacturer commercialising medical devices into Canada to comply with the MDSAP, which Sequana Medical completed in November 2021.

Compliance with regulations and standards for quality systems for medical device companies is complex, time consuming and costly, and there are changes in the regulations from time to time. Manufacturers (including Sequana Medical's external critical sub-contractors) were required to be certified according to the requirements of new ISO 13485:2016 by 28 February 2019. While management believes that Sequana Medical is compliant with existing QMS standards for medical devices at the date of this Prospectus, it is possible that Sequana Medical may be found to be non-compliant with new or existing regulations and standards in the future. In addition, Sequana Medical may be found to be non-compliant as a result of future changes in, or interpretation of, the regulations for quality systems. Typically, if a third party audit identifies a non-conformity with the requirements of the ISO13485 standard, the company would be given a specified period of time (typically 30 calendar days) to submit a corrective action plan and the issue identified would be required to be remedied by a specified deadline (which would depend on the severity of the finding). The certifying body would then conduct a follow-up review or audit focusing on the implementation of the corrective action and if that action is deemed insufficient, the company would be at risk of losing its ISO13485 certification and consequently its CE Mark. The loss of certification to ISO 13485 would impact Sequana Medical's regulatory position and its ability to sell the **alfa**pump®, and/or the DSR® product, as applicable. Therefore the key risk in relation to compliance with this standard is the potential for diversion of management attention and the costs incurred in remedying incidences of non-conformity and ultimately disruption to Sequana Medical's business if it is unable to implement appropriate corrective actions.

Sequana Medical's external vendors must, in general, also comply with the QSR and ISO13485. Any of its external vendors may become non-compliant with QSR or ISO13485, which could result in enforcement action by regulatory authorities, including by way of example a warning letter from the FDA or a requirement to withdraw from the market or suspend distribution, or export or use of products manufactured by one or more of Sequana Medical's vendors.

For drugs quality management systems will need to be implemented as part of GxP practices (including good manufacturing, laboratory, clinical and pharmacovigilance practices). Such quality management systems need to follow detailed regulations issued by FDA, European Commission, EMA and other equivalent regulatory authorities and will require additional personnel and resources in order to be implemented.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices and drugs. If Sequana Medical is found to have made false or misleading claims about the alfapump® the DSR® product and/or any future products, or otherwise have violated promotion or advertising restrictions, it may become subject to significant fines and/or other liabilities.

In Sequana Medical's target markets, promotional materials and training methods must comply with numerous applicable laws and regulations. Use of a device or drug outside of its cleared or approved indication is known as "off-label" use. Sequana Medical has only a limited influence over its distribution partners' marketing activities. Although Sequana Medical trains its distribution partners not to promote its products for "off-label" uses, and Sequana Medical's instructions for use in all markets specify that its products are not intended for use outside of those indications cleared for use, it cannot provide any assurance that no competent regulatory agency will hold Sequana Medical responsible for engaging in "off-label" promotion.

Sequana Medical must also sufficiently substantiate any claims that it make for its products, including claims comparing its products to other companies' products, and must abide by the FDA or a comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

If a relevant governmental authority determines that Sequana Medical's promotional materials or training constitute promotion of an "off-label" use or otherwise violate promotional and advertising requirements, it could request modifications to Sequana Medical's training or promotional materials or subject Sequana Medical to regulatory or enforcement actions, which may include the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. U.S, EU or other applicable governmental authorities might also take action if they consider Sequana Medical's promotional or training materials to constitute promotion of an un-cleared or unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, Sequana Medical's reputation could be damaged and adoption of Sequana Medical's products could be impaired. This risk will be heightened once Sequana Medical commercially launches the **alfa**pump® in the United States, given the FDA's focus on false or misleading claims and the potential for significant fines.

In addition, industry codes particularly in the pharmaceutical sector contain further requirements for pharmaceutical advertising and prohibit companies from engaging in certain promotional activities. Competitors may file complaints with industry associations and courts in which case such instances may enforce violations of such codes and applicable regulations with penalties including fines and publication of decisions. If Sequana Medical becomes subject to such enforcement or court actions its business, financial condition, reputation, stock price and prospects may be materially harmed.

Sequana Medical is subject to healthcare fraud and abuse and other laws applicable to Sequana Medical's business activities. If Sequana Medical is unable to comply with such laws, it could face substantial penalties.

While Sequana Medical has not yet commercially launched the **alfa**pump® in the United States, when it does so, it will become subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws may impact, among other things, Sequana Medical's proposed sales and marketing and education programmes and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, Sequana Medical may be subject to patient privacy and security regulations by both the federal government and the states in which Sequana Medical conducts its business. The laws that may affect Sequana Medical's ability to operate include, inter alia:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or wilfully soliciting, receiving, offering or paying any remuneration, overtly or covertly, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arrange for, or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payer program that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which established new federal crimes for, among other things, knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, wilfully obstructing a criminal investigation of a healthcare offense, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- an increasing number of state transparency laws that require manufacturers to provide reports to state governments on pricing and marketing information. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programmes, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, and to prohibit or limit certain other sales and marketing practices; and

- a federal law known as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the Centres for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Sequana Medical is also subject to European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

If Sequana Medical's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Sequana Medical's operations, the exclusion from participation in government healthcare programmes and individual imprisonment. In particular, the Anti-Kickback Statute provides for both criminal and civil penalties for violations. The criminal penalties include fines of up to US$25,000 per violation and five years' imprisonment. In addition, the Office of the Inspector General for the Department of Health and Human Services can pursue civil penalties of up to US$50,000 per violation plus three times the amount of any government overpayment. Penalties for Anti-Kickback Statute violations also frequently include a period of debarment or exclusion from participation in Medicare, Medicaid, and all other federal plans and programmes that provide health benefits, which could impact Sequana Medical's reimbursement for the **alfa**pump® and/or the DSR® product, as applicable, if it were deemed to have violated the statute. Violations of the other statutes referred to above can result in similar sanctions to the Anti-Kickback Statute.

Sequana Medical faces risks related to environmental matters and animal testing activities.

Sequana Medical's manufacturing facility is subject to a broad range of environmental laws and requirements, including those governing discharges to the air and water, remediation of contamination associated with the release of any hazardous substances at Sequana Medical's manufacturing facility and offsite disposal locations and occupational safety and health. Sequana Medical is also subject to strict laws and requirements governing the handling or disposal of solid and hazardous substances and wastes. For example, Sequana Medical must process non-functioning pumps that have been explanted from patients, including patients with hepatitis and other serious diseases, to identify the cause of the pump failure. Sequana Medical has made, and will continue to make, expenditures to comply with such laws and requirements. Future events, such as changes in existing laws and regulations, or the enforcement thereof, or the discovery of contamination at Sequana Medical's manufacturing facility, may give rise to additional compliance or remediation costs that could have a material adverse effect on Sequana Medical's business, financial condition, results of operations and prospects. Such laws and requirements are constantly changing, are different in every jurisdiction and can impose substantial fines and sanctions for violations. As a manufacturer, Sequana Medical is exposed to some risk of claims with respect to environmental matters, and material costs or liabilities may be incurred in connection with any such claims.

In addition, Sequana Medical has been required to use animals to test the **alfa**pump®, and DSR® product, and may be required to use animals to test future products. In particular in relation to the DSR® product, it has used pigs in the Healthy pig DSR proof of concept study and the heart failure pig DSR proof of concept

study and sheep and mice in the GLP animal studies. Animal testing activities have been the subject of controversy and adverse publicity. Testing on animals can be vital for the development of a product. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, Sequana Medical is no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop products in certain jurisdictions under the applicable marketing authorisations. In addition, negative publicity regarding Sequana Medical's use, or the industry's use, of animal subjects could harm Sequana Medical's reputation.

5. Risks relating to the Sequana Medical's dependence on third parties

Sequana Medical depends on third party suppliers for services, components and pharmaceutical ingredients used in the production and operation of the alfapump® and DSR® product and some of those services, components and pharmaceutical ingredients are supplied from a single source. Disruption of the supply chain, unavailability of third party services required for the production of the alfapump® and DSR® product, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.

The **alfa**pump® and DSR® product require customised components, pharmaceutical ingredients and services that are currently available from a limited number of sources. Most of these components, pharmaceutical ingredients and services are sourced externally from more than 70 external suppliers. In addition, for certain components, Sequana Medical relies on single source suppliers. If Sequana Medical has to switch to a replacement supplier for any of these components or pharmaceutical ingredients or for certain services required for the production and operation of the **alfa**pump® and DSR® product (for example, the sterilisation and coating of the product components), or if Sequana Medical has to commence its own manufacturing to satisfy market demand, it may face additional delays. For example, in the past, a supplier has discontinued its supply of certain components after it deemed Sequana Medical's purchase requirements to be of insufficient volume to justify the enhanced regulatory obligations that affect manufacturers of medical device components. In addition, as a result of problems with supply of a component of the **alfa**pump®, Sequana Medical prioritised the supply of **alfa**pump® systems for its clinical studies and as such experienced a temporary delay in the supply of the **alfa**pump® to commercial markets in Europe during the fourth quarter of 2020. However, this only temporarily impacted European commercial availability and the **alfa**pump® continued to be available for the POSEIDON, RED DESERT and SAHARA clinical studies. Normal supply resumed in the second half of 2021.

Third party suppliers may also be subject to circumstances which impact their ability to supply, including enforcement action by regulatory authorities, natural disasters (e.g. hurricanes, earthquakes, disease and terrorism), epidemics (e.g. the ongoing COVID-19 outbreak), industrial action (e.g. strikes), financial difficulties including insolvency, among a variety of other internal or external factors. Any such supply disruptions could in turn result in production disruptions for an extended period of time, which could delay completion of its clinical studies or commercialisation and prevent Sequana Medical from achieving or maintaining profitability. Alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals, or may not have in place an adequate QMS. Furthermore, modifications to a service or component made by a third party supplier could require new approvals from the relevant regulatory authorities before the modified service or component may be used.

In addition, Sequana Medical expects to be required to significantly increase manufacturing volumes as clinical studies on the **alfa**pump® and/or the DSR® product are expanded, as the commercialisation of the **alfa**pump® is expanded and the DSR® product reaches commercialisation, and/or as any future products undergo clinical studies or reach commercialisation. Most of its suppliers will need to increase their scale of production to meet the projected needs for commercial manufacturing, the satisfaction of which on a timely basis may not be met. If Sequana Medical is unable to secure an adequate supply of components, it may be unable to achieve or maintain successful commercialisation in target markets.

Any disruptions in the supply of components, pharmaceutical ingredients or services required for the manufacture of the **alfa**pump® and DSR® product could result in delays to Sequana Medical's clinical studies and could compromise its ability to commercially launch the **alfa**pump® in North America.

Sequana Medical relies on third parties to conduct its clinical studies, perform data collection and analysis, and provide regulatory advice and other services that are crucial to its business.

Sequana Medical relies, and will rely in the future, on medical institutions, Investigators, contract research organisations ("**CROs**"), contract laboratories and collaborators to perform data collection and analysis and to carry out Sequana Medical's clinical studies. For details of the arrangements into which Sequana Medical has entered for the conduct of its clinical studies, see *"Business Overview — Material contracts — Contract research organisations - Consultants" and " — Cooperative Research and Development Agreement"*. Sequana Medical's development activities or clinical studies conducted in reliance on third parties may be compromised if the third parties do not devote a sufficient amount of time or effort to Sequana Medical's activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines. Furthermore, if the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data, this could adversely affect clinical results or require Sequana Medical to repeat the affected study. In addition, Sequana Medical's third-party agreements usually contain a clause limiting such third party's liability, such that Sequana Medical may not be able to obtain full compensation for any losses that Sequana Medical may incur in connection with the third party's performance failures.

If the third parties upon which Sequana Medical depends do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or in the event of a default, bankruptcy or shutdown of, or a dispute with, a third party, Sequana Medical would be required to find a replacement third party to conduct the required activities. Sequana Medical may be unable to enter into a new agreement with another third party on commercially acceptable terms. While Sequana Medical believes that there are alternative sources to provide these services, in the event that Sequana Medical seeks such alternative sources, Sequana Medical may not be able to enter into replacement arrangements without incurring delays or additional costs.

If the third parties upon whom Sequana Medical depends fail to perform to the required standard or if Sequana Medical is required to replace such third parties, this could result in delays in the regulatory approval for the **alfa**pump®, the DSR® product and/or any future products in its target markets.

6. <u>Risks relating to commercialisation and reimbursement</u>

Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources and it could fail to achieve or maintain reimbursement levels sufficient to support commercialisation on a large scale.

The existence of coverage and adequate reimbursement for Sequana Medical's products by government and/or private payers will be critical to market adoption for the **alfa**pump®, the DSR® product and/or any future products. Physicians and hospitals are unlikely to use the **alfa**pump®, the DSR® product and/or any future products, at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilising Sequana Medical's product, and potential patients may be unwilling to pay for the **alfa**pump®, the DSR® product and/or any future products themselves.

In many countries, payment for the **alfa**pump®, the DSR® product and/or any future products will be dependent on obtaining a "reimbursement code" for the procedure and product. For details of the reimbursement arrangements in the countries in which Sequana Medical has commercialised or plans to commercialise the **alfa**pump®, the DSR® product, please refer to the Annual Report under the captions *"**alfa**pump® in liver disease and cancer — Commercial operations in Europe",* p. 58. Obtaining a reimbursement code can be a lengthy process (months to years) and Sequana Medical may not be able to obtain such a code at satisfactory levels, or at all. Following the grant of a "reimbursement code" payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the procedure(s) that use the **alfa**pump®, the DSR® product and/or any future products. Failure to obtain attractive reimbursement may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects. In addition, the United States will be one of Sequana Medical's target markets if the **alfa**pump® and/or the DSR® product receive marketing authorisation from the FDA. There is a risk that a portion of the patients in the United States suffering from recurrent or refractory liver ascites or malignant ascites or fluid overload in heart failure will not have any form of health insurance, and therefore that those patients will not seek treatment for their conditions, which could have a negative impact on the estimated market sizes for these indications.

The price that Sequana Medical may receive for, and the marketability of, the **alfa**pump®, the DSR® product and/or any future products for which Sequana Medical receives regulatory approval may suffer if the government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented. From time to time, legislation is enacted that could significantly change the statutory provisions governing the clearance or approval, manufacture, marketing or taxation of the **alfa**pump®, the DSR® product and/or any future products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect the **alfa**pump®, the DSR® product and/or any future products. It is impossible to predict whether legislation changes will be enacted or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Sequana Medical cannot predict what healthcare programmes and regulations will be ultimately implemented at the U.S. federal or state level, or at the EU level, or within the implementing legislation of the individual EU Member States, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way healthcare is delivered and financed, and may materially impact numerous aspects of Sequana Medical's business. Increasing downward pressure on healthcare pricing and/or any changes that lower reimbursements for Sequana Medical's products could result in product revenues generated from sales of the **alfa**pump®, the DSR® product and/or any future products being lower than anticipated. As a result, Sequana Medical could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical expects to experience pricing pressures in connection with the sale of the **alfa**pump®, as well as the DSR® product and/or any future products following the receipt of regulatory approval. Generally, hospitals, governments and third-party payers are increasingly exerting downward pressure on pricing and reviewing the cost-effectiveness of medical products, therapies and services. With this global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursement for new therapies.

If Sequana Medical is unable to obtain or maintain reimbursement for the **alfa**pump® or the DSR® product in its key markets, this would compromise its ability to commercialise these products on a large scale, which would in turn limit its opportunities to achieve profitability.

Sequana Medical is reliant on the Neue Untersuchungs- und Behandlungsmethoden (the "NUB") (New Research and Treatment Methods) reimbursement mechanism in Germany and will seek to obtain a German Diagnosis Related Group ("G-DRG") code for the alfapump® when its operations in Germany reach sufficient scale, which may not be granted.

In Germany, medical devices are reimbursed according to G-DRG codes, but the receipt of a G-DRG code requires the submission of data collected through usage of the device in selected hospitals. To encourage entry of new medical devices into the German healthcare system, there is an intermediate reimbursement mechanism known as the NUB application that provides hospitals with financial incentives to use a new medical device before it is reimbursed under the G-DRG system. Hospitals using the new medical device must submit an application for reimbursement, which (if approved) is available only to those hospitals that applied. NUB reimbursement must be renewed each year.

Currently, Sequana Medical relies on an existing NUB reimbursement for the **alfa**pump® in Germany, which it intends to renew every year until its operations in Germany reach sufficient scale to warrant the receipt of a G-DRG code. While Sequana Medical has not experienced issues in the past with the renewal of its NUB reimbursement, it may experience such issues in the future. Furthermore, if and when Sequana Medical seeks a G-DRG code for the **alfa**pump®, it may not be granted. The Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System), which is the organisation responsible for maintaining and developing the G-DRG system, rejected the acceptance of the **alfa**pump® in the 2016 G-DRG catalogue due to a lack of peer-reviewed papers on the **alfa**pump® at the time that the proposal for inclusion were submitted. In 2021, the **alfa**pump® was again rejected for inclusion in the G-DRG catalogue due to the small number of procedures performed in selected hospitals. Even if a G-DRG code is obtained, it may not provide reimbursement adequate to enable Sequana Medical to build a profitable business selling the **alfa**pump® in Germany. Failure to obtain NUB renewals or any future failure to obtain an attractive G-DRG code may leave the **alfa**pump® without reimbursement in Germany and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump®, the DSR® product and/or any future products in target markets.

At the date of this Prospectus, the **alfa**pump® is the only product that has been commercialised by Sequana Medical. Furthermore, the **alfa**pump® has only received regulatory approval in Europe (through a CE Mark). The **alfa**pump® was launched commercially in 2012, and to date has only been commercialised in a limited number of countries. Sales of the **alfa**pump® have only generated limited revenue while Sequana Medical has been working to gain commercial market acceptance of the **alfa**pump® in target markets. The **alfa**pump®, DSR® product and/or any future products launched by Sequana Medical may not gain commercial acceptance in target markets. If Sequana Medical fails to gain and maintain commercial market acceptance of the **alfa**pump® in its focus jurisdictions of Germany, France, the United States and Canada, in particular if Sequana Medical fails to secure and maintain regulatory approval and reimbursement arrangements for the **alfa**pump® (as further described below), the amount of revenue generated from sales of the **alfa**pump® in the future could continue to be limited, and could even decrease. In addition, the DSR® product has not received marketing approval in any jurisdictions and Sequana Medical's future financial performance will depend on the successful completion of its planned clinical studies on the DSR® product and its ability to secure strategic partnerships and alliances.

Many factors can influence market acceptance of the **alfa**pump®, the DSR® product and/or any future products, including:

- approval from the appropriate regulatory authorities or unavailability of Sequana Medical's products due to regulatory barriers;
- price and reimbursement levels from third party payers;
- successful completion of the clinical development of the and the DSR® product, including the ongoing MOJAVE study;
- FDA and other target market regulatory authority's approval of Sequana Medical's proprietary DSR 2.0;
- macroeconomic conditions in the countries in which the **alfa**pump® is marketed and sold, including the impact of the COVID-19 outbreak or any similar infectious disease outbreak and the resulting restrictions on non-essential medical procedures and hospital visits and on non-essential travel for Sequana Medical's employees and consultants;
- the timing of the launch of the **alfa**pump® or DSR® product in a particular market;
- inclusion in clinical practice guidelines;
- the availability of clinical evidence through studies and registries, including the POSEIDON, RED DESERT, SAHARA and MOJAVE clinical studies;
- accurate anticipation of patients', healthcare providers' and payers' needs and emerging technology trends;
- frequency and/or severity of complications or side effects arising from the implantation of the **alfa**pump® or the DSR® product, and/or market perception of the reliability and quality of the **alfa**pump®, or the DSR® product;
- competition, the convenience and ease of use of the **alfa**pump® or the DSR® product compared to competing products and other potential advantages and disadvantages over alternative products and services;
- production barriers such as interruptions to the supply of materials or sub-components or Sequana Medical's manufacturing activities being suspended by regulatory authorities;
- limitations on approved uses of the **alfa**pump® or the DSR® product;

- the quality of service that Sequana Medical establishes in order to support customers;

- the ability to demonstrate to physicians and other potential customers the benefits and cost-effectiveness of the **alfa**pump® and the DSR® product relative to other products available on the market;

- the ability of Sequana Medical to maintain relationships with key opinion leaders in the medical community;

- entrance into additional markets or indications and the scope of the indications approved by regulatory authorities;

- tariffs, trade barriers and other trade protection measures, import or export licensing requirements and any other restrictive actions by the U.S. or other governments;

- the ability of Sequana Medical to hire new sales and marketing personnel and their effectiveness in executing its business strategy; and

- the ability of Sequana Medical to secure development and commercial partnerships for the DSR® product.

These and other factors present obstacles to commercial market acceptance of the **alfa**pump®, the DSR® product and/or any future products in target markets. Moreover, once these products gain commercial acceptance, there is a risk that they will subsequently become obsolete, due to the rapid development of technology in the sphere in which Sequana Medical operates and changes to the operations of its suppliers. Failure, or any substantial delay, in gaining significant commercial market acceptance of the **alfa**pump®, the DSR® product and/or any future products in target markets, on a timely basis or at all, or the obsolescence of any of these products could limit the revenues Sequana Medical is able to earn from sales of its **alfa**pump® and DSR® product.

The success of the alfapump®, the DSR® product and/or any future products depends on their acceptance and adoption by physicians.

The success of the **alfa**pump®, the DSR® product and/or any future products will require acceptance and adoption by physicians. Such acceptance will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of the **alfa**pump®, the DSR® product and/or any future products and being prepared to undertake special training in certain cases. Furthermore, physicians will most likely not adopt the **alfa**pump®, the DSR® product and/or any future products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that the **alfa**pump®, the DSR® product and/or any future products are an attractive treatment solution.

Even if the safety and efficacy of the **alfa**pump®, the DSR® product and/or any future products is established, physicians may be hesitant to change their medical treatment practices or accept and adopt the **alfa**pump®, the DSR® product and/or any future products, including for the following reasons:

- general conservatism about the adoption of new treatment practices;

- history of adverse events and severe adverse events;

- lack or perceived lack of long-term evidence supporting additional patient benefits;

- perceived liability risks associated with the use of new products and procedures;

- limited or lack of reimbursement and coverage within healthcare payment systems;

- cost associated with the purchase of new products and equipment;

- other procedures competing for physician time and attention;

- the fact that the **alfa**pump® is an implantable device requiring surgery for implantation;

- the time commitment that may be required for special training;
- insufficient level of commercial attractiveness to physicians;
- the extent of ongoing support required by the clinician; and
- the extent of ongoing involvement of the patient in therapy.

Economic, psychological, ethical and other concerns may also limit general acceptance and adoption of the **alfa**pump®, the DSR® product and/or any future products. Lack of acceptance and adoption of the **alfa**pump®, the DSR® product and/or any future products by a sufficient number of relevant physicians would substantially reduce Sequana Medical's ability to achieve sales estimates and prevent Sequana Medical from achieving or maintaining profitability.

Sequana Medical may not be able to manufacture or outsource manufacturing of the alfapump®, the DSR® product and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive.

Sequana Medical's revenues and other operating results will depend, in large part, on its ability to manufacture and sell the **alfa**pump®, the DSR® product and/or any future products in sufficient quantities and quality, in a timely manner, and at a cost that is economically attractive.

Although Sequana Medical has produced more than 2,500 **alfa**pump® systems at the date of this Prospectus, Sequana Medical expects to be required to significantly increase manufacturing volumes as clinical studies on the **alfa**pump®, and/or DSR® product are expanded, as the commercialisation of the **alfa**pump® is expanded and/or the DSR® product reach commercialisation, and/or as any future products undergo clinical studies or reach commercialisation. In order to support future demand for the **alfa**pump®, DSR® product and/or any future products, Sequana Medical would likely need to expand its manufacturing capacity, which could require relocating to a new facility or outsourcing to a third party contract manufacturing organisation (a "**CMO**"). Relocating to a new manufacturing facility could involve significant additional expenses, including for the construction / refurbishment of a new facility, the movement and installation of key manufacturing equipment, the modification of manufacturing processes, and for the recruitment and training of new team members. In addition, Sequana Medical must also notify, and in most cases obtain approval from, regulatory authorities of any changes or modifications to its manufacturing facility and processes, and the regulatory authorities may not authorise Sequana Medical to proceed. Any failure by Sequana Medical to expand or to outsource its manufacturing capacity to meet future demand could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Furthermore, if Sequana Medical outsources production to a CMO, the contracted CMO may not be able to manufacture Sequana Medical's products in sufficient quantities, to the same exacting standards and at an economically attractive cost, or at all. In all of these cases, the commercialisation of the **alfa**pump®, the DSR® product and/or any future product may be material and adversely affected, which could prevent Sequana Medical from achieving or maintaining profitability.

Sequana Medical manufactures the **alfa**pump® according to manufacturing best practices applicable to medical devices and to specifications approved by the applicable regulatory authorities. If the **alfa**pump® is found to be non-compliant, Sequana Medical would be required to manufacture the **alfa**pump® again, which would entail additional costs and may prevent delivery of the **alfa**pump® to patients on time.

In addition, Sequana Medical's current business expectation is that the cost of goods sold will decline over time as the cumulative volume manufactured grows. However Sequana Medical and/or its suppliers may be unable to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, which could prevent Sequana Medical from achieving or maintaining profitability.

If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the alfapump®, DSR® product and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner, Sequana Medical may not be successful in commercialising the alfapump®, DSR® product and/or any future products in its target markets, if and when they are approved.

Sequana Medical will need to expand its internal sales and marketing organisation to commercialise the **alfa**pump®, the DSR® product and/or any future products in markets that it will target directly. There are risks involved with expanding Sequana Medical's own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay launch. In addition, Sequana Medical may experience challenges in recruiting qualified sales and marketing personnel.

Furthermore, Sequana Medical intends to enter into additional distribution agreements to distribute its products in other markets. If Sequana Medical is unable to find suitable distribution partners, loses these distribution partners or if Sequana Medical's distribution partners fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialisation of the **alfa**pump®, the DSR® product and/or any future products could be materially harmed, which could prevent Sequana Medical from achieving or maintaining profitability.

Further factors that may inhibit Sequana Medical's efforts to commercialise the **alfa**pump®, the DSR® product and/or any future products in target markets include the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any of Sequana Medical's future products, and the lack of complementary products to be offered by sales personnel, which may put Sequana Medical at a competitive disadvantage relative to companies with more products.

If Sequana Medical is unable to expand its own sales, marketing and distribution capabilities or enter into arrangements with other third parties to perform these services, Sequana Medical's revenue and profitability may be negatively affected.

7. Risks relating to intellectual property

Any inability to fully protect and exploit Sequana Medical's intellectual property may adversely impact Sequana Medical's financial performance and prospects.

Sequana Medical's patent portfolio consists of 78 patents granted across 20 patent families and a further 20 patent applications pending. Sequana Medical's products, and methods of use thereof, are covered by patents in the United States under 35 U.S.C. §287(a), including one or more of the following: the alfapump® system 7909790, 9039652, 9149613, 10252037, 11235131; DSR® 10898631, 10918778, 11559618; alfapump DSR® 9956336, 10569003, 11464891, 11602583. Sequana Medical also has international equivalent patent coverage. In addition to patents, it relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help maintain and develop its competitive position with respect to intellectual property. Sequana Medical may be unable to obtain the patents it applies for or to adequately protect its intellectual property rights or may become subject to a claim of infringement or misappropriation, which it is unable to settle on commercially acceptable terms. Although the first patents in connection with the DSR and **alfa**pump DSR® have been granted in the United States and Europe, Sequana Medical cannot be certain that patents will be issued with respect to Sequana Medical's pending or future patent applications. In addition, Sequana Medical does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

Sequana Medical's intellectual property rights may also be challenged, invalidated, circumvented or rendered unenforceable. Sequana Medical's competitors or other third parties may successfully challenge and invalidate or render unenforceable Sequana Medical's issued patents, including any patents that may be issued in the future. This could prevent or limit Sequana Medical's ability to stop competitors from marketing products that are identical or substantially equivalent to the **alfa**pump®, the DSR® product and/or any future products. In addition, competitors may be able to design around Sequana Medical's patents or develop products that provide outcomes that are comparable to the **alfa**pump®, the DSR® product and/or any future products but that are not covered by Sequana Medical's patents. Much of Sequana Medical's value is in its intellectual property, and any challenge to Sequana Medical's intellectual property portfolio (whether successful or not) may impact its value. Non-specific claims of inventorship have been made with respect to the **alfa**pump® and the DSR® product by a

former officer and director of Sequana Medical, but these were non-specific and no evaluation thereof could be made.

Sequana Medical decides on a case by case basis the countries in which to seek patent protection. It is not economically feasible or practical to seek patent protection in every country, and it is possible that one or more third parties may develop and market devices similar or identical to the **alfa**pump®, the DSR® product and/or any future products in countries where Sequana Medical has not obtained patent protection. Sequana Medical may not be able to prevent such third party action, which may limit Sequana Medical's ability to pursue those markets.

Finally, the Kreos Loan Agreement which the Company entered into with Kreos Capital in July 2022 is secured by a pledge of collateral which includes Sequana Medical's intellectual property rights. If the Company were to default on the loan, this would entitle Kreos Capital to enforce its security over these intellectual property rights, which would cause the Company to lose control over its intellectual property, thereby severely restricting its operations. For more information, see *"Business Overview"* and *"Material contracts"*, subsection "*Kreos Loan Agreement*".

Sequana Medical could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require Sequana Medical to pay damages, prevent Sequana Medical from marketing the alfapump®, the DSR® product and/or any future products, and/or reduce the margins for the alfapump®, the DSR® product and/or any future products.

The medical device industry is characterised by rapidly changing products and technologies and there is intense competition to establish intellectual property and proprietary rights covering the use of these new products and the related technologies. This vigorous pursuit of intellectual property and proprietary rights has resulted and will continue to result in extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the outcome of such disputes is often uncertain. There may be existing patents of which Sequana Medical is unaware that are inadvertently infringed by the **alfa**pump®, the DSR® product and/or any future products. Competitors may have or develop patents and other intellectual property that they assert are infringed by the **alfa**pump®, the DSR® product and/or any future products.

Any infringement claim against Sequana Medical, even if without merit, may cause Sequana Medical to incur substantial costs, and could place a significant strain on Sequana Medical's financial resources and/or divert the time and efforts of management from the conduct of Sequana Medical's business. In addition, any intellectual property litigation could force Sequana Medical to do one or more of the following: (i) stop selling the **alfa**pump®, the DSR® product and/or any future products or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license Sequana Medical's technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights Sequana Medical may be found to be infringing; or (iv) redesign those products that contain or utilise the allegedly infringing intellectual property. Any of these circumstances may materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

The requirement to obtain licenses to third party intellectual property could also arise in the future. If Sequana Medical needs to license any third party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, if Sequana Medical is required to obtain licenses to third party intellectual property, it may not be able to obtain such licenses on commercially reasonable terms or at all.

Intellectual property rights do not necessarily address all potential threats to Sequana Medical's competitive advantage.

The degree of protection afforded by Sequana Medical's intellectual property rights is uncertain because intellectual property rights are limited, and may not adequately protect Sequana Medical's business or permit it to maintain its competitive advantage or its ability to sell its products. For example:

- others may be able to develop, make and sell products that are similar to or different from products that deliver similar therapeutic benefits to the **alfa**pump®, the DSR® product and/or any future products without infringing claims of the Sequana Medical patents or other Sequana Medical intellectual property rights;

- pending patent applications may not lead to issued patents;
- issued patents may not provide Sequana Medical with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges;
- Sequana Medical's competitors might conduct research and development activities in countries where Sequana Medical does not have patent rights and sell the resulting competitive products in such countries, or use the information learned from such activities to develop competitive products for sale in major commercial markets;
- Sequana Medical may develop intellectual property that is not patentable; and/or
- the patents of others may dominate the patents of Sequana Medical, thereby preventing their use, or have an adverse effect on Sequana Medical's business.

8. Risks relating to business activities

Security breaches and other disruptions could compromise Sequana Medical's information and expose Sequana Medical to liability, which would cause Sequana Medical's business and reputation to suffer.

Sequana Medical's **alfa**pump® collects and stores confidential and sensitive information. This information includes, among other things, data from patients using the **alfa**pump®. It is important to Sequana Medical that this information remains secure and is perceived to be secure. Despite security measures, however, Sequana Medical's information technology ("**IT**") and network infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such attack or breach could compromise Sequana Medical's networks and stored information could be accessed, publicly disclosed, lost, stolen, corrupted or hijacked. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, delays and impediments to Sequana Medical's development efforts, and damage to Sequana Medical's reputation. Furthermore, the loss of pre-clinical or clinical study data from completed, ongoing or planned studies could result in delays in Sequana Medical's regulatory approval efforts and significantly increase Sequana Medical's costs to recover or reproduce the data. In addition, Sequana Medical may rely on third parties to store confidential and sensitive information and it is important that these third parties also take adequate measures to secure this information.

In addition, the introduction of the EU General Data Protection Regulation (the "**GDPR**") has resulted in additional obligations in relation to the use of customer data. The GDPR is a comprehensive update to the data protection regime in the EEA that became effective in May 2018 and imposes new requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third party processors. If Sequana Medical or the third parties on which it relies fails to comply with these standards, Sequana Medical could be subject to criminal penalties and civil sanctions, including fines and penalties for non-compliance with the GDPR, which provides for fines of up to EUR 10 million or up to 2% of the relevant company's global turnover in the preceding fiscal year, whichever is higher. Any such fines could be material for Sequana Medical, given the relatively limited scale of its operations.

Information technology forms a key support requirement within Sequana Medical's business. Any failure of Sequana Medical's IT systems could present a substantial risk to its business continuity.

The efficient operation of Sequana Medical's business and the use of the **alfa**pump® and the DSR® product depend on IT systems. Sequana Medical relies on its information technology systems for the collection of pump performance data using DirectLink technology and to effectively manage its marketing, accounting and financial functions, manufacturing processes, and its development functions. The regulatory and legal environment of Sequana Medical's industry requires Sequana Medical to maintain records for long periods of time, sometimes forever. In most cases, those records are kept in electronic form, and without paper copies.

Sequana Medical uses third party suppliers to provide computing, communication, data storage and backup services, and failure of any of those third party suppliers may have an adverse effect on Sequana Medical's ability to operate. Although industry standard practices are in place for regular information backup, failure of Sequana Medical's IT systems infrastructure may result in the inability to continue business until the

records are recreated. These events could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's employees and contractors may also work from home offices, in particular employees or contractors who need to be close to the customer base to enable rapid support (for example, field clinical specialists). This requires strong IT infrastructure support (telephone, e-mail, internet access), which must be continuously maintained. Sequana Medical's employees frequently utilise portable computers, smartphones, and tablets. Loss, theft or damage to a portable computer, smartphone, or tablet could result in loss of key information (in some cases to a competitor). Any failure in Sequana Medical's IT infrastructure or loss of critical information could cause reputational harm for Sequana Medical and/or could result in it becoming liable to patients or other third parties.

9. Risks relating to surgical procedures

Active implantable medical devices such as the alfapump® carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.

The **alfa**pump® is a medical device with complex electronic circuits and software. It is not possible to design and build electronic medical devices that are 100% reliable, as all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks and the effectiveness of any medical therapy varies between patients. The consequences of failure of the **alfa**pump®, complications arising through product use and associated surgical procedures can range from minor to life-threatening effects and even death.

All medical devices have associated risks. Regulatory authorities regard AIMDs as the highest risk category of medical devices, and accordingly, AIMDs are subject to the highest level of scrutiny when seeking regulatory approval. The risks include, among others, risks associated with any surgical procedure, such as infection, allergic reaction, and consequences of anaesthesia and risks associated with any implantable medical device such as device movement, electromagnetic interference, device failure, tissue damage including nerve damage, pain, psychological effects and death. Comprehensive lists of the risks associated with the **alfa**pump® are included in the documentation (labelling) provided with the device to both physicians and patients. Prior clinical studies involving treatment with the **alfa**pump® have resulted in patients experiencing serious adverse events, including renal dysfunction and infection.

Adverse events associated with these risks may lead some patients to blame Sequana Medical, the physician or other parties for such occurrences. This may result in product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, criminal charges or other harmful circumstances for Sequana Medical. Any of those circumstances may have a material adverse effect on Sequana Medical's ability to conduct its business, to continue selling the **alfa**pump®, to achieve revenue objectives, or to develop the DSR® product and/or future products.

10. Risks relating to the market in which Sequana Medical operates

Competition from medical device companies, pharmaceutical and biotechnology companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.

Sequana Medical may face intense competition from a number of companies that offer solutions and technologies in its target markets and competitors may develop new products or adapt existing products for the same patients that Sequana Medical targets with the **alfa**pump®, the DSR® product and/or any future products. Sequana Medical may not be able to compete successfully against its current and future competitors, including competitors with more resources and experience.

Any competitors' products currently in clinical studies or in development or developed in the future could have superior clinical results, could be easier to implement clinically, could be more convenient for patients and/or less expensive than the **alfa**pump®, the DSR® product and/or any future products or could reach commercialisation sooner in certain target markets. In addition, products are generally provided at no charge during clinical studies. Entry by a competitive product into clinical studies while the **alfa**pump®, the DSR® product and/or any future products are being commercialised could have an adverse effect on Sequana Medical's sales. Such occurrences could adversely affect Sequana Medical's ability to generate sufficient revenues to sustain its business and/or prevent Sequana Medical from achieving or maintaining profitability.

For the treatment of liver ascites, there are a number of products in development for non-alcoholic steatohepatitis ("**NASH**"), many of which are being developed by pharmaceutical companies that are far larger, with significantly greater resources than Sequana Medical. It is not clear how these new therapeutics may impact Sequana Medical's target markets, and if any of these products effectively prevent the development of NASH-related ascites, the **alfa**pump® may be rendered non-competitive or obsolete for the treatment of ascites resulting from NASH.

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrolment in Sequana Medical's clinical studies. Sequana Medical may successfully conclude its clinical studies and obtain regulatory approval, but may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication. Alternative treatments include drugs, devices and surgery, among others. New treatment options, or modifications of existing treatments, may emerge which yield clinical results equal to or better than those achieved with the **alfa**pump®, the DSR® product and/or any future products, possibly at a lower cost. Emergence of such new therapies may inhibit Sequana Medical's ability to develop and grow the market for the **alfa**pump®, the DSR® product and/or any future products. Furthermore, new entrants into the markets in which Sequana Medical operates could also decide to more aggressively compete on price, requiring Sequana Medical to reduce prices in an effort to maintain market share.

Risks relating to the New Shares

An active market for the Shares may not be sustained.

An active trading market for the New Shares may not develop (as the case may be, following their issuance), and the existing active trading market for the Shares may not be sustained or may not be sufficiently liquid. If an active trading market is not developed or sustained, as the case may be, the liquidity and trading price of the Shares (including New Shares) could be adversely affected.

The average daily trading volume of the Shares was equal to 5,618 in June 2023, 13,412 in May 2023 and 35,050 in April 2023.

The market price of the Shares may fluctuate widely in response to various factors and the market price of the Shares may be adversely affected by such factors.

Publicly traded securities from time to time experience significant price and trading volume fluctuations that may be unrelated to the results of operations or the financial condition of the companies that have issued them. These market shifts may be more pronounced in the medtech market than in the broader market because the medtech market is considered to be riskier and may react more strongly to perceptions of market shifts.

In addition, the market price of the Shares has historically been volatile, ranging from a high of EUR 12.40 on 4 January 2021 (with a daily trading volume of 86,958) and a low of EUR 2.83 on 12 May 2023 (with a daily trading volume of 36,168). The market price of the Shares may continue to fluctuate significantly in response to a number of factors, many of which are beyond Sequana Medical's control, including the following:

- continued macroeconomic, geopolitical and market turbulence, which may disrupt financial markets, including the impact of the ongoing conflict in Eastern Europe, the impact of major macroeconomic events (e.g. measures taken by central banks to contain inflation) and the further impact of the outbreak of the 2019 coronavirus (COVID-19) on Sequana Medical's clinical studies and on its business generally;

- announcements of technological innovations, clinical data in relation to existing or new products or collaborations by Sequana Medical or its competitors;

- market expectations for Sequana Medical's financial performance;

- actual or anticipated fluctuations in Sequana Medical's business, results of operations and financial condition;

- changes in the estimates of Sequana Medical's results of operations, downgrades of recommendations, or cessation of publication of research reports on Sequana Medical by securities analysts;

- potential or actual sales of blocks of the Shares in the market or short selling of the Shares, future issues or sales of the Shares, which may drive the trading price of the Shares down, stock market price, volume fluctuations in general, as well as volatility and instability in the market as a whole, which may have greater effects on the price of the Shares when liquidity in trading of the Shares is limited;

- the entrance of new competitors or new products in the markets in which Sequana Medical operates, which may impact the success of Sequana Medical's products and market acceptance, and hence may adversely affect the Company's prospects and business, or investor perception of Sequana Medical's markets and competitors;

- volatility in the market as a whole or investor perception of Sequana Medical's markets, industries, and competitors;

- changes in market valuation of similar companies;

- announcements by Sequana Medical or its competitors of significant contracts;

- loss of major partners or customers;

- acquisitions, strategic alliances, joint ventures, capital commitments or new products or services, which may be too costly, or may not be successful and hence adversely impact the Sequana Medical's prospects and business, which may lead to disruptions in the Sequana Medical's operations, particularly as the Sequana Medical's reliance on intellectual property and marketing efforts rely on qualified personnel and team work;

- additions or departures of key personnel, in view of the need of qualified intellectual property, medical and/or other specialized personnel;

- litigation, which is specifically targeting Sequana Medical or its products may impact Sequana Medical's prospects, business or financial condition;

- developments regarding intellectual property rights, including patents and infringements, particularly as Sequana Medical's business relies on intellectual property;

- regulatory, pricing and reimbursement developments in Europe, the United States and other jurisdictions, and new government regulation in general;

- general economic, financial and political conditions, considering the current macro-economic and political conditions and projections of specialists for the foreseeable future; and

- the risk factors relating to Sequana Medical's business and industry.

The market price of the Shares (including the New Shares) may be adversely affected by the preceding and/or other factors regardless of Sequana Medical's actual results of operations and financial condition.

In addition, stock markets have in the recent past experienced significant declines and price and trading volume fluctuations, particularly as a result of the outbreak of the 2019 coronavirus (COVID-19) and international geopolitical instability on the macroeconomic outlook. These fluctuations have not always been related to the performance of the specific companies whose shares are traded. These fluctuations, as well as general economic and political conditions, could have an adverse effect on the market price of the Shares (including the New Shares).

Future sales of substantial amounts of the Shares, or the perception that such sales could occur, could adversely affect the market value of the Shares.

Any sale of a significant number of the Shares (including the New Shares) on the public markets, notably by one of its major shareholders, or the perception that such sales could or will occur, may adversely affect the market price of the Shares (including the New Shares). The Company cannot make any predictions as to the sale or perception on the market price of the Shares (including New Shares). On the date of this Prospectus, the Company is not aware of any intentions of existing shareholders to sell substantial numbers of Shares. For an overview of the shareholders that notified the Company pursuant to applicable transparency disclosure rules and the articles of association of the Company, up to the date of this Prospectus, reference is made to chapter "Major Shareholders", section "*Overview of the Company's shareholder structure*".

Furthermore, in the context of the Private Placement, the Company has entered into a standstill undertaking with the Underwriters (defined below) for a period of 180 days as from 27 April 2023. For more information about this standstill undertaking, reference is made to chapter "*General information*", section "*Standstill Undertaking*".

In the context of the Private Placement, the Company's Chief Executive Officer and Chief Financial Officer have entered into lockup arrangements with the Underwriters (defined below) for a period of 180 days as from 27 April 2023. For more information about these lockup arrangements, reference is made to chapter "General information", section "*Lockup Arrangements*".

The Company will likely not be in a position to pay dividends in the near future and intends to retain all earnings.

The Company has not declared or paid dividends on the Shares in the past. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the board of directors.

Belgian law and the Company's articles of association do not require the Company to declare dividends. Currently, the board of directors of the Company expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

At the date of this Prospectus, the Subordinated Loan Agreements entered into with PMV-Standaardleningen (formerly known as PMV/z) in July 2020 and most recently amended in March 2023, also include restrictive covenants, which may limit the Company's ability (and require PMV-Standaardleningen 's prior consent) to make distributions by way of dividends or otherwise for so long as any monies or obligations, actual or contingent, are outstanding under the aforementioned loan agreements. Furthermore, under the Kreos Loan Agreement, no distributions by way of dividend may be declared or made without the consent of Kreos Capital (other than the payment of a dividend to the Company by any of its directly or indirectly wholly owned subsidiaries). For more information about these loan agreements, reference is made to the chapter "*Business Overview*", section "Material contracts" subsections "Subordinated Loan Agreements" and "*Kreos Loan Agreement*". Additional financial restrictions and other limitations may be contained in future credit agreements.

For more information about the Company's dividend policy, reference is made to the chapter "*New Shares*", section "*Rights attached to the New Shares*", subsection "*Voting rights attached to the New Shares*", part "*Dividends*" as well as section to 2.15.4. of the corporate governance statement on p. 129 of the 2022 Annual Report (as defined below) (incorporated by reference in this Prospectus). The Company's dividend policy may change from time to time by determination of the Company's board of directors.

Certain significant shareholders of the Company may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.

The Company has a number of significant shareholders. For an overview of the shareholders that notified the Company pursuant to applicable transparency disclosure rules and the articles of association of the Company, up to the date of this Prospectus, reference is made to chapter "*Major Shareholders*", section "*Overview of the Company's shareholder structure*".

On the basis of the transparency notifications received by the Company as at the date of this Prospectus, the largest shareholders include (a) Partners in Equity V B.V., (b) Société Fédérale de Participations et d'Investissement SA/Federale Participatie- en Investeringsmaatschappij NV and Belfius Insurance NV/SA, (c) NeoMed IV Extension L.P., NeoMed Innovation V L.P. and Erik Amble, (d) LSP Health Economics Fund Management B.V., (e) Rosetta Capital Ltd, and (f) Participatiemaatschappij Vlaanderen NV. The aforementioned Shares held by these shareholders represent together 60.13% of the voting rights attached to the Shares. The Company is not aware of shareholders of the Company that have entered into a shareholders' agreement or have agreed to act in concert. Nevertheless, the aforementioned shareholders could, alone or together, have the ability to elect or dismiss directors, and, depending on how widely the Shares are held, and depending at the number of Shares represented at the general shareholders' meetings of the Company, take certain shareholders' decisions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 50%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

Furthermore, within the framework of the Private Placement, the Company agreed that, provided that the closing of the Private Placement occurred, and existing shareholders PiE and Rosetta complied with certain subscription commitments (which effectively occurred on 27 April 2023 and 10 May 2023), the Company would propose to the Company's general shareholders' meeting to appoint respectively Mr Ids Van der Weij (a representative of PiE and currently observer to the Company's board of directors) and Dr Kenneth Macleod (a representative of Rosetta) as director of the Company. Dr Macleod's appointment as director was approved by the Company's shareholders' meeting on 26 June 2023. Mr Van der Weij's appointment as director still needs to be submitted to the Company's shareholders' meeting. The Company currently intends to submit this proposal to the Company's annual general shareholders' meeting to be held in 2024 (but it may also submit it to the extent a special or extraordinary general shareholders' meeting were to be held at an earlier occasion). PiE and Rosetta acknowledged that as soon as they cease to own 4% of the outstanding shares in the Company, they shall cause their representatives to resign from any and all of their corporate functions and mandates within the Company when so requested by the Company's board of directors.

Any future capital increases by the Company could have a negative impact on the price of the Shares and could dilute the interests of existing shareholders.

Sequana Medical announced on 25 April 2023 that it had successfully raised an amount of EUR 15.78 million in gross proceeds by means of a private placement of new shares and subscription rights (at a ratio of one new subscription right per four new shares) via an accelerated bookbuild offering of 4,445,205 new shares (being approximately 15.77% of the Company's outstanding shares) at an issue price of EUR 3.55 per new share and 1,111,294 new subscription rights (if exercised into 1,111,294 new shares, representing approximately 3.94% of the Company's outstanding shares) at an exercise price of EUR 5.10 per underlying new share. The aforementioned share issue resulted in a direct dilution of 15.77% of the then existing shareholders of the Company and of the relative voting power of each share in the Company at that time. For more information about the consequences of the Private Placement for the financial and shareholder rights of the shareholders of the Company, reference is made to the report of the board of directors in accordance with article 7:198 *juncto* articles 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code. This board report must be read together with the report prepared by the Company's statutory auditor, PwC Bedrijfsrevisoren BV, represented by Mr. Peter D'hondt, auditor, in accordance with article 7:198 *juncto* article 7:179, 7:180, and 7:191 of the Belgian Companies and Associations Code. The aforementioned reports are available on the Company's website at https://www.sequanamedical.com/wp-content/uploads/2023/06/Sequana-Project-Stuart-Board-Report-Warrant-Conditions.pdf for the report of the board of directors and at https://www.sequanamedical.com/wp-content/uploads/2023/05/Audit-Report-ENG.pdf for the report of the statutory auditor, and are incorporated by reference in this Prospectus.

Taking into account that the Company's ability to continue operations depends on its ability to raise additional capital and to refinance existing debt in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows, the Company continues to evaluate equity and debt financing options. The Company may in the future increase its share capital against cash or contributions in kind to finance any future acquisition or other investment or to strengthen its balance sheet. The

Company may also issue subscription rights that are exercisable for new shares, or raise capital through public or private offerings of convertible debt or equity securities, or rights to acquire these securities. In connection with such transactions, the Company may, subject to certain conditions, limit or dis-apply preferential subscription rights of existing shareholders otherwise applicable to capital increases through contributions in cash. In addition, preferential subscription rights do not apply to capital increases through contributions in kind. Such transactions could therefore dilute the stakes in the Company's share capital held by shareholders and could have a negative impact on the price of the Shares (including the New Shares). For more information about the working capital and the need for additional funds, reference is made to the risk factor "*Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs*" and the chapter "*Capitalisation and Indebtedness*", section "*Working capital statement*".

Investors resident in countries other than Belgium may suffer dilution if they are unable to participate in future preferential subscription rights offerings.

IMPORTANT INFORMATION

Responsibility statement

In accordance with article 26 of the Belgian Prospectus Act, the Company, represented by its board of directors, assumes responsibility for the information contained in this Prospectus. The Company, represented by its board of directors, declares that, to the best of its knowledge, the information contained in this Prospectus is in accordance with the facts and contains no omission likely to affect its import.

Prospectus approval

As competent authority under the Prospectus Regulation, the FSMA approved the English language version of this Prospectus on 26 July 2023 in accordance with article 20 of the Prospectus Regulation. The FSMA's approval does not imply any opinion by the FSMA on the suitability and the status of the New Shares or on the status of the Company, nor as an endorsement of the Company or of the quality of the New Shares. The FSMA only approves this Prospectus as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Investors should make their own assessment as to the suitability of investing in the New Shares.

Pursuant to articles 12(1) and 21(8) of the Prospectus Regulation, this Prospectus shall be valid until 26 July 2024, which is 12 months after its approval for admission of the New Shares to trading on the regulated market of Euronext Brussels, provided that it is completed by any supplement required pursuant to article 23 of the Prospectus Regulation and that not more than 3,280,307 New Shares are admitted to listing and trading on Euronext Brussels pursuant to this Prospectus. Any New Shares to be issued (upon exercise of Subscription Rights) after the expiration of the aforementioned 12 months' period (*i.e.*, after 26 July 2024) will not be admissible to listing and trading on Euronext Brussels pursuant to this Prospectus. The obligation to supplement this Prospectus in the event of significant new factors, material mistakes or material inaccuracies does not apply when this Prospectus is no longer valid.

Simplified disclosure regime

This Prospectus has been drawn up as a simplified prospectus in accordance with article 14 of the Prospectus Regulation.

Supplements to the Prospectus

This Prospectus has been prepared for the purposes of the admission of the New Shares to listing and trading on the regulated market of Euronext Brussels. The information in this Prospectus is as of the date printed on the front cover, unless expressly stated otherwise. The delivery of this Prospectus at any time does not imply that there has been no change in Sequana Medical's business or affairs since the date hereof or that the information contained herein is correct as of any time subsequent to the date hereof. In accordance with article 23 of the Prospectus Regulation, in the event of a significant new factor, material mistake or material inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the New Shares during the period from the date of approval of the Prospectus and the time when trading of the New Shares on Euronext Brussels begins, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus, and must be made public in the same manner as this Prospectus. Statements contained in any such supplement (or contained in any document incorporated by reference therein) shall, to the extent applicable (whether expressly, by implication or otherwise), be deemed to modify or supersede statements contained in this Prospectus. Any statement so modified or superseded shall, except as so modified or superseded, no longer constitute a part of this Prospectus.

Language versions

This Prospectus (including the summary) has been prepared in English and translated into Dutch. The Company is responsible for the consistency between the Dutch and English language versions of the Prospectus. Investors can rely on the Dutch language version of this Prospectus in their contractual relationship with the Company. In any event, in the case of discrepancies between the different language versions of this Prospectus, the English language version will prevail.

Availability of this Prospectus

This Prospectus is available in Belgium at no cost at the Company's registered office, located at Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium.

Subject to country restrictions, the Prospectus is also available under the 'Investors' section on the following website: www.sequanamedical.com.

The posting of the Prospectus or any summary thereof on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the Company's securities (including the New Shares and the Subscription Rights) to or from any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Although certain references are made to the Company's website, information on the Company's website (www.sequanamedical.com) (other than the Prospectus or any documents incorporated by reference therein) or any other website does not form part of the Prospectus and has not been scrutinised or approved by the competent authority. This Prospectus is valid only if circulated in accordance with applicable law.

The distribution of this Prospectus may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorised or to any person to whom it is unlawful to make such offer or solicitation.

The Company requires persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. The Company does not accept any legal responsibility for any violation by any person of any such restrictions.

Further information regarding the Company

The Company was initially incorporated as a limited liability company organised in the form of an Aktiengesellschaft/société anonyme under the laws of Switzerland. In 2018, its registered office was transferred from Switzerland to Belgium.

The Company must file its restated articles of association and all other deeds and resolutions that are to be published in the Annexes to the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur Belge*) with the clerk's office of the enterprise court of Ghent, division Ghent, where they are available to the public. The Company is registered with the legal entities register (Ghent, division Ghent) under enterprise number 0707.821.866. A copy of the Company's most recently restated articles of association (incorporated by reference in this Prospectus) and corporate governance charter are also available on its website (under the 'Investors' section) free of charge.

In accordance with Belgian law, the Company must prepare audited annual statutory and consolidated financial statements. The annual statutory and consolidated financial statements and the reports of the Company's board of directors and statutory auditor relating thereto must be filed with the National Bank of Belgium, where they are available to the public. Furthermore, as a company with shares listed on the regulated market of Euronext Brussels, the Company is also required to publish an annual financial report (which includes its audited condensed statutory financial statements and audited consolidated financial statements, the report of its board of directors and the report of the statutory auditor) and an annual announcement preceding the publication of the annual financial report, as well as a half-yearly financial report on the first six months of its financial year (which includes a condensed set of financial statements and an interim management report). Copies of these documents will be made available on the Company's website (under the 'Investors' section) and on STORI, the Belgian central storage mechanism, which is operated by the FSMA and can be accessed via stori.fsma.be or www.fsma.be.

The Company must also disclose inside information, information about its shareholder structure and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007 on the obligations of issuers of financial instruments that are admitted to trading on a regulated market and Regulation (EU) 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, as amended from time to time (the "**Market Abuse Regulation**") and related rules, as amended from time to time, such information and documentation is made available through the Company's website, press releases, the communication channels of Euronext Brussels, on STORI, or a combination of these means. All press releases published by the Company are made available on its website.

The Company can be contacted by phone (+32 (0) 498 05 35 79), email (IR@sequanamedical.com) or via the contact form available on Sequana Medical's website (www.sequanamedical.com/contacts/).

NOTICE TO INVESTORS

This Prospectus is intended to provide information to potential investors in the context of and for the sole purpose of evaluating a possible investment in the New Shares. It contains selected and summarised information (including information incorporated by reference). It does not express any commitment or acknowledgement or waiver, and does not create any right, express or implied, towards anyone other than a potential investor. Investors must assess, with their own advisers if necessary, whether the Company's Shares are a suitable investment for them, considering their personal income and financial situation. In case of any doubt about the risks involved in investing in the Shares, investors should abstain from investing in the Shares.

In making an investment decision, investors must rely on their own assessment, examination, analysis and enquiry of Sequana Medical, the terms of the admission of the New Shares to listing and trading on the regulated market of Euronext Brussels, and the contents of this Prospectus, including the merits and risks involved. Any purchase of Shares should be based on the assessments that an investor may deem necessary and including possible tax consequences that may apply, before deciding whether or not to invest in the Shares. In addition to their own assessment of Sequana Medical and the terms of the admission of the New Shares to listing and trading on the regulated market of Euronext Brussels, investors should rely only on the information contained in this Prospectus, including the risk factors described herein.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in the Prospectus may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the New Shares.

The Company, or any of its respective representatives, is not making any representation to any purchaser of Shares regarding the legality of an investment in the Shares by such purchaser under the laws applicable to such purchaser. Each investor should consult with its own advisers as to the legal, tax, business, financial and related aspects of a purchase of the Shares.

No person has been authorised to give any information or to make any representation in connection with the admission of the New Shares to listing and trading on the regulated market of Euronext Brussels, other than those contained in this Prospectus, and, if given or made, such information or representation must not be relied upon as having been authorised. Without prejudice to the Company's obligation to publish supplements to the Prospectus when legally required (as described above), neither the delivery of this Prospectus nor any sale of Shares made at any time after the date hereof shall, under any circumstances, create any implication that there has been no change in Sequana Medical's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since such date.

NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED STATES

This Prospectus is not for distribution, directly or indirectly, in or into the United States. It does not constitute or form a part of any offer or solicitation to purchase or subscribe for New Shares in the United States. The New Shares have not been and will not be registered under the Securities Act and may not be offered or sold in the United States unless registered under the Securities Act, or an exemption from the registration requirements of the Securities Act is available. The Company and its affiliates have not registered, and do not intend to register, the New Shares under the Securities Act, and do not intend to conduct a public offering of the New Shares in the United States.

NOTICE TO PROSPECTIVE INVESTORS IN THE EUROPEAN ECONOMIC AREA

This document is addressed to, and directed in, member states of the EEA (each, a "**Member State**") at persons who are 'qualified investors' within the meaning of article 2(e) of the Prospectus Regulation ("**Qualified Investors**"), but also to any other natural or legal persons that have invested, or intend to invest, in the Company's Shares (including the New Shares), it being noted that the Private Placement was only addressed to and directed at persons in the EEA who were Qualified Investors.

NOTICE TO PROSPECTIVE INVESTORS IN THE UNITED KINGDOM

In the United Kingdom this document is being distributed only to, and is directed only at, (i) persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended from time to time (the "**Order**"), (ii) high net worth entities etc. falling within Article 49(2)(a) to (d) of the Order, and (iii) any other person to whom it may otherwise lawfully be communicated (all such persons together being referred to as "**Relevant Persons**"). This document must not be acted on or relied on (i) in the United Kingdom, by persons who are not Relevant Persons, and (ii) in any member state of the EEA, by persons who are not qualified investors. Any investment or investment activity to which this document relates is available only to (a) Relevant Persons in the United Kingdom and will be engaged in only with Relevant Persons in the United Kingdom and (b) qualified investors in member states of the EEA.

NOTICE TO PROSPECTIVE INVESTORS IN THE SWITZERLAND

None of the Company's securities (including the New Shares and the Subscription Rights) were publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act ("**FinSA**") except to professional investors in accordance with and under the exemption of article 36(1)(a) FinSA. No application has been or will be made to admit the Company's securities (including the New Shares and the Subscription Rights) to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Company's securities (including the New Shares and the Subscription Rights) constitutes a prospectus or a similar communication as such terms are understood pursuant to articles 35 et seqq. and article 69 of the FinSA.

Neither this Prospectus nor any other offering or marketing material relating to the Private Placement, the Company or the Company's securities (including the New Shares and the Subscription Rights) have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with a Swiss prospectus review body and the offer of New Shares and Subscription Rights in the framework of the Private Placement has not been supervised by the Swiss Financial Market Supervisory Authority FINMA. Neither the Company's securities (including the New Shares and the Subscription Rights) nor the Private Placement have been, nor will they be, authorized under the Swiss Federal Act on Collective Investment Schemes ("**CISA**"). Accordingly, the investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of the Company's securities (including the New Shares and the Subscription Rights).

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Financial statements

This Prospectus contains references to the audited consolidated financial statements of the Company as of and for the year ended 31 December 2022 (the "**Annual Financial Statements**"). The Annual Financial Statements were prepared in accordance with the International Financial Reporting Standards, as adopted by the European Union ("**IFRS**").

The Annual Financial Statements have been audited by the Company's statutory auditor, which is PwC Bedrijfsrevisoren BV, a private company with limited liability organised and existing under the laws of Belgium, registered with the Belgian Institute of Registered Auditors (*Instituut van de Bedrijfsrevisoren/Institut des Réviseurs d'Entreprises*), with office address at Culliganlaan 5, 1831 Machelen, Belgium, represented by Mr. Peter D'hondt.

The statutory auditor issued an unqualified opinion in the statutory auditor's report on the Annual Financial Statements, which should be read in conjunction with the Annual Financial Statements. The opinion included a note with regard to material uncertainty related to the Company's going concern, referring to the fact that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals, and that it is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability, and that the Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The opinion also clarified that the impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear.

The Annual Financial Statements, as well as the audit report in relation to the Annual Financial Statements, have been included in this Prospectus (by reference) with the consent of PwC Bedrijfsrevisoren BV.

Rounding

Certain monetary amounts and other figures included in this Prospectus have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

Other Information

In this Prospectus, references to the "Company" are to Sequana Medical NV, and references to "Sequana Medical", "we," "us" or "our" are to the Company, its consolidated subsidiaries, Sequana Medical GmbH (Germany) and Sequana Medical US Inc. (the U.S.), and its branch in Switzerland.

In this Prospectus, references to "euro", "EUR" or "EUR" are references to the euro, the single currency of the participating member states in the Third Stage of European Economic and Monetary Union of the Treaty Establishing the European Community, as amended from time to time; references to "Swiss franc" or "CHF" are references to the Swiss franc, the lawful currency of Switzerland and Liechtenstein; references to "U.S. Dollar", "USD", "US$" or "$" are references to the U.S. Dollar, the lawful currency of the U.S.; references to "pound sterling", "U.K. pound sterling", "GBP" or "£" are references to the pound sterling, the official currency of the United Kingdom, Jersey, Guernsey, the Isle of Man, South Georgia and the South Sandwich Islands, the British Antarctic Territory, and Tristan da Cunha.

PRESENTATION OF INDUSTRY, MARKET AND OTHER INFORMATION

Where information was sourced from third parties, this information has been accurately reproduced. As far as Sequana Medical is aware and is able to ascertain from information published by those third parties, no facts have been omitted which would render the reproduced information inaccurate or misleading.

This Prospectus includes market, economic and industry data, which were obtained by Sequana Medical from scientific journals, industry publications, press releases, filings under various securities laws, data published by government agencies and industry reports prepared by consultants. These market data are primarily presented in the Company's 2022 Annual Report, which is incorporated in part by reference in this Prospectus. The market, economic and industry data have primarily been derived and extrapolated from reports and articles provided by third parties such as GlobalData, the World Health Organisation, the American Association for the Study of Liver Diseases, the European Association for the Study of the Liver, the U.S. Centers for Disease Control and Prevention, the Journal of the American College of Cardiology, the Journal of Hepatology and the Journal of the American College of Cardiology. For further information, see the sources sections on p. 216 of the 2022 Annual Report.

The third-party sources Sequana Medical has used generally state that the information they contain has been obtained from sources believed to be reliable. Some of these third-party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on significant assumptions. As Sequana Medical does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, Sequana Medical is unable to verify such information. Thus, as mentioned, while the information has been accurately reproduced, and that as far as Sequana Medical is aware and is able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading, and Sequana Medical believes it to be reliable, Sequana Medical cannot guarantee its accuracy or completeness. The inclusion of this third-party industry, market and other information should not be considered as the opinion of such third parties as to the value of the Shares or the advisability of investing in the Shares.

In addition, certain information in this Prospectus is not based on published data obtained from independent third parties or extrapolations therefrom, but rather is based upon Sequana Medical's best estimates, which are in turn based upon information obtained from trade and business organisations and associations, consultants and other contacts within the industries in which Sequana Medical operates, information published by Sequana Medical's competitors and Sequana Medical's own experience and knowledge of conditions and trends in the markets in which it operates.

Sequana Medical cannot assure that any of the assumptions it has made while compiling this data from third party sources are accurate or correctly reflect Sequana Medical's position in the industry and none of Sequana Medical's internal estimates have been verified by any independent sources. Sequana Medical does not make any representation or warranty as to the accuracy or completeness of this information. Sequana Medical has not independently verified this information and, while Sequana Medical believes it to be reliable, Sequana Medical cannot guarantee its accuracy.

FORWARD-LOOKING STATEMENTS

All statements in this Prospectus and in the documents which are incorporated by reference in this Prospectus that do not relate to historical facts and events are "forward-looking statements". Forward-looking statements can be found in the summary of this Prospectus, the chapter "*Risk Factors*", the chapter "*Business Overview*" and in other sections of this Prospectus and in the documents which are incorporated by reference in this Prospectus. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates", "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should" or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Prospectus and in documents which are incorporated by reference in this Prospectus. Forward-looking statements include statements regarding Sequana Medical's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which Sequana Medical operates. In particular, certain statements are made in this Prospectus and in the documents which are incorporated by reference in this Prospectus regarding management's estimates of future growth.

By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. Prospective investors in the Shares should not place undue reliance on these forward-looking statements. Any forward-looking statements are made only as of the date of this Prospectus and, without prejudice to the Company's obligations under applicable law in relation to disclosure and ongoing information, the Company does not intend, and does not assume any obligation, to update forward-looking statements set forth in this Prospectus.

Many factors may cause Sequana Medical's results of operations, financial condition, liquidity and the development of the industries in which Sequana Medical operates to differ materially from those expressed or implied by the forward-looking statements contained in this Prospectus.

These factors include, but are not limited to:

- the current macroeconomic conditions
- the impact of the ongoing conflict in Ukraine;
- commercial acceptance of existing and future products in target markets;
- acceptance and adoption by physicians of any existing and future products in target markets;
- uncertain, time consuming and expensive regulatory approvals;
- failure to obtain sufficient financing;
- changing regulatory regimes may delay, prohibit or reduce potential sales or create costs that are not economically attractive;
- disruption of supply chain for services and components used for manufacturing products;
- changes in government regulations, legislation and healthcare policies, including with respect to reimbursements;
- intense and increased competition from other companies;

- failure to fully protect and exploit intellectual property rights;
- difficulties in recruitment and attracting physicians;
- failure to manufacture or outsource manufacturing in a timely manner or at a cost that is economically attractive;
- product liability claims and no adequate insurance coverage for such claims;
- product recalls for defective products;
- failure to attract and retain management and other personnel;
- failure to penetrate markets outside of Europe, the U.S. and Canada;
- information security breaches and disruptions;
- failure of information technology systems;
- misconduct or other improper activities of employees, independent contractors, Investigators, consultants, commercial collaborators, service providers, distributors and other counterparties;
- changes in currency exchange rates; and
- changes in tax laws and regulations.

These risks and others described in the chapter "*Risk Factors*" are not exhaustive. Other sections of this Prospectus describe additional factors that could adversely affect Sequana Medical's results of operations, financial condition, liquidity and the development of the markets in which Sequana Medical operates. New risks can emerge from time to time, and it is not possible for Sequana Medical to predict all such risks, nor can Sequana Medical assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not rely on forward-looking statements as a prediction of actual results.

INFORMATION INCORPORATED BY REFERENCE

Certain information on Sequana Medical is included in documents, parts of which are incorporated by reference in this Prospectus.

The following reports are incorporated by reference in their entirety into this Prospectus:

- the report of the board of directors in accordance with article 7:198 *juncto* articles 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code, dated 24 April 2023 (which can be inspected via the following hyperlink: https://www.sequanamedical.com/wp-content/uploads/2023/06/Sequana-Project-Stuart-Board-Report-Warrant-Conditions.pdf; and

- the report of the Company's statutory auditor, PwC Bedrijfsrevisoren BV, represented by Mr. Peter D'hondt, auditor, in accordance with article 7:198 *juncto* articles 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code, dated 24 April 2023 (which can be inspected via the following hyperlink: https://www.sequanamedical.com/wp-content/uploads/2023/04/Audit-Report-NL.pdf).

The table below sets out the references to the Company's report on the audited consolidated financial statements of the Company for the year ended 31 December 2022 (the "**2022 Annual Report**"). The 2022 Annual Report is available on Sequana Medical's website and can be inspected via the following hyperlink: https://www.sequanamedical.com/wp-content/uploads/2023/04/SEQ012-Jaarverslag-2022-ENG-012a-spreads-02-final.pdf, which is incorporated by reference in this Prospectus.

The parts of the 2022 Annual Report that are not incorporated by reference in this Prospectus (and are consequently not included in the table below) are either not relevant for investors or are covered elsewhere in this Prospectus.

Topic	2022 Annual Report
Business Overview	
Principal activities	"*Proprietary **alfa**pump & DSR technologies*" in the business section of the 2022 Annual Report, p. 18-58 "***alfa**pump in liver disease and cancer*" in the business section of the 2022 Annual Report, p. 35-59 "*DSR in heart failure*" in the business section of the 2022 Annual Report, p. 61-79 See also chapter "*Business Overview*", section "*Principal activities*" in this Prospectus
Trends	
Trends	N/A
Management	
Members of the administrative, management or supervisory bodies	"*2. Corporate Governance Statement*" in the corporate governance section of the 2022 Annual Report, p. 107-131 See also chapter "*General Information*", sections "*Composition board of directors*", "*Composition senior management team*" and "*No Conflicts of Interest*" of this Prospectus.

Financial information	
Financial statements	Financial report section of the 2022 Annual Report, p. 144-213
Auditing of annual financial information	"*2. Statutory auditor's report*" in the financial report section of the 2022 Annual Report, p. 147-151
Related party transactions	
Related party transactions	"*12. Transactions with related parties*" in the notes to the consolidated financial statements in the financial report section of the 2022 Annual Report, p. 204-205
Dividend and dividend policy	
Dividend and dividend policy	"*2.15.4. Dividends and dividend policy*" in the corporate governance section of the 2022 Annual Report, p. 129 See also chapter "*New Shares*", section "*Rights attached to the New Shares*" of this Prospectus
Share capital structure	
Share capital structure	"*8.6. Share capital and Share Premium*" in the notes to the consolidated financial statements in the financial report section of the 2022 Annual Report, p. 187-188 "*2.15 Share Capital and Shares*" in the corporate governance section of the 2022 Annual Report, p. 126-128. "*3.6 Description of share option plans*" and "*3.7 Terms and conditions of the share option plans*" in the corporate governance section of the 2022 Annual Report, p. 140-143.
Remuneration and benefits	
Remuneration and benefits	"*3.2 Remuneration Policy*" in the corporate governance section of the 2022 Annual Report, p. 132 "*3. Remuneration Report*" in the corporate governance section of the 2022 Annual Report, p. 132-143 "*8.9. Post-employment benefits*" in the notes to the consolidated financial statements in the financial report section of the 2022 Annual Report, p. 194-199

NEW SHARES

Issuance of the New Shares

Private placement

The 3,280,307 New Shares consist of:

- 2,169,013 New Shares that were issued by the Company on 27 April 2023 and 10 May 2023 as part of an aggregate of 4,445,205 new Shares and 1,111,294 Subscription Rights (at a ratio of 1 new Subscription Right per 4 new Shares) that were placed with institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable securities law exemptions, via a private placement through an accelerated bookbuilding procedure (i.e., the Private Placement). The 4,445,205 newly issued shares (including 2,169,013 New Shares) were issued pursuant to a capital increase in cash that was decided by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company. All of the newly issued Shares were issued at a (gross) issue price of EUR 3.55 per Share. Of the 4,445,205 new Shares, 2,276,192 were immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance, while 2,169,013 new Shares, being a portion of the New Shares, were not immediately admitted to listing and trading on the regulated market of Euronext Brussels upon their issuance; and

- 1,111,294 New Shares that are to be issued by the Company upon exercise of the 1,111,294 Subscription Rights issued in the framework of the Private Placement (each Subscription Right giving the holder the right to subscribe for one new ordinary Share at an exercise price per underlying share of EUR 5.10). The 1,111,294 Subscription Rights were issued pursuant to a decision by the Company's board of directors within the framework of the authorised capital with dis-application of preferential subscription rights of existing shareholders of the Company and, insofar as required, of existing holders of subscription rights (stock options) issued by the Company.

The Subscription Rights have the following characteristics:

- *Subscription right for ordinary shares*: Each Subscription Right gives the right to subscribe for one New Share to be issued by the Company.

- *Issuance price*: Each Subscription Right has been granted free of charge.

- *Exercise price*: The exercise price of the Subscription Rights is EUR 5.10 per New Share that can be subscribed for.

- *Term*: The Subscription Rights have a term of five years, and will be exercisable as from 30 October 2023.

- *Form and transferability*: The Subscription Rights were issued in registered form and will in principle be transferable, but will not be admitted to trading or listing on any regulated market.

- *Change of control*: In the event of certain change of control events, the Company will offer to purchase the Subscription Rights in cash for an amount equal to the Black Scholes Value of the Subscription Rights. The Subscription Rights will no longer be exercisable after the completion of a change of control. This provision has been approved by the Company's general shareholders' meeting on 26 June 2023.

- *Fixed conditions*: The conditions of the Subscription Rights were fixed at the completion of the Private Placement, and will not be adjusted, except in case of (reverse) share splits or a reclassification of Shares.

The Company notes that the Subscription Rights will not be admitted to listing and trading on Euronext Brussels and are not the subject of this Prospectus. To date, none of the Subscription Rights have been exercised into New Shares.

Prior to the launch of the Private Placement, the Pre-Committing Investors, being PiE and Rosetta as well as another investor, pre-committed to submit subscription orders for new Shares in the Private Placement. PiE and Rosetta committed to subscribe at least for a pro rata portion of the new Shares that was equal to their shareholding percentage in the Company prior to the Private Placement. No guarantee has been given as to the final allocation to the Pre-Committing Investors nor any other investors, shareholders or persons, that any allocation will be made to them, or as to the size of any such allocation. The Pre-Committing Investors agreed to accept newly issued Shares that would not be immediately admitted to listing and trading upon their issuance. Accordingly, all of the 2,169,013 New Shares issued in the Private Placement were allocated to, and subscribed for by, the Pre-Committing Investors.

The Private Placement of New Shares resulted in a dilution of 15.77% of the then existing shareholders of the Company and of the relative voting power of each share in the Company at that time. The Private Placement of Subscription Rights resulted in a potential dilution (assuming that each Subscription Right would be exercise into one New Share) of 4.47% of the then existing shareholders of the Company and of the relative voting power of each share in the Company at that time. For more information about the consequences of the Private Placement for the financial and shareholder rights of the shareholders of the Company, reference is made to the report of the board of directors in accordance with article 7:198 *juncto* articles 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code. This board report must be read together with the report prepared by the Company's statutory auditor, PwC Bedrijfsrevisoren BV, represented by Mr. Peter D'hondt, auditor, in accordance with article 7:198 *juncto* articles 7:179, 7:180 and 7:191 of the Belgian Companies and Associations Code. The aforementioned reports are available on the Company's website at https://www.sequanamedical.com/wp-content/uploads/2023/06/Sequana-Project-Stuart-Board-Report-Warrant-Conditions.pdf for the report of the board of directors and at https://www.sequanamedical.com/wp-content/uploads/2023/05/Audit-Report-ENG.pdf for the report of the statutory auditor, and are incorporated by reference in this Prospectus.

The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Private Placement (including but not limited to legal publications, printing and translation of the Prospectus and listing related documents) and Euronext Brussels, is expected to amount to approximately EUR 1.1 million. The net proceeds of the Private Placement amounted to EUR 14.7 million.

Underwriting Agreement

1,430,139 of the new Shares that were issued within the framework of the Private Placement were offered through Bank Degroof Petercam NV/SA, KBC Securities NV and Van Lanschot Kempen N.V. (the "**Underwriters**"). On 25 April 2023, the Company entered into an underwriting agreement with the Underwriters (the "**Underwriting Agreement**"). The Underwriters had no obligation to underwrite any of the Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein).

Lock-up arrangements

Pursuant to the Underwriting Agreement, Ian Crosbie (Chief Executive Officer) and Kirsten Van Bockstaele (representing Fin-2K BV) (Chief Financial Officer) (the "**Locked Parties**") entered into lock-up arrangements for a period ending 180 days from the date of settlement of the Private Placement, *i.e.* 27 April 2023 (the "**Lock-up Period**"). Each Locked Party agreed and undertook that, except with the prior written consent of the Underwriters, neither he/she nor any person acting on his/her behalf will:

(a) directly or indirectly, issue, offer, pledge, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or lend or otherwise transfer or dispose of any Shares of the Company held by the relevant Locked Party on the date of the relevant lock-up letter (*i.e.*, 27 April 2023), or any securities convertible into or exercisable or exchangeable for Shares as well as any Shares that the Company issued as a result of the conversion, exercise or exchange of any such securities (including the Subscription Rights); or

(b) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of any Shares,

whether any such transaction described in (a) or (b) above is to be settled by delivery of Shares or other securities, in cash or otherwise; or

(c) publicly announce such an intention to effect any such transaction.

The restrictions to which the Locked Parties are subject will not prohibit the Locked Parties from (i) accepting a general take-over bid on all of the ordinary share capital of the Company (other than these already held by the bidder or persons with whom the bidder is affiliated or is acting in concert), giving an irrevocable commitment to accept such an offer, or disposing of Shares to an offeror or potential offeror during the period of such an offer; (ii) proceeding with any disposal required by law, regulation or a court of competent jurisdiction; (iii) transferring Shares intra-family for natural persons, provided that each such transferee will continue to be bound by the foregoing restrictions for the remainder of the Lock-Up Period; (iv) for legal persons transferring Shares to a controlling shareholder, provided that each such transferee will continue to be bound by the foregoing restrictions for the remainder of the Lock-Up Period; and (v) selling such number of Shares required for a cashless exercise of the stock options of the relevant Locked Party that would otherwise lapse following the termination of the employment or service agreement of the relevant Locked Party with the Company. For the avoidance of doubt, nothing in the relevant lock-up letters restrict the possibility of the relevant Locked Party to accept or exercise options giving right to acquire Shares.

The Shares subscribed for by the Pre-Committing Investors are not subject to a lock-up arrangement with the Company or the Underwriters.

Standstill undertaking

Within the framework of the Private Placement, the Company agreed with the Underwriters to enter into a standstill undertaking for a period ending 180 days from the date of settlement of the Private Placement, *i.e.* 27 April 2023. During this period, the Company will not, and will procure that none of its affiliates will, directly or indirectly, without the Underwriters' prior written consent:

(a) issue, offer, sell, contract to sell or otherwise transfer, (attempt to) dispose of, lend, or solicit any offer to buy (or publicly announce such action), directly or indirectly, any Shares or securities of the Company that are substantially similar to Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, shares or any such substantially similar securities,

(b) grant or issue any options, subscription rights, convertible or exchangeable securities, other guaranty, or other rights to subscribe for or purchase shares in the Company, or enter into any swap, hedge or other arrangement pursuant to which the economic consequences of its ownership of Shares in the Company are transferred to any other person or entity, in whole or in part, whether any such transaction is to be settled by delivery of Shares or such other securities, or cash or otherwise, or

(c) submit to its shareholders or any other body a proposal to effect any of the foregoing.

The foregoing undertaking does not apply in relation to: (i) the issue of the New Shares pursuant to the Underwriting Agreement; (ii) the issue of securities by the Company as part of mergers, acquisitions or other similar business transactions; (iii) the grant of subscription rights (warrants), stock options, share units or other share based incentives to employees, consultants, directors or other members of the personnel of the Company and/or its subsidiaries ("**Share Based Incentive Plans**"), or otherwise in the ordinary course of business, and the issuance of Shares pursuant to those Share Based Incentive Plans; (iv) the issue of securities pursuant to the exercise or conversion of outstanding securities issued prior to 21 March 2023; (v) the issue of Shares or subscription rights pursuant to the terms of the loan agreements entered into by the Company with PMV-Standaardleningen NV (formerly, PMV/z-Leningen NV) and the warrant and loan agreement entered into by the Company with Kreos Capital VI (UK) Limited and Kreos Limited Capital VII (UK) Limited prior to 21 March 2023; and (vi) the issue of Shares, subscription rights, or other securities exercisable, convertible or exchangeable for Shares (collectively the "**Alternative Financing Securities**") pursuant to alternative funding and/or additional funding obtained by the Company prior to or after 21 March 2023, provided that the gross proceeds from the issuance of such Alternative Funding Securities do not exceed an amount of EUR 20 million.

Form and transferability of the New Shares

The New Shares issued in the Private Placement are all ordinary Shares, are fully paid, and rank *pari passu* in all respects with all other existing and outstanding Shares of the Company. The New Shares to be issued upon exercise of the Subscription Rights will all be ordinary Shares and rank *pari passu* in all respects with all other existing and outstanding Shares of the Company at that time.

All of the Shares belong to the same class of securities and are in registered or dematerialised form. A register of registered Shares (which may be held in electronic form) is maintained at the Company's registered office. It may be consulted by any holder of Shares. A dematerialised Share will be represented by an entry on a personal account of the owner or holder, with a recognised account holder or clearing and settlement institution. Holders of Shares may elect, at any time, to have their registered Shares converted into dematerialised Shares, and vice versa, at their own expense.

The New Shares issued in the Private Placement are freely transferable. The New Shares to be issued upon exercise of the Subscription Rights will be freely transferable. The aforementioned is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements.

Admission to trading of the New Shares

All of the Shares (other than the New Shares) are admitted to listing and trading on the regulated market of Euronext Brussels under the symbol "SEQUA" with ISIN BE0974340722.

An application has been made for the listing and admission to trading on the regulated market of Euronext Brussels of 2,169,013 New Shares (issued in the framework of the Private Placement). These New Shares are expected to be listed under the symbol "SEQUA" with ISIN BE0974340722. Trading for these New Shares is expected to commence on or about 28 July 2023.

An application will be made for the listing and admission to trading on the regulated market of Euronext Brussels of 1,111,294 New Shares (to be issued upon exercise of the 1,111,294 Subscription Rights issued in the framework of the Private Placement). These New Shares are expected to be listed (when listed) under the symbol "SEQUA" with ISIN BE0974340722.

The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the listing of the New Shares (including but not limited to legal publications, printing and translation of the Prospectus and listing related documents) and the remuneration of the FSMA (which is estimated at EUR 15,000.00) and Euronext Brussels, is expected to amount to approximately EUR 0.15 million.

Currency of the New Shares

The New Shares do not (and will not) have a nominal value, but (will) each reflect the same fraction of the Company's share capital, which is denominated in euro.

Rights attached to the New Shares

The New Shares (will) have the same rights and benefits as the (then) existing outstanding Shares of the Company. The section below summarises certain material rights of the Company's shareholders under Belgian law and the Company's articles of association. The contents of this section are derived primarily from the Company's articles of association, which were last amended and restated by the board of directors on 10 May 2023. The description provided below is only a summary and does not purport to provide a complete overview of the Company's articles of association or the relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

Voting rights attached to the New Shares

Each shareholder of the Company is entitled to one vote per Share. Shareholders may vote by proxy, subject to the rules described below in subsection "*Right to attend and vote at general shareholders' meetings*", subsection "*Voting by proxy or remote voting*".

Voting rights can be mainly suspended in relation to Shares:

- which are not fully paid up, notwithstanding the request thereto of the board of directors of the Company;

- to which more than one person is entitled or on which more than one person has rights in rem (*zakelijke rechten/droits réels*) on, except in the event a single representative is appointed for the exercise of the voting rights vis-à-vis the Company;

- which entitle their holder to voting rights above the threshold of 3%, 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant general shareholders' meeting, in the event that the relevant shareholder has not notified the Company and the FSMA at least 20 calendar days prior to the date of the general shareholders' meeting in accordance with the applicable rules on disclosure of major shareholdings; and

- of which the voting right was suspended by a competent court or the FSMA.

Pursuant to article 7:217 of the Belgian Companies and Associations Code, the voting rights attached to Shares owned by the Company, or a person acting in its own name but on behalf of the Company, or acquired by a subsidiary of the Company, as the case may be, are suspended.

Generally, the general shareholders' meeting has sole authority with respect to:

- the approval of the annual statutory financial statements of the Company;

- the distribution of profits (except interim dividends (see subsection "*Dividends*" below);

- the appointment (at the proposal of the board of directors and upon recommendation by the remuneration and nomination committee) and dismissal of directors of the Company;

- the appointment (at the proposal of the board of directors and upon recommendation by the audit committee) and dismissal of the statutory auditor of the Company;

- the granting of release from liability to the directors and the statutory auditor of the Company;

- the determination of the remuneration of the directors and of the statutory auditor for the exercise of their mandate;

- the advisory vote on the remuneration report included in the annual report of the board of directors;

- the binding vote on the remuneration policy (which was for the first time approved by the general shareholders' meeting held on 27 May 2021, and a revised remuneration policy was approved by the general shareholders' meeting held on 10 February 2023), and subsequently upon every material change to the remuneration policy and in any case at least every four years; and

- the determination of the following features of the remuneration or compensation of directors, members of the executive management and certain other executives (as the case may be): (i) in relation to the remuneration of executive and non-executive directors, members of the executive management and other executives, an exemption from the rule that share based awards can only vest after a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of executive directors, members of the executive management and other executives, an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years, (iii) in relation to the remuneration of non-executive directors, any variable part of the remuneration (provided, however, that no variable remuneration can be granted to independent non-executive directors), and (iv) any service agreements to be entered into with executive directors, members of the executive management and other executives providing for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, eighteen (18) months' remuneration);

- the filing of a claim for liability against directors;

- the decisions relating to the dissolution, merger and certain other reorganisations of the Company; and

- the approval of amendments to the articles of association.

Right to attend and vote at general shareholders' meetings

Annual meetings of shareholders

The annual general shareholders' meeting is held at the registered office of the Company or at the place determined in the notice convening the general shareholders' meeting. The meeting is held each year on the fourth Thursday of the month May at 9:00 a.m. If this day would be a public holiday, even if it is only a public holiday in one of the cultural communities of Belgium, the meeting will be held on the next business day. At the annual general shareholders' meeting, the board of directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the board of directors and of the statutory auditor with respect thereto.

The general shareholders' meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Company's profit or loss, the release from liability of the directors and the statutory auditor, the approval of the remuneration report included in the annual report of the board of directors (it being understood that the vote on the remuneration report is only an advisory vote and that the Company must explain in the remuneration report of the subsequent financial year how it took into account the advisory vote of the general shareholders' meeting of the previous financial year), the approval of the remuneration policy (as the case may be), and, when applicable, the (re-) appointment or dismissal of the statutory auditor and/or of all or certain directors. In addition, as relevant, the general shareholders' meeting must also decide on the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the executive management and other executives providing (as the case may be) for severance payments exceeding twelve months' remuneration (or, subject to a motivated opinion by the remuneration and nomination committee, 18 months' remuneration) (see also subsection "*Voting rights attached to the New Shares*" above).

Special and extraordinary general shareholders' meetings

The board of directors or the statutory auditor (or the liquidators, if appropriate) may, whenever the interest of the Company so requires, convene a special or extraordinary general shareholders' meeting. Such general shareholders' meeting must also be convened within three weeks every time one or more shareholders holding, alone or together, at least 10% of the Company's share capital so request. Shareholders that do not hold at least 10% of the Company's share capital do not have the right to have the general shareholders' meeting convened.

Right to put items on the agenda of the general shareholders' meeting and to table draft resolutions

Shareholders who hold alone or together with other shareholders at least 3% of the Company's share capital have the right to put additional items on the agenda of a general shareholders' meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to general shareholders' meetings that are being convened on the grounds that the quorum was not met at the first duly convened meeting (see subsection "*Quorum and majorities*" below). Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialised Shares, on a certificate issued by the applicable settlement institution for the Shares concerned, or by a certified account holder, confirming the number of Shares that have been registered in the name of the relevant shareholders and, for registered Shares, on a certificate of registration of the relevant Shares in the share register book of the Company. In addition, the shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital (see also subsection "*Formalities to attend the general shareholders' meeting*" below). A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Company at the latest on the twenty-second calendar day preceding the date of the general shareholders' meeting concerned. If the Company receives a request, it will have to publish at the latest on the fifteenth calendar day preceding the general shareholders' meeting an update of the agenda of the meeting with the additional agenda items and draft resolutions.

Notices convening the general shareholders' meeting

The notice convening the general shareholders' meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed and the proposed resolutions. The notice must, as the case may be, include the proposal of the audit committee to nominate a statutory auditor responsible for auditing the statutory and consolidated financial statements. The notice also needs to contain a description of the formalities that security holders must fulfil in order to be admitted to the general shareholders' meeting and (as the case may be) exercise their voting right, information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which security holders can ask questions during the general shareholders' meeting and prior to the meeting via the Company's email address or a specific email address mentioned in the notice, information on the procedure to participate to the general shareholders' meeting by means of a proxy or to vote by means of a remote vote, and, as applicable, the registration date for the general shareholders' meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the general shareholders' meeting, the agenda with the proposed resolutions or, if no resolutions are proposed, a commentary by the board of directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the general shareholders' meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Company's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting. If Shares are held by an intermediary on behalf of a shareholder of the Company, the relevant intermediary is required to transmit the following information, without delay, from the Company to the shareholder: (a) the information which the Company is required to provide to the shareholder, to enable the shareholder to exercise rights attached to its Shares, and which is directed to all holders of Shares of that class; or (b) where the information referred to in point (a) is available to shareholders on the website of the Company, a notice indicating where on the website that information can be found, unless the Company provides this information directly to the shareholder.

The notice convening the general shareholders' meeting has to be published at least 30 calendar days prior to the general shareholders' meeting in the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur Belge*), in a newspaper that is published nation-wide in Belgium, in paper or electronically, in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis, and on the Company's website. A publication in a nation-wide newspaper is not needed for annual general shareholders' meetings taking place on the date, hour and place indicated in the articles of association of the Company if the agenda is limited to the treatment and approval of the financial statements, the annual report of the board of directors, the report of the statutory auditor, the remuneration report, the severance pay for executive directors, and the discharge from liability of the directors and statutory auditor. See also subsection "*Voting Rights attached to the New Shares*" above. In addition to this publication, the notice has to be distributed at least 30 calendar days prior to the meeting via the normal publication means that the Company uses for the publication of press releases and regulated information. The term of 30 calendar days prior to the general shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also further below under subsection "*Quorum and majorities*".

At the same time as its publication, the convening notice must also be sent to the holders of registered Shares, holders of registered convertible bonds, holders of registered subscription rights, holders of registered certificates issued with the co-operation of the Company (if any), and, as the case may be, to the directors and statutory auditor of the Company. This communication needs to be made by e-mail unless the addressee has informed the Company that it wishes to receive the relevant documentation by another equivalent means of communication. If the relevant addressee does not have an e-mail address or if it did not inform the Company thereof, the relevant documentation will be sent by ordinary mail.

Formalities to attend the general shareholders' meeting

All holders of Shares, profit-sharing certificates, non-voting Shares, convertible bonds, subscription rights or other securities issued by the Company, as the case may be, and all holders of certificates issued with the co-operation of the Company (if any) can attend the general shareholders' meetings insofar as the law or

the articles of association entitles them to do so and, as the case may be, gives them the right to participate in voting.

In order to be able to attend a general shareholders' meeting, a holder of securities issued by the Company must satisfy two criteria: being registered as holder of securities on the registration date for the meeting, and notify the Company:

- Firstly, the right to attend general shareholders' meetings applies only to persons who are registered as owning securities on the fourteenth calendar day prior to the general shareholders' meeting at midnight (Belgian time) via registration, in the applicable register book for the securities concerned (for registered securities) or in the accounts of a certified account holder or relevant settlement institution for the securities concerned (for dematerialised securities or securities in book-entry form).

- Secondly, in order to be admitted to the general shareholders' meeting, securities holders must notify the Company at the latest on the sixth calendar day prior to the general shareholders' meeting whether they intend to attend the meeting and indicate the number of Shares in respect of which they intend to do so. For the holders of dematerialised securities or securities in book-entry form, the notice should include a certificate confirming the number of securities that have been registered in their name on the record date. The certificate can be obtained by the holder of the dematerialised securities or securities in book-entry form with the certified account holder or the applicable settlement institution for the securities concerned.

The formalities for the registration of securities holders, and the notification of the Company must be further described in the notice convening the general shareholders' meeting.

Electronic participation

The board of directors has the possibility to organise the general shareholders' meeting by means of electronic communication which must (i) allow the Company to verify the capacity and identity of the shareholders using it; (ii) at least enable (a) the securities holders to directly, simultaneously and continuously follow the discussions during the meeting and (b) the shareholders to exercise their voting rights on all points on which the general shareholders' meeting is required to take a decision; and (iii) allow the securities holders to actively participate to the deliberations and to ask questions during the meeting.

Voting by proxy or remote voting

Each shareholder has, subject to compliance with the requirements set forth above under subsection "*Formalities to attend the general shareholders' meeting*", the right to attend a general shareholders' meeting and to vote at the general shareholders' meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders. The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law), through a form which shall be made available by the Company. The signed original paper (handwritten) or electronic form must be received by the Company at the latest on the sixth calendar day preceding the meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest, the keeping of a register and other transparency requirements.

The notice convening the meeting may allow shareholders to vote remotely in relation to the general shareholders' meeting, by sending a paper form or, if specifically allowed in the notice convening the meeting, by sending a form electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). These forms shall be made available by the Company. The original signed paper form must be received by the Company at the latest on the sixth calendar day preceding the date of the meeting. Voting through the signed electronic form may occur until the last calendar day before the meeting.

When votes are cast electronically, an electronic confirmation of receipt of the votes is sent to the relevant shareholders that cast the vote. After the general shareholders' meeting, shareholders can obtain, at least upon request (which must be made no later than three months after the vote), the confirmation that their

votes have been validly recorded and taken into account by the Company, unless that information is already available to them. Intermediaries receiving such confirmation must transmit it without delay to the shareholder.

The Company may also organise a remote vote in relation to the general shareholders' meeting through other electronic communication methods, such as, among others, through one or several websites. The Company shall specify the practical terms of any such remote vote in the convening notice.

Holders of securities who wish to be represented by proxy or vote remotely must, in any case comply with the formalities to attend the meeting, as explained above under subsection "*Formalities to attend the general shareholders' meeting*". Holders of Shares without voting rights, profit-sharing certificates without voting rights, convertible bonds, warrants or certificates issued with the cooperation of the Company may attend the general shareholders' meeting but only with an advisory vote.

Quorum and majorities

In general, there is no attendance quorum requirement for a general shareholders' meeting and decisions are generally passed with a simple majority of the votes of the Shares present or represented. However, capital increases (other than those decided by the board of directors pursuant to the authorised capital), decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganisations of the Company, amendments to the articles of association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Companies and Associations Code do not only require the presence or representation of at least 50% of the share capital of the Company but also a majority of at least 75% of the votes cast. An amendment of the Company's corporate purpose requires the approval of at least 80% of the votes cast at a general shareholders' meeting, which can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second general shareholders' meeting may validly deliberate and decide regardless of the number of Shares present or represented. The special majority requirements, however, remain applicable.

Right to ask questions

Within the limits of article 7:139 of the Belgian Companies and Associations Code, security holders have a right to ask questions to the directors in connection with the report of the board of directors or the items on the agenda of such general shareholders' meeting. However, directors may, in the interest of the Company, refuse to answer questions when the communication of certain information or facts is likely to cause prejudice to the Company or is contrary to the obligations of confidentiality entered into by them or by the Company.

Shareholders can also ask questions to the statutory auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions to the statutory auditor must be submitted to the Company at the same time. The statutory auditor may, in the interest of the Company, refuse to answer questions when the communication of certain information or facts is likely to cause prejudice to the Company or is contrary to its professional secrecy or to obligations of confidentiality entered into by the Company. The statutory auditor has the right to speak at the general meeting in connection with the performance of its duties.

Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained above under subsection "*Formalities to attend the general shareholders' meeting*".

Dividends

All of the New Shares issued in the Private Placement, entitle the holder thereof to an equal right to participate in dividends (if any) in respect of the financial year ending 31 December 2022 and future years. All of the New Shares to be issued upon exercise of the Subscription Rights will entitle the holder thereof to an equal right to participate in dividends (if any) in respect of the relevant financial year in which the New Shares are issued and future years. All of the Shares participate equally in the Company's profits (if any). Pursuant to the Belgian Companies and Associations Code, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the annual general shareholders' meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a

(non-binding) proposal of the Company's board of directors. In accordance with Belgian law, the right to collect dividends declared on Shares expires five years after the date the board of directors has declared the dividend payable, whereupon the Company is no longer under an obligation to pay such dividends. The Belgian Companies and Associations Code and the Company's articles of association also authorise the board of directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company has never declared or paid any cash dividends on its Shares. The Company does not anticipate paying cash dividends on its equity securities in the foreseeable future and intends to retain all available funds and any future earnings for use in the operation and expansion of its business.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e. summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), decreased with, except in exceptional circumstances, to be disclosed and justified in the notes to the annual accounts, the non-amortised costs of incorporation and extension and non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves.

In addition, pursuant to Belgian law and the Company's articles of association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit (nettowinst/bénéfices nets) to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the completion of the admission of the New Shares issued in the Private Placement to listing and trading at the regulated market of Euronext Brussels. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, limiting the Company's ability to pay out dividends to its shareholders.

At the date of this Prospectus, the Subordinated Loan Agreements entered into with PMV-Standaardleningen (formerly known as PMV/z) in July 2020 and most recently amended in March 2023, also include restrictive covenants, which may limit the Company's ability (and require PMV-Standaardleningen 's prior consent) to make distributions by way of dividends or otherwise for so long as any monies or obligations, actual or contingent, are outstanding under the aforementioned loan agreements. Furthermore, under the Kreos Loan Agreement, no distributions by way of dividend may be declared or made without the consent of Kreos Capital (other than the payment of a dividend to the Company by any of its directly or indirectly wholly owned subsidiaries). For more information about these loan agreements, reference is made to the chapter "*Business Overview*", section "Material contracts" subsections "Subordinated Loan Agreements" and "*Kreos Loan Agreement*".

Finally, additional financial restrictions and other limitations may be contained in future credit agreements.

Rights regarding liquidation

The Company can only be voluntarily dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes cast at an extraordinary general shareholders' meeting where at least 50% of the share capital is present or represented. In the event the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The second meeting of shareholders can validly deliberate and decide regardless of the number of Shares present or represented.

Pursuant to article 7:228 of the Belgian Companies and Associations Code, if, as a result of losses incurred, the ratio of the Company's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene a special general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalisation. At this general shareholders' meeting the board of directors needs to propose either the dissolution of the Company or the continuation of the Company, in which case the board of directors must propose measures to ensure the Company's continuity. The board of directors must justify its proposals in a special report to the shareholders. Shareholders

representing at least 75% of the votes validly cast at this meeting have the right to dissolve the Company, provided that at least 50% of the Company's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of the Company's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve the Company.

Pursuant to article 7:229 of the Belgian Companies and Associations Code, if the amount of the Company's net assets has dropped below EUR 61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium (*naamloze vennootschap/société anonyme*)), any interested party is entitled to request the competent court to dissolve the Company. The court can order the dissolution of the Company or grant a grace period within which the Company is to remedy the situation.

If the Company is dissolved for any reason, the liquidation must be carried out by one or more liquidators appointed by the general shareholders' meeting and whose appointment has been ratified by the enterprise court. Any balance remaining after discharging all debts, liabilities and liquidation costs must first be applied to reimburse, in cash or in kind, the paid-up capital of the Shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders (see also the chapter "*Risk Factors*", section "*Risks related to Sequana Medical's business and industry*", subsection "*Sequana Medical has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability*").

At the occasion of the preparation of the statutory (non-consolidated) financial statements of the Company for the financial year ended 31 December 2022, the board of directors of the Company determined that the net assets had fallen below the thresholds of the articles 7:228 and 7:229 of the Belgian Companies and Associations Code and submitted this matter to the Company's annual general shareholders' meeting that took place on 25 May 2023, at which the shareholders decided (i) to continue the operations of the Company (and not to dissolve the Company), and (ii) to approve the proposed measures to redress the financial situation of the Company. This process will be repeated if and to the extent required in accordance with applicable law.

Changes to the share capital

Changes to the share capital decided by the shareholders

In principle, changes to the share capital are decided by the shareholders. The general shareholders' meeting may at any time decide to increase or reduce the share capital of the Company. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described above under subsection "*Right to attend and vote at general shareholders' meetings*", subsection "*Quorum and majorities*".

Capital increases decided by the board of directors

Subject to the same quorum and majority requirements, the general shareholders' meeting may authorise the board of directors, within certain limits, to increase the Company's share capital without any further approval of the shareholders. This is the so-called authorised capital. This authorisation needs to be limited in time (i.e. it can only be granted for a renewable period of maximum five years) and size (i.e. the authorised capital may not exceed the amount of the registered capital at the time of the authorisation).

The capital increases that can be effected in accordance with the aforementioned authorisation can take place by means of contributions in cash or in kind, by capitalisation of reserves, whether available or unavailable for distribution, and capitalisation of issue premiums, with or without the issuance of new Shares, with or without voting rights, that will have the rights as will be determined by the board of directors. The board of directors is also authorised to use this authorisation for the issuance of convertible bonds or subscription rights (stock options), bonds with subscription rights or other securities.

The board of directors is authorised, when exercising its powers within the framework of the authorised capital, to restrict or cancel, in the interest of the company, the preferential subscription right of the shareholders. This restriction or cancellation of the preferential subscription right can also be done in favour of members of the personnel of the Company or of its subsidiaries, or in favour of one or more persons other than members of the personnel of the Company or of its subsidiaries.

By virtue of the resolution of the extraordinary general shareholders' meeting of the Company of 27 May 2022, as published by excerpt in the Annexes to the Belgian Official Gazette (*Belgisch Staatsblad/Moniteur belge*) under number 22337629 on 13 June 2022, the powers of the board of directors under the authorised capital have been renewed. As a result, the board of directors is authorised to increase the share capital of the Company on one or several occasions with a maximum amount of EUR 2,460,486.98 (excluding issue premium, as the case may be). The powers under the authorised capital are set out in article 8 of the Company's articles of association. The authorisation is valid for a period of five years as from 13 June 2022. The board of directors has used these powers for the issuance of the New Shares and Subscription Rights at the occasion of the Private Placement.

Preferential subscription right

In the event of a capital increase for cash with the issue of new Shares of the Company, or in the event of an issue of convertible bonds or subscription rights, the existing shareholders have a preferential right to subscribe, pro rata, to the new Shares of the Company, convertible bonds or subscription rights. These preferential subscription rights are transferable during the subscription period.

The general shareholders' meeting may decide to limit or cancel this preferential subscription right, subject to special reporting requirements. Such decision by the general shareholders' meeting needs to satisfy the same quorum and majority requirements as the decision to increase the Company's share capital.

The shareholders may also decide to authorise the board of directors to limit or cancel the preferential subscription right within the framework of the authorised capital, subject to the terms and conditions set forth in the Belgian Companies and Associations Code. As mentioned above, the board of directors of the Company has been granted certain powers to increase the Company's share capital within the framework of the authorised capital and to cancel the statutory preferential subscription rights of the shareholders (within the meaning of articles 7:191 and 7:193 of the Belgian Companies and Associations Code). The powers under the authorised capital have been set out in article 8 of the Company's articles of association.

Generally, unless expressly authorised in advance by the general shareholders' meeting, the authorisation of the board of directors to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the financial instruments of the Company. The Company's general shareholders' meeting did not grant such express authorisation to the board of directors.

Acquisition and sale of own Shares

The Company may acquire, pledge and dispose of its own Shares, profit certificates or associated certificates at the conditions provided for by articles 7:215 and following of the Belgian Companies and Associations Code. These conditions include a prior special shareholders' resolution approved by at least 75% of the votes validly cast at a general shareholders' meeting where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented.

Furthermore, Shares can only be acquired with funds that would otherwise be available for distribution as a dividend to the shareholders and the transaction must relate to fully paid-up Shares or associated certificates. Furthermore, an offer to purchase Shares must be made by way of an offer to all shareholders under the same conditions. Shares can also be acquired by the Company without offer to all shareholders under the same conditions, provided that the acquisition of the Shares is effected in the central order book of the regulated market of Euronext Brussels or, if the transaction is not effected via the central order book, provided that the price offered for the Shares is lower than or equal to the highest independent bid price in the central order book of the regulated market of Euronext Brussels at that time.

Generally, the general shareholders' meeting or the articles of association determine the number of Shares, profit certificates or certificates that can be acquired, the duration of such an authorisation which cannot exceed five years as from the publication of the proposed resolution as well as the minimum and maximum price that the board of directors can pay for the Shares. The prior approval by the shareholders is not required if the Company purchases the Shares to offer them to the Company's personnel, in which case the Shares must be transferred within a period of 12 months as from their acquisition.

The Company may, without prior authorisation by the general shareholders' meeting, dispose of the Company's own Shares, profit certificates or associated certificates in the limited number of situations set out in article 7:218 of the Belgian Companies and Associations Code.

As of the date of this Prospectus, the Company does not hold any own Shares and is not in the position to acquire or hold any own Shares.

Legislation and jurisdiction

Notification of significant shareholding

Pursuant to the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time (the "**Belgian Transparency Act**"), a notification to the Company and to the FSMA is required by all natural persons and legal entities (*i.e*. legal person, enterprise without legal personality, or trust), in the following circumstances:

- an acquisition or disposal of voting securities, voting rights or financial instruments that are treated as voting securities;
- the reaching of a threshold by persons or legal entities acting in concert;
- the conclusion, modification or termination of an agreement to act in concert;
- the downward reaching of the lowest threshold;
- the passive reaching of a threshold;
- the holding of voting securities in the Company upon first admission thereof to trading on a regulated market;
- where a previous notification concerning the financial instruments treated as equivalent to voting securities is updated;
- the acquisition or disposal of the control of an entity that holds voting securities in the Company; and
- where the Company introduces additional notification thresholds in the articles of association,

in each case where the percentage of voting rights attached to the securities held by such persons reaches, exceeds or falls below the legal threshold, set at 5% of the total voting rights, and 10%, 15%, 20% and so on in increments of 5% or, as the case may be, the additional thresholds provided in the articles of association. The Company has provided for an additional threshold of 3% in its articles of association.

The notification must be made promptly and at the latest within four trading days following the moment on which the person who is subject to the notification obligation received knowledge or could be deemed to have received knowledge of the acquisition or disposal of the voting rights triggering the reaching of the threshold. Where the Company receives a notification of information regarding the reaching of a threshold, it has to publish such information within three trading days following receipt of the notification. Subject to certain exceptions, no shareholder may, pursuant to article 25/1 of the Belgian Transparency Act, cast a greater number of votes at a general shareholders' meeting of the Company than those attached to the rights and securities that it has notified in accordance with the aforementioned disclosure rules at least 20 calendar days prior to the date of the general shareholders' meeting.

The forms on which such notifications must be made, as well as further explanations, can be found on the website of the FSMA (http://www.fsma.be). Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA may also impose administrative sanctions.

The Company is required to publicly disclose any notifications received regarding increases or decreases in a shareholder's ownership of the Company's securities, and must mention these notifications in the notes to its financial statements. A list as well as a copy of such notifications will be accessible on the Company's website (https://www.sequanamedical.com/investors/shareholder-information/).

The obligation to disclose significant shareholdings as well as certain other provisions of Belgian law (e.g. merger control, authorised capital and the requirement to have certain change of control clauses approved by a special shareholders' meeting) that may apply to the Company, may make an unsolicited tender offer, merger, change in management or other change in control, more difficult. Such provisions could discourage potential takeover attempts that third parties may consider and that other shareholders may consider to be in their best interest and could adversely affect the market price of the Shares (including the New Shares). These provisions may also deprive shareholders of the opportunity to sell their Shares (including the New Shares) at a premium (which is typically offered in the context of a takeover bid).

Right to identify shareholders and facilitation of exercise of shareholders' rights

The Company is entitled, pursuant to the Belgian Transparency Act, to request information from intermediaries (such as investment firms, credit institutions and central securities depositories) regarding the identity and holding of the Company's shareholders. If multiple intermediaries are involved in the relationship between the Company and a shareholder, the Company is entitled to address a request for information to any intermediary in the chain. Intermediaries are required to respond to the Company's requests without delay.

The following information regarding the Company's shareholders can be requested by the Company:

- name and contact details, including the full address, the e-mail address (where available) and the registration number (if the shareholder is a legal entity); and
- the number and classes of Shares held and the date from which the Shares have been held.

The Company is required to provide in due time to intermediaries all information necessary to allow shareholders to exercise the rights attached to their Shares. Alternatively, the Company may make such information available on its website, in which case the Company is required to provide to intermediaries a notice regarding the location on its website where the information can be found. Intermediaries have a duty to relay the information so received from the Company to the shareholders on behalf of whom they are holding Shares.

Disclosure of Net Short Positions

Pursuant to the Regulation (EU) No. 236/2012 of the European Parliament and of the Council of 14 March 2012 on short selling and certain aspects of credit default swaps, any person that acquires or disposes of a net short position relating to the Company's issued share capital, by a short sale of Shares or by entering into a transaction which creates or relates to a financial instrument where the effect or one of the effects of the transaction is to confer a financial advantage on the person entering into that transaction in the event of a decrease in the price or value of such Shares, is required to notify the FSMA where the net short position reaches or falls below 0.2% of the Company's issued share capital, and each 0.1% above that. If the net short position reaches 0.5%, and each 0.1% above that, the FSMA will disclose the net short position to the public.

Public takeover bids

Public takeover bids for the Company's Shares and other securities giving access to voting rights (such as subscription rights or convertible bonds, if any) are subject to supervision by the FSMA. Any public takeover bid must be extended to all of the Company's voting securities, as well as all other securities giving access to voting rights. Prior to making a bid, a bidder must publish a prospectus which has been approved by the FSMA prior to publication.

Belgium has implemented the Thirteenth Company Law Directive (European Directive 2004/25/EC of 21 April 2004) by the Belgian Act of 1 April 2007 on public takeover bids, as amended from time to time (the "**Belgian Takeover Act**") and the Belgian Royal Decree of 27 April 2007 on public takeover bids, as amended from time to time (the "**Belgian Takeover Decree**"). The Belgian Takeover Act provides that a mandatory bid must be launched if a person, as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly holds more than 30% of the voting securities in a company having its registered office in Belgium and of which at least part of the voting securities are traded

on a regulated market or on a multilateral trading facility designated by the Belgian Takeover Decree. The mere fact of exceeding the relevant threshold through the acquisition of Shares will give rise to a mandatory bid, irrespective of whether the price paid in the relevant transaction exceeds the current market price. The duty to launch a mandatory bid does not apply in certain cases set out in the Belgian Takeover Decree such as (i) in case of an acquisition if it can be shown that a third party exercises control over the company or that such party holds a larger stake than the person holding 30% of the voting securities or (ii) in case of a capital increase with preferential subscription rights decided by the Company's general shareholders' meeting.

There are several provisions of Belgian company law and certain other provisions of Belgian law, such as the obligation to disclose significant shareholdings (see subsection "*Notification of significant shareholdings*" above) and merger control, that may apply towards the Company and which may create hurdles to an unsolicited tender offer, merger, change in management or other change in control. These provisions could discourage potential takeover attempts that other shareholders may consider to be in their best interest and could adversely affect the market price of the Shares of the Company. These provisions may also have the effect of depriving the shareholders of the opportunity to sell their Shares at a premium.

In addition, pursuant to Belgian company law, the board of directors of Belgian companies may in certain circumstances, and subject to prior authorisation by the shareholders, deter or frustrate public takeover bids through dilutive issuances of equity securities (pursuant to the "authorised capital") or through share buy-backs (i.e. purchase of own Shares). In principle, the authorisation of the board of directors to increase the share capital of the Company through contributions in kind or in cash with cancellation or limitation of the preferential subscription right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the securities of the Company. The general shareholders' meeting can, however, under certain conditions, expressly authorise the board of directors to increase the capital of the Company in such case by issuing Shares in an amount of not more than 10% of the existing Shares at the time of such a public takeover bid. (see also section "*Rights attached to the New Shares*", subsection "*Changes to the share capital*", subsection "*Capital increases decided by the board of directors*").

The Company's articles of association do not provide for any specific protective mechanisms against public takeover bids.

For more information about control arrangements, reference is made to the chapter "*Major Shareholders*", section "*Control over the Company*".

Squeeze-outs

Pursuant to article 7:82 of the Belgian Companies and Associations Code or the regulations promulgated thereunder, a person or legal entity, or different persons or legal entities acting alone or in concert, who own, directly or indirectly, as the case may be together with the Company, at least 95% of the securities with voting rights in a public company are entitled to acquire the totality of the securities with voting rights in that company following a squeeze-out offer. The securities that are not voluntarily tendered in response to such an offer are deemed to be automatically transferred to the bidder at the end of the procedure. At the end of the squeeze-out procedure, the company is no longer deemed a public company, unless convertible bonds issued by the company are still spread among the public. The consideration for the securities must be in cash and must represent the fair value (verified by an independent expert) as to safeguard the interests of the transferring shareholders.

A squeeze-out offer is also possible upon completion of a public takeover bid, provided that the bidder holds at least 95% of the voting capital and 95% of the voting securities of the public company. In such a case, the bidder may require that all remaining shareholders sell their securities to the bidder at the offer price of the takeover bid, provided that, in case of a voluntary takeover offer, the bidder has also acquired 90% of the voting capital to which the offer relates. The Shares that are not voluntarily tendered in response to any such offer are deemed to be automatically transferred to the bidder at the end of the procedure.

Sell-out right

Within three months after the end of an acceptance period related to a public takeover bid, holders of voting securities or of securities giving access to voting rights may require the offeror, acting alone or in concert, who owns at least 95% of the voting capital and 95% of the voting securities in a public company following a takeover bid, to buy their securities from them at the price of the bid, on the condition that, in case of a voluntary

takeover offer, the offeror has acquired, through the acceptance of the bid, securities representing at least 90% of the voting capital subject to the takeover bid.

CAPITALISATION AND INDEBTEDNESS

Capitalisation and indebtedness table

The following tables set forth Sequana Medical's consolidated capitalisation and net financial indebtedness as at 30 April 2023 on an actual basis.

The second column of the tables below reflects the financial consequences of the capital increase completed on 10 May 2023 (pursuant to which 140,845 New Shares were issued in the framework of the Private Placement at an issue price of EUR 3.55 per New Share). As a result of the aforementioned transaction (i) the share capital was increased by an amount of EUR 14,591.54, (ii) the share premium was increased by an amount of EUR 485,408.21, and (iii) the cash and cash equivalents were increased by an amount equal to the proceeds of said capital increase (being EUR 499,999.75). For further details on the Private Placement, see chapter "*New Shares*" of this Prospectus.

Other than as set forth above, there have been no material changes to Sequana Medical's consolidated capitalisation and net financial indebtedness since 30 April 2023.

	As at 30 April 2023	**As at 30 April 2023** ***(taking into account the capital increase of 10 May 2023)***
	(in €000)	***(in €000)***
Total current debt	**3,202**	**3,202**
Guaranteed	0	0
Secured [(1)]	1,633	1,633
Unguaranteed/unsecured [(2)]	0	0
Other current financial liabilities [(3)]	1,569	1,569
Total non-current debt	**16,189**	**16,189**
Guaranteed	0	0
Secured [(1)]	8,181	8,181
Unguaranteed/unsecured [(2)]	8,008	8,008
Total other liabilities	**7,817**	**7,817**
Trade payables	1,749	1,749
Other payables	1,960	1,960
Accrued liabilities	4,108	4,108
Shareholders' equity	**1,733**	**2,233**
Share capital	2,906[(4)]	2,921
Transaction costs for equity instruments [(5)]	-5,714	-5,714
Share premium	185,159[(6)]	185,644
Reserves	2,690	2,690
Loss brought forward	-184,096	-184,096
Cumulative translation adjustment	787	787
Total	**28,941**	**29,441**

Notes:
(1) Secured debt representing lease commitments following the implementation of IFRS 16 and the Kreos Loan Agreement (as defined above).
(2) Includes indebtedness pursuant to the Subordinated Loan Agreements (as defined above).

(3) Other current financial liabilities relating to the valuation of the Bootstrap Warrants (as defined below) as well as the Kreos Subscription Rights (as defined below) in accordance with IAS 32 - Financial Instruments: Presentation. This does not include the accounting treatment of the Subscription Rights, which is still under review.

(4) Includes the issuance of 1,430,139 New Shares on 27 April 2023 at the (gross) issue price of EUR 3.55 per new Share (or EUR 15,280,478.00) in the context of the Private Placement, of which an amount of (rounded) EUR 0.1036 per new Share (equal to the fractional value of the Company's shares prior to the capital increase) was booked as share capital (or EUR 445,931.70 in total). The amount excludes the issuance of 140,845 New Shares on 10 May 2023 at the (gross) issue price of EUR 3.55 per new Share (or EUR 499,999.75) in the context of the Private Placement, of which an amount of (rounded) EUR 0.1036 per new Share (equal to the fractional value of the Company's shares prior to the capital increase) was booked as share capital (or EUR 14,591.54 in total) (which share capital amount has been reflected in the second column above).

(5) Represents the expenses related to the capital increase until 30 April 2023 accounted for in equity and represents the incremental costs attributable to new Shares.

(6) Includes the issuance of 1,430,139 New Shares on 27 April 2023 at the (gross) issue price of EUR 3.55 per new Share (or EUR 15,280,478.00) in the context of the Private Placement, of which an amount of (rounded) EUR 3.4464 per new Share was booked as issue premium (or EUR 14,834,546.30 in total). The amount excludes the issuance of 140,845 New Shares on 10 May 2023 at the (gross) issue price of EUR 3.55 per new Share (or EUR 499,999.75) in the context of the Private Placement, of which an amount of (rounded) EUR 3.4464 per new Share was booked as issue premium (or EUR 485,408.21 in total) (which issue premium amount has been reflected in the second column above).

The following table sets out the net financial indebtedness of Sequana Medical as at 30 April 2023:

		As at 30 April 2023	**As at 30 April 2023** ***(taking into account the capital increase of 10 May 2023)***
		(in €000)	***(in €000)***
A	Cash[(1)]	21,197	21,697
B	Cash equivalents	0	0
C	Other current financial assets.....	0	0
D	**Liquidity** (A + B + C) **.....**	**21,197**	**21,697**
E	Current financial debt (including debt instruments but excluding current portion of non-current financial debt)	1,569	1,569
F	Current portion of non-current financial debt.....	1,633	1,633
G	**Current financial indebtedness** (E + F) **.....**	**3,202**	**3,202**
H	**Net current financial indebtedness** (G - D) **.....**	**-17,995**	**-18,495**
I	Non-current financial debt (excluding current portion and debt instruments).....	16,189	16,189
J	Debt instruments	0	0
K	Non-current trade and other payables	0	0
L	**Non-current financial indebtedness** (I + J + K) **.....**	**16,189**	**16,189**
M	**Net financial indebtedness** (H + L)**.....**	**-1,807**	**-2,307**

Note:

(1) The cash balance on 30 April 2023 amounted to EUR 21.2 million. Taking into account the aforementioned capital increase of EUR 499,999.75 completed on 10 May 2023, the adjusted cash balance as at 30 April 2023 amounted to EUR 21.7 million.

As at 30 April 2023 Sequana Medical has no contingent or indirect indebtedness.

Working capital statement

On the date of this Prospectus, Sequana Medical is of the opinion that, taking into account its available cash and cash equivalents, it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus.

The Company has incurred operating losses and negative operating cash flows in each period since it was founded in 2006, and as of 31 December 2022, the Company has a loss brought forward of EUR 173.5 million. Since the end of 2022, the Company successfully raised EUR 15.78 million (in April and May 2023) via the Private Placement and entered into amendments agreements in order to amend the repayment terms under certain loan agreements. Other than the Subordinated Loan Agreements and the Kreos Loan Agreement (under which the Company cannot make further drawings), the Company has no other outstanding debt facilities under which it can make additional drawings. (see also *"Business Overview"* and *"Material contracts"*, subsections "*Subordinated Loan Agreements*" and "*Kreos Loan Agreement*".).

Together with existing cash resources, the net proceeds from the Private Placement (and taking into account the amendments to the repayment terms of certain loan agreements) are expected to extend the current cash runway of the Company into the first quarter of 2024.

However, the Company's 12 month working capital shortfall as of the date of this Prospectus is approximately EUR 11.7 million to mid July 2024.

The Company is still in its development phase for its alfapump® and DSR® products, and is conducting several clinical trials in order to achieve regulatory marketing approvals for these products. This entails various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability.

The Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows.

The Company continues to evaluate equity and debt financing options (including discussions with existing and/or new investors), as well as potential strategic collaboration and licensing arrangements, it being noted that on the date of this Prospectus no concrete (refinancing) options or proposals are under consideration by the Company. If Sequana Medical is unable to obtain necessary financing or enter into other arrangements to sustain its operations, it may not be able to achieve its strategic objectives (including commercialisation of the alfapump® in North America or the commercialisation of the DSR® product) or ensure its going concern. The Company's executive management and board of directors remain however confident that the liquidity requirements for the next twelve months can be secured.

In view hereof, the executive management and the board of directors also remain confident about the strategic direction. However, the impact of macroeconomic conditions and the geopolitical situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear at this point in time and will remain under review by the Company's executive management and the board of directors.

Furthermore, over the longer term (in particular, following the abovementioned 12 months period), Sequana Medical's existing capital resources will be insufficient to fund, among other things, the completion of the clinical development of the DSR® product required to bring them to market in Europe and North America.

In view of the Company's working capital needs, the Company's statutory auditor, PwC Bedrijfsrevisoren BV, represented by Mr. Peter D'hondt, auditor, has included a note in the audit report on the Annual Financial Statements with regard to material uncertainty related to the Company's going concern, referring to the fact that the Company is still in its development phase conducting clinical trials in order to achieve regulatory marketing approvals, and that it is subject to various risks and uncertainties, including but not limited to the uncertainty of the development process and the timing of achieving profitability, and that the Company's ability to continue operations also depends on its ability to raise additional capital and to refinance existing debt, in order to fund operations and assure the solvency of the Company until revenues reach a level to sustain positive cash flows. The opinion also clarified that the impact of macroeconomic conditions and the geopolitical

situation in Ukraine on the Company's ability to secure additional financing rounds or undertake capital market transactions remains unclear.

For further information, see also the risk factor "*Sequana Medical does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus and will require additional funds beyond this period in order to meet its capital and expenditure needs.*" in the chapter "*Risk Factors*", section "*2. Risks relating to Sequana Medical's financial situation*".

BUSINESS OVERVIEW

Principal activities

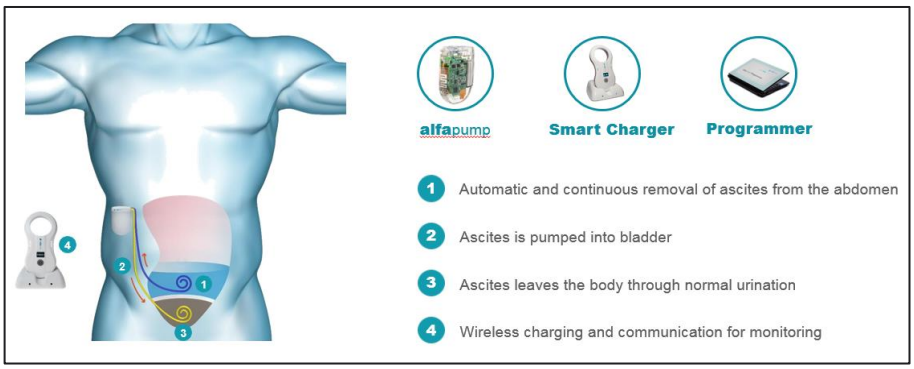
Sequana Medical is a commercial stage medical device company utilizing its proprietary **alfa**pump® and DSR® (Direct Sodium Removal) technologies to develop innovative treatments for fluid overload in liver disease, malignant ascites and heart failure when diuretics are no longer effective.

Sequana Medical is uniquely positioned in two large markets, thereby focussing on: (i) the direct commercialisation of the **alfa**pump® for liver cirrhosis in North America, and (ii) the clinical development of DSR® therapy for congestive heart failure. Sequana Medical's products are protected by a strong intellectual property portfolio.

- **Sequana Medical's alfapump®: Eliminating fluid from the peritoneal cavity – working in partnership with the bladder**

The **alfa**pump® is a unique, fully implanted system that automatically pumps fluid from the abdominal cavity into the bladder, where it is naturally eliminated through urination. It has a number of distinctive features:

- Fully implanted
- Automatic operation
- Battery charged wirelessly through the skin
- Pump settings easily and wirelessly adjusted
- Remote pump performance data monitoring
- Easy, long-term implantation & catheter patency
- Monitors bladder and peritoneal pressure via pressure sensors
- Removing up to 4 litres of fluid / day
- Virtually non-clogging
- No significant heating during charging and operation
- Strong IP barriers through extensive patent portfolio & know-how



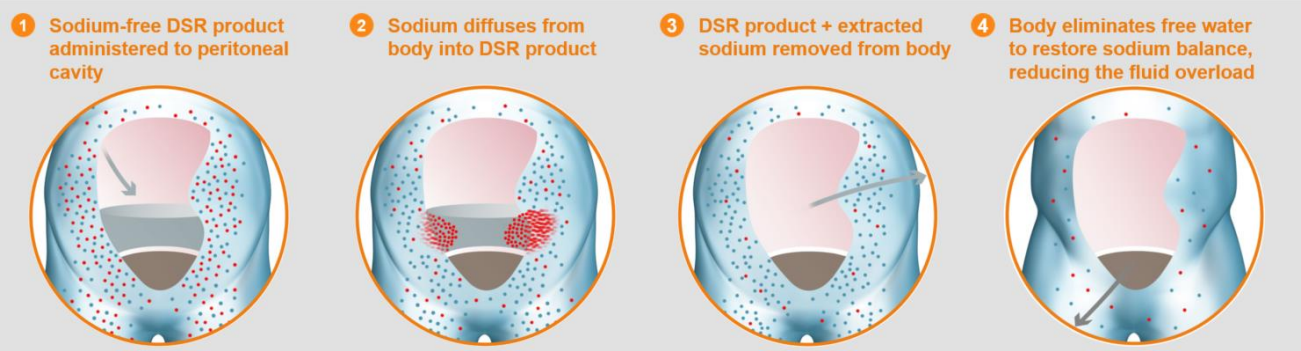
The **alfa**pump® is approved in Europe for the treatment of refractory liver ascites and malignant ascites and has been included in key European treatment guidelines. In the U.S., the **alfa**pump® has been granted breakthrough device designation by the Food and Drug Administration (FDA) for the treatment of recurrent or refractory liver ascites. To date, over 950 **alfa**pump® systems have been implanted.

The pivotal POSEIDON study to support the approval of the **alfa**pump® in North America has reported positive primary endpoint data, enabling the filing of a Pre-Market Approval (PMA) application with the FDA planned for H2 2023. Sequana Medical plans to directly commercialize the **alfa**pump in the U.S. by establishing its own specialty sales force focused on the 125 adult liver transplant centers, leveraging its experience from Europe and the North American studies.

For more information about the **alfa**pump®, reference is made to section "*Proprietary **alfa**pump & DSR technologies*", p. 18 and following, and section "***alfa**pump in liver disease and cancer*", p. 35 and following, of the 2022 Annual Report, which is incorporated by reference into this Prospectus.

- **Sequana Medical's DSR®: Eliminating fluid spread across the body – working in partnership with the kidneys**

DSR® therapy uses a sodium-free product administered into the peritoneal cavity to remove excess sodium from the body via diffusion, to which the kidneys respond and eliminate excess free water naturally through urination, leading to reduced fluid overload.



Clinical proof-of-concept data with its first-generation DSR® product (DSR® 1.0) indicated that DSR® therapy is able to safely, effectively and rapidly eliminate fluid overload and restore euvolemia without the need of any loop diuretics, as well as deliver a considerable benefit in patients' cardiovascular and renal status and a dramatic and sustained improvement in their diuretic responsiveness, thereby dramatically reducing the need for oral loop diuretics for many months post-therapy. In both RED DESERT and SAHARA studies, there were no congestion-related hospital readmissions, all patients improved their NYHA status by at least one class, and the predicted one year mortality was reduced by 75% (calculated using the Seattle Heart Failure model).

In parallel, Sequana Medical developed its proprietary DSR® 2.0, a second-generation product expected to have an improved therapeutic profile and favourable safety profile and with a robust intellectual property protection that will drive a high margin recurring revenue stream. GLP animal studies and a single-dose Phase 1 CHIHUAHUA study demonstrated that DSR® 2.0 was safe and well-tolerated, and indicated a compelling dosing profile. Sequana Medical received clearance of the IND for DSR® 2.0 and plans to commence its MOJAVE study, a U.S. multi-center, randomized controlled Phase 1/2a clinical study of DSR® 2.0 in Q2 2023. Based on the results from the MOJAVE study, the Company plans to establish a strategic partnership for further clinical development and commercialisation of its DSR® therapy. This will enable Sequana Medical to leverage the strengths of an established heart failure player to realize the strong commercial potential of its DSR® therapy.

For more information about DSR®, reference is made to section *"Proprietary **alfa**pump & DSR technologies"*, p. 18 and following, *and* "*DSR in heart failure*", p. 61 and following, of the 2022 Annual Report, which is incorporated by reference into this Prospectus.

Changes since the date of the last financial information

Except as a result of the geopolitical instability on the macroeconomic outlook and the events set out in note 14 to the Annual Financial Statements, there has been no material adverse change in the prospects of Sequana Medical since the end of the last financial period covered by its last published audited financial statements, nor has there been any significant change in the financial performance of Sequana Medical since the end of the last financial period for which financial information has been published to the date of this Prospectus. See also note 4 to the Annual Financial Statements (as defined above) and risk factor "*The Russian*

invasion of Ukraine could have a destabilising impact on Sequana Medical's operations, both directly as a result of the conduct of studies in neighbouring countries and indirectly due to the impact on global macroeconomic conditions."

Trends

Trends in sales

At the date of this Prospectus, sales levels are lower than the levels at 31 December 2022 (*i.e.*, EUR 922,687.00) on a pro-rata basis (as a result of the implementation in April 2023 of several measures in order to reduce costs and expenditures, which included the reduction of the Company's European commercial team by moving to a "reactive" rather than "proactive" commercial stance (i.e., ready to act on clinician interest and maintaining dialogue with key centres, instead of actively promoting the therapy)).

Trends in inventory

At the date of this Prospectus, inventory levels are more or less in line with the levels at 31 December 2022 (*i.e.*, EUR 2,621,197.00).

Trends in costs and selling prices

At the date of this Prospectus, costs and selling prices did not change since the end of the reporting period (31 December 2022), in line with sales. Total selling prices for 2022 amounted to EUR 922,687.00. Total costs for products sold for 2022 amounted to EUR 204,597.00.

Trends in production and engineering

At the date of this Prospectus, production and engineering costs are higher than the levels at 31 December 2022 (*i.e.*, respectively, EUR 3,157,666.00 and EUR 3,853,153.00) on a pro-rata basis (as a result of increased costs related to the preparation of the submissions for marketing approval of the **alfa**pump® in the US and Canada).

Material contracts

Supplier and service agreements

The large majority of sub-components of the **alfa**pump®, including the batteries, printed circuit board, motor, charger, docking station, catheter and surgical accessories are sourced externally, from a total of more than 70 external suppliers. Sequana Medical's suppliers are predominantly headquartered in Europe and the U.S. and range from large multinational companies to smaller private companies. In Sequana Medical's opinion, the suppliers of the critical components of the **alfa**pump® are experienced and well-respected manufacturers with multiple customers and have existing quality control programmes and registrations with the appropriate regulatory authorities.

In relation to the DSR® product and the implementation of certain software, Sequana Medical relies on service agreements with several companies.

The tenure of Sequana Medical's relationships with suppliers and service providers usually extends beyond a single contract term with automatic agreement renewals for successive one-year periods over the life of the relationship. Sequana Medical determines whether it is appropriate to have a long term or short term agreement in place with a supplier or service provider on a case by case basis. Both parties can typically terminate the relevant agreement with six months' advance notice prior to the expiration of the initial term of the agreement or the relevant renewal period.

The prices of the supplier components and/or services are set in Sequana Medical's supplier and service agreements, in some cases for the period of the contract and in other cases agreed per each purchase order placed by Sequana Medical.

Contract research organisations and consultants

Sequana Medical has entered into contracts with CROs and consultants, primarily in connection with clinical studies, the development of the **alfa**pump® and DSR® product. These contracts with CROs are generally entered into for the duration of the study or limited period of time (up to 3 years), with early termination options for both parties, including for convenience (but subject to the payment of some or part of the costs and fees already, or to be, incurred by the CRO).

All of the contracts with CROs contain confidentiality and intellectual property rights clauses. The confidentiality clauses in these contracts generally remain applicable for a period which varies between the different contracts and ranges from the duration of the contract to a period of up to 10 years after termination of the contract. The intellectual property rights clauses in these contracts grant Sequana Medical all proprietary rights with respect to the results of the study and the performance of the agreement.

In October 2019, the Company entered into a services agreement with a consultant, based in the United States, pursuant to which the consultant has agreed to provide services to the Company with respect to the development of the **alfa**pump DSR® and its components in exchange for certain fees payable by the Company. Either party is entitled to terminate the consultancy agreement by written notice to the other party in a limited number of circumstances set out in the services agreement. The Company will acquire title to all work product developed by the consultant for the Company in the course of the provision of services pursuant to the services agreement which have been funded by the Company or for which the data was provided by the Company. The consultant will transfer to the Company the rights to all intellectual property related to such work product. The services agreement also contains conflicts of interests and confidentiality provisions.

In October 2022, the Company entered into a services agreement with another consultant, based in the United States, pursuant to which the consultant has agreed to provide services to the Company with respect to the implementation and coordination of clinical trials. Either party is entitled to terminate the consultancy agreement by written notice to the other party in a limited number of circumstances set out in the services agreement. The Company may terminate the consultancy agreement for no reason by written notice to the other party. The Company will acquire title to all work product developed by the consultant for the Company in the course of the provision of services pursuant to the services agreement which have been funded by the Company or for which the data was provided by the Company. The consultant will transfer to the Company the rights to all intellectual property related to such work product. The services agreement also contains conflicts of interests and confidentiality provisions.

Cooperative Research and Development Agreement

In January 2020, the Company entered into a Principal Investigator Initiated Study Cooperative Research and Development Agreement (CRADA) with a federal U.S. government agency, represented by a medical center, and a research institute, all based in the United States, in respect of collaborative research in relation to a multi-center study of outpatients with cirrhosis (NACSELD-III). The Company is required to make payments and provide certain capital equipment in connection with the study under the CRADA. The CRADA can be terminated by mutual consent or unilaterally (i) at any time by providing written notice at least sixty (60) days before the desired termination date; or (ii) immediately upon a material breach, for good cause, for subject safety, or upon termination of the study by the FDA. The CRADA provides that each party shall retain ownership of and title to inventions made by its employees in the context of the performance of the agreement. The agreement also includes certain license options for the Company.

Subordinated Loan Agreements

In July 2020, the Company entered into the Subordinated Loan Agreements with PMV Standaardleningen (as defined above), Sensinnovat (as defined above) and Belfius Insurance (as defined above), in the aggregate principal amount of EUR 7.3 million, of which loans in the principal amount of EUR 1.4 million may be converted into new Shares in the event of an equity financing or sale of the Company. In March 2021, as a result of the equity raising by the Company that took place on 15 February 2021, Sensinnovat and Belfius Insurance exercised their conversion rights in the aggregate amount of EUR 618,916.67 (representing principal and interests) into an aggregate of 97,084 new Shares in accordance with the terms of the Subordinated Loan Agreements, thereby settling the convertible portion of their loans through a contribution in kind of their payables due by the Company under the relevant loans. In December 2021, the Company entered into amendment agreements related to the outstanding Subordinated Loan Agreements with the lenders, thereby (i) extending the duration of such loans, (ii) increasing the interest rates retroactively, and (iii) introducing

payment by instalments. In March 2023, the Company entered into new amendment agreements, thereby (i) amending the repayments terms and (ii) further increasing the interest rates retroactively. Consequently, the loans have a term of 60 months and are repayable in four equal quarterly instalments of EUR 1,675,000 on 30 September 2024, 31 December 2024, 31 March 2025 and 30 June 2025. The Subordinated Loan Agreements bear an interest rate of 7.0% per annum, except that the convertible portion of the loan granted by PMV-Standaardleningen bears an interest rate of 6.0% per annum. The loans with PMV-Standaardleningen, Belfius Insurance and Sensinnovat allow the Company to prepay the relevant loans together with all accrued interest, provided that the Company pays a termination indemnity equal to six months of interest on the prepaid loan. The convertible portion of the loan granted by PMV-Standaardleningen can be converted in the event of an equity financing or sale of the Company, at a price per share that is equal to 75% of the price of the Company's shares as will be reflected in the relevant equity financing or sale.

The loan agreements with PMV-Standaardleningen furthermore provide that the Company should require prior approval of PMV-Standaardleningen (which may not be unreasonably delayed or repudiated) in case of, among other things, (i) any dividend distribution or other return of equity by the Company to its shareholders, or (p)repayment of loan(s) granted by shareholders (ii) any borrowings, guarantees, indemnities or other contingent commitments or the granting of any security over the Company's assets, outside the ordinary course of business, by the Company, (iii) any type of (de)merger and/or acquisitions, and/or similar transaction(s) with respect to the Company, (vi) any change to the nature of Company's principal business, or any addition of any new business, and (v) the subordination of payment obligations under the loan agreements with PMV-Standaardleningen *vis-à-vis* any of the Company's current or future payment obligations under loans borrowed or to be borrowed by the Company from its shareholders.

PMV-Standaardleningen, Sensinnovat and Belfius Insurance will also have the right to demand the early repayment of the loans in the event of a change of control.

Kreos Loan Agreement

In July 2022, the Company entered into a secured loan facility agreement with Kreos Capital (as defined above) in the amount of EUR 10.0 million pursuant to which the Company is permitted to request an increase of the facilities in the amount of a maximum of EUR 10.0 million on an uncommitted basis. In April 2023, the facility agreement has been amended as clarified below.

The main elements of the Kreos Loan Agreement can be summarised as follows:

- *Term:* The loan facility matures on 30 September 2025. During the initial period of six months from the first drawdown (extendable by mutual agreement), the Company only had to pay interest, with the loans amortising thereafter in equal monthly instalments of principal and interest until maturity.

  The amendment in April 2023 aimed at reducing the repayment of principal amounts that would otherwise be due during a specified period of time (the "**Initial Restructuring Period**"). The Initial Restructuring Period is the period starting on 27 April 2023 until either (i) 31 December 2023 or (ii) 31 March 2024, if the Company initiates its first clinical trial site for its Phase 1/2a US study of proprietary DSR 2.0 product (a sodium-free dextrose / icodextrin solution for direct sodium removal) in the United States (MOJAVE) by no later than 31 December 2023. During the Initial Restructuring Period, each scheduled principal repayment will be reduced at a rate of 75%. If the Company raises additional equity for an aggregate gross amount of at least EUR 20,000,000 before 31 December 2023, each scheduled principal repayment will be reduced by 50% during a period of six months after the end of the Initial Restructuring Period (the "**Additional Restructuring Period**"). The final repayment date remains 30 September 2025, meaning that the scheduled principal repayments falling after the Initial Restructuring Period and Additional Restructuring Period will be increased.

- *Interest:* The loans under the facility accrue interest at a fixed rate of 9.75% per annum.

- *Fees:* A number of fees are payable to Kreos Capital, principally consisting of (i) a transaction fee equal to 1.25% of the total loan facility amount, which has been paid upon execution of the Kreos Loan Agreement and (ii) an end of loan payment, payable upon final repayment of the loan, corresponding to 1.25% of the amount drawn.

In the framework of the amendment in April 2023, the Company (i) paid an amendment fee of EUR 100,000 to Kreos Capital and (ii) agreed to increase the end of loan payment mentioned above to 1.75% provided that the Initial Restructuring Period enters into effect (which occurred on 27 April 2023).

- *Board observer:* Kreos Capital is entitled to appoint a board observer to attend meetings of the Company's board of directors in a non-voting capacity.

- *Collateral:* The loans are secured by the Company's bank accounts, receivables and movable assets, including IP rights.

- *Change of control:* The Kreos Loan Agreement contains a change of control clause and requires such clause to be approved by the Company's general shareholders' meeting at the latest at the date of the annual shareholders' meeting of the Company to be held in 2023.

- *Contractual restrictions:* The Kreos Loan Agreement does not contain financial covenants, but does contain other customary restrictions on the business of the Company and its subsidiaries (such as limitations on future disposals, limitations on the incurrence of financial indebtedness, security and acquisitions, subject to certain carve-outs and limitations) and on the ability of the Company to distribute dividends as long as loans are outstanding.

On 9 September 2022, the Company made a first drawdown in the amount of EUR 10.0 million.

In the framework of the Kreos Loan Agreement, the Company and Kreos Capital VII Aggregator SCSp entered into a subscription rights agreement in July 2022 (the "**Kreos Subscription Rights Agreement**") pursuant to which the Company agreed to issue and allocate 875,000 subscription rights to Kreos Capital VII Aggregator SCSp (the "**Kreos Subscription Rights**") to subscribe to 161,404 new shares of the Company. The issuance of the Kreos Subscription Rights to the benefit of Kreos Capital VII Aggregator SCSp has been approved by the Company's extraordinary general shareholders' meeting on 10 February 2023. The Kreos Subscription Rights have an initial term which expires five years after the date of the Kreos Loan Agreement or (if earlier) the completion of (i) a public takeover bid with respect to the Shares and other outstanding voting securities of the Company or securities granting access to voting rights, or (ii) a sale of the entire issued share capital of the Company to a bona fide third party on arm's length terms for cash consideration (a "**Share Sale**"). If at the end of the initial five-year period the subscription rights have not been fully exercised and no Share Sale has yet taken place, the Company will issue new subscription rights on similar terms for an additional period of two years (or until the completion of a Share Sale, if earlier). For more information about the Kreos Subscription Rights, reference is made to the report of the board of directors in accordance with articles 7:180, 7:191 and 7:193 of the Belgian Companies and Associations Code (available on the Company's website at: https://www.sequanamedical.com/wp-content/uploads/2023/01/6-Board-Report-ENG-final-including-annex.pdf).

Regulatory environment

Europe

In Europe, regulatory approval for the **alfa**pump® (and potentially any future products) is obtained via the CE Mark (conformity assessment) process according to Regulation (EU) 2017/745 on Medical Devices (the "**EU MDR**") which provides approval for the European Economic Area (EEA) (including the European Union, Iceland, Liechtenstein and Norway) and is accepted by certain other non-EEA countries, including Switzerland. (In Switzerland, the Swiss Federal Council adopted an amendment on May 19, 2021 to the Swiss Ordinance on Medical Devices establishing conditions for the trade of medical devices covered by EU issued certificates, including the CE Mark, on the Swiss market. This includes the recognition of existing certificates issued under the Medical Devices Regulation (EU) 2017/745 by conformity assessment bodies established in the EU or EEA and transitional timelines for the designation of a representative in Switzerland for EEA manufacturers of medical devices until 31 December 2021). In Switzerland, Sequana Medical has appointed an authorised representative and registered with the local regulatory authority, Swissmedic, having consequently received a CHRN (Swiss Single Registration number). Sequana Medical has received a CE Mark under the EU MDR for the **alfa**pump® for single patient use in patients with liver refractory ascites and in patients with malignant ascites

in February 2022. This approval is limited to those indications and the jurisdictions that accept the CE Mark. The CE certificates are valid for 5 years and must be renewed before expiry.

The Medical Devices Regulation, which was adopted on 5 April 2017 and has become applicable from 26 May 2021, contains further obligations with which Sequana Medical is required to comply. In addition to the certification requirement for medical devices under the EU MDR, which for the **alfa**pump® was complied with in February 2022, the EU MDR requires the application of a unique device identifier ("**UDI**") for implantable devices, Eudamed registration and entry of data in relation to the devices (for 24 months following the date of the EC notice of full functionality of Eudamed currently announced for Q2 2024). The EU MDR influences the way Sequana Medical conducts business in Europe and include, among other things, the following:

- stricter rules for placing devices on the market with increased evidence requirements for CE Marking requiring additional clinical investigations, as well as subsequent post-market surveillance and clinical follow-up once they are available;

- stricter rules for the assessment of certain high-risk devices, such as (active) implantable medical devices such as the **alfa**pump®, which may need to undergo additional testing (for example, on safety or efficacy) and may be subject to additional scrutiny by independent experts before they are placed on the market;

- re-approval requirements for the organisations responsible for assessing whether manufacturers and their medical devices meet applicable regulatory requirements ("**Notified Bodies**") and stricter rules for such Notified Bodies to operate under;

- explicit provisions on the responsibilities of manufacturers and other supply chain actors including the EU authorised representative (for manufacturers based outside of the EEA), importer and distributor for the follow-up of the quality, performance and safety of devices placed on the market;

- better traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; and

- a central database and increased transparency requirements to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

In addition, in Europe, the **alfa**pump® in conjunction with the Smart Charger falls within the scope of radio equipment and is therefore also subject to the Radio Equipment Directive 2014/53/EU (the "**RED**"), which imposes requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum.

The DSR® product may be marketed as a medicine in Europe and therefore subject to an extensive body of pharmaceutical laws and regulations. In the EEA, medicinal products can only be commercialised after obtaining a marketing authorisation. Marketing authorisations can be obtained under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

A centralised marketing authorisation is issued centrally by the European Commission based on the opinion of the Committee for Medicinal Products for Human Use (the "**CHMP**") of the European Medicines Agency (the "**EMA**"). It is valid throughout the entire territory of the EEA. The centralised procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The centralised procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

Under the centralized authorisation procedure, the European Medicines Agency will conduct a scientific evaluation of the safety, efficacy and quality of medicinal products. The process is complex and involves extensive consultation with the regulatory authorities of Member States and a number of experts. If the EMA through the CHMP concludes that the quality, safety and efficacy of the medicinal product is sufficiently proven, it adopts a positive opinion. The CHMP's opinion is sent to the European Commission, which uses the opinion

as the basis for its decision whether or not to grant a marketing authorisation. If the CHMP opinion is negative, information is given as to the grounds on which this conclusion was reached and a re-examination of the CHMP opinion can be requested by the applicant. A Commission decision to refuse the granting of a marketing authorisation can be challenged in the European courts. After approval, the EMA continues to monitor the product throughout its life cycle and may take measures in relation to the marketing authorisation to preserve public health.

Under the mutual recognition, decentralised and national procedures, national marketing authorisations are issued by the competent authorities of the Member States of the European Union and Norway, Iceland and Liechtenstein and only cover their respective territory. National marketing authorisations are available for products not falling within the mandatory scope of the centralized procedure. National procedures are followed in case a marketing authorisation is sought in only one Member State of the EU, mutual recognition or decentralised procedure must be followed in case a marketing authorisation is sought in more than one Member State and one Member State will take the lead in the scientific evaluation (Reference Member State) which will be coordinated with the other concerned Member States for harmonised outcomes. Any negative outcomes are to be challenged in national courts. After approval, the national competent authorities under the lead of the Reference Member State will continue to monitor the product throughout its life cycle and may take measures in relation to the marketing authorisation to preserve public health.

Generally, the development, manufacturing, approval, distribution, marketing and promotion and post-market monitoring of medicines are subject to extensive requirements which are considered even more strict than those applicable to medical devices. Key regulations at EU level include Directive 2001/83/EC on the Community code relating to medicinal products for human use, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use. Key differences with the medical devices framework include:

- Manufacturing, import and wholesale distribution of medicines is subject to a license to be issued by the national competent authority in the member state where the manufacturer, importer or wholesale distributor is based
- For pharmaceuticals paediatric clinical trials must be undertaken unless a waiver applies
- Innovative medicinal products (including both small molecules and biological medicinal products) may qualify for eight years of data exclusivity upon marketing authorisation and an additional two years of market exclusivity (extendable with 1 year). During this period generics and biosimilars referencing the data of the innovative medical product cannot enter the market.
- Detailed requirements for good laboratory, clinical, manufacturing, distribution and pharmacovigilance practices
- Multiple reporting obligations including start and end dates of commercialisation, shortage notifications, and any information affecting the benefit risk balance of the product or changing the particulars submitted in support of a marketing authorisation.

On 26 April 2023, the European Commission adopted a proposal for a Regulation and a Directive aiming to overhaul the EU pharmaceutical legislation ("pharma package"). When adopted the pharma package will have far reaching implications for the pharmaceutical industry in Europe. One of the key measures is the reduction of the standard period of data exclusivity from 8 to 6 years and the introduction of limited and conditional extensions to such data protection (such as, e.g., 2 additional years for making the medicine available in all Member States of the EU covered by the authorisation). Furthermore, the pharma package proposes to simplify and streamline regulatory procedures but at the same time imposes additional obligations on marketing authorisation holders concerning the availability of medicines and the protection of the environment (such as submitting an enhanced environmental risk assessment as part of the marketing authorisation application for any medicine). The legislative process is expected to take several years and the European Council and Parliament may amend the proposed wording during the process.

United States

U.S. Review and Approval Process

Medical device and drug products are extensively regulated, including, the research, development, testing, quality control, approval, manufacturing, labeling, post-approval monitoring and reporting, recordkeeping, packaging, promotion, storage, advertising, distribution, marketing and export and import. Manufacturing is also subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal and state statutes and regulations require the expenditure of substantial time and financial resources.

In the U.S., regulatory approval for the **alfa**pump® (and potentially any future medical device products) is obtained via submission of a pre-market approval ("**PMA**") application to the U.S. Food and Drug Administration (the "**FDA**"). The PMA application process requires submission of a PMA application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices such as the **alfa**pump® and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with Investigational Device Exemption (IDE) regulations. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed and the date of filing. The 180-day period for review of a PMA starts on the date of filing.

The **alfa**pump® has received FDA breakthrough device designation, but a PMA for the product has not yet been submitted to FDA. Timing for regulatory approval of the **alfa**pump® via a PMA is uncertain. There is a risk that the **alfa**pump® may not receive FDA approval at all. Once approved, the PMA does not have an expiry date, however regulatory approvals may be withdrawn if, for example, a new and unexpected risk emerges which would make continued marketing of the relevant product no longer acceptable. The Federal Communications Commission must also determine that wireless medical devices, such as the **alfa**pump® are compatible with other uses of the spectrum on which the device operates, and that power levels and the frequency spectrum of the wireless energy transfer comply with applicable regulations.

In relation to the DSR® product, Sequana Medical is engaging with the FDA to pursue approval as a drug product. The DSR® product is in very early pre-clinical stage development. The results from preclinical testing of a drug candidate may not predict the results that will be obtained in later phase clinical trials of the drug candidate, and clinical data to support the safety and effectiveness of the drug product will be required in order to obtain approval of a marketing application in the U.S. The data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

FDA regulates medical devices and drug products under the Federal Food, Drug, and Cosmetic Act (the "**FDCA**") and implementing regulations. Failure to comply with the applicable FDA requirements at any time pre- or post-approval may result in a delay of approval or administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

Pre-Clinical and Clinical Studies

Pre-clinical tests include laboratory evaluations as well as animal studies, to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practice. The results of pre-clinical tests are submitted to the FDA as part of an Investigational New Drug ("IND") application and an IDE and are reviewed by the FDA before the commencement of human clinical trials.

Clinical trials involve the administration of the investigational drug or device to patients under the supervision of qualified investigators following FDA's good clinical practices regulations. Clinical trials are conducted under protocols that detail the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. The informed written consent of each participating subject is required. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, for example, the data safety monitoring board ("**DSMB**"). This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the

ongoing trial. The suspension or termination of development can occur during any phase of clinical trials if it is determined that the participants or patients are being exposed to an unacceptable health risk. In addition, there are requirements for the registration and entry of certain clinical trial information related to ongoing clinical trials of FDA-regulated drugs and medical devices on public registries, such as clinicaltrials.gov, and the disclosure of certain information pertaining to the trials as well as clinical trial results after completion.

Investigational Device Exemption

An IDE allows an investigational device to be used in a clinical study to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. Clinical evaluations of devices that do not have marketing approval require: (1) an investigational plan approved by an institutional review board ("IRB"); (2) informed consent from all patients; (3) labeling stating that the device is for investigational use only; (4) monitoring of the study; and (5) required records and reports.

An IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with certain requirements of the FDCA that would otherwise apply to a device in commercial distribution. An IDE is considered approved 30 days after it has been received by the FDA, unless the FDA otherwise informs the sponsor via email prior to 30 calendars days from the date of receipt, that the IDE is approved, approved with conditions, or disapproved. Absence of FDA objection to an IDE does not necessarily mean that the FDA will ultimately approve a marketing application based on the clinical trial data. If disapproved, the sponsor has the opportunity to respond to the deficiencies and/or request a regulatory hearing.

The decision to terminate development of an investigational device may be made by either a health authority body, such as the FDA, or by a company for various reasons at any time during development. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the device has been associated with unexpected serious harm to patients.

Investigational New Drug Application

An IND is an application submitted to FDA to request authorization from the FDA to administer an investigational drug product to humans. This authorisation is required before interstate shipping and administration of any new drug product to humans that is not the subject of an approved new drug application (NDA). A waiting period of at least 30 days after the submission of each IND is required prior to the commencement of clinical testing in humans to allow FDA an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin or, alternatively the FDA may issue a "study may proceed" letter. Absence of FDA objection to an IND does not necessarily mean that the FDA will ultimately approve a marketing application based on the clinical trial data.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Phase I clinical trials may be conducted in patients or healthy volunteers to evaluate the product's safety, dosage tolerance and pharmacokinetics and, if possible, seek to gain an early indication of its effectiveness. Phase II clinical trials usually involve controlled trials in a larger but still relatively small number of subjects from the relevant patient population to evaluate dosage tolerance and appropriate dosage; identify possible short-term adverse effects and safety risks; and provide a preliminary evaluation of the efficacy of the drug for specific indications. Phase III clinical trials are typically conducted in a significantly larger patient population and are intended to further evaluate safety and efficacy, establish the overall risk-benefit profile of the product, and provide an adequate basis for physician labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA. Sponsors are required to notify FDA in writing of any adverse experience associated with the use of the drug that is both serious and unexpected or any findings from tests in laboratory animals that suggest a significant risk for human subjects including reports of mutagenicity, teratogenicity, and carcinogenicity.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The decision to terminate development of an investigational drug product may be made by either a health authority body, such as the FDA, or by a company for various reasons at any time during development. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution 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.

Pre-market Approval for Medical Devices

Authorization to distribute a new medical device through the PMA process requires the submission of a PMA application to the FDA to demonstrate that the device is safe and effective for its intended use. The applicant must receive FDA approval of its PMA application prior to marketing. A PMA is the most stringent type of device marketing application required by FDA. The technical sections of a PMA are typically divided into non-clinical laboratory studies and clinical investigations and contain data and information to allow FDA to determine whether to approve or disapprove the application. The non-clinical laboratory studies section includes information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests. The clinical investigations section includes study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations.

All manufacturers of Class III devices are required to follow design controls during the development of the device. PMA submissions should include a complete description of design controls that the manufacturer implements to comply with the Quality System Regulation (QSR). FDA will conduct a preapproval inspection to assess the company's capability to design and manufacture the device as claimed in the PMA and confirm that the firm's QSR is in compliance with FDA regulations.

After a PMA is filed, FDA will conduct an administrative and limited scientific review to determine whether the PMA is suitable for filing. The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to begin an in-depth review. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed. The letter will include the PMA reference number and the date FDA filed the PMA. Within 100 days of the filing of the PMA, the applicant may request to meet with FDA to discuss the review status of the application. Prior to the meeting, FDA will inform the applicant of any identified deficiencies and the information required to correct the deficiencies. FDA must promptly notify the applicant if it identifies additional deficiencies or any additional information required to complete its review.

The 180-day period for review of a PMA starts on the date of filing. FDA will rely upon only valid scientific evidence to determine whether there is reasonable assurances that the device is safe and effective. Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to certain characteristics of the device, its conditions of use, the existence and adequacy of warnings or other restrictions, and the extent of experience with its use. For novel technologies, the FDA may seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device during the review process. After review of the PMA, FDA will issue one of the following: an approval order, an approvable letter, a not approvable letter, or an order denying approval. The FDA will issue an approval order if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the QSR. Approval will be based on the condition that the applicant submits to FDA a copy of the final printed labeling before marketing. FDA will issue an approvable letter if the application substantially meets the requirements of the FDCA, and FDA believes that it can approve the application if specific additional information is submitted or specific conditions are agreed to by the applicant. FDA will send a not approvable letter if the agency believes that the application may not be approved or if FDA is unable to reach an approvable decision due to a lack of significant information in the application. FDA will identify what is necessary to make the PMA approval and the applicant may amend or withdraw the PMA or consider the letter to be a denial of approval of the PMA and request administrative review. FDA may deny approval of a PMA if the applicant fails

to follow the requirements of the PMA regulation or if the agency determines that any of the grounds for denying approval of the PMA specified under the FDCA apply. FDA may also deny approval of a PMA for a number of additional reasons, including, for example, if the PMA contains a false statement of material fact.

Postapproval inspections are conducted within 8 to 12 months of approval of the PMA submission and primarily focus on any changes that may have been made in the device design, manufacturing process, or quality systems. FDA's approval of a product may limit the intended use(s), which could restrict the commercial value of the product. After FDA has approved a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making any change affecting the safety or effectiveness of the device unless FDA has provided guidance that an alternate type of submission is permitted for a particular change.

New Drug Applications

In order to obtain approval to market a drug in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the drug product for the proposed indication. The application includes all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA.

In most cases, the NDA must be accompanied by a substantial user fee; there may be some instances in which the user fee is waived. The FDA will initially review the NDA for completeness before it accepts the NDA for filing. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. After the NDA submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten months of submission. The FDA can extend this review by three months to consider certain late-submitted information or information intended to clarify information already provided in the submission. The FDA does not always achieve its performance goal and its review of NDAs can take significantly longer. The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP. The FDA may refer applications for novel drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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 will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect the sponsor and one or more clinical sites to assure compliance with GCP. After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, time or information in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. The approval process is lengthy and difficult and notwithstanding the submission of any requested additional information, the FDA ultimately may refuse to approve an NDA if applicable regulatory criteria are not satisfied or if the FDA believes additional clinical data or other data and information are required. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than a company interprets the same data.

An approval letter authorises commercial marketing of the drug with the specific prescribing information reflecting FDA's finding regarding the safety and effectiveness of the drug under the labeled conditions of use. FDA's approval of a product may be significantly limited to specific disease and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may

require that certain contraindications, warnings, or precautions be included in the product labeling. In addition, as a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("**REMS**"), to help ensure that the benefits of the drug outweigh the potential risks. REMS can include certain risk mitigation strategies designed to reinforce medication use behaviors and actions that support the safe use of the medication, including medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, restricted distribution, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, or modification to a REMS, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar in quality and content to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

The FDA actively monitors compliance with its laws and regulations through review and inspection of design and manufacturing practices, establishment registration and product listing requirements, record-keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain drugs or medical devices, detain or seize adulterated or misbranded products, order recall or market withdrawal of and require notification of health professionals and others with regard to products that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the FDCA, or initiate action for criminal prosecution of such violations.

As a condition of approval of an NDA or PMA, the FDA may require the applicant to conduct additional post-approval studies or post market testing and surveillance to further monitor and assess the product's safety and efficacy. In addition, manufacturing establishments in the U.S. and abroad are subject to periodic inspections by the FDA and must comply with cGMP or QSR requirements. To maintain compliance, manufacturers must expend funds, time and effort in the areas of production and quality control.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

FDA regulations prohibit the promotion of an investigational product for an unapproved use. The FDA distinguishes impermissible promotion of an investigational product from the permissible exchange of scientific and medical information among healthcare professionals, which may include company-sponsored scientific and educational activities.

Canada

In Canada, medical devices are regulated by Health Canada, the department of the government of Canada with responsibility for national public health, which reviews medical devices to assess their safety, effectiveness, and quality based on clinical data before authorising their sale in Canada according to the Medical Devices Regulation SOR/98-282. Prior to marketing the alfapump® and/or any future product in Canada, Sequana Medical must obtain a medical device licence (MDL) from Health Canada and fulfil the necessary quality requirements established under the Medical Devices Single Audit Program (the "MDSAP") which Sequana Medical completed in November 2021. Health Canada also monitors medical devices after they are placed on the market to ensure their continued safety and effectiveness. If a medical device is found to no longer be safe and effective, its medical device license can be suspended or the manufacturer may be requested to recall or refurbish the medical device.

Material investments

No material investments have been made by the Company since 31 December 2022, and no material investments are in progress, nor for which firm commitments have been made by the Company.

MAJOR SHAREHOLDERS

Overview of the Company's shareholder structure

The Company has an international shareholder base with both large and smaller specialised shareholders focused on the healthcare and life sciences sectors, and a number of more local retail investors. Based on the number of Shares on the date of this Prospectus and transparency notifications received by the Company until that date, the shareholder base of the Company is as set out in the table below. Applicable transparency disclosure rules and the articles of association of the Company provide for shareholder notification thresholds of 3%, 5%, or a multiple of 5% (*i.e.* 10%, 15%, 20%, etc.) of the total number of existing voting rights. Although the applicable transparency disclosure rules require that a disclosure be made by each person passing or falling under one of the relevant thresholds (as set out above), it is possible that the information below in relation to a shareholder is not or no longer up-to-date. All transparency notifications are available under the 'Investors' section of www.sequanamedical.com/investors/shareholder-information/.

		On a non-diluted basis	On a fully diluted basis	On a fully diluted basis
	Date of Notification	% of the voting rights attached to Shares[1]	% of the voting rights attached to Shares[2] (taking into account the exercise of Subscription Rights)	% of the voting rights attached to Shares[3] (not taking into account the exercise of Subscription Rights)
Partners in Equity V B.V. [4]	16 March 2022	15.31%	13.45%	13.93%
Société Fédérale de Participations et d'Investissement SA – Federale Participatie- en Investeringsmaatschappij NV / Belfius Insurance NV/SA [5]	18 February 2020	12.70%	11.16%	11.56%
NeoMed IV Extension L.P. / NeoMed Innovation V L.P. / Erik Amble [6]	6 February 2023	12.09%	10.62%	11.00%
LSP Health Economics Fund Management B.V. [7]	19 February 2021	9.25%	8.13%	8.42%
Rosetta Capital Ltd [8].....	6 February 2023	5.97%	5.24%	5.43%
Participatiemaatschappij Vlaanderen NV [9].....	11 May 2023	4.80%	4.21%	4.37%
Newton Biocapital I SA [10]	15 March 2022	4.64%	4.08%	4.22%
GRAC Société Simple [11].	22 March 2022	4.25%	3.73%	3.86%
Sensinnovat BV [12]	15 March 2022	3.79%	3.33%	3.45%
Optiverder B.V. [13] ……..…...	10 May 2023	3.29%	2.89%	2.99%

Notes:

(1) The percentage of voting rights is calculated on the basis of the number of outstanding Shares at the date of the relevant transparency notifications. On the date of this Prospectus, the share capital of the Company amounts to EUR 2,921,010.22. It is divided into 28,191,733 Shares of no nominal value, each representing the same fraction of the share capital.

(2) The percentage of voting rights is calculated on the basis of a total of 32,097,054 Shares, consisting of 28,191,733 Shares outstanding on the date of this Prospectus and the issuance of 3,905,321 additional Shares, assuming that (i) 302,804 new Shares were issued upon the exercise of the ten Bootstrap Warrants (as defined below) (in the form of subscription rights) that are still outstanding (at the date of this Prospectus), (ii) 261,895 new Shares were issued upon the exercise of 90,780 share options that are still outstanding (at the date of this Prospectus) under the "Executive Share Options" plan for staff members and consultants of the Company, entitling the holder thereof to acquire approximately 2.88 Shares when exercising one of his or her share options, (iii) 1,067,924 new Shares were issued upon the exercise of 1,067,924 share options (each share option having the form of a subscription

right) that are still outstanding under the "2018 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire one new Share when exercising one of his or her share options, (iv) 1,000,000 new Shares were issued upon the exercise of 1,000,000 share options (each share option having the form of a subscription right) that are still outstanding (at the date of this Prospectus) under the "2021 Share Options" plan for directors, employees and other staff members of the Company and its subsidiaries, entitling the holder thereof to acquire new Shares when exercising one of his or her share options, (v) 161,404 new Shares were issued upon the exercise of the Kreos Subscription Rights, and (vi) 1,111,294 new Shares were issued upon the exercise of the Subscription Rights.

(3) The percentage of voting rights is calculated on the basis of a total of 30,985,760 Shares, consisting of 28,191,733 Shares outstanding on the date of this Prospectus and the issuance of 2,794,027 additional Shares (i.e., the 3,905,321 Shares referred to in footnote (2) above, but excluding the 1,111,294 new Shares to be issued upon the exercise of the Subscription Rights).

(4) A parent undertaking or a controlling person of PiE (as defined above) and Partners in Equity III B.V. ("**PiE III**"), informed the Company, by means of a notification dated 16 March 2022, that, on 10 March 2022 PiE's shareholding crossed the threshold of 15% of the outstanding voting rights of the Company. Notably, it followed from the notification that PiE held 3,636,363 Shares, representing 15.31% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification furthermore specified that PiE V is 100% owned by PiE III and that no natural or legal person has exclusive control of PiE III.

(5) A parent undertaking or a controlling person of Société Fédérale de Participations et d'Investissement SA / Federale Participatie- en Investeringsmaatschappij NV ("**SFPI-FPIM**"), Belfius Bank NV/SA and Belfius Insurance, informed the Company, by means of a notification dated 18 February 2020, that the aggregate shareholding of SFPI-FPIM and Belfius Insurance crossed the threshold of 10% of the outstanding voting rights of the Company on 17 February 2020. Notably, it followed from the notification that an aggregate of 2,004,358 Shares, representing 12.70% of the then 15,778,566 outstanding Shares and voting rights of the Company, were held through the following entities: SFPI-FPIM (holding 1,297,234 voting securities) and Belfius Insurance (holding 707,124 voting securities). The joint notification specified furthermore that SFPI-FPIM is the parent company of Belfius Bank NV/SA (ex Dexia Banque SA), which in its turn is the parent company of Belfius Insurance. The notification also stated that SFPI-FPIM acts in its own name, but on behalf of the Belgian State and that it is owned for 100% by the Belgian State. It followed from the notification that Belfius Bank NV/SA did not own any voting securities or voting rights in the Company.

(6) A parent undertaking or a controlling person of NeoMed IV Extension L.P. ("**NeoMed IV**"), NeoMed Innovation V L.P. ("**NeoMed V**") and NeoMed Management (Jersey) Limited ("**NeoMed Management**") informed the Company, by means of a notification dated 6 February 2023, that on 31 January 2023 the aggregate shareholding of Erik Amble, NeoMed IV and NeoMed V crossed below the threshold of 15% of the outstanding voting rights of the Company. Notably, it followed from the notification that an aggregate of 2,871,854 Shares, representing 12.09% of the 23,746,528 outstanding Shares and voting rights of the Company, is held through the following entities: NeoMed IV (holding 2,853,673 voting securities) and Erik Amble (holding 18,181 voting securities). The notification furthermore specified that NeoMed IV and NeoMed V are each a private limited company incorporated in Jersey, and are each controlled by their investment manager NeoMed Management (a private limited company incorporated in Jersey) and that NeoMed Management is controlled by Claudio Nessi, Dina Chaya, Erik Amble and Pål Jensen within the meaning of Articles 1:14 and 1:16 of the Belgian Companies and Associations Code. The notification also stated that (a) NeoMed IV and NeoMed V do not own the securities of the Company but manage funds that own the voting rights attached to the securities, and (b) as general partners to their funds, NeoMed IV and NeoMed V exercise the voting rights attached to the securities at their discretion in the absence of specific instructions.

(7) A parent undertaking or a controlling person of LSP Management Group B.V. ("**LSP Management Group**") and LSP Health Economics Fund Management B.V. ("**LSP**"), informed the Company, by means of a notification dated 19 February 2021 that LSP's shareholding crossed below the threshold of 10% of the outstanding voting rights of the Company on 15 February 2021. Notably, it followed from the notification that LSP held 1,706,077 Shares, representing 9.25% of the then 18,438,435 outstanding Shares and voting rights of the Company. The notification specified furthermore that LSP is controlled by LSP Management Group within the meaning of the articles 1:14 and 1:16 of the Belgian Companies and Associations Code and that LSP Management Group is not a controlled company. The notification also stated that LSP was not an owner of the Shares of the Company, but manages the funds that own the Shares of the Company, that LSP exercises the voting rights of the Shares held by the funds as a management company, including the voting rights associated with the Company's Shares, that LSP can exercise the voting rights of the funds at its own discretion at the general meeting of shareholders of the Company, and that LSP HEF Sequana Holding B.V. is the fund that owns the shares in the Company as of the date of notification.

(8) Rosetta Capital Ltd ("**Rosetta Capital**"), a person that notifies alone, informed the Company, by means of a notification dated 6 February 2023, that, on 31 January 2023 Rosetta Capital's shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. Notably, it followed from the notification that Rosetta Capital held 1,417,134 Shares, representing 5.97% of the then 23,746,528 outstanding shares and voting rights of the Company. The notification furthermore specified that Rosetta Capital is not controlled and acts as the investment manager that can exercise the voting rights at its discretion, in the absence of specific instructions.

(9) A parent undertaking or a controlling person of Participatiemaatschappij Vlaanderen NV ("**PMV**"), informed the Company, by means of a notification dated 11 May 2023 that, on 27 April 2023, PMV's aggregate number of voting rights passively crossed down the threshold of 5% of the outstanding voting rights of the Company. Notably, it

followed from the notification that PMV held 1.346.074 Shares, representing 4.80% of the then 28,050,888 outstanding Shares and voting rights of the Company. The notification further specified that PMV is controlled by Het Vlaams Gewest and that Het Vlaams Gewest is not controlled.

(10) Newton Biocapital I SA ("**Newton Biocapital**") (acting as a person that notifies alone) informed the Company, by means of a notification dated 15 March 2022, of the passive crossing of a threshold. The notification furthermore specified that Newton Biocapital is not a controlled entity on 10 March 2022. Notably, it followed from the notification that Newton Biocapital held 1,102,529 Shares, representing 4.64% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification also stated that Newton Biocapital acts as discretionary asset manager and holds the voting rights attached to the shares on behalf of its clients, which it can exercise at its own discretion without instructions from its clients.

(11) GRAC société simple ("**GRAC**") (acting as a person that notifies alone) informed the Company, by means of a notification dated 22 March 2022, that, on 10 March 2022, the shareholding of GRAC passively crossed below the threshold of 5% of the outstanding voting rights of the Company. Notably, it followed from the notification that GRAC held 1,008,333 Shares, representing 4.25% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification further specified that GRAC is not controlled by another entity or holding.

(12) A parent undertaking or a controlling person of Sensinnovat BV ("**Sensinnovat**") informed the Company, by means of a notification dated 15 March 2022, that, on 10 March 2022 Sensinnovat's shareholding crossed the threshold of 3% of the outstanding voting rights of the Company. Notably, it followed from the notification that Sensinnovat holds 900,769 Shares, representing 3.79% of the 23,746,528 outstanding Shares and voting rights of the Company. The notification furthermore specified that Sensinnovat is jointly controlled by Rudi de Winter and Françoise Chombar via Maatschap Chione.

(13) A parent undertaking or a controlling person of Optiverder B.V. ("**Optiverder**") informed the Company, by means of a notification dated 10 May 2023, that, on 27 April 2023 Optiverder's aggregate number of voting rights crossed the threshold of 3% of the outstanding voting rights of the Company. Notably, it followed from the notification that Optiverder holds 922,535 Shares, representing 3.29% of the then 28,050,888 outstanding Shares and voting rights of the Company. The notification furthermore specified that Optiverder is 100% owned by Mr. C.A.C.M. Oomen.

No other shareholders, acting alone or in concert with other shareholders, notified the Company of a participation or an agreement to act in concert in relation to 3% or more of the current total existing voting rights attached to the voting securities of the Company.

Each shareholder of the Company is entitled to one vote per Share.

Control over the Company

The Company has a relatively widely held shareholder base, and no single shareholder controls the Company.

To the best knowledge of the Company, there are no arrangements in place which may, at a subsequent date, result in a change in control of the Company.

No takeover bid has been instigated by third parties in respect of the Company's equity during the last financial year and the current financial year.

On the date of this Prospectus, the Company is a party to the following significant agreements and arrangements; which, upon a fundamental change in shareholders or change of control of the Company or following a takeover bid can be terminated by the other party thereto:

- the employment agreement between the Company and Ian Crosbie (Chief Executive Officer) contains takeover provisions. Agreements concluded between the Company and certain of its employees also provide for compensation in the event of a change of control;

- the loan agreements entered into with PMV Standaardleningen, Sensinnovat and Belfius Insurance in July 2020 and amended in December 2021 and March 2023, contain change of control provisions. For further information regarding the aforementioned agreements, see also the chapter "*Business Overview*", section "*Material contracts*", subsection "*Subordinated Loan Agreements*";

- the Kreos Loan Agreement contains a change of control clause, which has been approved by the shareholders on the Company's extraordinary general meeting held on 10 February 2023. For further information regarding the aforementioned agreements, see also the chapter "*Business Overview*", section "*Material contracts*", subsection "*Kreos Loan Agreement*"; and

- the 'Warrant Agreement', dated 2 September 2016, that was entered into between the Company and Bootstrap, and that has been amended and supplemented by an amendment agreement dated 28 April 2017, a second amendment agreement dated 1 October 2018, an amendment letter dated 20 December 2018, and an agreement dated 1 September 2021 (the "**Former Bootstrap Warrant**"), also contains take-over provisions. The extraordinary general shareholders' meeting held on 27 May 2022 resolved to renew the Former Bootstrap Warrant through the issuance of ten new warrants represented by ten separate subscription rights (the "**Bootstrap Warrants**"), including the take-over provisions.

- the terms and conditions of the Subscription Rights issued in the Private Placement provide that in the event of certain change of control events, the Company will offer to purchase the Subscription Rights in cash for an amount equal to the Black Scholes Value of the Subscription Rights. The Subscription Rights will no longer be exercisable after the completion of such change of control event. The aforementioned change of control provision has been approved by the Company's general shareholders' meeting on 26 June 2023.

In addition, the Company's subscription rights plans provide for an accelerated vesting of the subscription rights in case of a change of control event. These plans are described in more detail in the Remuneration Report on p. 132 and following of the 2022 Annual Report, which is incorporated by reference into this Prospectus, and is available at https://www.sequanamedical.com/wp-content/uploads/2023/04/SEQ012-Jaarverslag-2022-ENG-012a-spreads-02-final.pdf.

GENERAL INFORMATION

Capital structure

On the date of this Prospectus, the share capital of the Company amounts to EUR 2,921,010.22. It is divided into 28,191,733 Shares of no nominal value, each representing the same fraction of the share capital. The share capital is entirely and unconditionally subscribed and fully paid up.

Composition board of directors

The table below gives an overview of the current and proposed members of the Company's board of directors and their terms of office:

Name	Age	Position	Start of Current Term	End of Current Term
Mr Pierre Chauvineau	59	Chair, Independent Non-Executive Director	2021	2025
Mr Ian Crosbie	55	CEO, Executive Director	2021	2025
Dr Rudy Dekeyser	61	Non-Executive Director	2021	2025
Mr Wim Ottevaere(1)	66	Independent Non-Executive Director	2021	2025
Mrs Jackie Fielding	58	Independent Non-Executive Director	2022	2026
Mr Doug Kohrs	64	Independent Non-Executive Director	2023	2026
Mrs Alexandra Clyde	58	Independent Non-Executive Director	2023	2026
Mr Kenneth Macleod	63	Independent Non-Executive Director	2023	2027

Notes:
(1) Acting as permanent representative of WIOT BV.

Mr Pierre Chauvineau is an independent non-executive director and the chair of the Company's board of directors. Mr Chauvineau has over 31 years of international business leadership in corporate and start-up companies within the medical technology industry. He started his career with Medtronic where he spent 20 years before joining Cameron Health, a VC-funded medical device company based in California where he was responsible for commercialising their innovative implantable defibrillator across international markets. Cameron Health was acquired by Boston Scientific two years later in June 2012, after which Mr Chauvineau went on to lead Boston Scientific's largest European Business Unit for 5 years. Today, Mr Chauvineau continues to mentor and coach, he is also an executive board member with London based Rhythm AI and Lausanne based Comphya. He is also the chairman of Galway based Aurigen Medical and Grenoble based Aryballe. Pierre Chauvineau holds an MBA degree in International Management from the Monterey Institute of International Studies (Monterey, California, U.S.A.) and a BA degree from IPAG (Paris, France).

Mr Ian Crosbie is an executive director of the Company since 2019 and the Company's Chief Executive Officer since 2016. Mr Crosbie has over 25 years of experience in the healthcare sector, both in-house at medical device and pharmaceutical companies, and as an investment banker at leading global firms. He has extensive expertise and a strong track record in capital markets, licensing and strategic transactions. Prior to joining Sequana Medical, Mr Crosbie was Chief Financial Officer of GC Aesthetics Ltd based in Dublin. Before that, Ian was Senior Vice President, Corporate Development at Circassia Pharmaceuticals plc, a late-stage biopharmaceutical company focused on allergy immunotherapy where he led the execution of the company's £210 million initial public offering, as well as the M&A and licensing activities. Prior to Circassia, Ian enjoyed a 20-year career in corporate finance, including Managing Director, Healthcare Investment Banking at Jefferies International Limited and Director, Healthcare Investment Banking at Deutsche Bank. He has a degree in Engineering, Economics and Management from Oxford University.

Dr Rudy Dekeyser is a non-executive director of the Company. He is managing partner of the LSP Health Economics Fund 2, a EUR 280 million fund investing in medical device, diagnostic and digital health companies in Europe and the US. Besides serving on the Company's board of directors, Dr Dekeyser currently also serves on the board of directors of Lumeon, Nobi, reMYND and EMBLEM and has served on many other

biotech boards such as Ablynx (acquired by Sanofi), Devgen (acquired by Syngenta), CropDesign (acquired by BASF), Actogenix (acquired by Intrexon) and Multiplicom (acquired by Agilent). Prior to joining LSP, he was one of the founders of VIB and co-managing director of this leading life sciences research institute for 17 years, during which he was also responsible for all business development. Under his leadership VIB has built a patent portfolio exceeding 200 patent families, signed 800 R&D and license agreements, spun out twelve companies and laid the foundation for bio-incubators, bio-accelerators and the biotech association FlandersBio. Dr Dekeyser is member of the advisory board of several foundations investing in life sciences innovation and has been one of the catalysts in the foundation of Oncode, a Dutch cancer research institute. Dr. Dekeyser holds a Ph.D in molecular biology from the University of Ghent.

Mr Wim Ottevaere (WIOT BV) is an independent non-executive director of the Company. Mr Ottevaere is currently active as a non-executive consultant for biotechs and CFO of Biotalys. Mr Ottevaere was the Chief Financial Officer of Ablynx until September 2018, a Belgian biopharmaceutical company engaged in the development of proprietary therapeutic proteins based on single-domain antibody fragments. Ablynx was listed on Euronext Brussels and Nasdaq and acquired by Sanofi in June 2018. From 1992 until joining Ablynx in 2006, Mr Ottevaere was Chief Financial Officer of Innogenetics (now Fujirebio Europe), a biotech company that was listed on Euronext Brussels at the time. From 1990 until 1992, he served as Finance Director of Vanhout, a subsidiary of the Besix group, a large construction enterprise in Belgium. From 1978 until 1989, Mr Ottevaere held various positions in finance and administration within the Dossche group. Wim Ottevaere holds a Master's degree in Business Economics from the University of Antwerp, Belgium.

Mrs Jackie Fielding is an independent non-executive director of the Company. Mrs Fielding spent 28 years with Medtronic, most recently as Vice President UK / Ireland, where she was responsible for more than 700 staff and revenue of approximately $750 million. She held a number of external posts alongside her role at Medtronic, including Chair of the BCIA (British Cardiovascular Intervention Association) and council member of the BCIS (British Cardiovascular Intervention Society). In 2010, she was elected to the board of directors of ABHI (Association of British HealthTech Industries) and in 2015 was appointed Vice Chair. Jackie has worked with the UK's NHS (National Health Service) Clinical Entrepreneur programme and was a member of the Ministerial Medical Technology Strategy Group. She is Non-Executive Director on the Boards of UK's NICE (National Institute for Health and Care Excellence), 3D Life Prints and Northumbria Primary Care, of which she is also Chair.

Mr Doug Kohrs is an independent non-executive director of the Company. Mr Kohrs currently serves as the President and CEO of Responsive Arthroscopy, a company he founded that focusses on innovative surgical solutions for orthopedic surgery centers. In 2013, he also founded Responsive Orthopedics, a value-based medical device company, where he served as CEO until it was acquired by Medtronic in June 2016. From 2006 to 2012, he was CEO and President of Tornier NV, and from 1999 to 2005 he was CEO and President of American Medical Systems. Mr Kohrs was also a founder of Spine Tech, a pioneering spinal surgery company, where he worked in R&D and Marketing roles from 1991 to 1998. Prior to that, he spent seven years with Johnson and Johnson Orthopedics as the Chief Designer for the Press Fit Condylar (PFC) knee and PFC hip systems. Mr Kohrs currently serves on the board of directors of Cerapedics, Lima Orthopedics, Osteal Therapeutics, UroTronic, and Vergent Bioscience. Mr Kohrs has previously served on the public company boards of ev3 (acquired by Covidien), Kyphon (acquired by Medtronic), and Protolabs, and the private company boards of Imascap (acquired by Wright Medical), Pioneer Surgical (acquired by RTI Surgical), SpineCore (acquired by Stryker), and five other boards. Mr Kohrs holds a B.S. in Bioengineering from Texas A&M University, a B.A. in Engineering Sciences from Austin College and an MBA from Northeastern University.

Mrs Alexandra Clyde is an independent non-executive director of the Company. Mrs Clyde is Senior Vice President of Global Health Economics, Policy, and Reimbursement for Medtronic plc. In this role, she leads a global function of more than 300 reimbursement and health economics professionals and provides company-wide leadership on health and payment policy. She is a member of the Duke Margolis Value-Based Payment and Innovative Technology Consortium, the Health Technology Assessment International (HTAi) Policy Forum, and the Advisory Board for the Center for the Evaluation of Value and Risk in Health (CEVR) at the Institute for Clinical Research and Health Policy Studies at Tufts Medical Center. She is a former member of the Health Care Payment Learning and Action Network's (HCP-LAN) Guiding Committee which is charged by the US Secretary of Health and Human Services with accelerating the health care system's transition to alternative payment models (APMs) by combining the innovation, power, and reach of the public and private sectors. She has also participated in various Centers for Medicare and Medicaid Services (CMS) technical advisory councils as well as other private and public sector initiatives to improve value in health care. Mrs Clyde graduated from Colgate University with a B.A. in Economics and from Harvard University with a M.S. in Health Policy and Management.

Dr Kenneth Macleod is a Partner at Rosetta Capital, a venture capital firm focused on life sciences and medical devices. Dr Macleod has over 35 years' experience in the life sciences sector in a career combining senior operating roles in healthcare companies (Abbott Laboratories, Serono SA) and life science fund management (SV Health Investors, Paul Capital Partners, Visium Healthcare Partners). Dr Macleod currently holds board positions at JenaValve Technology Inc. and Oxular Limited and has previously held board roles including at Pharming Group N.V. (NASDAQ:PHAR) and On-X Life Technologies, Inc., a mechanical heart valve company sold to Cryogenics Inc. (now NASDAQ:AORT). Dr Macleod received a BSc in Biological Sciences from the University of Manchester and a D.Phil. from the University of York.

The business address of each of the directors for the purpose of their mandate is the address of the Company's registered office: Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium.

As mentioned, within the framework of the Private Placement, the Company agreed that, provided that the closing of the Private Placement occurred, and existing shareholders PiE and Rosetta complied with certain subscription commitments (which effectively occurred on 27 April 2023 and 10 May 2023), the Company would propose to the Company's general shareholders' meeting to appoint respectively Mr Ids Van der Weij (a representative of PiE and currently observer to the Company's board of directors) and Dr Kenneth Macleod (a representative of Rosetta) as director of the Company. Dr Macleod's appointment as director was approved by the Company's shareholders' meeting on 26 June 2023. Mr Van der Weij's appointment as director still needs to be submitted to the Company's shareholders' meeting. The Company currently intends to submit this proposal to the Company's annual general shareholders' meeting to be held in 2024 (but it may also submit it to the extent a special or extraordinary general shareholders' meeting were to be held at an earlier occasion). PiE and Rosetta acknowledged that as soon as they cease to own 4% of the outstanding shares in the Company, they shall cause their representatives to resign from any and all of their corporate functions and mandates within the Company when so requested by the Company's board of directors.

Composition senior management team

The executive management of the Company consists of the following members:

Name	Age	Position
Mr Ian Crosbie	55	Chief Executive Officer
Mrs Kirsten Van Bockstaele(1)	48	Chief Financial Officer

Note:
(1) Acting as permanent representative of Fin-2K BV.

Mr Ian Crosbie is the Chief Executive Officer and a director of the Company. Please see his biography under the section "*composition board of directors*" above.

Mrs Kirsten Van Bockstaele is the Chief Financial Officer of Sequana Medical. She is a seasoned finance executive with extensive international experience in the healthcare industry. Mrs Van Bockstaele joined Sequana Medical from Fagron (formerly Arseus), an international pharmaceutical compounding company. Within Fagron, she held a number of senior financial roles, most recently as Vice President of Finance, North America. In this role, Mrs Van Bockstaele was responsible for creating and overseeing the company's financial strategy and policy, positioning Fagron's North American companies for growth. She also played a pivotal role in building out the North American headquarters, supporting the financial integration of acquisitions and assisting in redirecting the company's strategy. Mrs Van Bockstaele previously served as Chief Financial Officer for Arseus Dental & Medical Solutions, where she was instrumental in the coordination, support and control of financial activities in key European countries. Her previous roles include Financial Controller at Omega Pharma and Audit Manager at PwC. Kirsten Van Bockstaele has a degree in Business Economics from EHSAL and a degree in Financial and Fiscal Sciences from the University of Antwerp, Belgium.

The senior management team of the Company consists of the members of the executive management, together with the following members:

Name	Age	Position
Dr Oliver Gödje	58	Chief Medical Officer
Mr Martijn Blom	49	Chief Commercial Officer

Mr Timur Resch	41	Global Vice President QM/QA/RA
Dr Gijs Klarenbeek	46	Senior Medical Advisor
Dr Andreas Wirth	54	Vice President Engineering
Mr Dragomir Lakic	40	Global Vice President Manufacturing

Dr Oliver Gödje is the Chief Medical Officer of the Company. Dr. Gödje is a highly experienced clinician and medtech industry executive with 18 years of international experience in medical and commercial roles. Prior to joining Sequana Medical, Dr. Gödje served as Chief Medical Officer at Humedics GmbH, Medical Director and VP Sales & Marketing at Hepa Wash GmbH, Chief Medical Officer and Chief Marketing Officer at Tensys Medical Inc., and Medical & Marketing Director of PULSION Medical Systems AG, all medtech companies in the liver or cardiovascular field. He holds a PhD and Professorship in Human Medicine and built an extensive knowledge of cardiology during his time as a Cardiac Surgeon at leading German Universities. He was a Consultant and Vice Chairman of the Department of Cardiac Surgery at the University Hospital of Ulm until 2002.

Dr Gijs Klarenbeek is the Senior Medical Advisor of the Company. Dr Klarenbeek has over 14 years academic and healthcare industry experience. After his training in abdominal surgery at the University of Leuven, he held multiple positions in Medical Affairs, Clinical and Marketing at large pharmaceutical (Sanofi, AstraZeneca) and medical device companies. These include roles as Director of Medical Affairs Europe at Boston Scientific, providing leadership to the medical support for the portfolio of products in the Structural Heart and Medical / Surgical divisions, and as Worldwide Medical Director Clinical Research at Johnson & Johnson's medical device division (Cordis and Cardiovascular Care Franchise), supporting the clinical development of different products through regulatory submission (CE mark & IDE), post-market commitments and development. Dr Klarenbeek holds an MD from the University of Leuven, Belgium and a degree in Business Administration from the Institute for Pharmaceutical Business Administration (IFB).

Mr Timur Resch is the Global Vice President QM/QA/RA and Person Responsible for Regulatory Compliance (PRRC) of Sequana Medical. Mr Resch has over 10 years of experience within quality management and regulatory affairs in the regulated medical device industry. In 2010, Mr Resch graduated as an engineer in medical technology from the University of Applied Sciences in Lübeck, Germany and began his professional career as a process and management consultant at Synspace AG. Thereafter, Mr Resch continued as Head of Quality Management & Regulatory Affairs at Schaerer Medical AG and prior to joining Sequana Medical held the position of Manager & Team Leader Regulatory Affairs at Medela AG. His experience includes the establishment of quality management systems, auditing, international product registrations for Class I to Class III medical devices, ensuring compliance with applicable regulatory requirements as well as being the liaison to Notified Bodies and Health Authorities. Mr Resch serves as member of quality and regulatory task forces and expert groups within Germany and Switzerland.

Dr Andreas Wirth is the Global Vice President Engineering of the Company. Dr Wirth has over 12 years of experience within leading R&D departments in regulated industries. Most recently he was Director of R&D at Carl Zeiss Meditec and responsible for refractive surgery products. Previous to his time at Carl Zeiss Meditec he was the Head of metrology development at Schott and responsible for pharmaceutical primary packaging across 17 plants worldwide. Prior to this, he was head of R&D at medi Group managing seven small R&D groups in Germany, France and the US and project manager at Amaxa / Lonza Biologics of medical and laboratory devices. Dr Wirth holds a PhD in applied science and studied physics at the University of Osnabrück, Germany.

Mr Martijn Blom is the Chief Commercial Officer of the Company. Mr Blom has over 15 years' experience in the life sciences industry. Most recently he was the Director of International Marketing at Myriad Genetics, responsible for the marketing development of genetic testing in the international markets. Previous to Myriad, Mr Blom worked as Director of Marketing and Market Development at PulmonX, a start up from Redwood City focusing on developing and marketing minimally-invasive medical devices and technologies to expand and improve treatment options for emphysema patients. Prior to this Mr Blom was Director, International Marketing with Alere where he spent more than 7 years leading the marketing, training and marketing communications teams, for all of their business units: Cardiology, Women's Health, Oncology, Infectious Diseases, Blood Borne Pathogens, Toxicology and Health Management. Mr Blom studied economics at the MEAO in Breda and specialized at de Rooi Pannen in Marketing and Sales management.

Mr Dragomir Lakic is the Global Vice President Manufacturing of the Company. Mr Lakic spent almost his whole career in the field of medical devices, with 15 years at Zimmer Biomet and Smith + Nephew, and brings an in-depth knowledge of the medical device industry. He joined Sequana Medical from Smith + Nephew, a leading portfolio medical technology company where he was responsible for planning, procurement, logistics, and supply chain. Before joining Smith + Nephew, he had a successful 12-year career at Zimmer Biomet, holding progressively senior leadership positions in Engineering and Manufacturing. Mr Lakic holds a degree in Engineering and Management from the University of Applied Sciences and Arts of Italian Switzerland and a Master of Business Administration (MBA) degree from the ZHAW (Zurich University of Applied Sciences).

The business address of each of the members of the executive management for the purpose of their mandate is the address of the Company's registered office: Kortrijksesteenweg 1112 (box 102), 9051 Ghent, Belgium.

Other mandates by directors and senior managers

In the five years preceding the date of this Prospectus, the directors and members of the senior management have held the following directorships (apart from their functions within Sequana Medical) and memberships of administrative, management or supervisory bodies and/or partnerships:

Name	**Current**	**Past**
Rudy Dekeyser	Noby NV Remynd NV Emblem GmbH Life Sciences Partners Lumeon Inc R.A.D. Life Sciences BVBA SystemUnoDue GCV	Celyad SA Curetis NV
Wim Ottevaere (WIOT BV)	Woconsult BV Vlaams Instituut voor Biotechnologie Biotalys NV	Ablynx NV(1)
Pierre Chauvineau	Rhythm AI in London NED Aurigen Medical Aryballe CEO-CF AlpineX	Boston Scientific Inc. Creavo Medical Technologies Ltd Pathena
Jackie Fielding	NICE NPC Ltd 3DLP Ltd	Medtronic UK/Ireland Ltd
Doug Kohrs	Responsive Arthroscopy Cerapedics Lima Orthopedics Osteal Therapeutics UroTronic Vergent Bioscience	N/A
Alexandra Clyde	Medtronic plc	N/A
Kenneth Macleod	Partner Rosetta Capital JenaValve Technology Inc. Oxular Limited	Agate Strategic Advisors Ltd Phase III Development Company SARL
Ian Crosbie	N/A	N/A
Kirsten Van Bockstaele(2)	Fin-2K BV	N/A
Oliver Gödje	MDIC	Humedics GmbH Advitos GmbH Tensys Medical

Name	Current	Past
Martijn Blom	N/A	N/A
Timur Resch	N/A	N/A
Gijs Klarenbeek	Melfin Medical Consulting	N/A
Andreas Wirth	N/A	N/A
Dragomir Lakic	N/A	N/A

Notes:
(1) Acting through WIOT BV.
(2) Acting through Fin-2K BV.

Family relationships

There are no family relationships among any of the members of the Company's executive management and/or the Company's board of directors.

Confirmations by directors and members of the senior management

Each of the directors and each of the members of the senior management confirmed to the Company that neither he or she nor the company through which he or she acts (as the case may be) was subject to (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years. In addition, each of them has confirmed to the Company that neither he or she nor the company through which he or she acts (as the case may be) is subject to any bankruptcies, receiverships, liquidations or administration of any entities in which he, she or it held any office, directorships, or partner or senior management positions during the past five years.

No conflicts of interest

On the basis of information provided by the relevant directors and members of the senior management of the Company, there are, on the date of this Prospectus, no potential conflicts of interest between any duties of the members of the board of directors and members of the senior management to the Company and their private interest and/or other duties.

Related party transactions

Other than disclosed in "*12. Transactions with related parties*" in the notes to the consolidated financial statements in the financial report section on p. 204 of the 2022 Annual Report the Company has not undertaken any related party transactions since 31 December 2022.

Legal and arbitration proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware), during the previous 12 months which may have, or have had in the recent past, significant effects on Sequana Medical and/or Sequana Medical's financial position or profitability.

Expenses of the listing of the New Shares

The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the listing (including but not limited to legal publications, printing and translation of the Prospectus and listing related documents) and the remuneration of the FSMA (which is estimated at EUR 15,000.00) and Euronext Brussels, is expected to amount to approximately EUR 0.15 million.

MATERIAL INFORMATION DISCLOSED SINCE JULY 2022

The table below sets out the information disclosed under the Market Abuse Regulation and other relevant information during the last 12 months. The press releases are available under the 'News and Events' section on https://www.sequanamedical.com/news-events/press-releases/ and, subject to country restrictions, under the 'Investors < Equity placement Jan 2020' section on https://www.sequanamedical.com/investors/equity-placement-2020/, under the 'Investors < Equity placement Feb 2021' section on https://www.sequanamedical.com/investors/equity-placement-feb-2021/, under the 'Equity Placement MAR 2022' section on https://www.sequanamedical.com/equity-placement-mar-2022/, and under the 'Equity Placement APRIL 2023' section on https://www.sequanamedical.com/equity-placement-april-2023/.

Date	Press Release
26 June 2023	**Sequana Medical announces results of Special General Meeting of Shareholders** On 26 June 2023, the Company announced that all proposed resolutions – relating to the appointment of Dr. Kenneth Macleod as non-executive director of the Company and the approval in accordance with Article 7:151 of the Belgian Companies and Associations Code of the terms and conditions of the subscription rights issued in the framework of the equity offering that was successfully completed on 25 April 2023 in the event of certain change of control events - submitted to the Special General Meeting of Shareholders were approved.
21 June 2023	**Sequana Medical announces additional data on safety, quality of life and survival from North American pivotal alfapump® study (POSEIDON)** On 21 June 2023, the Company announced additional data on safety, quality of life and survival from POSEIDON, its North American pivotal study of alfapump for the treatment of patients with recurrent or refractory ascites due to liver cirrhosis. These data were presented during a poster session and were selected for an oral poster presentation on June 23rd at the EASL Congress in Vienna, Austria.
26 May 2023	**Sequana Medical announces Special General Meeting of Shareholders on 26 June 2023** On 26 May 2023, the Company invited the holders of securities issued by the Company to attend the Special General Meeting of Shareholders on Monday, 26 June 2023. The items on the agenda of the meeting include the proposed approval of the appointment of Dr Kenneth Macleod as non-executive director of the Company and the approval in accordance with Article 7:151 of the Belgian Companies and Associations Code of the terms and conditions of the subscription rights issued in the framework of the Offering in the event of certain change of control events.
25 May 2023	**Sequana Medical announces results of Annual General Meeting of Shareholders** On 25 May 2023, the Company announced that all proposed resolutions - relating to (amongst other things) the approval of a number of resolutions relating to the financial year ended on 31 December 2022 and the application of Article 7:228 of the Belgian Companies and Associations Code - submitted to the Annual General Meeting of Shareholders were approved.
15 May 2023	**Transparency Notifications from Shareholders** On 15 May 2023, the Company announced that it received notifications from PMV and Optiverder. On 11 May 2023, PMV informed the Company that the shareholding of PMV passively crossed below the threshold of 5% of the outstanding voting rights of the Company.

	On 10 May 2023, Optiverder informed the Company that the shareholding of Optiverder crossed the threshold of 3% of the outstanding voting rights of the Company.
25 April 2023	**Sequana Medical successfully raises EUR 15.78 million in an equity placement** On 25 April 2023, the Company announced that it successfully raised an amount of EUR 15.78 million in gross proceeds by means of a private placement of new shares and subscription rights (at a ratio of one (1) new subscription right per four (4) new shares) via an accelerated bookbuild offering of 4,445,205 new shares (being approximately 18.72% of the Company's current outstanding shares) at an issue price of EUR 3.55 per new share and 1,111,294 new subscription rights (if exercised into 1,111,294 new shares, representing approximately 4.68% of the Company's current outstanding shares) at an exercise price of EUR 5.10 per underlying new share. Ian Crosbie, Chief Executive Officer of Sequana Medical, commented: "We are very pleased to announce the closing of this financing round, despite challenging market conditions. This is a testimony to the commercial potential of our programs, our track record of delivering on key milestones and commitment to deliver long-term shareholder value. I would particularly like to thank our existing investors for their continued support. Over the past year, we have delivered very positive clinical data in both our **alfa**pump and DSR programs, and this financing will allow us to progress these further towards key milestones. We look forward to reporting on the progress in both programs and bringing these innovative treatment options to the patients that need dramatically improved treatment options."
25 April 2023	**Sequana Medical announces Annual General Meeting of Shareholders on 25 May 2023** On 25 April 2023, the Company invited the holders of securities issued by the Company to attend the Annual General Meeting of Shareholders on Thursday, 25 May 2023. The items on the agendas of the meeting include (amongst other things) the proposed approval of a number of resolutions relating to the financial year ended on 31 December 2022 and the application of Article 7:228 of the Belgian Companies and Associations Code.
24 April 2023	**Sequana Medical launches equity placement and amends certain existing loan agreements** On 24 April 2023, the Company announced the launch of an equity offering to raise an amount of approximately EUR 15 million by means of a private placement of new shares and subscription rights (at a ratio of one (1) new subscription right per four (4) new shares) via an accelerated bookbuild offering, with the possibility to increase the size of the offering.
10 February 2023	**Sequana Medical announces results of Extraordinary General Meeting of Shareholders** On 10 February 2023, the Company announced that all proposed resolutions - relating to (amongst other things) the approval of a number of resolutions relating to the financial year ended on 31 December 2021, the confirmation of the appointment of a director, the approval of a number of change of control clauses, the renewal of the authorization to the board of directors to increase the share capital within the framework of the authorized capital, and the issuance of "Bootstrap Warrants" (in the form of subscription rights) - submitted to the Extraordinary General Meeting of Shareholders were approved.

9 February 2023	**Sequana Medical announces 2022 Full Year Results and 2023 Outlook** On 9 February 2023, the Company announced its financial results for the year ended 31 December 2023, and provided a business update and outlook for 2023. <u>2022 highlights</u> **Alfa**pump in liver disease • POSEIDON – North American pivotal study of the **alfa**pump in patients with recurrent or refractory ascites due to liver cirrhosis successfully met primary endpoint data: o Reported positive top-line results in October 2022 from 40 patients of the Pivotal Cohort at six months post-implantation, including primary effectiveness endpoints substantially exceeding the predefined thresholds for study success and safety in line with expectations: o 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs pre-implantation (p<0.001), vs hypothesis of at least 50% reduction. o 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation (p<0.001), vs hypothesis of at least 50% of patients. o Six primary safety events of which three involved explants due to wound or skin erosion, and three explants due to patient-reported discomfort (all patient-reported discomfort events were adjudicated by the Clinical Events Committee as moderate severity), in line with expectations. o Reported results of a preliminary interim analysis of patient survival from the Roll-In Cohort in April 2022 including 70% survival rate at one year post-implantation, comparing favorably to published literature of 50% survival rate for refractory ascites patients after one year. o Wong presented safety, efficacy and quality of life data from the Roll-In Cohort at the AASLD The Liver Meeting® in November 2022. • US patient preference study initiated: o Survey study to quantify patients' preferences for the **alfa**pump including treatment effectiveness and risks of treatment-related adverse events. The results of this study are expected to be presented in H2 2023. • European PMSR data published in Liver International: o Final safety and efficacy results of the Post Marketing Surveillance Registry (PMSR) study of the **alfa**pump published in *Liver International*, the peer-reviewed publication of the International Association for the Study of the Liver. DSR in heart failure • SAHARA – Phase 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion showed important and long-lasting clinical benefits: o Reported positive top-line data from ten evaluable patients with its first-generation DSR product (DSR 1.0) in November 2022, including i) safe, effective and rapid elimination of fluid overload and restoration of euvolemia, ii) improvement of cardiovascular and renal health, iii) restoration of the diuretic-response of the kidney, and iv) dramatic reduction in the need for oral loop diuretics up to 15 months post-therapy – demonstrating a durable improvement in the heart failure status of these patients.

	• Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy:
	  o No heart failure congestion-related re-hospitalizations during study follow-up.
	  o All patients improved their NYHA status by at least one class.
	  o Clinical benefits result in a 75% reduction in predicted one-year mortality pre- vs. post-intensive DSR therapy based on the Seattle Heart Failure Model.
	• Focus on Short Term DSR therapy with proprietary DSR 2.0:
	  o Based on the results of RED DESERT and SAHARA, the Company expects that an intensive treatment period of three to four weeks of DSR therapy may deliver at least twelve months of important clinical benefits.
	  o As a result of the strong, durable clinical signals observed, the Company will focus the heart failure development program on Short Term DSR with its proprietary second-generation DSR product (DSR 2.0) administered via a peritoneal catheter.
	  o DSR 2.0 is expected to have an improved therapeutic and favorable safety profile with robust intellectual property protection.
	• MOJAVE – US Phase 1/2a randomized controlled multi-center study of DSR 2.0 in diuretic-resistant chronic heart failure patients with persistent congestion, on track to start in Q2 2023:
	  o Good progress of DSR 2.0 in product development and GLP animal studies.
	  o Approval to start two Phase 1 single-arm, open-label, single-dose studies in Canada (YUKON) and Mexico (CHIHUAHUA) to evaluate the safety, tolerability and efficacy of DSR 2.0, with first patient dosed successfully in YUKON.
	  o Data from the GLP animal and Phase 1 CHIHUAHUA studies are intended to support the US IND application filing of DSR 2.0, planned for Q1 2023.
	  o Preparations ongoing to start the MOJAVE study, planned for Q2 2023, assuming FDA approval of the US IND application. The intention is to enroll 30 diuretic-resistant chronic heart failure patients with persistent congestion, with 20 patients randomized to DSR 2.0 administered via a peritoneal catheter on top of usual care for congestive heart failure (CHF) for up to four weeks and ten patients randomized to usual care for CHF alone.
	
	<u>Outlook for 2023:</u>
	
	• PMA submission for the **alfa**pump program to the US FDA planned for H2 2023
	• Phase 1/2a MOJAVE randomized controlled study expected to commence in Q2 2023, with Short Term DSR therapy using DRS 2.0

9 February 2023	**Transparency Notifications from Shareholders** On 9 February 2023, the Company announced that it received transparency notifications from Rosetta Capital Ltd and Neomed IV Extension Limited, Neomed Innovation V Limited and NeoMed Management (Jersey) Limited. On 6 February 2023, Rosetta Capital Ltd informed the Company that, on 31 January 2023, its shareholding crossed the threshold of 5% of the outstanding voting rights of the Company. On 6 February 2023, NeoMed IV Extension Limited, NeoMed Innovation V Limited and NeoMed Management (Jersey) Limited informed the Company, that, on 31 January 2023, the aggregate shareholding of Erik Amble, NeoMed IV and NeoMed V crossed below the threshold of 15% of the outstanding voting rights of the Company.

11 January 2023	**Sequana Medical announces Extraordinary General Meeting of Shareholders on 10 February 2023** On 11 January 2023, the Company invited the holders of securities issued by the Company to attend the Extraordinary General Meeting of Shareholders on Friday, 10 February 2023. The items on the agendas of the meeting included (amongst other things) the proposed approval of the appointment of Douglas Kohrs and Alexandra Taylor Clyde as independent non-executive directors, the approval of certain amendments to the Company's remuneration policy, and the issuance of "Kreos Subscription Rights" (in the form of subscription rights).

15 November 2022	**Sequana Medical announces positive top-line results from SAHARA Ph. 2a study of DSR 1.0 in diuretic-resistant heart failure patients with persistent congestion and first patient dosed successfully with DSR 2.0 in YUKON**
	
	On 15 November 2022, the Company announced the following with regard to SAHARA, the Phase 2a study using its first generation DSR (Direct Sodium Removal) product (DSR 1.0):
	
	• Data from SAHARA with first-generation DSR product (DSR 1.0) confirm:
	  ○ Safe, effective and rapid elimination of persistent congestion following intensive DSR therapy
	  ○ Considerable benefit in cardio-renal status maintained till end of study (16 weeks post-intensive DSR therapy)
	  ○ Dramatic and sustained improvement in diuretic response up to 15 months post intensive DSR therapy
	  ○ No congestion-related heart failure re-hospitalizations during entire study
	  ○ One class improvement of NYHA status and 75% reduction in predicted one-year mortality based on Seattle Heart Failure model
	• First patient dosed successfully in YUKON, Ph. 1 study of second-generation DSR product (DSR 2.0)
	• MOJAVE, US Ph. 1/2a randomized controlled multi-center study of DSR 2.0, on track to start in H1 2023

25 October 2022	**Sequana Medical announces positive top-line results from the North American pivotal alfapump® study (POSEIDON)**
	
	On 25 October 2022, the Company announced the following with regard to the North American pivotal POSEIDON study of the **alfa**pump:
	
	• **alfa**pump achieves pre-specified primary effectiveness endpoints with statistical significance at six months post-implantation:
	  ○ 100% median per-patient reduction in therapeutic paracentesis (TP) post- vs pre-implantation ($p<0.001$)
	  ○ 77% of patients with at least 50% reduction in number of TP post- vs pre-implantation ($p<0.001$)
	• **alfa**pump primary safety endpoint data in line with expectations
	• On track to file Pre-Market Approval (PMA) application with FDA in H2 2023
	• Third party market analysis estimates prevalence of recurrent or refractory liver ascites in North America at over 60,000 patients in 2022, growing at six to seven percent annually
	
	In addition, the Company announced that its management would attend AASLD The Liver Meeting® from November 4 - 6 in Washington, DC.

8 September 2022	**Sequana Medical announces H1 2022 results and provides business update**
	
	On 8 September 2022, the Company provided a business update for the half year ended on 30 June 2022 and its outlook for the remainder of the year and into 2023.
	
	Business highlights for the half year ended on 30 June 2022:
	• **alfa**pump®
	  ○ Strong interim data;
	  ○ Reporting primary endpoint data from POSEIDON pivotal cohort planned for Q4 2022.
	• DSR®
	  ○ Strong clinical observations from RED DESERT and SAHARA studies in diuretic-resistant heart failure patients support heart failure disease-modifying profile of DSR therapy*;*
	  ○ *Preparations ongoing to start US phase 1b/2a MOJAVE study in H1 2023.*
	
	Financial highlight:
	Total liquidity position of EUR 23.8 million, and a cash runway into Q3 2023.

25 August 2022	**Alexandra Clyde to be appointed to Sequana Medical Board of Directors** On 25 Augustus 2022, the Company announced that Alexandra Clyde had been appointed to its board of directors. Furthermore, the Company announced that Erik Amble would resign as a member of the board of directors after the board meeting of the Company that has been held on 7 September 2022, and will continue to attend the Company's board meetings as a board observer in a non-voting capacity.
20 July 2022	**Sequana Medical secures EUR 10 million loan facility with Kreos Capital** On 20 July 2022, the Company announced that it had entered into the Kreos Loan Agreement.
19 July 2022	**Doug Kohrs appointed to Sequana Medical Board of Directors** On 19 July 2022, the Company announced that Doug Kohrs had been appointed to its board of directors.
19 July 2022	**Sequana Medical completes enrollment in Phase 2a SAHARA I DSR study, reports disease-modifying profile for Short Term DSR and provides business update** On 19 July 2022, the Company announced the following in relation to its DSR® (Direct Sodium Removal) heart failure drug development: • Completed enrollment in SAHARA I with first-generation DSR product, DSR 1.0 – extending study with second-generation DSR product, DSR 2.0, to support U.S. IND filing by end of 2022; • Proof-of-concept delivered in diuretic-resistant heart failure patients with dramatic and durable improvements in validated clinical measures; • Heart failure disease-modifying profile – safe, rapid and effective decongestion with no congestion-related heart failure re-hospitalisations observed; • Clinical outcomes from RED DESERT and SAHARA result in a 75% reduction in predicted one-year mortality based on Seattle Heart Failure model; and • Heart failure development program to focus on Short Term DSR with DSR 2.0. In addition, the Company announced that the PMA submission to the FDA in relation to the alfapump® in North America is expected in the second half of 2023.

TAXATION OF NEW SHARES

Belgian taxation

The paragraphs below present a summary of certain Belgian federal income tax consequences of the ownership and disposal of the Shares by an investor. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect. Belgian tax legislation, as well as the relevant tax legislation of a prospective investor's country of origin, may have an impact on the income received from the New Shares.

Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the investment in, ownership in and disposal of the Shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, Shares as a position in a straddle, Share repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the tax regime applicable to Shares held by Belgian tax residents through a fixed basis or a permanent establishment situated outside Belgium. This summary does in principle not address the local taxes that may be due in connection with an investment in the Shares, other than Belgian local surcharges which generally vary from 0% to 9% of the investor's income tax liability.

For purposes of this summary, a Belgian resident is an individual subject to Belgian personal income tax (i.e. an individual who is domiciled in Belgium or has his seat of wealth in Belgium or a person assimilated to a resident for purposes of Belgian tax law), a company subject to Belgian corporate income tax (i.e. a corporate entity that has its main establishment, its administrative seat or seat of management in Belgium[1]), an Organisation for Financing Pensions ("**OFP**") subject to Belgian corporate income tax (i.e. a Belgian pension fund incorporated under the form of an OFP), or a legal entity subject to Belgian income tax on legal entities (i.e. a legal entity other than a company subject to Belgian corporate income tax, that has its main establishment, its administrative seat or seat of management in Belgium).

A non-resident is any person that is not a Belgian resident. Investors should consult their own advisers regarding the tax consequences of an investment in the Shares in the light of their particular circumstances, including the effect of any state, local or other national laws.

Belgian taxation of dividends on Shares

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Companies and Associations Code is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal capital. This fiscal capital is, in principle, the capital that is formed through contributions in cash or in kind, other than labour, and, subject to certain conditions, the paid-up issuance premiums and the amounts subscribed to, in cash or in kind, other than labour, at the time of the issue of profit sharing certificates. However, a repayment of capital decided upon by the shareholder's meeting as of 1 January 2018 and which is carried out in accordance with the Belgian Companies and Associations Code is partly considered to be a dividend distribution, more specifically with respect to the portion that is deemed to be the distribution of the existing taxed retained earnings (irrespective of whether they are incorporated into the capital) and/or of the tax-free retained earnings incorporated into the capital. Such portion is determined on the basis of the ratio of the taxed retained earnings (except for the legal reserve up to the legal minimum and certain unavailable retained earnings) and the tax-free retained earnings incorporated into the capital (with a few exceptions) over the aggregate of such retained earnings and the fiscal capital.

Belgian withholding tax of 30% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

[1] A corporate entity that has its statutory seat in Belgium is presumed, in the absence of evidence to the contrary, also to have its main establishment, its administrative seat or seat of management in Belgium. Such evidence to the contrary shall be admissible only if it is also demonstrated that the tax domicile of the company is established in a State other than Belgium under the tax legislation of that other State.

In case of redemption of the Shares, the redemption gain (i.e. the redemption proceeds after deduction of the portion of fiscal capital represented by the redeemed Shares) will be treated as a dividend subject to a Belgian withholding tax of 30%[2], subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if such redemption is carried out on Euronext or a similar stock exchange and meets certain conditions.

In case of liquidation of the Company, the liquidation gain (i.e. the amount distributed in excess of the fiscal capital) will in principle be subject to Belgian withholding tax at a rate of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Non-Belgian dividend withholding tax, if any, will neither be creditable against any Belgian income tax due nor reimbursable to the extent that it exceeds Belgian income tax due.

Belgian resident individuals

For Belgian resident individuals who acquire and hold the Shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where such individual opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% withholding tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income (local surcharges will not apply). If the dividends are reported, the dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Shares. This condition is not applicable if the individual can demonstrate that he has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends. The first EUR 800 (amount applicable for income year 2023) of reported ordinary dividend income will be exempt from tax. For the avoidance of doubt, all reported dividends (hence, not only dividends distributed on the Shares) are taken into account to assess whether said maximum amount is reached.

For Belgian resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with local surcharges. Withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the Shares for an uninterrupted period of twelve months prior to the attribution of the dividends.

Belgian resident companies

Corporate income tax

For Belgian resident companies, the dividend withholding tax does not fully discharge the corporate income tax liability. For such companies, the gross dividend income (including the withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 25%. Subject to certain conditions, a reduced corporate income tax rate may apply.[3]

Any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified; and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable (a) if the company can demonstrate that it has held the Shares in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends; or (b) if, during said period, the Shares never belonged to a taxpayer other than a resident company or a non-resident

[2] It is possible that the upcoming Belgian tax reform will modify certain provisions of the BITC regarding withholding taxes (e.g., a decrease of the standard withholding tax rate of 30% to 25% is envisaged while certain specific beneficial regimes would be deleted) but no formal draft legislative texts are currently available and the reform is still subject to political discussion.

[3] Subject to certain conditions, a reduced corporate income tax rate of 20% applies for Small and Medium Sized Enterprises (as defined by article 1:24 §1 to §6 of the Belgian Companies and Associations Code) on the first EUR 100,000 of taxable profits.

company which has, in an uninterrupted manner, invested the Shares in a permanent establishment ("**PE**") in Belgium.

As a general rule, Belgian resident companies can (subject to certain limitations) deduct 100% of gross dividends received from their taxable income (dividend received deduction)[4], provided that at the time of a dividend payment or attribution: (1) the Belgian resident company holds Shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least EUR 2,500,000; (2) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code (the "**article 203 ITC Taxation Condition**") are met (together, the "**Conditions for the application of the dividend received deduction regime**"). Under certain circumstances the conditions referred to under (1) and (2) do not need to be fulfilled in order for the dividend received deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

Withholding tax

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends and as beneficial owner thereof, at least 10% of the share capital of the Company and such minimum participation is held or will be held during an uninterrupted period of at least one year.

In order to benefit from this exemption, the Belgian resident company must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions. If the Belgian resident company holds the required minimum participation for less than one year, at the time the dividends are paid on or attributed to the Shares, the Company will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the Belgian resident company certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The Belgian resident company must also inform the Company or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the share capital of the Company before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the Belgian resident company.

Please note that the above described dividend received deduction and withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*"/"*acte juridique ou un ensemble d'actes juridiques*") for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine ("*kunstmatig*"/"*non authentique")* and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent-Subsidiary Directive of 30 November 2011 (2011/96/EU) ("**Parent-Subsidiary Directive**") in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Belgian resident organisations for financing pensions

For OFPs, i.e. Belgian pension funds incorporated under the form of an OFP ("*organismen voor de financiering van pensioenen*"/"*organismes de financement de pensions*") within the meaning of article 8 of the Belgian Act of 27 October 2006, the dividend income is generally tax exempt.

Subject to certain limitations, any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due.

[4] It is possible that the upcoming Belgian tax reform will modify certain provisions of the BITC regarding the dividends received deduction but no formal draft legislative texts are currently available and the reform is still subject to political discussion.

Belgian (or foreign) OFPs not holding the Shares - which give rise to dividends - for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*"/"*acte juridique ou un ensemble d'actes juridiques*") which are connected to the dividend distributions, are not genuine ("*kunstmatig*"/"*non authentique*"). The withholding tax exemption will in such case not apply and/or any Belgian dividend withholding tax levied at source on the dividends will in such case not be credited against the corporate income tax, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine.

Other Belgian resident legal entities subject to Belgian legal entities tax

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Non-resident individuals or non-resident companies

Non-resident income tax

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the Shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If the Shares are acquired by a non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident personal or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident personal or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if (a) the non-resident individual or the non-resident company can demonstrate that the Shares were held in full legal ownership for an uninterrupted period of twelve months prior to the attribution of the dividends or (b) with regard to non-resident companies only, if, during said period, the Shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a Belgian PE.

Non-resident companies whose Shares are invested in a Belgian PE may deduct 100% of the gross dividends received from their taxable income if, at the date the dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime are met. See also subsection "*Belgian resident companies*" under section "*Belgian taxation of capital gains and losses on Shares*" below. Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Belgian dividend withholding tax relief for non-residents

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for the tax exemption with respect to ordinary dividends in an amount of up to EUR 800 (amount applicable for income year 2023) per year. For the avoidance of doubt, all dividends paid or attributed to such non-resident individual (and hence not only dividends paid or attributed on the Shares) are taken into account to assess whether said maximum amount is reached. Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Shares, such non-resident individual may request in its Belgian non-resident income tax return that any Belgian withholding tax levied on up to such an amount be credited and, as the case may be, reimbursed. However, if no Belgian non-resident income tax return has to be filed by the non-resident individual, any Belgian withholding tax levied on up to such an amount could in principle be reclaimed by filing a request thereto addressed to the tax official ("*Adviseur-generaal Centrum Buitenland*"/"*Conseiller-général du Centre Étranger*") appointed by the Belgian Royal Decree of 28 April 2019. Such a request has to be made at the latest on 31 December of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the non-resident individual status and certain other formalities determined in the Royal Decree.

Under Belgian tax law, withholding tax is not due on dividends paid to a foreign pension fund which satisfies the following conditions: (i) it is a non-resident saver within the meaning of article 227, 3° of the Belgian Income Tax Code which implies that it has separate legal personality and has its tax residence outside of Belgium; (ii) whose corporate purpose consists solely in managing and investing funds collected in order to pay

legal or complementary pensions; (iii) whose activity is limited to the investment of funds collected in the exercise of its corporate purpose, without any profit making aim; (iv) which is exempt from income tax in its country of residence; and (v) provided that it is not contractually obliged to redistribute the dividends to any ultimate beneficiary of such dividends for whom it would manage the Shares, nor obliged to pay a manufactured dividend with respect to the Shares under a securities borrowing transaction. The exemption will only apply if the foreign pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the Shares and that the above conditions are satisfied. The organisation must then forward that certificate to the Company or its paying agent.

A pension fund not holding the Shares - which give rise to dividends - for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*"/"*acte juridique ou un ensemble d'actes juridiques*") which are connected to the dividend distributions, are not genuine ("*kunstmatig*"/"*non authentique*"). The withholding tax exemption will in such case be rejected, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the Shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the share capital of the Company and such minimum participation is held or will be held during an uninterrupted period of at least one year. A non-resident company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the EU Parent-Subsidiary Directive, as amended from time to time, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime. In order to benefit from this exemption, the non-resident company must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are attributed to the Shares, the Company must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides the Company or its paying agent with a certificate confirming, in addition to its qualifying status, the date as of which it has held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform the Company or its paying agent when the one-year period has expired or if its shareholding drops below 10% of the Company's share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

Please note that the above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*"/"*acte juridique ou un ensemble d'actes juridiques*") for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine ("*kunstmatig*"/"*non authentique*") and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the Parent-Subsidiary Directive in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed by a Belgian company to non-resident companies on a share participation of less than 10% will under certain conditions be subject to an exemption from withholding tax, provided that the non-resident companies (i) are either established in another Member State of the EEA or in a country with which Belgium has concluded a double tax treaty, where that treaty, or any other treaty concluded between Belgium and that jurisdiction, includes a qualifying exchange of information clause; (ii) have a legal form as listed in Annex I, Part A to the Parent-Subsidiary Directive as amended from time to time, or a legal form similar to the legal forms listed in the aforementioned annex and which is governed by the laws of another Member State of the EEA or a similar legal form in a country with which Belgium has concluded a double tax treaty; (iii) hold a share participation in the Belgian dividend distributing company, upon payment or attribution of the dividends,

of less than 10% of the Company's share capital but with an acquisition value of at least EUR 2,500,000; (iv) hold or will hold the Shares which give rise to the dividends in full legal ownership during an uninterrupted period of at least one year; and (v) are subject to the corporate income tax or a tax regime similar to the corporate income tax without benefiting from a tax regime which deviates from the ordinary regime. The exemption from withholding tax is only applied to the extent that the Belgian withholding tax, which would be applicable absent the exemption, could not be credited nor reimbursed at the level of the qualifying, dividend receiving, company. The non-resident company must provide the Company or its paying agent with a certificate confirming, in addition to its full name, legal form, address and fiscal identification number (if applicable), its qualifying status and the fact that it meets the required conditions mentioned under (i) to (v) above, and indicating to which extent the withholding tax, which would be applicable absent the exemption, is in principle creditable or reimbursable on the basis of the law as applicable on 31 December of the year preceding the year during which the dividend is paid or attributed.

Belgian dividend withholding tax is also subject to a relief as may be available under applicable tax treaty provisions. Belgium has concluded tax treaties with more than 95 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable treaty rate.

Prospective holders of Shares should consult their own tax advisers to determine whether they qualify for a reduction in withholding tax upon payment or attribution of dividends, and, if so, to understand the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

Belgian taxation of capital gains and losses on Shares

Belgian resident individuals

In principle, Belgian resident individuals acquiring the Shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Shares and capital losses will not be tax deductible.

However, capital gains realised by a Belgian resident individual are taxable at 33% (plus local surcharges) if the capital gain on the Shares is deemed to be speculative or realised outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible.

Moreover, capital gains realised by Belgian resident individuals on the disposal of the Shares, outside the exercise of a professional activity, to a non-resident company (or body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the EEA, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his/her spouse or with certain relatives, a substantial shareholding in the Company (i.e. a shareholding of more than 25% in the Company). Capital losses are, however, not tax deductible in such event.

Capital gains realised by Belgian resident individuals upon redemption of the Shares or upon liquidation of the Company will generally be taxable as a dividend. See also subsection "*Belgian resident individuals*" under section "*Belgian taxation of dividends on Shares*".

Belgian resident individuals who hold the Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realised upon the disposal of the Shares, except for the Shares held for more than five years, which are taxable at a separate rate of 10% (capital gains realised in the framework of the cessation of activities under certain circumstances) or 16.5% (other), plus local surcharges. Capital losses on the Shares incurred by Belgian resident individuals who hold the Shares for professional purposes are in principle tax deductible.

Belgian resident companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realised upon the disposal of the Shares provided that the Conditions for the application of the dividend received deduction regime are met.

If one or more of the Conditions for the application of the dividend received deduction regime are not met, any capital gain realised would be taxable at the standard corporate income tax rate of 25%, unless the reduced corporate income tax rate of 20% applies.

Capital losses on the Shares incurred by Belgian resident companies are as a general rule not tax deductible.

Shares held in the trading portfolios of Belgian qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. The capital gains on such Shares are taxable at the ordinary corporate income tax rate of 25%, unless the reduced corporate income tax rate of 20% applies, and the capital losses on such Shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realisation.

Capital gains realised by Belgian resident companies upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends.

Belgian resident organisations for financing pensions

Capital gains on the Shares realised by OFPs within the meaning of article 8 of the Belgian Act of 27 October 2006 are in principle exempt from corporate income tax and capital losses are not tax deductible.

Capital gains realised by Belgian OFPs upon the redemption of ordinary shares or upon the liquidation of the Company will in principle be taxed as dividends.

Other Belgian resident legal entities subject to Belgian legal entities tax

Capital gains realised upon disposal of the Shares by Belgian resident legal entities are in principle not subject to Belgian income tax and capital losses are not tax deductible.

Capital gains realised upon disposal of (part of) a substantial participation in a Belgian company (i.e. a participation representing more than 25% of the share capital of the Company at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.5%.

Capital gains realised by Belgian resident legal entities upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends.

Non-resident individuals, non-resident companies or non-resident entities

Non-resident individuals, companies or entities are, in principle, not subject to Belgian income tax on capital gains realised upon disposal of the Shares, unless the Shares are held as part of a business conducted in Belgium through a fixed base in Belgium or a PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the Shares for professional purposes), Belgian companies, Belgian resident organisations for financing pensions or other Belgian resident legal entities subject to Belgian legal entities tax.

Non-resident individuals who do not use the Shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the Shares to Belgium, might[5] be subject to tax in Belgium if the capital gains are obtained or received in Belgium and arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or in case of disposal of a substantial participation in a Belgian company as mentioned in the tax treatment of the disposal of the shares by Belgian individuals. See subsection (a) (Belgian resident individuals) above. Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realised by non-resident individuals or non-resident companies upon redemption of the Shares or upon liquidation of the Company will, in principle, be subject to the same taxation regime as dividends.

[5] Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realised by residents of those countries. Capital losses are generally not tax deductible.

Belgian tax on stock exchange transactions

The purchase and the sale and any other acquisition or transfer for consideration of existing Shares (secondary market transactions) is subject to the Belgian tax on stock exchange transactions ("*taks op de beursverrichtingen*"/"*taxe sur les opérations de bourse*") if (i) it is entered into or carried out in Belgium through a professional intermediary, or (ii) deemed to be entered into or carried out in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both referred to as a "**Belgian Investor**").

The tax on stock exchange transactions is levied at a rate of 0.35% of the purchase price, capped at EUR 1,600 per transaction and per party.

Such tax is separately due by each party to the transaction and is collected by the professional intermediary. However, if the order is made directly or indirectly to a professional intermediary established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. In the latter case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement ("*bordereau*"/"*borderel*"), at the latest on the business day after the day the transaction concerned was realised. The qualifying order statements must be numbered in series and a duplicate must be retained by the financial intermediary. The duplicate can be replaced by a qualifying day-today listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian stock exchange tax representative ("**Stock Exchange Tax Representative**"), which will be liable for the tax on stock exchange transactions in respect of the transactions executed through the professional intermediary and for complying with the reporting obligations and the obligations relating to the order statement in that respect. If such a Stock Exchange Tax Representative has paid the tax on stock exchange transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the tax on stock exchange transaction.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2, 9° and 10° of the Belgian Act of 2 August 2002 on the supervision of the financial sector and financial services; (ii) insurance companies described in article 2, §1 of the Belgian Act of 9 July 1975 on the supervision of insurance companies; (iii) pension institutions referred to in article 2,1° of the Belgian Act of 27 October 2006 concerning the supervision of pension institutions; (iv) undertakings for collective investment; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

Belgian annual tax on securities accounts

The Belgian Act of 17 February 2021 has introduced an annual tax on securities accounts which entered into force on 26 February 2021.

The annual tax on securities accounts is a subscription tax, levied on securities accounts and not on the holders thereof. A securities account is defined as an account on which financial instruments can be credited and debited.

The tax applies to securities accounts held both in Belgium and abroad when the account holder is a Belgian resident or when the account forms part of the assets of a Belgian establishment of a non-Belgian resident. The tax applies to natural persons residing in Belgium, as well as to companies and legal entities subject to the tax for legal entities that are established in Belgium.

The tax is also applicable to securities accounts held by non-Belgian residents (both natural persons and legal persons), if the securities account is held in Belgium. If the applicable double tax treaty however allocates the right to tax capital to the jurisdiction of residence, Belgium would be prevented from applying the annual tax on securities accounts to the Belgian securities accounts held by non-Belgian residents. As described above, the tax applies whether or not the account is held in Belgium if the account forms part of the assets of a Belgian establishment of a non-Belgian resident.

The annual tax on securities accounts is applicable to securities accounts of which the average value of the assets amounts to more than EUR 1,000,000 during the reference period. In principle, this reference period starts on 1 October and ends on 30 September of the following year.. The aforementioned threshold is

assessed on the average value of the assets in the securities account at reference points within the reference period (in principle 31 December, 31 March, 30 June and 30 September). The threshold is assessed per securities account and not per account holder.

The applicable tax rate is 0.15%, which is levied on the average value of the assets held in the securities account that exceeds the EUR 1,000,000 threshold. It is however limited to 10% of the difference between the average value and the threshold of EUR 1,000,000.

The annual tax on securities accounts is in principle withheld, reported and paid by the Belgian intermediary. If the intermediary is established outside of Belgium, the tax must in principle be reported and paid by the account holder, unless the account holder can demonstrate that the tax has already been reported and paid by an intermediary. Intermediaries established outside of Belgium can appoint a representative in Belgium (the "**Annual Tax on Securities Accounts Representative**"), which will be liable for reporting and paying the tax in respect of securities accounts in scope of the tax that are managed by such intermediaries. If the Annual Tax on Securities Accounts Representative would have reported and paid the tax, the relevant account holder will, as per the above, no longer be the debtor of the tax.

The annual tax on securities accounts is however not applicable on securities accounts held by certain categories of account holders active in the financial or fund sector, as listed in the law (e.g. credit institutions, insurance companies, investment companies, and certain collective investment undertakings). These exemptions do however not apply if a non-qualifying third party has a direct or indirect claim on the value of the securities account.

The law provides for both a general anti-abuse provision, as well as specific anti-abuse provisions targeting (i) the splitting of a securities account in multiple securities accounts held at the same intermediary and (ii) the conversion of taxable financial instruments, included in a securities account, into registered financial instruments. However, in its judgment of 27 October 2022, the Constitutional Court annulled the specific anti-abuse provisions as well as the retroactive effect up to 30 October 2020 of the general anti-abuse provision. As a result, only the general anti-abuse provision can still be validly applied and, moreover, only as of 26 February 2021.

Prospective investors are strongly advised to seek their own professional advice in relation to the possible impact of the new annual tax on securities accounts on their own personal tax position

Common Reporting Standard

Following recent international developments, the exchange of information is governed by the Common Reporting Standard ("**CRS**"). More than 100 jurisdictions have signed the multilateral competent authority agreement ("**MCAA**"). The MCAA is a multilateral framework agreement to automatically exchange financial and personal information, with the subsequent bilateral exchanges coming into effect between those signatories that file the subsequent notifications.

More than 45 jurisdictions, including Belgium, have committed to a specific and ambitious timetable leading to the first automatic information exchanges in 2017, relating to income year 2016 ("**Early Adopters**"). More than 50 jurisdictions have committed to exchange information as from 2018.

Under CRS, financial institutions resident in a CRS country are required to report, according to a due diligence standard, financial information with respect to reportable accounts, which includes interest, dividends, account balance or value, income from certain insurance products, sales proceeds from financial assets and other income generated with respect to assets held in the account or payments made with respect to the account. Reportable accounts include accounts held by individuals and entities (which includes trusts and foundations) with fiscal residence in another CRS country. The standard includes a requirement to look through passive entities to report on the relevant controlling persons.

On 9 December 2014, EU Member States adopted Directive 2014/107/EU on administrative cooperation in direct taxation ("**DAC2**"), which provides for mandatory automatic exchange of financial information as foreseen in CRS. DAC2 amends the previous Directive on administrative cooperation in direct taxation, Directive 2011/16/EU.

The mandatory automatic exchange of financial information by EU Member States as foreseen in DAC2 started as of 30 September 2017 (as of 30 September 2018 for Austria).

The Belgian government has implemented said Directive 2014/107/EU, respectively the Common Reporting Standard, per the Belgian Act of 16 December 2015 regarding the exchange of information on financial accounts by Belgian financial institutions and by the Belgian tax administration, in the context of an automatic exchange of information on an international level and for tax purposes.

As a result of the Belgian Act of 16 December 2015, the mandatory automatic exchange of information applies in Belgium (i) as of income year 2016 (first information exchange in 2017) towards the EU Member States, (ii) as of income year 2014 (first information exchange in 2016) towards the US and (iii), with respect to any other non-EU States that have signed the MCAA, as of the respective date as determined by the Belgian Royal Decree of 14 June 2017. The Belgian Royal Decree provides that (i) for a first list of 18 countries, the mandatory exchange of information applies as of income year 2016 (first information exchange in 2017) and (ii) for a second list of 44 countries, the mandatory automatic exchange of information applies as of income year 2017 (first information exchange in 2018), (iii) as from 2019 (for the 2018 financial year) for another single jurisdiction and (iv) as from 2020 (for the 2019 financial year) for a third list of 6 jurisdictions.

Investors who are in any doubt as to their position should consult their professional advisers.

The proposed Financial Transaction Tax (FTT)

On 14 February 2013 the EU Commission adopted the Draft Directive on a common Financial Transaction Tax. Earlier negotiations for a common transaction tax among all 28 EU Member States had failed. The current negotiations between the Participating Member States (i.e. Austria, Belgium, France, Germany, Greece, Italy, Portugal, Slovakia, Slovenia and Spain) are seeking a compromise under "enhanced cooperation" rules, which require consensus from at least nine nations. Estonia already left the negotiations by declaring it would not introduce the FTT.

The Draft Directive currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force.

Pursuant to the Draft Directive, the FTT would be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT would, however, not apply to (inter alia) primary market transactions referred to in article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT would be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions would in general be determined by reference to the consideration paid or owed in return for the transfer or the market price (whichever is higher). The FTT should be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, would become jointly and severally liable for the payment of the FTT due.

In case of implementation any sale, purchase or exchange of Shares would become subject to the FTT at a minimum rate of 0.1% provided the above mentioned prerequisites are met. The issuance of New Shares would not be subject to the FTT.

In January 2019 Germany and France proposed that a French-style FTT be levied on the acquisition of shares of listed companies whose head office is in a Member State of the European Union and whose market capitalisation exceeds EUR 1 billion on 1 December of the preceding year. The tax should be levied on the transfer of ownership when shares of listed public limited companies are acquired. Initial public offerings, market making and intraday trading should not be taxable.

The tax rate should be no less than 0.2 per cent.

On 11 March 2019 the finance ministers of the Participating Member States met in the margins of the Ecofin meeting. There is consensus among the ministers that the FTT should continue to be negotiated according to the Franco-German proposal.

However, the introduction of the FTT remains subject to negotiations between the Participating Member States. It may therefore be altered prior to any implementation, of which the eventual timing and fate remains unclear. Additional EU Member States may decide to participate or drop out of the negotiations. The project will be terminated if the number of Participating Member States falls below nine.

In the framework of the Multiannual Financial Framework (MFF)/Own Resources negotiations, the European Parliament supported the introduction of the FTT as an Own Resource. The Commission agreed to issue a declaration as part of the overall political agreement. The Commission has recently clarified that "should there be an agreement on this Financial Transaction Tax, the Commission will make a proposal in order to transfer revenues from this Financial Transaction Tax to the EU budget as an own resource. If there is no agreement by end of 2022, the Commission will, based on impact assessments, propose a new own resource, based on a new Financial Transaction Tax. The Commission shall endeavour to make these proposals by June 2024 in view of its introduction by 1 January 2026".

In February 2021, EU Member States have been consulted on their current position regarding the FTT.

On 18 May 2021, the Commission again mentioned in a Communication that it will propose additional new own resources, which could include a Financial Transaction Tax.

Prospective investors should consult their own professional advisors in relation to the FTT.

GLOSSARY OF SELECTED TERMS

The following definitions apply throughout this Prospectus unless the context requires otherwise:

2022 Annual Report	the Company's annual report for the financial year ended 31 December 2022.
Additional Restructuring Period	a period of six months after the end of the Initial Restructuring Period.
Affordable Care Act	the Patient Protection and Affordable Care Act.
AIMD	Active implantable medical devices.
AKI	Acute kidney injury.
Alternative Financing Securities	(i) the issue of the New Shares pursuant to the Underwriting Agreement; (ii) the issue of securities by the Company as part of mergers, acquisitions or other similar business transactions; (iii) the grant of subscription rights (warrants), stock options, share units or other share based incentives to employees, consultants, directors or other members of the personnel of the Company and/or its subsidiaries, or otherwise in the ordinary course of business, and the issuance of Shares pursuant to those Share Based Incentive Plans; (iv) the issue of securities pursuant to the exercise or conversion of outstanding securities issued prior to 21 March 2023; (v) the issue of Shares or subscription rights pursuant to the terms of the loan agreements entered into by the Company with PMV-Standaardleningen NV (formerly, PMV/z-Leningen NV) and the warrant and loan agreement entered into by the Company with Kreos Capital VI (UK) Limited and Kreos Limited Capital VII (UK) Limited prior to 21 March 2023; and (vi) the issue of Shares, subscription rights, or other securities exercisable, convertible or exchangeable for Shares.
Annual Financial Statements	the audited consolidated financial statements of the Company as of and for the year ended 31 December 2022.
Annual Tax on Securities Accounts Representative	a representative in Belgium appointed by intermediaries established outside of Belgium.
Article 203 ITC Taxation Condition	the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code.
Belfius Insurance	Belfius Insurance NV/SA.
Belgian Investor	private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium.
Belgian Prospectus Act	the Belgian Act of 11 July 2018 on the offering of investment instruments to the public and the admission of investment instruments to the trading on a regulated market, as amended.
Belgian Takeover Act	the Belgian Act of 1 April 2007 on public takeover bids, as amended.
Belgian Takeover Decree	the Belgian Royal Decree of 27 April 2007 on public takeover bids, as amended.
Belgian Transparency Act	the Belgian Act of 2 May 2007 on the disclosure of significant shareholdings in issuers whose securities are admitted to trading on a regulated market and containing various provisions, as amended from time to time.
Bootstrap	Bootstrap Europe S.C.SP.

Bootstrap Warrants	the ten warrants, represented by ten separate subscription rights, issued by the extraordinary general shareholders' meeting held on 27 May 2022 to renew the Former Bootstrap Warrant.
BSI	the British Standards Institution.
CHMP	the Committee for Medicinal Products for Human Use.
CISA	the Swiss Federal Act on Collective Investment Schemes.
CMDCAS	the Canadian Medical Devices Conformity Assessment System.
CMO	the Contract Manufacturing Organisation.
Company	Sequana Medical NV.
Conditions for the application of the dividend received deduction regime	(1) the Belgian resident company holds Shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least EUR 2,500,000; (2) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code.
CROs	Contract Research Organisations.
CRS	Common Reporting Standards.
DAC2	the Directive 2014/107/EU on administrative cooperation in direct taxation.
DSMB	the Data Safety Monitoring Board.
EEA	European Economic Area.
EMA	the European Medicines Agency.
EU MDD	the Directive 93/42/EEC on medical devices.
Early Adopters	the more than 45 jurisdictions, including Belgium, that have committed to a specific and ambitious timetable leading to the first automatic information exchanges in 2017, relating to income year 2016.
Euronext Brussels	the regulated market of Euronext Brussels.
FDA	U.S. Food and Drug Administration.
FDCA	the Federal Food, Drug, and Cosmetic Act.
FinSA	the Swiss Financial Services Act.
Former Bootstrap Warrant	the 'Warrant Agreement', dated 2 September 2016, that was entered into between the Company and Bootstrap, and that has been amended and supplemented by an amendment agreement dated 28 April 2017, a second amendment agreement dated 1 October 2018, an amendment letter dated 20 December 2018, and an agreement dated 1 September 2021.
FSCAs	Field Safety Corrective Actions.
FSMA	Belgian Financial Services and Markets Authority.
GDPR	the EU General Data Protection Regulation.
G-DRG	the German Diagnosis Related Group.
GRAC	GRAC société simple.
IFRS	the International Financial Reporting Standards, as adopted by the European Union.

Initial Restructuring Period	a specified period of time in which the repayment of the principal amounts would otherwise be due.
Investigator	A physician at each clinical study centre to maintain overall responsibility for conduct of the clinical study.
IRBs	Institutional Review Boards.
IT	Information Technology.
Kreos Capital	Kreos Capital VII (UK) Limited.
Kreos Loan Agreement	the secured loan facility agreement entered into by and between the Company and Kreos Capital on 19 July 2022.
Kreos Subscription Rights	the subscription rights issued and allocated by the Company to Kreos Capital VII Aggregator SCSp in the framework of the Kreos Subscription Rights Agreement.
Kreos Subscription Rights Agreement	the subscription rights agreement entered into by and between the Company and Kreos Capital VII Aggregator SCSp on 19 July 2022 in the framework of the Kreos Loan Agreement pursuant to which the Company agreed to issue and allocate the Kreos Subscription Rights.
Listing	the admission to listing and trading of the New Shares on the regulated market of Euronext Brussels.
Listing Date	on or about 28 July 2023.
Locked Parties	Ian Crosbie (Chief Executive Officer) and Kirsten Van Bockstaele (acting through Fin 2-K BV) (Chief Financial Officer).
Lock-up Period	a period ending 180 days from the date of settlement of the Private Placement, *i.e*. 27 April 2023.
LSP	LSP Health Economics Fund Management B.V.
LSP Management Group	LSP Management Group B.V.
LVP	Large Volume Paracentesis.
Market Abuse Regulation	Regulation (EU) 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, as amended from time to time.
MCAA	the multilateral competent authority agreement to automatically exchange financial and personal information, with the subsequent bilateral exchanges coming into effect between those signatories that file the subsequent notifications.
MDR	Medical Device Reporting.
MDSAP	Medical Device Single Audit Program.
Medical Devices Regulation	Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
Member State	Member States of the EEA.
MHRA	the Medicines and Healthcare Products Regulatory Agency.
NDA	New Drug Application.
NASH	non-alcoholic steatohepatitis.
New Shares	the 3,280,307 new shares of the Company that are not yet admitted to listing and trading on the regulated market of Euronext Brussels.
Newton Biocapital	Newton Biocapital I SA.

NeoMed IV	NeoMed IV Extension L.P.
NeoMed Management	NeoMed Management (Jersey) Limited.
NeoMed V	NeoMed Innovation V L.P.
Notified Bodies	the organisations responsible for assessing whether manufacturers and their medical devices meet applicable regulatory requirements.
NUB	Neue Untersuchungs- und Behandlungsmethoden.
OFP	Organisation for Financing Pensions.
Optiverder	Optiverder B.V.
Order	Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended from time to time.
Parent-Subsidiary Directive	the EU Parent-Subsidiary Directive of 30 November 2011 (2011/96/EU), as amended.
PAS	Post-Approval Studies.
PE	a Permanent Establishment.
PHSA	the Public Health Service Act.
PiE	Partners in Equity V B.V.
PiE III	Partners in Equity III B.V.
PMA	Pre-market Approval.
PMV	Participatiemaatschappij Vlaanderen NV.
PMV Standaardleningen	PMV-Standaardleningen NV.
Pharma package	The proposal for a Regulation and a Directive aiming to overhaul the EU pharmaceutical legislation.
Pre-Committing Investors	the investors that were supportive of the Private Placement and pre-committed to submit subscription orders for newly issued shares that were to be issued in the Private Placement.
Private Placement	an offering of the New Shares to institutional, qualified, professional and/or other investors, in and outside of Belgium, on the basis of applicable securities law exemptions, via a private placement through an accelerated bookbuilding procedure.
Prospectus	this prospectus in relation to the listing and admission to trading on Euronext Brussels of the New Shares.
Prospectus Regulation	Regulation 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC, as amended from time to time.
PSURs	Periodic safety update reports.
QMS	Quality Management System.
QSR	Quality Systems Regulations.
Qualified Investors	Relevant Persons within the meaning of article 2(e) of the Prospectus Regulation.
RED	the Radio Equipment Directive 2014/53/EU.
Regulation S	Regulation S under the U.S. Securities Act.
Relevant Persons	qualified investors within the meaning of article 2 of the UK Prospectus Regulation: (i) who have professional experience in matters relating to investments falling within article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended; or (ii) who are high net

	worth entities falling within articles 49(2)(a) to (d) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended; or (iii) who are other persons to whom it may otherwise lawfully be communicated.
REMS	the risk evaluation and mitigation strategy.
Rosetta	Rosetta Capital VII, LP.
Rosetta Capital	Rosetta Capital Ltd.
Securities Act	the U.S. Securities Act, as amended from time to time.
Sensinnovat	Sensinnovat BV.
Sequana Medical	the Company together with its consolidated subsidiaries.
SFPI-FPIM	Société Fédérale de Participations et d'Investissement SA / Federale Participatie- en Investeringsmaatschappij NV.
Share Based Incentive Plans	the grant of subscription rights (warrants), stock options, share units or other share based incentives to employees, consultants, directors or other members of the personnel of the Company and/or its subsidiaries.
Shares	the Company's shares from time to time.
Share Sale	a sale of the entire issued share capital of the Company to a bona fide third party on arm's length terms for cash consideration.
Stock Exchange Tax Representative	the Belgian stock exchange tax representative appointed by professional intermediaries.
Subordinated Loan Agreements	the subordinated loan agreements entered into by and between the Company and PMV Standaardleningen, Sensinnovat and Belfius Insurance NV in July 2020, in the aggregate principal amount of EUR 7.3 million, of which loans in the principal amount of EUR 1.4 million may be converted into new shares in the event of an equity financing or sale of the Company.
Subscription Rights	the 1,111,294 subscription rights of the Company issued in the framework of the Private Placement.
UDI	a Unique Device Identifier.
UK FSMA	the UK Financial Services and Markets Act 2000, as amended.
UK MDR 2002	the Medical Devices Regulations 2002 (SI 2002 No 618, as amended).
Underwriters	Bank Degroof Petercam NV/SA, KBC Securities NV and Van Lanschot Kempen N.V.
Underwriting Agreement	the underwriting agreement entered into by and between the Company and the Underwriters on 25 April 2023.