sequanamedical

Initial Public Offering Sequana Medical NV[1]

Sequana Medical, a commercial stage medical device launches its Initial Public Offering on Euronext Brussels

Sequana Medical is a commercial stage medical device company focused on the development of innovative treatment solutions for the management of liver disease, heart failure, malignant ascites and other fluid imbalance disorders.

The first product, **alfa**pump®, is a fully implantable, programmable, wirelessly-charged, battery-powered system that is CE-marked for the management of refractory ascites (chronic fluid build-up in the abdomen) due to liver cirrhosis and malignant ascites with proven safety, efficacy and quality of life benefits demonstrated in multiple clinical studies and over 650 implants and a North American pivotal study is planned to commence in the second half of 2019. The number of patients with refractory ascites is forecast to increase dramatically due to the growing prevalence of NASH (Non-alcoholic Steatohepatitis), particularly in North America. Since 2018, the **alfa**pump® is included in the EASL clinical practice guidelines for decompensated cirrhosis.

The second product, **alfa**pump® DSR (Direct Sodium Removal), is Sequana Medical's proprietary and breakthrough approach to the management of volume overload in heart failure. The approach focuses on the removal of sodium from the body, and allows the body to naturally remove the excess fluid via urination and osmotic ultrafiltration. There are an estimated one million hospitalisations due to heart failure in the US each year, of which 90% are due to fluid overload. The estimated cost of heart failure related hospitalisations in the US is $13 billion.

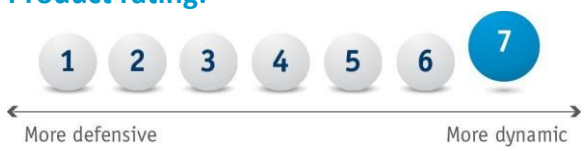
We list the main features for you at a glance:

- **FOCUS ON LIVER DISAESE AND HEART FAILURE** – Large growing markets driven by unhealthy lifestyles and ageing populations. Liver cirrhosis is one of the leading manifestations of liver failure and the key cause of liver cirrhosis is dramatically changing, with non-alcholic steatohepatitits (NASH) serving as the leading growth driver and a major public health threat, in particular in the U.S. Market expectations are that NASH will become the main underlying reason for the strong expected growth of late-stage liver disease. Next to this, volume overload is a major clinical complication of heart failure and the leading cause of hospitalisations for patients suffering from heart-failure.
- **ALFA**PUMP® **IS A PROVEN STEP CHANGE IN THE MANAGEMENT OF LIVER REFRACTORY ASCITES AND MALIGNANT ASCITES** – The **alfa**pump® has received regulatory approval in Europe and offers significant benefits over existing treatments. Sequana Medical has strong clinical and commercial experience that has been derived from the implantation of more than 650 **alfa**pumps®.
- **ALFA**PUMP® **DSR OFFERS A BREAKTHROUGH APPROACH TO THE TREATMENT OF VOLUME OVERLOAD IN HEART FAILURE** – The **alfa**pump® DSR leverages the technical and clinical experience of the validated **alfa**pump® system to deliver a convenient and fully implanted system for DSR (Direct Sodium Removal) therapy.
- **STRONG ORGANISATION LED BY AN EXPERIENCED LEADERSHIP TEAM, PROVEN CAPABILITIES TO PRODUCE THE ALFA**PUMP® **AND A STRONG IP POSITION**

An investment in the Offered Shares involves substantial risks and uncertainties. Prospective investors should read the entire Prospectus, and, in particular, should see Part 2 - (Risk Factors) beginning for a discussion of certain factors that should be considered in connection with an investment in the Offered Shares, including the risks that 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 Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump® (Sequana Medical's only commercial-stage product at the date of this Prospectus), the alfapump® DSR and/or any future products in target markets, and that Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital. See Part 1 - (Summary), Section D - (Risks) and Part 2 - (Risk Factors). Not taking into account any proceeds of the Offering, the Issuer does not have sufficient working capital to meet its working capital needs for a period of at least 12 months from the date of the Prospectus. All of these factors should be considered before investing in the Offered Shares. Prospective investors must be able to bear the economic risk of an investment in the Offered Shares and should be able to sustain a partial or total loss of their investment.

Is this something for you?

Product rating:



Along with the volatility of the market, this product rating, developed by KBC, also takes other factors into account such as scheduled repayment of capital, credit worthiness, asset allocation, exposure to foreign currencies and liquidity. You can find more information under "Product Rating".

Client risk profile:

This product focuses in the first place on investors with a very dynamic profile. We recommend you to only invest in this product if you understand the essential characteristics of the product and more specifically if you understand what risks are associated with this product. In case you wish to buy this product outside the context of investment advice, the bank must determine whether you have sufficient knowledge and experience in relation to the product. If this is not the case, the bank has to warn you that the product is not appropriate for you. If the bank offers the product in the context of investment advice, the bank must ascertain whether the product is suitable for you, taking into account your knowledge and experience in relation to the product, your investment goals and your financial capacity. Ask your KBC adviser for advice. For the complete overview of customer risk profiles, go to **www.kbc.be/riskprofile**.

[1] The Company, together with its subsidiaries (each a "Group Company", and together with the Company, the "Group" or "Sequana Medical"),

About Sequana Medical

Commercial stage medical device company focused on innovative treatment solutions for liver disease, heart failure, malignant ascites and other fluid imbalance disorders

Fast facts

- Founded in 2006
- Headquarters in Ghent, Belgium
- Manufacturing in Zurich, Switzerland
- 34 employees
- Approximately €90 million in private funding to date
- Leading specialist life science investors
- Highly experienced leadership team
- Vast industry and business know-how within the board, which amongst others includes Rudy Dekeyser & Wim Ottevaere
- Strong IP position
- Global network of KOLs in Europe and North America
- Targeted commercial roll-out across Europe

alfapump® is approved in Europe for the treatment of liver refractory ascites and malignant ascites. Ascites is the accumulation of excess fluid (up to 15L) in the abdomen due to liver disease or cancer. Over 650 systems have been implanted and a North American pivotal study is planned to commence in the second half of 2019. The US Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the **alfa**pump for the treatment of liver recurrent or refractory ascites.

alfapump Direct Sodium Removal (DSR) builds upon the proven **alfa**pump platform to deliver a convenient and fully implanted system for volume overload in heart failure.

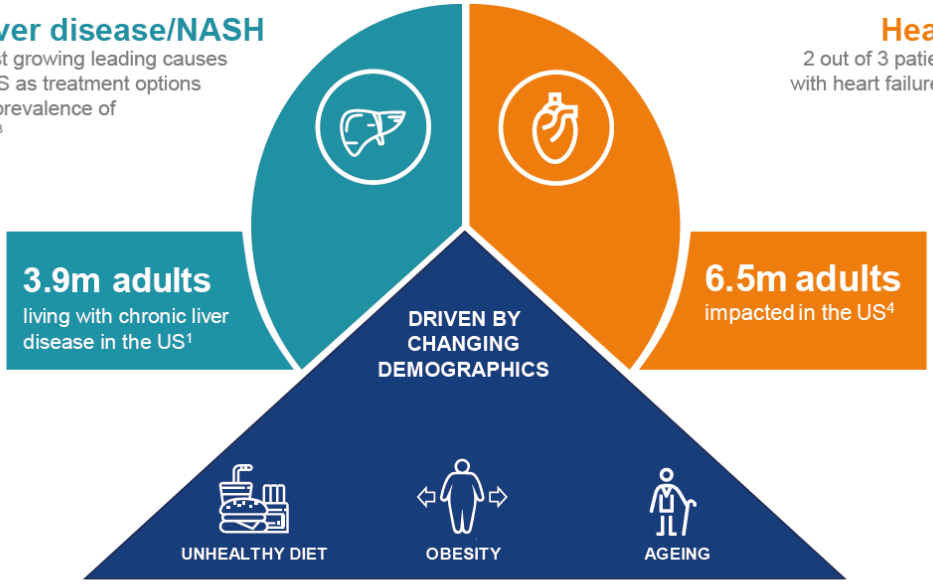
Focus on liver disease and heart failure, large and growing markets driven by unhealthy lifestyles, obesity and an ageing population

Chronic liver disease/NASH

One of the fastest growing leading causes of death in the US as treatment options are limited[2] and prevalence of NASH increases[3]

Heart failure

2 out of 3 patients diagnosed with heart failure will die within 5 years[5]



Liver Cirrhosis:

The market is forecast to grow dramatically due to increasing prevalence of fatty liver disease / NASH (non-alcoholic steatohepatitis) – especially in the US. Approximately three to four million people in the US will be suffering from liver cirrhosis due to NASH in the near- to medium- term.[6]

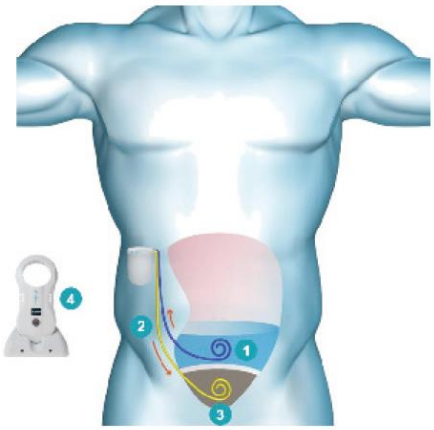
Volume Overload in Heart Failure:

Volume overload is a major clinical complication of heart failure.

Approximately one million hospitalisations for heart failure occur in the US each year, 90% of which are due to volume overload, costing approximately $13 billion.[7]

alfapump: proven step change in the management of liver refractory ascites and malignant ascites

Fully-implanted, wirelessly-charged, CE-marked system that automatically and continuously pumps ascites from the abdominal cavity into the bladder, where the body eliminates the ascites naturally.



1. Automatic and continuous removal of ascites from peritoneal cavity
2. Ascites is pumped into bladder
3. Ascites leaves the body through normal urination
4. Wireless charging and communication for monitoring

Since April 2018, the **alfa**pump has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for decompensated cirrhosis.

alfapump DSR: breakthrough development for the management of volume overload due to heart failure

DSR therapy is Sequana Medical's proprietary and breakthrough approach to the management of volume overload in heart failure. The approach focuses on the removal of sodium from the body, and allows the body to naturally remove the excess fluid via urination and osmotic ultrafiltration. **alfa**pump DSR is under development and builds on the **alfa**pump platform to deliver a convenient and fully implanted system for DSR therapy. Animal studies at Yale have shown DSR therapy to be both safe and effective, and a first-in-human study is ongoing.

Sequana Medical: Long-term plans

North American Liver & Cancer
- ✓ Clinical feasibility study (MOSAIC)
- ○ US Pivotal Study in liver recurrent and refractory ascites commencing in H2 2019

North America & Europe Heart Failure
- ✓ Animal studies (Yale University)
- ○ First in human studies: single dose (underway) and repeated dose with **alfa**pump (commencing H2 2019)

Europe Liver & Cancer
- ✓ CE mark and EASL clinical practice guidelines
- ✓ Clinical studies (RCT, PMSR, retrospective malignant)
- ○ Prospective studies in malignant ascites & albumin
- ○ Focused expansion in UK, DE, CH & FR

Sources
1: Centres for Disease Control and Prevention (CDC)
2: Big pharma bets billions on 'silent' liver disease, Financial times
3: Estes et al. 2018, GlobalData Nash Epidemiology Forecast to 2026
4: Mozzafarian D, Benjamin EJ, Go AS, et al. Heart disease and stroke statistics—2017 update (adults: >=20 years of age)
5: Mamas (2017) Do patients have worse outcomes in heart failure than in cancer?
6: Management estimate based on Estes (2018), GlobalData Nash Epidemiology Forecast to 2026, Noureddin et al. 2013
7: Costanzo et al. (2007), Ambrosy et al. 2014, Kilgore et al. 2017

***Important Regulatory Disclaimer:** alfapump DSR is under development and neither CE-marked nor available for clinical use.*

Consolidated statements of profit and loss (in €000)

	For the nine months ended 30 September		For the year ended 31 December		
	2018	2017	2017	2016	2015
	(unaudited)			*(audited)*	
Revenue	**686**	**957**	**1,304**	**1,489**	**1,685**
Costs of goods sold	(107)	(198)	(212)	(321)	(360)
Gross margin	**580**	**760**	**1,092**	**1,168**	**1,325**
Sales and marketing	(1,479)	(1,091)	(1,506)	(3,337)	(2,988)
Clinical affairs	(1,040)	(1,310)	(1,749)	(3,325)	(2,790)
Quality and regulatory	(816)	(974)	(1,225)	(1,492)	(1,091)
Supply chain	(729)	(862)	(1,041)	(1,775)	(1,795)
Engineering	(885)	(743)	(1,004)	(1,146)	(995)
General and administration	(3,547)	(1,709)	(1,988)	(4,059)	(3,286)
Other income	-	-	3	21	264
Total operating expenses	**(8,496)**	**(6,689)**	**(8,510)**	**(15,113)**	**(12,681)**
Earnings before interest and taxes (EBIT)	**(7,916)**	**(5,929)**	**(7,418)**	**(13,945)**	**(11,356)**
Financial income	-	-	-	3	4
Financial expense	(670)	(487)	(636)	(190)	(89)
Foreign exchange gains/(losses), net	(23)	(8)	(153)	198	(72)
Total net financial expense	**(693)**	**(495)**	**(789)**	**11**	**(157)**
Taxes	(25)	(12)	(18)	(41)	(44)
Net loss for the period	**(8,634)**	**(6,436)**	**(8,225)**	**(13,975)**	**(11,557)**

Features

COMPANY	Sequana Medical NV (with its corporate seat in Ghent) is a limited liability company organised in the form of a naamloze vennootschap/société anonyme under the laws of Belgium.
ISIN CODE	Application has been made to list all Ordinary Shares under the symbol "SEQUA" on Euronext Brussels under ISIN Code: BE0974340722.
SYNDICATE	Joint Global Coordinators and Joint Bookrunners: KBC Securities NV/SA, Kempen & Co N.V. Lead Manager: Mirabaud Securities Limited (Altogether the "**Underwriters**")
ROLE OF KBC BANK NV	Selling Agent
CURRENCY	EUR
OFFERING AND OVER-ALLOTMENT OPTION	The Offering consists of up to 3,235,294 new shares issued by Sequany Medical NV. The number of new shares in the Offering may be increased by up to 15% (the "**Increase Option**"). The new shares initially offered and the shares offered as a result of the possible exercise of in the Increase Option are collectively being referred to as the "New Shares". KBC Securities NV/SA, as stabilisation manager (the "**Stabilisation Manager**"), acting on behalf of the Underwriters, is expected to be granted by the Issuer an option, in the form of a warrant, to subscribe for additional New Shares for an aggregate number equal to up to 15% of the number of New Shares subscribed to cover over-allotments or short positions, if any, in connection with the Offering (the "**Over-allotment Option**"). The additional new Shares issued pursuant to the Over-allotment Option and the New Shares are collectively referred to as the "**Offered Shares**". The Offering consists of: (i) a public offering to retail and institutional investors in Belgium; (ii) a private placement in the U.S. to persons who are reasonably believed to be "**qualified institutional buyers**" ("**QIBs**") as defined in Rule 144A ("**Rule 144A**") under the U.S. Securities Act of 1933, as amended (the "**U.S. Securities Act**"), in reliance on Rule 144A; and (iii) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world (those qualified and/or institutional investors together with the QIBs are collectively being referred to as the "**Institutional Investors**"). The Offering outside the U.S. will be made in compliance with Regulation S under the U.S. Securities Act. Private placements may take place in member states of the EEA pursuant to an exemption under the European Prospectus Directive as implemented in the relevant EEA member state.
PRE-COMMITMENT	Certain existing shareholders of the Issuer and other investors have irrevocably committed to subscribe for an aggregate amount of €20.5 million in the Offering at the Offer Price, subject to closing of the Offering. In the event of over-subscription of the Offering, the Subscription Commitments for an amount of €12.5 million can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments for the remaining amount shall not be reduced but be allocated entirely.
OFFER PRICE	The price per Offered Share (the "**Offer Price**") will be determined during the Offering Period on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. The Offer Price is expected to be between €8.50 and €9.00 per Offered Share (the "**Price Range**"). The Offer Price may be set within the Price Range or below the lower end of the Price Range but will not exceed the higher end of the Price Range. The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. Other changes to the Price Range will also be published in the financial press and by means

	of a press release, through electronic information services, as well as in a supplement to the Prospectus. Investors who have submitted subscription orders will not be notified individually.
OFFERING PERIOD	The offering period (the "Offering Period") will begin on 31 January 2019 and is expected to end no later than 4:00 p.m. (CET) on 7 February 2019, subject to early closing or extension, provided that the Offering Period will in any event be open for at least six business days as from the start of the Offering Period.
RIGHT TO WITHDRAW	In the event of a significant new development, or material mistake or inaccuracy relating to the information included in the Prospectus which is capable of affecting the assessment of the Offered Shares during the period from the date of approval of the Prospectus to the Listing Date, a supplement to the Prospectus shall be published. Investors who have already agreed to subscribe for the Offered Shares before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares.
ALLOCATION	The number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer in agreement with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors. In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased in an equal manner if subscription orders received from them exceed or do not reach, respectively, 10% of the Offered Shares effectively allocated. In case of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria that may be used for this purpose are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Bank and KBC Securities NV/SA in Belgium, and at the counters of the affiliate of Kempen & Co N.V. in Belgium (i.e. Van Lanschot), and the number of Shares for which applications are submitted by Retail Investors.
CLOSING DATE	The closing date is expected to be on or about 12 February 2019 subject to acceleration or extension of the timetable for the Offering.
LISTING	On the regulated market of Euronext Brussels
DIVIDEND POLICY	The Issuer has not declared or paid dividends on its shares in the past. Currently, the board of directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.
USE OF PROCEEDS	The Company estimates to receive net proceeds of approximately €23.4 million in case of a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and approximately €31.8 million in case of a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option). The principal purpose of the Offering is to obtain additional capital to support the execution of the Company's strategy. In particular, the Issuer intends to use the net proceeds of the Offering to fund: • POSEIDON, the North American pivotal study on the **alfa**pump® for the treatment of liver recurrent and refractory ascites (which management estimates will cost around €11 million to complete and to acquire data to support reimbursement); • the European commercial roll-out; • the development of the **alfa**pump® DSR, the Company's breakthrough therapy for the management of volume overload in heart failure, including the Single Dose DSR Proof of Concept and Repeated Dose DSR Proof of Concept (which management estimates will together cost around €1 million to complete);

	• other clinical programmes, including a study on the **alfa**pump® for malignant ascites (which management estimates will cost around €1 million to complete), TOPMOST, a registry for cirrhosis patients that have been implanted with the **alfa**pump® (which management estimates will cost around €0.4 million annually and includes the Fitbit® Study) and a study on the impact of albumin replacement therapy on clinical outcomes in **alfa**pump® patients (which management estimates will cost around €0.25 million to complete); • partial repayment of the principal outstanding under a loan with Bootstrap Europe S.C.Sp., equal to a maximum of €1.5 million, payment of €0.44 million in accrued and unpaid interest on the loan and payment of up to €0.33 million for the portion of the 'Exit Fee' under the the loan that is payable in cash; and • general corporate purposes. The Company intends to fund the European commercial roll-out with most of the net proceeds of the Offering that are not allocated to the clinical studies or the payments on the loan with Bootstrap Europe S.C.Sp. described above. The Company intends to fund its commercial operations directly in the form of payments to the commercial team and sales and marketing expenses, as well as to indirectly fund commercial operations through significant investments in general corporate purposes to establish the infrastructure necessary to enable growth in the Company's commercial operations, such as investments in quality assurance and regulatory affairs and general and administrative personnel to provide critical support to the Company's commercial operations. The European commercial roll-out will also be funded by revenues from sales of the **alfa**pump®, but the amount of revenues that the **alfa**pump® will generate is uncertain. The Company cannot predict with certainty all of the particular uses for the proceeds from the issuance of the Offered Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Company's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of the **alfa**pump® and the **alfa**pump® DSR, regulatory or competitive developments, the net proceeds actually raised by it in the Offering, amounts received by way of revenues and the Company's operating costs and expenditures. As such, the Company's management assumes significant flexibility in applying the net proceeds from the issue of the Offered Shares and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from this Offering, the Company intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit. Furthermore, the Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Shares lower than the maximum number of Offered Shares in the Offering. In the event that the Company would proceed with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements of the above proposed uses.
INVESTMENT OBJECTIVE	A share has an unlimited maturity and does not offer any scheduled repayment of the capital. These shares are expected to trade on the regulated market of Euronext Brussels, which may lead to capital gains or losses. These shares may be entitled to dividends, even if not expected for the foreseeable future. In the event of liquidation the shareholder ranks only after all other creditors. Usually shareholders do not recover anything. As a shareholder of the Company your rights will be governed by Belgian law.
DOCUMENTATION	The Prospectus was approved on 30 January 2019 by the Belgian Financial Services and Markets Authority (the "**FSMA**") (the "Prospectus") and is available in English and Dutch. The Prospectus will be made available to prospective investors at no cost at the Issuer's registered office, located at AA Tower, Technologiepark 122, 9052 Ghent, Belgium, and at your KBC Bank branch and via KBC Live at +32 (0)78 152 153. You can also view the Prospectus at www.kbc.be/sequana, www.bolero.be/nl/sequana and www.kbcsecurities.com, on the website of the Company (www.sequanamedical.com) and on the website of the FSMA (www.fsma.be).

Risk

REDEMPTION	This investment comprises a share and does not offer any scheduled repayment of capital.
DIVERSIFICATION	None: investment in a single security

MARKET SENSITIVITY	The stock market price may fluctuate considerably over time depending on how the business develops, the sector in which the business operates, movements on the financial markets and other macroeconomic conditions.
RISKS THAT ARE SPECIFIC TO THE ISSUER'S INDUSTRY AND BUSINESS	The Issuer is subject to the following material risks, in addition to other risks that are mentioned in Part 2 (Risk Factors), section 2.1 (Risks related to Sequana Medical's business and industry) of the Prospectus: **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. As of 30 September 2018, Sequana Medical has a loss brought forward of €79.7 million. These losses have resulted principally from costs incurred in the development and commercialisation of the alfapump® technology, 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 alfapump® and the alfapump® DSR, to expand manufacturing capabilities, to seek further regulatory and marketing approvals for the alfapump®, to secure reimbursement by payers, to maintain, protect and expand Sequana Medical's intellectual property portfolio and to expand sales and marketing activities. Sequana Medical expects to begin a pivotal study in the second half of 2019 on the alfapump® for the treatment of liver recurrent and refractory ascites in the U.S. and Canada (the "POSEIDON (North American pivotal) Study"), which management estimates will be completed in the second half of 2021 and cost around €11 million to complete and to acquire data to support reimbursement. Sequana Medical also plans to conduct additional clinical studies and as a result management expects that clinical affairs expenses will increase significantly over the next several years. These expenses, together with anticipated general and administrative expenses, will likely result in Sequana Medical incurring further losses for at least the next few years. There can be no assurance that Sequana Medical will achieve profitability, which could impair its ability to sustain operations or obtain any required additional funding. If Sequana Medical does achieve profitability in the future, it may not be able to sustain profitability in subsequent periods, and it may suffer net losses and/or negative operating cash flows in subsequent periods. **Sequana Medical's future financial performance will depend on the commercial acceptance of the alfapump® (Sequana Medical's only commercial-stage product at the date of this Prospectus), the alfapump® DSR and/or any future products in target markets.** At the date of this Prospectus, the alfapump® is the only product that has been commercialised by Sequana Medical. Furthermore, the alfapump® has only received regulatory approval in Europe (through a CE-Mark). The alfapump® received a CE-Mark for the treatment of liver refractory ascites (for a period of up to two years) in 2011, and in 2012 for the treatment of malignant ascites (for patients with a life expectancy of six months or less). The alfapump® was launched commercially in 2012, and to date has only been commercialised in a limited number of countries. Sales of the alfapump® have only generated limited revenue while Sequana Medical has been working to gain commercial market acceptance of the alfapump® in target markets. There can be no assurance that the alfapump®, the alfapump® DSR and/or any future products launched by Sequana Medical will gain commercial acceptance in target markets. If Sequana Medical fails to gain and maintain commercial market acceptance of the alfapump® in its focus jurisdictions of Germany, Switzerland, France, the U.K., the U.S. and Canada, in particular if Sequana Medical fails to secure and maintain regulatory approval and reimbursement arrangements for the alfapump® (as further described below), the amount of revenue generated from sales of the alfapump® in the future could continue to be limited, and could even decrease. In addition, the alfapump® DSR has not received marketing approval in any jurisdictions and Sequana Medical's future financial performance will depend on the successful completion of its ongoing and planned clinical studies on the alfapump® DSR , including the ongoing first-in-human clinical study in approximately 20 patients in the U.S. at Yale University to demonstrate the safety, tolerability and dynamics of a single dose of DSR therapy (no alfapump®) (the "Single Dose DSR Proof of Concept"), the planned study that is expected to be conducted in clinical centres in Europe in approximately 5-10 patients with volume overload in heart failure to demonstrate the safety, tolerability and efficacy of the alfapump® DSR in connection with multiple dose DSR therapy over a 90-day period the ("Repeated DSR Dose Proof of Concept"), the planned multi-national 3-month feasibility study to assess the safety and efficacy of the alfapump® DSR in patients with volume overload in heart failure (the "Multi-national Feasibility Study") and the planned multi-national pivotal study in patients with volume

overload in heart failure to demonstrate the efficacy and cost-effectiveness of the alfapump® DSR versus LVP standard of care (the"Multi-national Pivotal Study"), Many factors can influence market acceptance of the alfapump®, the alfapump® DSR and/or any future products. Failure, or any substantial delay, in gaining significant commercial market acceptance of the alfapump®, the alfapump® DSR and/or any future products in target markets, on a timely basis or at all, could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit Sequana Medical's access to additional capital.

Sequana Medical anticipates using the proceeds of the Offering as described in Element E.2 (Use of Proceeds), including to fund:

- the POSEIDON (North American pivotal) Study, which management estimates will cost around €11 million to complete and to acquire data to support reimbursement;
- the Single Dose DSR Proof of Concept and the Repeated DSR Dose Proof of Concept, which management estimates will together cost around a total of €1 million to complete;
- the controlled study in Europe to evaluate the efficacy and clinical impact of the alfapump® versus standard of care in 50 malignant ascites patients (the "Malignant Ascites CT"), which management estimates will cost around €1 million to complete;
- the European registry study in cirrhosis patients that have been implanted with the alfapump® ("TOPMOST"), which management estimates will cost around €0.4 million annually and includes the quality of life study in 20 patients to measure the impact of the alfapump® vs. standard of care on patient activity (the "Fitbit® Study"); and
- the European study on the impact of albumin replacement therapy on clinical outcomes in 10-15 patients implanted with the alfapump® (the "Albumin Replacement Study"), which management estimates will cost around €0.25 million to complete.

Positive outcomes from these clinical studies will likely result in Sequana Medical requiring additional funding in the future in order to continue development and conduct regulatory approval activities, to expand marketing and sales capabilities, to expand manufacturing capabilities and to take advantage of new business opportunities. Sequana Medical may also strategically decide to seek additional capital if market conditions are favourable. In addition, while the above estimates reflect management's current expectations concerning the cost of Sequana Medical's planned clinical studies, these amounts are only estimates and there are many factors that could cause the actual costs of one or more of these clinical studies to be substantially greater than anticipated

On the date of this Prospectus, Sequana Medical is of the opinion that, taking into account its available cash and cash equivalents (and excluding any proceeds of the Offering), 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 from the date of the Prospectus. Furthermore, over the longer term, the net proceeds from the Offering, together with Sequana Medical's existing capital resources, will be insufficient to fund, among other things, the completion of the clinical development of the alfapump® DSR required to bring it to market in Europe and the U.S., including the Multi-national Feasibility Study or the Multi-national Pivotal Study, to fund the commercial roll-out of the alfapump® in the U.S., if approved, or to pay in full the total CHF 5.90 million in principal and interest outstanding under the secured loan from Bootstrap Europe S.C.Sp. ("Bootstrap") that was signed in September 2016, as amended (the "Bootstrap Loan").

Equity and/or debt financing might not be available when needed or, if available, might not be available on commercially favourable terms. If the necessary 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. Sequana Medical may also be required to significantly curtail, delay, reduce or terminate all or part of its development programmes or the commercialisation of the alfapump®, the alfapump® DSR and/or any future products, or it may be unable to take advantage of future business opportunities or to respond to certain business challenges, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Seeking and obtaining regulatory approval for medical devices 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.

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 policy or legislation applying to active implantable medical devices ("AIMDs"). 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 alfapump® is the only product that has been commercialised by Sequana Medical. Furthermore, the alfapump® has only received regulatory approval in Europe (through a CE-Mark). The alfapump® DSR 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. There can be no assurance that using the alfapump® DSR will be safe and efficacious, or that the alfapump® DSR will receive regulatory approval in any market.

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 alfapump®, the alfapump® DSR or any future products, or to change materials. The regulatory approval process may delay or prevent the launch and/or commercialisation of the alfapump®, the alfapump® DSR 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 alfapump®, the alfapump® DSR or any future products in target markets, on a timely basis or at all, the marketing and sale of the alfapump®, the alfapump® DSR and/or any future products in certain markets may be delayed or may not be achieved, which could materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.

Sequana Medical's success is largely contingent on third party payment from government providers, healthcare insurance providers or other public or private sources. Healthcare policy changes, including legislation to reform the U.S. healthcare system, could have a material adverse effect on Sequana Medical. 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.

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 alfapump®, the alfapump® DSR and/or any future products. Physicians and hospitals are unlikely to use the alfapump®, the alfapump® DSR 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 alfapump®, the alfapump® DSR and/or any future products themselves. Failure to obtain attractive reimbursement may 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 alfapump®, as well as the alfapump® DSR 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.

In the U.S., the emphasis on managed care and the influence of health maintenance organisations has increased and is expected to continue to increase the pressure on healthcare pricing. Hospitals are financially incentivised to improve the quality of care and consequent patient satisfaction, as well as patient throughput (the cycling of patients through a hospital's physical resource base). To contain costs, the Centers for Medicare & Medicaid Services and other third-party payers are increasingly challenging the price, scrutinising the medical necessity and reviewing the cost-effectiveness of medical treatments. Similar cost-containment initiatives are also being emphasised in Canada. In Europe, the downward pressure on healthcare costs has also become very intense, and as a result, increasingly high barriers are being erected to the entry of new products. In some countries, cross-border imports from lower-priced markets also exert a commercial pressure on pricing. Securing adequate or attractive reimbursement often

depends on the successful outcome of a medical economics study, which is a clinical study designed to demonstrate the cost effectiveness of a product or procedure. For example, in order to obtain reimbursement in France, the ARIA Pump Study is being conducted by a group of French clinicians. There is no assurance that this study will demonstrate cost-effectiveness of the alfapump® in a timely manner or at all, which could leave the alfapump® without reimbursement in France and materially and adversely affect Sequana Medical's business, financial condition, results of operations and prospects.
The price that Sequana Medical may receive for, and the marketability of, the alfapump®, the alfapump® DSR 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. 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 alfapump®, the alfapump® DSR 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 is also subject to the following risks, in addition to other risks mentioned in the Prospectus in relation to Sequana Medical's business and industry:

- 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's manufacturing facilities 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 depends on third party suppliers for services and components used in the production of the **alfa**pump® and **alfa**pump® DSR, and some of those services and components 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 **alfa**pump® DSR, component modifications or failure to achieve economies of scale could have a material adverse effect on Sequana Medical.
- Seeking and obtaining regulatory approval under the new Medical Devices Regulation can be an uncertain process, and Notified Bodies have limited resources and may experience backlogs in the transition period leading up to the May 2020 effective date of the new regulations.
- Changes in regulatory requirements, guidance from regulatory authorities or unanticipated events (including adverse events and/or severe adverse events) during Sequana Medical's clinical studies could necessitate changes to clinical study protocols or additional clinical study requirements, which would result in increased costs to Sequana Medical and delay the development timeline. Sequana Medical may not be able to afford such additional costs.
- Sequana Medical may not receive a German Diagnosis Related Group code for the **alfa**pump® in Germany, a target European market.
- Competition from medical device companies, pharmaceutical companies, and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected to increase.
- Sequana Medical has entered into a loan agreement with Bootstrap, which contains covenants that may limit Sequana Medical's ability (or require Bootstrap's prior consent) to take certain actions including the incurrance of certain additional indebtedness. Sequana Medical may not have cash available in an amount sufficient to enable Sequana Medical to make interest or principal payments on its indebtedness when due.
- Any inability to fully protect and exploit Sequana Medical's intellectual property may adversely impact Sequana Medical's financial performance and prospects.
- Attracting physicians and subjects to perform clinical studies and meet clinical study objectives is costly and uncertain. If Sequana Medical experiences delays or difficulties in

	the recruitment of Investigators or enrolment of subjects in clinical studies, its receipt of necessary regulatory approvals could be delayed or prevented. • Even though Sequana Medical has obtained regulatory approval in Europe for the **alfa**pump® in liver refractory ascites and malignant ascites, there is no guarantee that the **alfa**pump® will perform as intended. • Sequana Medical may not be able to manufacture or outsource manufacturing of the **alfa**pump®, the **alfa**pump® DSR and/or any future products in sufficient quantities, in a timely manner or at a cost that is economically attractive. • The success of the **alfa**pump®, the **alfa**pump® DSR and/or any future products depends on its acceptance and adoption by physicians. • Active implantable medical devices such as the **alfa**pump® and the **alfa**pump® DSR 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. • Sequana Medical faces an inherent risk of product liability claims and may not have adequate insurance coverage. • If Sequana Medical's products are defective, or otherwise pose safety risks, the relevant governmental authorities could require their recall, or Sequana Medical may need to initiate a recall of its products voluntarily. • Sequana Medical may be unable to attract and retain management and other personnel it needs to succeed. • For the marketing of the **alfa**pump®, Sequana Medical will be largely dependent on Fresenius in Belgium and the Netherlands, Vingmed in Denmark and Gamida in Israel. • If Sequana Medical is unable to expand its sales, marketing and distribution capabilities for the **alfa**pump®, the **alfa**pump® DSR and/or any future products, whether it be with internal infrastructure or an arrangement with a commercial partner such as the ones that Sequana Medical has entered into with Fresenius, Vingmed and Gamida, Sequana Medical may not be successful in commercialising the **alfa**pump®, the **alfa**pump® DSR and/or any future products in its target markets, if and when they are approved. • Sequana Medical's future profitability may depend on its ability to penetrate markets outside of Europe and North America, where Sequana Medical would be subject to additional regulatory burdens and other risks and uncertainties. • The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. If Sequana Medical is found to have made false or misleading claims about the **alfa**pump® and/or the **alfa**pump® DSR and/or any future products, or otherwise have violated promotion or advertising restrictions, Sequana Medical may become subject to significant fines and/or other liabilities. • Compliance with regulations for quality systems for medical device companies is difficult, 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. • Intellectual property rights do not necessarily address all potential threats to Sequana Medical's competitive advantage.
RISKS RELATED TO THE SHARES AND THE OFFERING	The Shares and Offering are subject to the following material risks: • The fact that no minimum amount is set for the Offering may affect Sequana Medical's investment plan and the liquidity of the shares. • There has been no prior public market for the shares and an active market for the shares may not develop. • The market price of the shares may fluctuate widely in response to various factors. • Future sales of substantial amounts of the Issuer's shares, or the perception that such sales could occur, could adversely affect the market value of the shares. • The Issuer has no fixed dividend policy and will probably not be in a capacity to pay dividends in the foreseeable future. • Certain significant shareholders of the Issuer after the Offering may have different interests from the Issuer and may be able to control the Issuer, including the outcome of shareholder votes. • Any future capital increase by the Issuer could have a negative impact on the price of the Shares and could dilute the interests of existing shareholders

	These and the other risks related to the shares and the Offering are described in more detail in Section "Risk Factors" of the Prospectus.
FURTHER INFORMATION	For further information, please read the Prospectus carefully, paying particular attention to the "Risk Factors" section.

Product rating

PRODUCT RATING	**7** on a scale of 1 (low risk) to 7 (high risk). If estimates of the factors used to determine product ratings change owing to market circumstances, the product rating can also change. Investors will be informed through the usual communication channels of any change in the risk profile (a product rating of 1 corresponds with a highly defensive risk profile, a product rating of 2-3 with a defensive profile, a product rating of 4-5 with a dynamic profile and a product rating of 6-7 with a highly dynamic profile). For more information and background on the various factors used to determine the product ratings see www.kbc.be/productrating

Charges

SUBSCRIPTION CHARGES	None
COSTS RELATING TO THE OFFERING	The aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus and Offering related documents, and expenses incurred by the Underwriters (which are estimated at €50,000)) and the remuneration of the FSMA and Euronext Brussels, is expected to amount to approximately €2.9 million. Additionally, fees and commissions payable to the Underwriters by the Issuer are expected to be maximum €1.9 million assuming a placement of the maximum number of New Shares in the Offering (including the conversion of the Bridge Loans in full, but excluding the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, or €2.7 million assuming a placement of the maximum number of Offered Shares in the Offering (including the conversion of the Bridge Loans in full, and including the exercise in full of the Increase Option and the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range.
CUSTODY FEE	Charges for holding the shares in custody account: to be borne by the subscriber (see Schedule of Rates and Charges).
FINANCIAL SERVICES	Free of charge at KBC Bank NV (see Schedule of Rates and Charges).
SCHEDULE OF RATES AND CHARGES	All rates and charges applying at KBC Bank NV can be found at http://kbc-pdf.kbc.be/vermogensopbouw/tarieven_effecten_en.pdf

Liquidity

INITIAL LISTING	Trading of the shares is expected to commence on or about 11 februari 2019 (unless in case of extension of the Offering Period) on the regulated market of Euronext Brussel
NEGOTIABILITY	Daily.

Tax treatment

GENERAL	The tax treatment will depend on each investor's individual circumstances and may change in the future. The general principles are set out in the section "Taxation in Belgium" of the Prospectus.
TAX ON STOCK MARKET TRANSACTIONS	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. The tax on stock exchange transactions is not due upon the issuance of the New Shares (primary market transactions).
TAX TREATMENT IN BELGIUM	Dividends are currently (i.e. on the date of this product info sheet) subject to withholding tax at the rate of 30% on the gross amount. The withholding tax constitutes the final tax for Belgian individuals, which means that any income from the shares does not have to be declared in their annual tax return.

Glossary

For an overview of financial and economic terms, go to **www.kbc.be/lexicon** (available in Dutch and French)

Additional information or subscription details can be obtained from:

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