REGISTRATION DOCUMENT



OBSERVE MEDICAL ASA

(A public limited company incorporated under the laws of Norway)

The date of this Registration Document is 18 June 2020

IMPORTANT INFORMATION

This Registration document (the "**Registration Document**") has been prepared by Observe Medical ASA (the "**Company**"), a public limited company incorporated under the laws of Norway (together with its consolidated subsidiaries, "**Observe Medical**" or the "**Group**") to comply with the Norwegian Securities Trading Act of 29 June 2007 no. 75 (the "**Norwegian Securities Trading Act**") and related secondary legislation, including Regulation (EU) 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 2014/71/EC, as amended, and as implemented in Norway in accordance with section 7-1 of the Norwegian Securities Trading Act (the "**EU Prospectus Regulation**"). This Registration Document has been prepared solely in the English language. This Registration Document has been approved by the Financial Supervisory Authority of Norway (Nw.: *Finanstilsynet*) (the "**Norwegian FSA**"), as competent authority under the EU Prospectus Regulation. The Norwegian FSA only approves this Registration Document as meeting the standards of completeness, comprehensibility and consistency imposed by the EU Prospectus Regulation, and such approval should not be considered as an endorsement of the issuer or the quality of the securities that are the subject of this Registration Document. Investors should make their own assessment as to the suitability of investing in the securities.

For definitions and certain other terms used throughout this Registration Document, see Section 13 "Definitions and Glossary".

The information contained herein is current as at the date hereof and is subject to change, completion and amendment without notice. In accordance with Article 23 of the EU Prospectus Regulation, significant new factors, material mistakes or material inaccuracies relating to the information included in this Registration Document, which may affect the assessment of the Company's shares (the "**Shares**") and which arises or is noted between the time when the Registration Document is approved by the Norwegian FSA and the listing of the Shares on Oslo Axess, will be mentioned in a supplement to this Registration Document without undue delay. Neither the publication nor distribution of this Registration Document, nor the sale of any Shares, shall under any circumstances imply that there has been no change in the Group's affairs or that the information herein is correct as at any date subsequent to the date of this Registration Document.

No person is authorised to give information or to make any representation concerning the Group other than as contained in this Registration Document. If any such information is given or made, it must not be relied upon as having been authorised by the Company or by any of its affiliates, representatives or advisors.

The distribution of this Registration Document in certain jurisdictions may be restricted by law. This Registration Document does not constitute an offer of, or an invitation to purchase, any of the Shares. Neither this Registration Document nor any advertisement or any other offering material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with applicable laws and regulations. Persons in possession of this Registration Document are required to inform themselves about and to observe any such restrictions. In addition, the Shares are subject to restrictions on transferability and resale and may not be transferred or resold except as permitted under applicable securities laws and regulations. Investors should be aware that they may be required to bear the financial risks of this investment for an indefinite period of time. Any failure to comply with these restrictions may constitute a violation of applicable securities laws. For further information on the sale and transfer restrictions of the Offer Shares, see Section 11 "Selling and transfer restrictions".

Any reproduction or distribution of this Registration Document, in whole or in part, and any disclosure of its contents is prohibited.

This Registration Document shall be governed by and construed in accordance with Norwegian law. The courts of Norway, with Oslo as legal venue, shall have exclusive jurisdiction to settle any dispute which may arise out of or in connection with this Registration Document.

In making an investment decision, prospective investors must rely on their own examination, and analysis of, and enquiry into the Group, including the merits and risks involved. The Company is not making any representation to any investor in the Shares regarding the legality of an investment in the Shares by such investor under the laws applicable to such investor. Each reader of this Registration Document should consult with his or her advisors as to the legal, tax, business, financial and related aspects of a purchase of the Shares.

All Sections of the Registration Document should be read in context with the information included in Section 3 "General Information".

Investing in the Shares involves certain risks. See Section 1 "Risk Factors" beginning on page 3.

ENFORCEMENT OF CIVIL LIABILITIES

The Company is a public limited company incorporated under the laws of Norway. As a result, the rights of holders of the Shares will be governed by Norwegian law and the Company's articles of association (the "Articles of Association"). The rights of shareholders under Norwegian law may differ from the rights of shareholders of companies incorporated in other jurisdictions. The members of the Company's board of directors (the "Board Members" and the "Board of Directors", respectively) and the members of the Group's senior management (the "Management") are not residents of the United States, and all of the Company's assets are located outside the United States. As a result, it may be difficult for investors in the United States to effect service of process on the Company or its Board Members and members of Management in the United States or to enforce in the United States judgments obtained in U.S. courts against the Company or those persons, including judgments based on the civil liability provisions of the securities laws of the United States or any State or territory within the United States. Uncertainty exists as to whether courts in Norway will enforce judgments obtained in other jurisdictions, including the United States, against the Company or its Board Members or members of Management under the securities laws of those jurisdictions. In addition, awards of punitive damages in actions brought in the United States or elsewhere may not be enforceable in Norway. The United States does not currently have a treaty providing for reciprocal recognition and enforcement of judgements (other than arbitral awards) in civil and commercial matters with Norway.

TABLE OF CONTENTS

1	RISK FA	ACTORS	3
	1.1	Risks related to the Group and the industry in which the Group operates	.3
	1.2	Risks related to financing and market risk	.5
	1.3	Risk related to laws, regulation and litigation	.6
2	RESPON	SIBILITY FOR THE REGISTRATION DOCUMENT	.8
3	GENERA	AL INFORMATION	9
	3.1	The approval of this Registration Document by the Norwegian Financial Supervisory Authority	9
	3.2	Other important investor information	.9
	3.3	Financial information	9
	3.4	Presentation of other information	10
	3.5	Cautionary note regarding forward-looking statements	11
4	DIVIDE	NDS AND DIVIDEND POLICY	13
	4.1	Dividend policy	13
	4.2	Legal constraints on the distribution of dividends	13
	4.3	Manner of dividend payments	13
5	INDUST	RY AND MARKET OVERVIEW	14
	5.1	Introduction	
	5.2	The Global market	
	5.3	The EU market	
	5.4	The Norwegian market	
	5.5	Urine Bag and Meter Markets	
	5.6	Urine Meter Market: Sippi [®] Market	
	5.7	Urine Bag Market: Market for Sippcoat [®] /Sippbag [™]	
	5.8	Corona: Effect on ICU beds market and the market for Sippi [®]	
6	BUSINE	SS OF THE GROUP	21
	6.1	Introduction to Observe Medical	21
	6.2	History and important events	21
	6.3	Description of Observe Medical's products and services	23
	6.4	Research and development	26
	6.5	The Group's competitive advantages	26
	6.6	Strategy and objectives	26
	6.7	Market Launch	26
	6.8	Competition	27
	6.11	The Group's intellectual property rights	29
	6.12	Material contracts	29
	6.13	Dependency on contracts, patents and licenses	29
	6.14	Employees	30
	6.15	Regulatory and environmental matters	30
	6.16	Insurance	30
	6.17	Legal proceedings	31
7	OPERAT	TING AND FINANCIAL REVIEW	32
	7.1	Presentation of Financial Information	
	7.2	Significant factors affecting the Group's results of operations and financial performance	32
	7.3	Recent developments and trends	33
	7.4	Results of operations	33
	7.5	Consolidated statement of financial position	35
	7.6	Liquidity and capital resources	36

	7.7	Cash flows
	7.8	Investments
	7.9	Borrowings and other contractual obligations
	7.10	Financial risk management
	7.11	Significant changes
8	BOARD	OF DIRECTORS, MANAGEMENT AND CORPORATE GOVERNANCE
	8.1	Introduction
	8.2	The Board of Directors
	8.3	Management
	8.4	Remuneration and benefits
	8.5	Audit committee
	8.6	Nomination committee
	8.7	Corporate governance
	8.8	Conflict of interests etc
9	RELATE	D PARTY TRANSACTIONS
10	CORPOR	ATE INFORMATION AND DESCRIPTION OF THE SHARE CAPITAL
	10.1	Company corporate information
	10.2	Legal structure
	10.3	Share capital and share capital history
	10.4	Share options
	10.5	Major shareholders
	10.6	Authorisations to acquire treasury shares
	10.7	Authorisation to increase the share capital and to issue Shares
	10.8	Other financial instruments
	10.9	Shareholder rights
	10.10	The Articles of Association
	10.11	Shareholders agreement
11	SELLING	G AND TRANSFER RESTRICTIONS
12	ADDITIO	DNAL INFORMATION
	12.1	Independent auditor
	12.2	Documents available
	12.3	Incorporated by reference
13	DEFINIT	TONS AND GLOSSARY

1 RISK FACTORS

An investment in the Company and the Shares involves inherent risk. Before making an investment decision with respect to the Shares, investors should carefully consider the risk factors and all information contained in this Registration Document and the Company's Financial Information (as defined in Section 3.3 "Financial information", including the related notes in such Financial Information). The risks and uncertainties described in this Section 1 "Risk Factors" are the material known risks and uncertainties specific for the Group as of the date hereof that the Company believes are the material risks relevant to an investment in the Shares. An investment in the Shares is suitable only for investors who understand the risks associated with this type of investment and who can afford to lose all or part of their investment.

The risk factors included in this Section 1 "Risk Factors" are presented in a limited number of categories, where each risk factor is sought placed in the most appropriate category based on the nature of the risk it represents. Within each category the risk factors deemed most material for the Group, taking into account their potential negative affect and the probability of their occurrence, are set out first. This does not mean that the remaining risk factors are ranked in order of their materiality or comprehensibility, nor based on a probability of their occurrence. The absence of negative past experience associated with a given risk factor does not mean that the risks and uncertainties in that risk factor are not genuine and potential threats, and they should therefore be considered prior to making an investment decision. If any of the following risks were to materialise, either individually, cumulatively or together with other circumstances, it could have a material adverse effect on the Group and/or its business, results of operations, cash flows, financial condition and/or prospects, which may cause a decline in the value and trading price of the Shares, resulting in loss of all or part of an investment in the Shares. Additional factors of which the Company is currently unaware, or which it currently deems not to be risks, may also have corresponding negative effects.

1.1 Risks related to the Group and the industry in which the Group operates

The Group is dependent on sale of its product Sippi® in order to generate revenues

Currently, the Group has only one product, Sippi[®] with supporting functions/products SippSense[®] and SippCoat[®], in the market and the number of units sold of these products will have a direct effect on the Group's results of operations as they are the only revenue generating products that the Group' currently offers. Sippi[®], which is developed by the Group, was launched for sale in 2013 and the second generation called Sippi[®]BLE was launched in Q4 2019. Because of the short period of time the product has been in the market, the sale of Sippi[®]BLE has not started in a large scale. Low sales of Sippi[®] will have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern without raising additional liquidity financing either through equity offering or further debt financing.

Competing products may be launched to the market before the Group is able to establish a viable market share for Sippi[®]

As the process of monitoring urine output, as part of measuring the critical fluid balance of patients, has remained unchanged for several decades competing products may be launched to the market before the Group is able to establish a viable market share for Sippi[®]. The markets in which the Group operates are highly competitive and there is strong competition in developing and bringing new health care products to the market. The players competing with the Group are all kind of companies ranging from big medtech corporations to start-up companies and some competitors have advantages, such as vertical integration, product diversity, greater financial resources or economies of scale, which may adversely affect the Group's ability to compete on sustainable terms. As the field in which Sippi[®] brings new technology has been unchanged for several decades, there is a possibility that other companies develop competing products that achieve the same results as Sippi[®] and as such compete for market shares against the Group. There is also a possibility that a competing product has alternative or new solutions which outdate the technology that is used in Sippi[®]. If the Group is unable to remain competitive, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group may not obtain the prices it requires for its products

The urine measurement market is a mature market dominated by few big suppliers. There is a constant price pressure in this market since it is mainly driven by tenders from private purchasing groups or governmental procurement bodies. Sippi[®] is an innovative and more technically advanced product solution (digital, automated, wireless connection and bacteria control) and it has therefore higher manufacturing costs, relative to current competitors. This requires the Group to obtain a value based pricing for Sippi[®], in order to secure profitability and Sippi[®] is therefore priced in the upper range of urine meters which may become a challenging market barrier. If the Group does not obtain the prices it requires for its products, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group is dependent upon a limited number of customers, primarily private and public health care clinics and hospitals

The Group's target market is Intensive Care Units ("**ICUs**") which are typically located at university clinics and larger central hospitals. There are limited number of beds per country since ICUs are expensive to operate. The Group faces the risk that one dissatisfied customer could spread the word to the other few hospitals in a country or region. In addition, university hospitals are constantly under cost saving regimens and adding a more expensive product as Sippi[®] can be challenging. New environmental demands from the Group's customers, e.g. non-PVC products, could potentially cause exemption or significant delays in the Group's ability to deliver products and hence generate sales. A customer contract is normally a one-time sale of a number of Sippi[®] units with no obligation for the customer to purchase additional units. The Group is therefore dependent on entering into contracts with new customers and to sell its add-on products such as the Sippcoat[®] and SippbagTM in the relevant markets. If the Group is unable to enter into new customer contracts for Sippi[®] or not establish a larger market for Sippcoat[®] and SippbagTM, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group's risk related to distributing partners and suppliers

The Group has contracts with distributors in some European markets outside the Nordics. The Group will also establish new distributor partnerships in other territories in order to launch Sippi[®] on the global market. Thus, the Group will be dependent on those distributors' ability to perform and operate in their respective territories. Furthermore, there is a risk that these companies go out of business. The Group also faces a risk in upscaling production, where product performance can differ. Additionally, the Group has one supplier contract with a minimum purchase obligation. The Group risks a penalty in the amount of EUR 50,000 if it does not fulfil the minimum purchase obligation. The relevant agreement is automatically renewed for a one year term at the time enabling the Group to minimize its risk for being liable to pay the penalty amount for more than one year if in breach. If the Group's distributing partners or suppliers fail to deliver pursuant to their contractual obligations or the Group cannot meet its minimum purchase volumes, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group's intellectual property rights, including trademarks and trade names, may be infringed, misappropriated or challenged by others; the Group may be subject to liability if it infringes upon the intellectual property rights of third parties

The Group's brands and related intellectual property rights are important to its continued success. In general, the Group has a strong position with regard to the intellectual property rights and has ensured broad international coverage. Since the key competitive advantage of the Group's products is the innovative technology on which the products are based, it is specifically important for the Group to protect such technology in order to avoid being copied by competitors. This is a specific challenge for the Group as it is bringing an innovative product to market. Thus, if the Group was to fail to successfully protect its intellectual property rights for any reason, or if any third party misappropriates, dilutes or infringes its intellectual property, the value of its brands may be harmed, which could have an adverse effect on its business, results of operations or financial condition. Any damage to the Group's brand value could lower sale volumes of its products or make it more difficult to obtain new customer agreements.

The Group may also from time to time be required to initiate litigation to enforce its trademarks, trade names, service marks and other intellectual property rights. Third parties may also assert that the Group has infringed, misappropriated or otherwise violated their intellectual property rights, which could lead to litigation against the Group. The outcome of litigation is inherently uncertain and the litigation process, regardless of outcome, could divert the attention of the Management, result in substantial legal fees and costs, damages, and diversion of resources, and may thus affect the Group's ability to develop its business in accordance with its business plan. Furthermore, litigation, whether as a claimant or plaintiff, could also result in negative publicity, as well as negatively affect the Group's sales and profitability, regardless of whether the Group is able to successfully enforce or defend its rights. The Group is likely to incur additional costs in defending such litigation. The realisation of these risks could ultimately have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The risk for Sippi[®] having malfunctions that need to be further researched on

The Group operates in the urine measurement field where almost all of the offered products are analogue system. The only digital system on the market has had limited success and other digital products that have been launched have been withdrawn later. Urine is a difficult substance to measure since it produces biofilm and can have blood clots, debris and proteins. Even analogue systems have had recalls due to problems with de-airing and blocked systems. There is a risk

that the Group will experience similar problems with Sippi[®]. In addition, the Group uses Bluetooth Low Energy technology to send data to its Bluetooth receiver for data handling in its software SippLink[™]. Sending Bluetooth signals in an ICU environment can be affected by other equipment in the ICU which could affect Sippi[®]'s operation negatively. So far the Group has not been able to conduct tests in many hospitals and hence the Group does not have the full overview of Sippi[®]'s operating performance or negative effects from other equipment. The Group also depends on other vendor's PDMS systems and hardware which also can have a negative impact on Sippi[®]'s functionality or ability to access such systems. If the Group's products would appear to have malfunctions that needs to be re-designed, this could a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group and the industry in which it operates may be adversely affected by global economic market conditions

The Group's performance and further development depends on the continued stable growth of the global market for medicine devises and its value chain, which could be adversely affected by a material adverse change in the world economy and the global economic market conditions. The global economy is currently experiencing a period of significant downturn and uncertainty caused by the recent outbreak of the COVID-19 virus, declared a pandemic by the World Health Organization in March 2020. The extraordinary measures imposed by authorities worldwide to contain the COVID-19 virus have already had a large impact on the world economy as of the date of this Registration Document. Even if the medtech market in general has so far not been significantly affected by the extraordinary measures imposed by authorities, a prolonged duration and/or increase of the restrictive measures and a continued downturn in the global economy could result in serious impact on the healthcare system and the patients with further impact on the Group's revenues and operations. As the Group is in launch phase with the next generation of Sippi®, the Group is highly dependent on dialogue with current and potential customers and with other stakeholders. The current situation, however, with national travel restrictions and a healthcare system, and healthcare providers, fully occupied with acute handling of COVID-19, provides constraints to the launch efforts for Sippi®, with some of the sales projects and other projects being slowed down or stalled. Furthermore, a general decline in the world economy may lead to global changes in the consumers' demand for certain of the Group's products or substantial decrease in the general price level which could result in significantly reduced sales for the Group. If such risks materialise, this could have a material adverse effect on the Group's revenues, liquidity, cash flow, financial position and the Group's ability to continue as a going concern.

1.2 Risks related to financing and market risk

The Group will require additional capital in the future in order to execute its commercialisation and growth strategy or for other purposes, which may not be available on favourable terms, or at all

Because the Group currently is in an early phase of its commercialisation and development process of its products, the Group will require additional funds in order to execute and complete its commercialisation and growth strategy, or for other purposes. Since the date the Shares were listed on Oslo Axess on 4 November 2019 (the "Listing"), the Group's principal source of liquidity has been cash from its borrowing agreements (see Section 7.9.1), and will in the future still be cash generated from financing, equity and debt, in addition to net cash flows generated from sales, and consequently there is a risk that the borrowing arrangement and available liquidity sources that the Group has in place are not sufficient to cover the Group's existing or future expenditures. According to the Group's current proposed scale of operations, the Group expects that it will need approximately NOK 10 million in order to have sufficient working capital for the period covering at least 12 months from the date of this Registration Document. The Group expects to obtain the required additional funds through a fully underwritten rights issue contemplated to be completed during July 2020 raising gross proceeds of NOK 45 million. There is also the possibility of a breach of the lender's obligations under the Company's existing borrowing arrangement, as the lender is an industrial player and the Company's largest shareholder and not an ordinary financing institution. When the Group requires additional funds in order to execute its commercialisation and growth strategy, or for other purposes, there is a risk that adequate sources of funds may not be available, or available at acceptable terms and conditions, when needed. If the Group raises additional funds by issuing additional equity securities, the existing shareholders may be significantly diluted. If funding is insufficient at any time in the future, the Group may be unable to fund its current and ongoing commercialisation of its products and lose business opportunities and thereby risk to fail to respond to competitive pressures. If the Group for any reason does not obtain additional funding as needed in the future, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group's existing or future debt arrangements could limit the Group's liquidity and flexibility in obtaining additional financing, in pursuing other business opportunities or corporate activities or the Company's ability to declare dividends to its shareholders

The Group has as of the date for this Registration Document a loan provided by Navamedic ASA ("**Navamedic**") in the aggregate amount of NOK 34,000,000 excl. accrued interest. However, the Group may incur additional indebtedness in the future as also provided for in its existing borrowing arrangement. This level of debt could have important consequences to the Group, including the following:

- The Group's ability to obtain additional financing for working capital, capital expenditures, acquisitions or other purposes may be impaired or such financing may be unavailable on favourable terms;
- The Group's costs of borrowing could increase as it becomes more leveraged;
- The Group may need to use a substantial portion of its cash from operations to make principal and interest payments on its debt, reducing the funds that would otherwise be available for operations, future business opportunities and dividends to its shareholders;
- The Group's debt level could make it more vulnerable than its competitors with less debt to competitive pressures, a downturn in its business or the economy generally; and
- The Group's debt level may limit its flexibility in responding to changing business and economic conditions.

The Group's ability to service its future debt will depend upon, among other things, its future financial and operating performance, which will be affected by prevailing economic conditions as well as financial, business, regulatory and other factors, some of which are beyond its control. If the Group's operating income is not sufficient to service its current or future indebtedness, the Group will be forced to take action such as reducing or delaying its business activities, acquisitions, investments or capital expenditures, restructuring or refinancing its debt or seeking additional equity capital. The Group may not be able to affect any of these remedies on satisfactory terms, or at all. If any such risk materialise, it could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group is exposed to exchange rate fluctuations

As a consequence of its international operations, including operations in Sweden and Denmark, administration in Norway, expected sales to the Nordic region and rest of Europe, especially Germany, the Group is exposed to exchange rate fluctuations. This includes when operating revenues and operating costs are denominated in different currencies. Furthermore, subsequent to the refinancing of debt, the Company will have debt to Navamedic in NOK, and net receivables on its foreign subsidiaries in other currencies. With different functional currencies, the Group will be exposed to currency gains and losses on debt and receivables between the companies, which will affect its reported profit or loss. The Group has not, but may in the future enter into hedging agreements, but there can be no assurance that such arrangements will fully, or at all, protect the Group from exchange rate risk (in particular in the long term) or that the Group is able to enter into such hedging arrangements on commercially reasonable terms. Exchange rate fluctuations could have a significant adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

1.3 Risk related to laws, regulation and litigation

The Group is dependent on its products fulfilling the customers' requirements to product quality and safety

The Group is dependent on its products fulfilling national and international requirements for product quality and safety. The approval process for medical devices differs between countries and hospital systems, which means that there is an uncertainty related to the amount of resources the Group will have to devote to meet the requirements for required approvals. It cannot be guaranteed that the Group will be able to obtain or maintain such permits/approvals, or that fulfilling applicable requirements may be done on commercially satisfactory terms. The Group obtained FDA registration (US Food and Drug Administration) in 2013 for Sippi[®] and CE approval (Communauté Européenne) for Sippi[®]BLE in 2019. If the Group was to lose any of its permits or not obtain the permits required, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

The Group may be subject to litigation, including claims related to product liability that arise for the use of its products

The Group may in the future be subject to legal claims, including those arising in the normal course of business. Many of the Group's contracts contain penalty clauses for the Group's failure to timely deliver or failure to meet agreed service levels and the Group may face claims as a result of breach of contract for, for example, failure to deliver (including on time), material defects or negligence in the delivery of a service or solution. The Group could also face claims related to product liability arising from the use of its products. An unfavourable outcome on any litigation or arbitration matter could require that the Group pays substantial damages, prevent the Group from selling certain of its products, or in connection with any intellectual property infringement claims, require that the Group pays ongoing royalty payments. The Group's provisions for losses related to pending legal proceedings may not be adequate to cover its ultimate costs in relation to such proceedings and may need to be adjusted as a result of subsequent developments in or the final outcome of such legal proceedings. Whether or not the Group ultimately prevails, litigation and arbitration are costly and can divert Management's attention from the Group to incur significant costs. A settlement or an unfavourable outcome on any litigation or arbitration matter could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

Laws and regulations could hinder or delay the Group's operations, increase the Group's operating costs and reduce demand for its services

Changes in laws and regulations, e.g. demand of PVC free urine collection systems, applicable to the Group could increase compliance costs, mandate significant and costly changes to the way the Group implements its services and solutions, and threaten the Group's ability to continue to serve certain markets. If there were to be any material changes in the laws and regulations applicable to the Group or the regulatory environment regulating the Group's products, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial positions and the Group's ability to continue as a going concern.

Norwegian law subjects Navamedic and the Company to joint liability after the Demerger

Through the Demerger (see Section 6.2.2 "The Demerger establishing the Group"), the obligations of Navamedic were divided between the Company and Navamedic in accordance with the principles set forth in the joint demerger plan regulating the Demerger. If either the Company or Navamedic is liable under the demerger plan for an obligation that arose prior to consummation of the Demerger and fails to satisfy that obligation, the non-defaulting party will, pursuant to the Norwegian Public Limited Companies Act, be subject to a secondary joint liability for that obligation. This statutory liability is unlimited in time, but is limited in amount to the net value allocated to the non-defaulting party in the Demerger and does not apply in respect of obligations incurred after consummation of the Company being held liable for the obligations incurred prior to the completion of the Demerger which have remained in Navamedic, in case Navamedic fails to satisfy such obligation. However, the Company can only be liable for an amount limited to the net value allocated to the Company in the Demerger, i.e. the Company's potential liability under the secondary joint liability is limited to the net value allocated to the company in the Demerger, i.e. the Company's potential liability under the secondary joint liability is limited to the net value allocated to the company in the Demerger, i.e. the Company's potential liability under the secondary joint liability is limited to the net value of the assets which were transferred to the Company at the completion date of the Demerger.

If the Company is to be held liable under the statutory rule of secondary joint liability in connection with the Demerger, this could have a material adverse effect on the Group's revenues, profitability, liquidity, cash flow, financial position and the Group's ability to continue as a going concern.

2 **RESPONSIBILITY FOR THE REGISTRATION DOCUMENT**

The Board of Directors of Observe Medical ASA accepts responsibility for the information contained in this Registration Document. The members of the Board of Directors confirm that, having taken all reasonable care to ensure that such is the case, to the best of their knowledge, the information contained in this Registration Document is in accordance with the facts and that the Registration Documents contains no omission likely to affect its import.

18 June 2020

The Board of Directors of Observe Medical ASA

Terje Bakken Chairperson Kathrine Elisabeth Gamborg Andreassen Board member

Kristin Nyberg Board member Thomas Grünfeld Board member

3 GENERAL INFORMATION

3.1 The approval of this Registration Document by the Norwegian Financial Supervisory Authority

The Financial Supervisory Authority of Norway (Nw.: *Finanstilsynet*) (the "**Norwegian FSA**") has reviewed and approved this Registration Document, as competent authority under Regulation (EU) 2017/1129 (the EU Prospectus Regulation). The Norwegian FSA only approves this Registration Document as meeting the standards of completeness, comprehensibility and consistency imposed by the EU Prospectus Regulation, and such approval should not be considered as an endorsement of the issuer or the quality of the securities that are the subject of this Registration Document. This Registration Document was approved by the Norwegian FSA on 18 June 2020. Investors should make their own assessment as to the suitability of investing in the securities.

3.2 Other important investor information

The Company has furnished the information in this Registration Document.

Each investor should make their own assessment as to the suitability of investing in the Shares and should consult with his or her own advisors as to the legal, tax, business, financial and related aspects of an investment in the Shares.

Investing in the Shares involves a high degree of risk. See Section 1 "Risk Factors" beginning on page 3.

As the Company first with effect from the completion of the Demerger (see Section 6.2.2 "The Demerger establishing the Group" for more information) has served as the parent company of the Group, certain information described herein relates to the period prior to that date when Navamedic ASA, a Norwegian public limited company listed on Oslo Børs with company registration number 985 012 059 and OSE ticker "NAVA" (Navamedic), and not the Company, was the parent company of the Group. For more information in this respect, see Section 6.2.2 "The Demerger establishing the Group" and specifically for the financial information included herein, Section 3.3.1 "Historical financial information" below.

3.3 Financial information

3.3.1 Historical financial information

The Company's audited consolidated financial statements as of and for the year ended 31 December 2019 (the "**2019 Financial Statements**") and the Company's unaudited consolidated interim financial presentation as of and for the three month period ended 31 March 2020 including comparative interim financial information for the same period in the prior financial year (the "**Q1 Financial Presentation**"), have been incorporated by reference hereto, see Section 12.3 "Incorporated by reference".

As the Company was incorporated on 13 June 2019, the Company has not prior to the financial year 2019 prepared any historical financial statements and the Company's subsidiary, Observe Medical International AB ("**OMI**"), has neither previously prepared any consolidated financial statements. For the financial years ended 31 December 2018 and 2017, carve-out financial statements have been prepared for the Group from Navamedic's audited consolidated financial statement of comprehensive income, carve-out statement of changes in equity, carve-out cash flow statement and accounting policies and explanatory notes (the "**Carve-out Annual Financial Statements**"), incorporated by reference hereto, see Section 12.3 "Incorporated by reference".

The 2019 Financial Statements, the Q1 Financial Presentation and the Carve-out Annual Financial Statements are jointly referred to as the "**Financial Information**".

The 2019 Financial Statements have been prepared in accordance with International Financial Reporting Standards ("**IFRS**") as adopted by the European Union (the "**EU**"). The Carve-out Annual Financial Statements have been prepared in compliance with IFRS to the extent appropriate since IFRS does not provide explicit guidance for the preparation of carve-out financial information. The Q1 Financial Presentation has not been prepared in accordance with IFRS or in accordance with International Accounting Standard 34 "Interim Financial Reporting" ("**IAS 34**"), however, when the Company prepared the Q1 Financial Presentation it applied the same measurement principles and recognition criteria as applied in the 2019 Financial Statements.

The 2019 Financial Statements and the Carve-out Annual Financial Statements have been audited by KPMG AS ("**KPMG**"). The auditor's report on the 2019 Financial Statements and on the Carve-out Annual Financial Statements have been incorporated by reference hereto (see Section 12.3 "Incorporated by reference"). The Q1 Financial Presentation has not been audited. Other than the 2019 Financial Statements and the Carve-out Annual Financial

Statements, KPMG has not audited, reviewed or produced any report on any other information provided in this Registration Document.

For information regarding accounting policies and the use of estimates and judgments, please refer to notes 2 and 4 of the 2019 Financial Statements and notes 2 and 4 of the Carve-out Annual Financial Statements.

3.3.2 Alternative performance measures (APMs)

The Company presents the following alternative performance measures ("**APMs**") as defined by the European Securities and Markets Authority ("**ESMA**") in this Registration Document:

- Net interest bearing debt: Non-current and current interest bearing debt deducted cash deposits.
- Operating result: Result before net financial items and income tax expenses/income.

3.4 Presentation of other information

3.4.1 Industry and market data

This Registration Document contains statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data pertaining to the Group's future business and the industries and markets in which it may operate in the future. Unless otherwise indicated, such information reflects the Company's estimates based on analysis of multiple sources, including data compiled by professional organizations, consultants and analysts and information otherwise obtained from other third party sources, such as annual financial statements and other presentations published by listed companies operating within the same industry as the Company may do in the future. Unless otherwise indicated in the Registration Document, the basis for any statements regarding the Company's competitive position in the future is based on the Company's own assessment and knowledge of the potential market in which it may operate.

The Company confirms that where information has been sourced from a third party, such information has been accurately reproduced and that as far as the Company is aware and is able to ascertain from information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. Where information sourced from third parties has been presented, the source of such information has been identified, however, source references to websites shall not be deemed as incorporated by reference to this Registration Document.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. The Company has not independently verified and cannot give any assurances as to the accuracy of market data contained in this Registration Document that was extracted from these industry publications or reports and reproduced herein. Market data and statistics are inherently predictive and subject to uncertainty and not necessarily reflective of actual market conditions. Such statistics are based on market research, which itself is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market.

As a result, prospective investors should be aware that statistics, data, statements and other information relating to markets, market sizes, market shares, market positions and other industry data in this Registration Document (and projections, assumptions and estimates based on such information) may not be reliable indicators of the Company's future performance and the future performance of the industry in which it operates. Such indicators are necessarily subject to a high degree of uncertainty and risk due to the limitations described above and to a variety of other factors, including those described in Section 1 "Risk Factors" and elsewhere in this Registration Document.

3.4.2 Other information

In this Registration Document, all references to "**NOK**" are to the lawful currency of Norway, all references to "**SEK**" are to the lawful currency of Sweden, all references to "**DKK**" are to the lawful currency of Denmark, all references to "**EUR**" are to the lawful common currency of the EU member states who have adopted the Euro as their sole national currency. No representation is made that the NOK, SEK or EUR amounts referred to herein could have been or could be converted into NOK, SEK or EUR, as the case may be, at any particular rate, or at all. The Financial Information is published in NOK.

3.4.3 Rounding

Certain figures included in this Registration Document have been subject to rounding adjustments (by rounding to the nearest whole number or decimal or fraction, as the case may be). Accordingly, figures shown for the same category presented in different tables may vary slightly. As a result of rounding adjustments, the figures presented may not add up to the total amount presented.

3.5 Cautionary note regarding forward-looking statements

This Registration Document includes forward-looking statements that reflect the Company's current views with respect to future events and financial and operational performance. These forward-looking statements may be identified by the use of forward-looking terminology, such as the terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology. These forward-looking statements as a general matter are all statements other than statements as to historic facts or present facts and circumstances. They appear in Section 4 "Business of the Group" of the Registration Document, and include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, financial strength and position of the Group, operating results, liquidity, prospects, growth, the implementation of strategic initiatives, as well as other statements relating to the Group's future business development and financial performance, and the industry in which the Group operates.

Prospective investors in the Shares are cautioned that forward-looking statements are not guarantees of future performance and that the Group's actual financial position, operating results and liquidity, and the development of the industry and potential market in which the Group may operate in the future, may differ materially from those made in, or suggested by, the forward-looking statements contained in this Registration Document. The Company cannot guarantee that the intentions, beliefs or current expectations upon which its forward-looking statements are based will occur.

By their nature, forward-looking statements involve, and are subject to, known and unknown risks, uncertainties and assumptions as they relate to events and depend on circumstances that may or may not occur in the future. Because of these known and unknown risks, uncertainties and assumptions, the outcome may differ materially from those set out in the forward-looking statements. Important factors that could cause those differences include, but are not limited to:

- implementation of the Group's strategies;
- failure by the Group to adequately perform on projects or under contracts;
- the competitive nature of the business the Group operates in and the competitive pressure and changes to the competitive environment in general;
- earnings, cash flow, dividends and other expected financial results and conditions;
- inaccuracy relating to estimates or calculations of costs on large projects;
- failure by counterparties to meet their obligations;
- failure to attract, retain and motivate qualified personnel;
- increases in labour cost;
- legal proceedings;
- damage to the Group's reputation and business relationships;
- technological changes and new products and services introduced into the Group's market and industry;
- fluctuations of interest and exchange rates;
- changes in general economic and industry conditions, including changes to tax rates and regimes;
- political, governmental, social, legal and regulatory changes;

- access to funding;
- operating costs and other expenses; and
- consequences of consolidation in the industry, resulting in fewer but stronger competitors.

The risks that are currently known to the Company and which could affect the Group's future results and could cause results to differ materially from those expressed in the forward-looking statements are discussed in Section 1 "Risk Factors".

The information contained in this Registration Document, including the information set out under Section 1 "Risk Factors", identifies additional factors that could affect the Company's financial position, operating results, liquidity and performance. Prospective investors in the Shares are urged to read all Sections of this Registration Document and, in particular, Section 1 "Risk Factors" and the Financial Information for a more complete discussion of the factors that could affect the Group's future performance and the industry in which the Group operates when considering an investment in the Company.

These forward-looking statements speak only as at the date on which they are made. The Company undertakes no obligation to publicly update or publicly revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to the Company or to persons acting on the Company's behalf are expressly qualified in their entirety by the cautionary statements referred to above and contained elsewhere in this Registration Document.

4 DIVIDENDS AND DIVIDEND POLICY

4.1 Dividend policy

The Company has previously not paid any dividends. The Group is focusing on the development and commercialization of medical technology products and does not anticipate paying any cash dividend until sustainable profitability is achieved.

4.2 Legal constraints on the distribution of dividends

In deciding whether to propose a dividend and in determining the dividend amount in the future, the Board of Directors must take into account applicable legal restrictions, as set out in the Norwegian Public Limited Companies Act, the Company's capital requirements, including capital expenditure requirements, its financial condition, general business conditions and any restrictions that its contractual arrangements in place at the time of the dividend may place on its ability to pay dividends and the maintenance of appropriate financial flexibility. Except in certain specific and limited circumstances set out in the Norwegian Public Limited Companies Act, the amount of dividends paid may not exceed the amount recommended by the Board of Directors.

Dividends may be paid in cash or in some instances in kind. The Norwegian Public Limited Companies Act provides the following constraints on the distribution of dividends applicable to the Company:

Section 8-1 of the Norwegian Public Limited Companies Act regulates what may be distributed as dividend, and
provides that the Company may distribute dividends only to the extent that the Company after said distribution
still has net assets to cover (i) the share capital and (ii) other restricted equity (i.e. the reserve for unrealised
gains and the reserve for valuation of differences).

The calculation of the distributable equity shall be made on the basis of the balance sheet included in the approved annual accounts for the last financial year, provided, however, that the registered share capital as of the date of the resolution to distribute dividend shall be applied. Following the approval of the annual accounts for the last financial year, the general meeting may also authorise the Board of Directors to declare dividends on the basis of the Company's annual accounts. Dividends may also be resolved by the general meeting based on an interim balance sheet which has been prepared and audited in accordance with the provisions applying to the annual accounts and with a balance sheet date not further into the past than six months before the date of the general meeting's resolution.

• Dividends can only be distributed to the extent that the Company's equity and liquidity following the distribution is considered sound.

Pursuant to the Norwegian Public Limited Companies Act, the time when an entitlement to dividend arises depends on what was resolved by the general meeting when it resolved to issue new shares in the company. A subscriber of new shares in a Norwegian public limited company will normally be entitled to dividends from the time when the relevant share capital increase is registered with the Norwegian Register of Business Enterprises. The Norwegian Public Limited Companies Act does not provide for any time limit after which entitlement to dividends lapses. Subject to various exceptions, Norwegian law provides a limitation period of three years from the date on which an obligation is due. There are no dividend restrictions or specific procedures for non-Norwegian resident shareholders to claim dividends.

4.3 Manner of dividend payments

The Company's equity capital is denominated in Norwegian kroner and all dividends on the Shares will therefore be declared in Norwegian kroner. As such, investors whose reference currency is a currency other than the Norwegian krone may be affected by currency fluctuations in the value of the Norwegian krone relative to such investor's reference currency in connection with a dividend distribution by the Company. Any future payments of dividends on the Shares to shareholders will be denominated in the currency of the bank account of the relevant shareholder, and will be paid to the shareholders through the VPS Registrar (as defined below). Shareholders registered in the VPS who have not supplied the VPS with details of their bank account, will not receive payment of dividends unless they register their bank account details with the VPS Registrar. The exchange rate(s) that is applied when denominating any future payments of dividends will be credited automatically to the VPS registered shareholders' accounts, or *in lieu* of such registered account, at the time when the shareholder has provided the VPS Registrar with their bank account details, without the need for shareholders to present documentation proving their ownership of the Shares. Shareholders' right to payment of dividend will lapse three years following the resolved payment date. Following the expiry of such date, the remaining, not distributed dividend will be returned from the VPS Registrar to the Company.

5 INDUSTRY AND MARKET OVERVIEW

The Company has used industry and market data obtained from independent industry publications, market research, and other publicly available information. While the Company has compiled, extracted and reproduced data from external sources, the Company has not independently verified the correctness of such data. The Company therefore cautions investors not to place undue reliance on the above-mentioned data. Unless otherwise indicated, the basis for any statements regarding the Group's competitive position is based on the Company's own assessment and knowledge of the market in which it operates.

The Company confirms that, where information has been sourced from a third party, such information has been accurately reproduced. As far as the Company is aware and is able to ascertain, no facts have been omitted that would render the reproduced information inaccurate or misleading. Where information sourced from third parties is presented, the source of such information is identified.

Industry publications or reports generally state that the information they contain has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. The Company has not independently verified and can thus not give any assurances as to the accuracy of market data, which has been extracted from such publications or reports and reproduced herein. Market data and statistics are inherently predictive and subject to uncertainty and do not, necessarily, reflect actual market conditions. Such statistics are based on market research, which, itself, is based on sampling and subjective judgments by both the researchers and the respondents, including judgments about what types of products and transactions should be included in the relevant market.

As a result, investors should be aware that statistics, statements and other information relating to markets, market sizes, market shares, market positions and other industry data set forth in the following (and projections, assumptions and estimates based on such data) may not be reliable indicators of the Group's future performance and the future performance of the paper industry.

The following discussion contains Forward-looking Statements, see Section 3.5 "Cautionary note regarding forwardlooking statements". The Forward-looking Statements in this section are not guarantees of future outcomes and these future outcomes could differ materially from current expectations. Numerous factors could cause or contribute to such differences, and such indicators are necessarily subject to a high degree of uncertainty and risk due to the limitations described above and to a variety of other factors, including those described in Section 1 "Risk Factors" and elsewhere in this Registration Document.

5.1 Introduction

The Group operates in the Medtech market which is dominated by large global corporations such as Bard (part of Becton, Dickinson and Co, "**BD**"), Convatec, Cardinal Health and others. These corporations are often present in several countries as distributors of their own product portfolio and in some cases other products as well. The large corporations will typically have strong in-house research and development ("**R&D**"), sales & marketing, regulatory and health economy departments enabling them to develop and launch products in any market. In addition to own R&D it is not uncommon that these corporations acquire products or small innovative companies to add to their portfolio – similar to the well-known dynamics of the pharma industry.

The Medtech industry also has a large number of early-stage companies that develop novel technology and products, like the Group. By nature, many of these can be characterised as "born globals", since their products or services are designed for the global market. In the Group's region, a high proportion of these companies would expect the large and distant markets of the U.S., China and Japan to be their most important export markets in 3-5 years. The typical approach would be to develop products on a home market (e.g. the Nordics) and then approach the larger international markets, but sometimes it could prove to be a better strategy to approach selected international markets right away. Very few Nordic Medtech companies would have the opportunity to grow and develop their own organisation globally. It might happen in selected markets, but in general the chosen strategy would be to go with a strong local partner or distributor in each foreign market.

Even though a product may have been developed for a global market, it would still require local approvals through regulatory processes in the various countries and markets. For example, the U.S., EU, Japan and China have their own regulations and regulatory bodies that control the approval of new products and the regulations and required documentation may vary from market to market.

The key factors for success in a new market is to adapt to country-specific distribution models and sales channels, invest in local technology infrastructure and collaborate with domestic value chain stakeholders. These varies from strong and wealthy patient-organizations in the U.S. executing patient-pull for cutting edge technology and safety when hospitalized, to more long-term negotiation processes with procurement bodies in Northern Europe with a very strong cost containment focus.

5.2 The Global market

Hospital Supplies Market – growth, trends and forecast (2019 – 2024)

The factors, such as increased incidences of communal diseases coupled with the growing public awareness about hospital-acquired infections are contributing to the overall growth of the hospital supplies market. The demand of the hospital supplies market is also on the rise in developing countries. Countries, such as Brazil and India are gradually increasing their hospital bed density figures when compared to the major countries, present globally. However, several countries face a high unmet need for hospital supplies, like sterilization and disinfectant equipment and patient examination devices, which restricts the growth of this market. Furthermore, it generates a high demand for hospital supplies in developing countries. A growing healthcare infrastructure and rising government initiatives to enhance and expand health care facilities are augmenting the demand for hospital supplies, which is expected to boost the market globally.

Disposable hospital supplies hold the major share in the Hospital Supplies Market

The disposable hospital supplies segment followed by syringes and needles contributes the largest share to the overall studied market. The disposable hospital supplies are one-time use products, such as consumables, medical apparatus, and disposable devices, which are consumed in large figures across all hospitals. These products, such as suction catheters, bandages and wraps, exam gowns, surgical sponges, face masks, hypodermic needles, gloves, needles, and others, are in continuous use to all hospital professionals in any domain from the cleaning to the surgical theatres, as well as administrative departments in some cases. A continuous growth has been observed in the adoption of these devices, owing to the rising concern of safety and cleanliness against hospital-acquired infections, as well as to maintain the hygiene across the hospitals.¹

The table below shows the global medical device market by region, based upon manufacturer prices, 2017²:

Region	% of global market
US	43%
Europe	27%
Japan	7%
China	6%
Canada	2%
Brazil	1%
Russia	1%
Others	13%

The ecosystem and key drivers in this market are complex and come from various systems.

Trends and societal issues:

- Growing and aging populations;
- Increase of chronic diseases; and
- General cost-containment focus (more in public health service areas where tax payer's money is the carrier).

At the same time there is an increased focus and demand for technical and monetary improvements:

- Quality treatment and care use of cutting edge science and devices;
- Demand to decrease the incidence of hospital-acquired infections by means of infection prevention which ultimately decreases the need and use of antibiotics and thus fights the global threat of antibiotic resistance;
- Digitization (integrate, collect, combine and deliver data for insight and analysis to improve patient outcome; and

¹ Source: https://www.mordorintelligence.com/industry-reports/global-hospital-supplies-market-industry

² Source: https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-

^{2.}pdf

• Cost/Value transition, e.g. see the patient healthcare cost related to the whole treatment in a public perspective.

In the Group's opinion, Sippi[®] and the Sippi[®] product family with its digital solution fulfils all these bullet points and is part of the solution for the future healthcare challenges whether it is in a public or private hospital market.

5.3 The EU market

The EU market

The European medical technology market is estimated at roughly ≤ 115 billion in 2017. Based upon manufacturer prices, the European medical technology market is estimated to make up 27% of the world market. It is the second largest medical technology market after the US (+/- 43%). The European medical device market has been growing on average by 4.3% per annum over the past 10 years. Demand fell in 2009 due to the economic crisis, resulting in a growth rate of only 1%. The market recovered in 2010, but growth rates fell back in 2011. In general, there is ever since a 2-5% growth per annum.³

In Europe, an average of approximately 10% of gross domestic product (GDP) is spent on healthcare. Out of the total healthcare expenditure, around 7.2% is attributed to medical technologies, i.e. less than 1% of GDP. The spending on medical technology is estimated to vary significantly across European countries, ranging from around 5% to 10% of the total healthcare expenditures. Expenditure on medical technology per capita in Europe is at around $\in 213$ (weighted average)⁴.

The table below shows the European medical device market by country, based upon manufacturer prices, 2017⁵:

Country	% of EU market
Germany	27,4%
France	15%
UK	11%
Italy	10,2%
Spain	6%
Netherlands	4,1%
Belgium	3,9%
Switzerland	2,7%
Sweden	2,5%
Austria	2.4%
Others	14,7%

In the European Union, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, pre- and post-market. Over the next few years, the European medical technology sector will transition from being regulated under the current medical devices directives to two new regulations.

Classification of in-vitro diagnostic medical devices

Today, the in-vitro diagnostic (IVD) sector is regulated by Directive 98/79/EC. From 26 May 2022, the new Regulation 2017/746/EU will fully apply.

Classification of Medical Devices

The medical device (MD) sector is regulated by Directives 93/42/EC and 90/385/EEC. From 26 May 2021, the new Regulation 2017/745/EU will fully apply. Until this date, manufacturers can choose to comply with either the Directives or the Regulation. Originally the new regulation was due May 26 2020, but due to COVID-19 it was shifted one year later.

Classification of medical devices (estimated to be more than 500.000) drives many pre- and post-market requirements. Due to the large variety of products, the level of control made by a third-party (the "notified body") before placing them in the market depends on the level of impact on the human body that their use might imply. The same notified body is involved post-market to ensure the continued safety and performance of medical devices.

Under the MD Directive, MDs are classified into 4 classes following a risk based classification system:

³ **Source**: https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-2.pdf

⁴ **Source:** https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-2.pdf

⁵ **Source:** https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-in-figures-2019-2.pdf

Class	Example of products
Class I	e.g. simple bandages or would care products
Class IIa	e.g. syringes for pump infusion
Class IIb	e.g. anaesthesia machines
Class III	e.g. stents

Under the new MD Regulation, the risk based classification system contained in the current Directives has been maintained, although some changes/additions have been introduced. The principle is the same: to link the class of the device to the potential risk posed to the health of the public and an individual as result of fault in the functioning. All MDs are classified under class I, IIA, IIB or III, with class III being the highest risk class.

5.4 The Norwegian market

The Norwegian market

Medtech in Norway had several demanding years of low growth from 2000 to 2012. The weak period turned in 2013, and the growth has been positive until 2017. Over the entire period from 2007 to 2017, Medtech had an average annual revenue growth of 4 percent. The growth estimates for 2018 indicates that the industry had revenue growth of 9 percent in 2018 and the forecast for 2019 is a full 13 percent. Thus, Medtech expects identical growth in 2018 as the Health industry overall, but a clearly higher growth than the industry overall in 2019 (9 percent). On the other hand, the operating margin has seen a negative development over the period, from levels of between six and seven per cent in the period until 2009, to levels around three per cent from 2009 to 2016.⁶

Norway, being part of the European Economic Area (the "EEA"), with a high level of academic culture, early adapters of IT technology, plenty of resources and well-integrated and high consumers of IT/digital solutions, may provide a good testbed for Sippi®. Potentially, the purchasing system could also enable a swift uptake nationwide compared to other countries with more fragmented procurement systems.

The Norwegian government and politicians have expressed a positive attitude to promoting and building a Norwegian health industry both for national business development and export. The Norway Health Tech organisation and its CEO is a respected speaker and contributes to the political debate and strategy. Alignment to the political strategy is of importance and the two following documents are steering tools for the future health industry.

<u>The Health&Care21 (Nw. HelseOmsorg21)</u> strategy process was launched by the Norwegian Ministry of Health and Care Services in 2013. The aim of the Health&Care21 process is to promote evidence-based health and care services characterised by high quality, patient safety and efficiency. The Health&Care21 process is based on the same model as the other strategy processes on research and innovation for the 21st century, such as climate research (Klima21), oil and gas research (OG21) and marine research (HAV 21)

The Norwegian government's health industry policy (Nw. Helsenæringsmeldingen)

The Norwegian government wants to improve the competitiveness of the Norwegian health industry and at the same time contribute to a more sustainable health and care service, through more efficient prevention, treatment and care. Developing better health and care services requires constructive cooperation with the health industry, both at a national and international level. This will enable an innovative and competitive Norwegian health industry to help achieve health policy goals. Better cooperation can also form the basis for growth in the Norwegian health industry. The health policy goal of good, efficient patient treatment will indirectly contribute to reaching the industrial policy goal of greater overall value creation in the Norwegian economy within a sustainable framework.

5.5 Urine Bag and Meter Markets

The Group is active in the urine measurement and urine bag market, initially for the hospital segment and potentially in the future also for the use in care centres and at home.

Urine bags are used daily by millions around the world. All catheterized patients need a urine bag for collecting the urine and measuring the volume. Within the intensive care setting the produced urine volume is measured every hour 24/7, since it is a critical parameter of kidney function. In a regular ward the urine production is measured every now and then during a 24-hour shift to keep track of the kidney function.

⁶ Source: https://www.menon.no/helsenaeringens-verdi-2019/

The kidneys are a vital organ and if they stop functioning the patient's life is at risk. Traditional urine meters are analogue and consist of a pre-chamber with gradients for better accuracy and a soft bag behind or underneath where the hourly measured volume is dumped. The registered volume is then noted down manually and registered in the patient journal and compared with the volume of fluid inserted into the patient - the so-called fluid balance. In critically ill patients, the fluid balance is often negative, meaning the patient is producing too little urine. Kidney failure can be an early indicator of a very serious situation for the patient.

Urine meters are single patient use products and need to be changed after a certain number of days. This to avoid retrograde contamination (infection) of the urine bladder. Statistics show that after seven to ten days 50% of all catheterized patients have developed bacteria in the urine and up to 30% will acquire a urinary tract infection⁷. Currently there are no or limited warning systems or technology to prevent retrograde contamination available on the market.

Sippi[®] comprises two features to prevent urinary infections: Sippcoat[®] preventing early retrograde contamination and Sippsense[®] which warns the intensive care unit ("**ICU**") staff to change bag when the system detects critical levels of bacteria.

The majority of urine bags are used in wards or home settings where there often is no set-up for hourly volume measurements. The Group has identified an additional market for Sippi[®] in the regular wards where patients would benefit from hourly urine/fluid balance measurement and a system that prevents retrograde urinary infections. Since Sippi[®] is fully automated and measures hourly volume it is well suited to be used for unstable patients in the normal ward setting.

In addition, there could be a large market for a version of Sippi[®] with only Sippcoat[®] as a regular urine bag. Preventing retrograde urinary infections in the care and home settings would reduce patient suffering and the unnecessary use of antibiotics.

5.6 Urine Meter Market: Sippi[®] Market

The market for urine meters has one key driver which is the ICU. Nearly all patients in ICUs have a urine catheter installed attached to a urine meter and collection bag. Thus, the number of ICU beds will be indicative of the market for urine meter systems like Sippi[®].

An ICU typically consists of around 10 beds and larger hospitals can have several ICUs. The number of ICUs per capita varies between countries. In total, the Group has estimated that there are about 400,000 ICU beds worldwide and the U.S. and Europe represent the two most important markets. Within the EU, the average is 10-12 ICU beds per 100,000 inhabitants. By far the largest market in Europe is Germany with about 29 ICU beds per 100,000 inhabitants, equal to about 23,000 ICU beds.⁸

Hospital care is organized differently around the world. In the Nordic countries for example, special care is centralized to a few major hospitals with a larger number of staff, while in Germany it is more decentralized with many regional hospitals and fewer staff per ICU. There are also great differences between markets regarding private and public hospitals as well as the payment models. Thus, there may be markets or market segments which could be more attractive for automated urine meters which ensures the quality and accuracy of the data and reduces the risk of urinary infections.

In addition to intensive care, urine meters are used in the emergency room ("**ER**"), for longer surgical procedures and to some extent in general hospital wards. Again, practice varies from country to country and thus the total market available to Sippi[®] is difficult to estimate. There are no official statistics from today's market players, which makes it difficult to estimate global numbers in detail. The Group's best estimate is that about 20 million urine meters are sold globally each year to a value of about NOK 2 billion where about 95% of sales are to intensive care departments.

Urine meters - today the only analogue measured vital parameter

All patients under intensive care are monitored for fluid balance, which is a sign of the function of the kidneys. Measurement of the patient's fluid balance is important because urine production is a vital indication of the patient's

⁷ **Source**: Diane K. Newman, RNC, MSN, CRNP, FAAN Co-Director Penn Center for Continence and Pelvic Health University of Pennsylvania Health System Division of Urology Philadelphia, Pennsylvania)

⁸ **Source**: "The variability of critical care bed numbers in Europe" (2012), Department of Intensive Care Medicine, St George's Healthcare NHS Trust and University of London

condition. A weak urine production can be a sign of kidney failure which again can be the indication of a very serious situation for the patient.

The volume amount of urine is recorded 24/7 and urine output per hour is calculated. Urine meter is a disposable product that is changed regularly to avoid retrograde bacterial formation and thereby to reduce the risk of urinary tract infection.

With today's manual system the healthcare staff manually reads the amount of urine in the collection chamber every hour, then empties the chamber and manually calculates the fluid balance after which data is entered into the patient journal system. The process leaves room for errors due to the human factor since the readings are to be made at exact 60 min intervals (periodicity) and then to be calculated and registered into the patient journal system.

In addition to the lack of precision and the risk of errors, the process of urine measurement is time consuming for the staff. At an intensive care unit with twelve beds, it takes about ten man-hours a day to measure, calculate and record urine production for these patients (the Group's estimate). This makes urine measurement a top ten task counted in time in an intensive care unit. With Sippi[®] urine measurement becomes an activity that happens automatically while data accuracy is secured.

5.7 Urine Bag Market: Market for Sippcoat[®] /Sippbag[™]

One of the biggest challenges within current healthcare is the rapid increase in Hospital Associated Infections ("**HAI**"). HAI leads to unnecessary complications and suffering for the patients and increased care costs for the hospitals. Furthermore, HAI requires the use of antibiotics and in the long run increased use of antibiotics leads to the development of resistant infections, which again implies a vicious circle of prolonged treatment periods, use of more advanced antibiotics and potential death for the patient. Within the EU every tenth patient acquires an infection when visiting a hospital and in the ICU it is even worse comprising 30%. Alone in the EU 25,000 patients die every year⁹ from these infections. In 2015, in US acute care hospitals there were an estimated 687,000 HAIs and 72,000 hospital patients with HAI died.¹⁰ Due to drug-resistant infections, it is estimated that the global burden of deaths could reach ten million each year by 2050 if no actions are taken.¹¹

The only way to decrease antibiotic resistance is to minimize bacterial infections by means of infection preventive actions/solutions. There are many initiatives to fight this within the hospitals including: standard operating procedures for how to handle catheterization, use of drainage systems, cleaning airways etc. The majority of all Hospital Acquired Infections (HAI) are generated from urine catheters. The current market to treat Catheter Associated Urinary Tract Infections ("**CAUTI**") are coated catheters, closed system thinking and hand hygiene minimizing the risk of personnel contaminating urine bags and catheters.

However, none of these procedures will stop about 40-50% of the origin for CAUTI, being retrograde contamination originating from bacteria fertilizing within the urine bag which then travels inside the system back to the urine bladder. Sippcoat[®] is developed to stop this.

This is a vast problem and a huge market. The Group estimates that 500 million urine bags are used within the EU and U.S. every year. The Group assumes that the total market for Sippcoat[®] could be as high as NOK 20 billion. The global UTI treatment market was valued at USD 9,527.9 million in 2016 and is likely to reach USD 10,594.68 million by 2021, growing at a CAGR of 2.1%.¹²

5.8 Corona: Effect on ICU beds market and the market for Sippi[®]

As COVID-19 spreads across the world, the intensive care units have to prepare for the challenges associated with this pandemic. The market for ICU beds is experiencing exponential growth due to hospitals around the world increasing their ICU capacity to deal with the surge in COVID-19 patients. The global ICU beds market is expected to grow from USD 1.9 billion in 2019 to about USD 3.8 billion in 2020. The market is expected to stabilize and reach USD 2.8 billion in 2023.¹³

 ⁹ Source:
 "European
 strategic
 action
 plan
 on
 antibiotic
 resistance",
 10
 June
 2011,

 http://www.euro.who.int/__data/assets/pdf_file/0008/147734/wd14E_AntibioticResistance_111380.pdf
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9
 9</td

 $^{^{10}\ \}textbf{Source: https://www.cdc.gov/hai/data/portal/index.html}$

 $^{^{11} \}textbf{Source:} https://www.ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antibiotic-resistance-policy-briefing.pdf$

¹² **Source**: Technavio "Global Urinary Tract Infection Treatment Market 2017-2021", https://www.technavio.com/report/global-urinary-tract-infection-treatment-market

¹³ **Source**: "ICU Beds Global Market Report 2020-30: Covid 19 Implications and Growth" (2020), Research and Markets

The Group expects increase in the number of ICU beds with 10-15% annually post COVID-19. Consequently, and due to expected significant increase of contingency capacity, the Group assumes a 20-30% growth in the global market for Sippi[®] and a 100% growth of the market value of Sippi[®] globally. The assumption on the increased market value of Sippi[®] is based on, inter alia, the expected increased need for automation to meet the ICU's demands due to shortage of staff, digital patient data being necessary to avoid human errors, remote patient monitoring required to reduce staff exposure and infection control for patients in long-term hospitalisation.

As regards the market for Sippi[®] in the Nordics and Europe specifically, the Group expects up to three times market value growth post COVID-19 considering, inter alia, the increased ICU bed capacity and staff resource constraints, leveraged by expected political pressure on governments and health institutions with the possibility to make budgets available to support investments in capacity and automation.

6 BUSINESS OF THE GROUP

6.1 Introduction to Observe Medical

The Group is a Medtech group which is in the business of developing innovative medical technology products that benefit patients and healthcare professionals. The Company is the parent company of the Group, which only business is to own all shares in the operating company Observe Medical International AB (OMI) and its subsidiaries Observe Medical AB and Observe Medical Aps. The Group's core and first product is Sippi[®], an automated digital urine meter for use in intensive care wards. The Group is headquartered in Oslo, Norway, but the Group's operational business is conducted in Gothenburg, Sweden. The Group's subsidiary Observe Medical Aps is registered as the holder of the Group's patents.

The Group's current business is specifically within the hospital segment where its products contribute to increased patient safety, reduced use of antibiotics and a more efficient care system.

The Group has developed the product Sippi[®] which is an automatic and digital urine meter and the technology Sippcoat[®] which prevents bacterial migration in closed collection systems. Sippi[®] is approved for sale in Europe and registered for sale in the U.S. As at the date of this Registration Document, the Group has shipped approximately 100-200 base units and around 7,000 disposable units to customers in the EU since it started the commercialization process of its products. The Group is now in an important launch phase for the next generation base unit named Sippi[®]BLE, which comprises a digital urine meter with wireless connection to the hospital's digital patient journal system. Sippi[®]BLE is approved for sale in Europe.

The Group employs seven persons in Norway and Sweden.

6.2 History and important events

6.2.1 Important historical events

OMI was founded by Magnus Emmoth, Michael Charléz and Michael Löfgren in 2009. Based on their prior experience in sales and product development within medical technology, the three founders identified a clear need for modernization of urine measurement within intensive care.

Development and prototyping of Sippi[®] was initiated in 2010. In 2011, the first patent for the product was approved, and OMI also received ISO certification for the development, manufacture and sale of its products. Seed Capital (DK) invested in OMI in 2011. In 2012, the first base unit was fully developed and in 2013 Sippi[®] was registered with FDA for sale in the U.S as well as CE marking for sale in Europe, starting the commercialisation process of Sippi[®]. The first system was sold to intensive units in Sweden and Denmark in 2013 and in 2014 the sale of Sippi[®] in Germany started. During this period, Sippcoat[®] was also developed by OMI, which prevents biofilm build-up and greatly reduces the chance of catheter associated urinary tract infections. During these initial years, the intellectual property was developed in several patent portfolios.

In parallel with the initial launch period there happened to be a rapid development in the use of patient data management systems ("**PDMS**") in the hospitals in the Nordics and in several major countries in Europe. Such systems are delivered by major IT companies like GE Healthcare and iMDSoft and the systems are either proprietary or open source based. This resulted in the immediate demand for the development of a second generation of Sippi[®] with wireless integration with the PDMS systems. This was a demanding task and the system called Sippi[®]BLE was not released until June 2019. Currently Sippi[®]BLE is being tested at Karolinska University Hospital and Sahlgrenska University Hospital.

Date	Event				
2009	OMI was founded by Magnus Emmoth, Michael Charléz and Michael Löfgren				
2010	 Development and prototyping of Sippi[®] was initiated 				
2011	 First patent for Sippi[®] was approved 				
	- OMI received ISO certification for the development, manufacture and sale of $Sippi^{\texttt{®}}$				
	Seed Capital (DK) invested in OMI				
2012	The first base unit was fully developed				
2013	 Sippi[®] was registered with FDA for sale in the U.S. as well as CE marking for sale in Europe, starting the commercialisation process 				
	The first system was sold to intensive units in Sweden and Denmark				
2014	Commercialisation towards Germany started				

	Development of Sippcoat [®]
2015	OMI was acquired by Navamedic
	 Sippi[®] was rewarded a tender by Stockholms Läns Landsting (SLL)
2016	 New patent granted pertaining to Sippcoat[®], broadening the innovative encapsulated silicone-oil technology for biofilm inhibition to any patient drainage device
	 An agreement with Pennine Healthcare as distributor for the UK market was closed (contract to be updated according to new MD (medical device) Directives
2017	 Development of a wireless version of Sippi[®] that communicated directly with the patient monitoring systems was initiated
	 First patent for Sippi[®] approved in the EU
	Sippi [®] was launched in the Italian market through an agreement with SimItalia
	 The Sippcoat[®] patent approved in the EU
2018	 Launch of first version of Sippi[®]BLE interrupted due to unstable Bluetooth connection – own Bluetooth receiver developed
	 Software for connection to one of the EU's largest patient data management systems (iMDSoft/Metavision/GE/CCC) released
	 Patent pertaining to Sippi[®] base technology, including the use of silicone oil to protect surfaces and Sippcoat[®] was approved in the U.S.
	An agreement with Västra Götalands Region (VGR) was signed
2019	 Launch of Sippi[®]BLE with full wireless integration with the hospitals patient data management system
	 Observe Medical AB was certified according to the new Medical Device directive ISO 13485:2016 and a Declaration of Conformity for Sippi[®]BLE and disposable bag issued accordingly
	 The Company's Shares were listed on Oslo Axess on 4 November 2019.

The Company's Shares were listed on Oslo Axess on 4 November 2019.

6.2.2 The Demerger establishing the Group

On 31 October 2019, Navamedic completed a demerger of its medtech-division to the Company (the "**Demerger**"). The Demerger was carried out as a demerger with a transfer to an existing entity (demerger and merger) in accordance with Chapter 14 of the Norwegian Public Limited Companies Act.

Navamedic's shares in Observe Medical International AB ("**OMI**") and a conditional deferred earn-out obligation which Navamedic had towards the previous shareholders of OMI in connection with Navamedic's acquisition of OMI, was transferred from Navamedic to the Company in the Demerger, while all other assets, rights and liabilities remained with Navamedic.

The board of directors of Navamedic and the Company agreed in that the exchange ratio in the Demerger should be based on assessed fair values of Navamedic and the part transferred to the Company, which gave an exchange ratio of 74% (remaining) / 26% (transferred). The exchange ratio was based on an assessment made by the boards, based on a valuation carried out by an external party, and founded on principles of discounted cash flow analysis, analysis of comparable transactions and the implied trading multiples of listed comparable companies.

The Demerger was implemented by way of decreasing the share capital of Navamedic through a reduction of the nominal value of the shares. The size of the share capital decrease in the Company reflected the allocation of the net values between the companies in the Demerger. The shareholders of Navamedic received shares in the Company by way of increasing the share capital in the Company through issuance of new shares as demerger consideration. Prior to the share capital increase in the Company, Navamedic's shareholding in the Company was redeemed in its entirety. Upon completion of the Demerger, but prior to completion of the debt conversion described below (the "**Debt Conversion**"), the shareholders of Navamedic became shareholders in the Company in the same ratio as they owned shares in Navamedic when the Demerger became effective.

On 1 October 2019, Navamedic subscribed for 3,200,000 shares in the Company by setting-off a loan the Company had to Navamedic in the amount of NOK 16,000,000 as contribution in kind. The subscription price in the share issue was NOK 5.00 per share. The completion of the Debt Conversion was conditional upon the Demerger being completed. Upon the completion of the Debt Conversion, Navamedic owned approximately 21% of the shares in OMASA.

6.3 Description of Observe Medical's products and services

6.3.1 Introduction

During the last decade, there has been a digitalization of the intensive care where pulse and blood pressure are measured, and data is delivered in real time to the patient monitoring systems. Systems for intravenous delivery of drugs and fluids are also digitalized.

Urine production however, which is an important parameter, is still recorded and calculated in an old-fashioned manual manner. Thus, the Group realised there is a huge unmet market need for a fully automated digital urine meter.

6.3.2 Sippi[®]

Sippi[®] - the first digital urine meter running on AA batteries

The system consists of a base unit which is attached to the hospital bed. Connected to the base unit is the single use device, which consists of a measuring chamber connected to the base units where the sensors are located and a urine bag for collecting the urine. The sensors and measurement technology, Sippsense[®], are covered by patents.

The base unit has a display in which last hour and accumulated urine production are continuously displayed. The base unit is robust and easy to handle, and the system has low weight and a flexible hanger that fits all hospital beds. Furthermore, the system has low power consumption and is powered by standard AA batteries. The base unit together with the single use kit forms a solution that is easy to handle and enables a more accurate and efficient measurement of urine production.



Unique solution to reduce the risk of infection

One problem in all urine systems is that so-called biofilm is formed in the collection bag. The biofilm is an invisible coating that provides a breeding ground for bacteria that can migrate up the catheter and cause urinary tract infection in the patient. Urinary tract infection is a common problem when using urinary catheter. To reduce the risk of bacterial formation, traditional urine meters are changed every seven days.

To manage and minimize the problem of biofilm and the increased infection risk, the Group has developed Sippcoat[®] and Sippsense[®]. Sippcoat[®] is a solution that inhibits the growth of biofilm. In the cassette there is a capsule with silicone oil that inhibits biofilm. In use, the capsule is dissolved and forms a layer within the collection chamber which hinders the formation of biofilm.

In order to ensure that biofilm does not reach critical levels and run the risk of migrating upwards in the urinary catheter, the Group has developed Sippsense[®] which is a sensor that can record whether there is biofilm on the inside of the

measuring chamber and warn when a critical level is reached. Sippcoat® and Sippsense® minimize and detect the risk of bacterial migration and hence urinary tract infections ("UTI").

Sippcoat[®] and Sippsense[®] are solutions that are unique to Sippi[®] and are both patented.



Wireless version of Sippi® launched in 2019

Sippi® automatically measures urine output and stores the information in the base unit. The Group has also developed a version of Sippi® which via Bluetooth Low Energy (BLE) can communicate through a BLE receiver with the patient monitoring system.

With the wireless version, the last manual step is eliminated, and urine production can automatically be integrated into the patient journal system in the same way as pulse, blood pressure, temperature, infusion and other parameters are integrated today. The wireless version was launched in Q4 2019.

With the wireless version of Sippi[®], the Group digitizes the last manual process in intensive care.



Windows Terminal

6.3.3 New products or services

In the short term the Group will focus on three areas regarding new products and services:

PDMS Connectivity

Connectivity to the markets patient data management systems (PDMS) system is of significant importance since it is asked for by the Group's customers. There are currently six key suppliers of proprietary PDMS systems and two open source systems on the market. The Group has established connectivity with two of the proprietary systems (GE and iMDsoft) and are in development stages with the remaining ones. The Group aims to have all six on board before the end of 2020.

The current status regarding Sippi[®] PDMS connectivity is as follows:

PDMS system supplier	Туре	Sippi [®] connectivity		
iMDsoft/Metavison	Bronrioton	Yes		
GE/Centricity	Proprietary			
Dräger				
Phillips	Proprietary	Expected before end of 2020		
COPRA				
HIM				
EPIC		Yes (Connectivity is done locally at		
Cerner	Open source	customer site)		

Sippi[®] Disposable unit Holder™

During the first market launch there has been a demand for using the Sippi[®] disposable unit without the base unit: During surgery, during x-rays and for a period of time after stay in the ICU when the patient still needs the bag but not an hour by hour measurement. For this use the Group has started development of a plastic holder. The production tool for this product is completed. The date of release for sale is not yet decided.

<u>Sippbag</u>™

The Group is will pursue further alternative options, labelled "Sippbag^M range" for urine collection outside the ICU and/or in the case where bacterial infections are expected to be critical to avoid for the patient. The Sippbag^M might potentially include several options, such as:

- The original Sippi[®] disposable unit, used together with Sippi[®] Disposable unit Holder[™] when the customer wants to use the disposable unit without the base unit, but want to have the opportunity to use it with base unit later on, if relevant.
- A modified Sippi[®] disposable unit without the measurement chamber, but with Sippcoat[®] capsule, if the customer does not intend to use the Sippi[®] base unit but want a urine bag with the bacterial control properties provided by the Sippbag[®] technology.

The Sippbag[™], in any configuration, can be used for all catheterized patients and can follow the patient in all clinical settings. In addition, leg bags or other standard bags for use in the care centres and home use can also be developed.

Sippcoat[®] (OEM)

The Group believes that Sippcoat[®] could have a great potential in inhibiting biofilm growth within fluid handling systems. It has been documented that Sippcoat[®] works based upon company laboratory and patient data. The Sippcoat[®] encapsulated technology is already produced and in stock for Sippi[®] and the same capsule can also be sold as original equipment (like Intel Inside) to other suppliers of urine and body fluid bags. Currently the OEM strategy Sippcoat[®] is being developed.



6.4 Research and development

The Group's research and development has in the past two years included: SippLinkTM – a wireless receiver of data for connection to patient data monitor systems, integration of the same towards GE Healthcare's CCC and Imdsoft's Metavision, upgrade of the disposable unit and improved shelf-life, compliance with RED radio directive, improvement of signal algorithm for volume measurement and battery life time for wireless transmissions.

Ongoing and upcoming activities are:

- **Development of SippBridge[™]**: The wireless connection between Sippi® and PDMS systems is today realised by SippLink[™], a software running on a hospital medical PC. As an alternative to SippLink[™], the Group is in process of developing a stand-alone hardware solution, SippBridge[™]. Being able to offer both a software and a hardware solution will be beneficial for the Group's customers, since each clinic can implement the optimal set-up in their case.
- Instruction manual: Update of instruction manual and migration to an electronical user manual.

6.5 The Group's competitive advantages

The Group's proprietary technologies Sippi[®], SippCoat[®] and Sippsense[®] form an umbrella of competitive advantages in the market. In the Group's opinion, Sippi[®] has first and foremost potentially the most stable measuring technology of volume using contactless capacitive sensors. Most other volume measurement technologies have proven to be either too sensitive or not working in contact with urine. Hence, the strategic focus for the Group is to establish its product portfolio as the digital urine measurement device with wireless stable volume measurement technology as well as the best intraluminal biofilm control.

The business model for Sippi[®] is based on a system sale, where the base unit is an unique hardware and where the disposable unit is specific and thus no copies can be used. Each base unit will generate ongoing sales of disposable units. Each intensive care unit needs a base unit per bed plus a few additional units in reserve. The Group expects the base unit to last on average between three to five years and will then need to be replaced with new units.

For each new patient, a disposable unit is used for up to seven days, which is sufficient for most intensive care patients. If the biofilm indicator shows that critical levels begin to be reached within seven days, the disposable unit will need to be replaced. The Group estimates that each base unit in full operation could generate sales of about seven to eight consumables per month.

As a consequence of the business model, customers are locked to the Group's disposable unit and thus a recurring sale can be expected. As the number of base units sold increases, the Group would expect a steady and repetitive sale of disposable units with a significant gross margin.

6.6 Strategy and objectives

The Group's strategy is to enable innovations to be commercialised on a global market for the benefit of society, healthcare professionals and patients. The Group's prospects include continued growth of its platform and portfolio to address healthcare challenges, through ongoing R&D and acquisition strategies in line with the Group's goals and vision.

During first part of 2020 the Group continued to execute the set strategy with Sippi[®] sales and customer relations in focus. In the Nordics and in rest of Europe, the Group pursues Sippi[®] implementations, with high activity levels and interaction with the Group's distributors.

The current COVID-19 situation may represent a future challenge since the pace of the roll out of Sippi[®] will depend on the progress of the COVID-19 situation in hospitals. However, it also highlights the fundamental challenges for the healthcare – time/resources, data accuracy and hospital acquired infections – all of which are addressed by Sippi[®].

6.7 Market Launch

The Group is in the launch phase of Sippi[®]BLE, which is approved for sale in Europe. The first wave, which started in the autumn 2019, will be in the Nordics and potentially in selected other European countries, whereof Germany will be prioritized. The second wave starting in 2020 is planned to be in selected other EU countries, selected rest of the World ("**RoW**") territories and the U.S. with potential U.S. launch in 2022 or later depending on considerations and experience from the EU launch rollout as well as the prevailing market conditions. The Group does not intend to build a large inhouse sales organization, but will mainly work via distributors, except in the Nordic countries where the Group will

conduct own sales and marketing to maintain close customer contact. The Group believes in close customer contact to receive swift feedback, discover any hurdles or initial start-up challenges and have own in-house technical expertise to handle this. This will also ease the roll-out and market entry anywhere else.

A successful launch requires close cooperation with the distributors, for which the Group provides training, references and support services. Service beyond the product is one key for success. A launch is resource-intensive and in order to have a step by step process for smooth roll-out and positive user experience, the Group wants to focus on a few important market and centres of excellence. Hence, with the great potential in Germany, the Group has chosen to focus its resources on this important market during 2019. However, the Group will also support its existing distributors in Italy and the UK. The Group's chosen distributors are mid-sized companies with strategic focus on either the ICU or Urine collection market or both. The Group believe that it will gain more attention when Sippi[®] becomes a significant part of these distributors' portfolio rather than using large companies with extensive pipelines.

The long-term objective is to achieve a market share of 10% within 18 to 24 months on each launched market at clinics with compatible PDMS. As Sippi[®] is launched in an increasing number of markets, an installed base of Sippi[®] will be built up that generates recurring sales of consumables.

Due to Sippi[®]'s effective solution, urine measurement is also possible in general care, which opens up a new market segment for the Group.

The U.S. is considered the largest single market globally. In the U.S., urine meters are integrated with the urine catheter, requiring the Group to produce a kit for the U.S. market and it has therefore initiated contact with catheter suppliers and plans to develop an integrated product for the U.S. market. In order for the Group to launch an U.S. initiative, the Group aims to hire three additional persons to secure operations in the U.S. and to enter into a collaboration agreement with an established player with products in urology or intensive care products in order to achieve growth and access in the U.S. market. By launching through an already established U.S. organisation the Group will benefit from local knowhow and insight regarding kit production, sales and marketing resources, local regulatory knowledge etc.

To ensure a smooth and successful entry in the U.S., the Group is collaborating for market access through Norway Health Tech, the commercial section at the U.S. embassy in Norway as well as Innovasjon Norge.

Entry into RoW

The Group's organization is too small to build own market presence in territories outside the Nordics. Therefore, in the Rest of the World (RoW) territories like Asia, the Group aims for market access through a pan-Asian distributor, with the same qualities and necessary knowhow as for the U.S. market. In order to be able to start such operations, the Group anticipates that it will need to employ two to three new employees. All features necessary for Medtech products will be needed, such as technicians, resources for service beyond the product, regulatory issues, import etc.

6.8 Competition

There are a number of players that provide urine meters, all of whom are larger companies with broad product portfolios that usually include catheters and other products in urology and consumables. These actors are large global medical technology companies. The Group markets the currently only digital urine meter with wireless integration to electronic patient journal systems (PDMS). The competitive picture differs between Europe and the U.S. In Europe, there are currently five established players in urology, three of which market urine meters actively. The two largest players in the European market are Convatec and B.Braun. Convatec had a revenue of approximately EUR 1.8 billion in 2018 and approximately 9,500 employees¹⁴.

The other major player in the EU is B. Braun whose urine meters has a market share on par with Convatec. B. Braun is also a major supplier within medical technology and had a turnover of approximately EUR 6.9 billion in 2018 with 63,000 employees¹⁵.

Another player in Europe, which is also amongst the largest vendors in medical technology, is Cardinal Health, with a revenue of over USD 137 billion in 2018 and approximately 50,000 employees¹⁶.

¹⁴ **Source:** https://convatecgroup.com/media/1560/convatec_ar2018_interactive.pdf

 $^{^{15} \}textbf{Source}: \ \texttt{https://www.bbraun.com/en/company/organization-facts-figures/annual report-2018. \ \texttt{https://www.bbraun.com/en/company-company-company-com/en/company-company-company-company-com/en/company-company-com/en/company-com/en/com/en/com/en/com/e$

¹⁶ **Source**: https://s1.q4cdn.com/238390398/files/doc_financials/annual/2018/342622_CardinalHealth_Annual-Report.pdf

⁽fortsetter neste side)

In addition to the three above-mentioned vendors, there are another two major players in urology in Europe that provide catheters and other products. These are American Teleflex and BD, which had a turnover of USD 2.5 billion in 2018¹⁷ and USD 16 billion in 2018¹⁸, respectively.

The U.S. market for urine meters differs slightly from the European market, since urine meters are usually integrated with the catheter, the container sits in front of the bag and when emptied it is folded over the bag behind. The U.S. market for urine meters is dominated by three players. The largest in the American market is BD. The second vendor in the U.S. is Cardinal Health (which is the only manufacturer with market shares in both the EU and the U.S.). The third competitor is Medline with a turnover of USD 11 billion and 20,000 employees.¹⁹

Approximately one and a half year ago from the date of this Registration Document, Portreo Medical launched a digital urine meter in the U.S. market. The Accuryn product uses the same measurement technology, ultrasound, as BD's digital product Criticore. Ultrasonic measurement technology is more sensitive to movements. In addition to Criticore, Accuryn has a pressure measurement in the bladder which is used to alert for blockage in the tubing as well as an automatic relief thereof. The disposable unit price is set at a level which is expected to be in the range of 5-10 times that of a Sippi[®] disposable price. Comparing to existing digital urine meters, Sippi[®] is priced low, however compared to standard analogue meters Sippi[®] is priced higher.

To the best of the Group's knowledge, Sippi[®] is the only fully automated, digital, wireless urine meter, which also contains an infection prevention feature for intraluminal migration of bacteria.

	CardinalHealth"	ConvaTec A Bristol-Myers Source Company	BBRAUN	BAIRD	POTRERO MEDICAL	BARD	* observe	•
	Curity Precision	Unometer	Ureofix	Bardia	Accuryn	Criticore	Sippi	ì
Wireless connection to electronic patient journal	NO	NO	NO	NO	NO	NO	I I YES I	1
Measure technology	Analogue	Analogue	Analogue	Analogue	Optic sensor	Optic sensor	Capacitive sensor	1
Sensitivity	Low	Low	Low	Low	High	High	Low	1
Mobility	High	High	High	High	Low	Low	l High	1
Power	n.a.	n.a.	n.a.	n.a.	A/C	A/C	AA Batteries	Γ,
Pricing	Low	Medium	Medium	Medium	Very high	High	Medium	Ľ
Customer acceptance	All beds	All beds	All beds	All beds	Niche product	Niche product	All beds	Ľ,
Bacteria Control	NO	NO	NO	NO	NO	NO	YES-Sippcoat	1

Competitor Overview

Source: "Accuracy and ease of use of a novel electronic urine output monitoring device compared with standard manual urinometer in the intensive care unit" (2009), Einav, S., Hersch, M., and Izbicki, G., Journal of Critical Care 24.4

6.9 Customers

Urine meters are used every day in hospitals around the world and 95% of the use of urine meters is in Intensive Care Units (ICU). The operation of urine meters is today a time consuming task but important since urine output is a vital parameter for patients in ICUs. ICUs are common in larger hospitals and university clinics as they provide specialised care which are associated with high costs.

In countries with large public sectors (e.g. the Nordic countries), the Group's typical contracting parties for the purchase of the Group's products are the hospitals and university clinics with ICUs as well as larger procurement bodies responsible for procuring medical equipment in a region (covering all health enterprises in such region) (e.g. regional health authorities, municipalities etc.). However, in many of the Group's target markets hospitals may be private and/or connected to a private purchasing group, were direct negotiations with hospitals or the group is typical for entering into sale agreements.

6.10 Manufacturing

Sippi[®] consists of two components: the base unit and the disposable unit.

¹⁷ Source: https://teleflexincorporated.gcs-web.com/static-files/49a13a80-d283-4a2d-b6ae-a59e8197d63e

¹⁸ **Source**: https://investors.bd.com/static-files/759c8ae1-c56b-4346-9365-1a56c06873ee

¹⁹ Source: https://www.medline.com/pages/about-us/our-company/

Both the base unit and the disposable unit is entirely developed by the Group. All costs in relation to the development have been borne solely by the Group.

All manufacturing steps of the base unit and the disposable unit have been outsourced; however, all manufacturing tools and rigs are owned by the Group in order for it to be in control of and being able to facilitate a potential move of manufacturing or assembly in the future.

The base unit is manufactured by Inission in Borås, Sweden. Their facility is located close to the Group's development office, making surveillance and adjustments easy and fast.

The disposable unit consists, in simple terms, of three components: tube, bag and measuring siphon. Knudsen Plast is manufacturing the plastic siphon components and assembles the chamber. The tubing, bags and assembly of the entire kit is sourced through Unomedical/Convatec in Slovakia, which pursuant to the Company's knowledge is one of Europe's biggest plant for urine bags. This contractor ensures scalability and low-cost production at high volumes.

6.11 The Group's intellectual property rights

The Group has a strong global patent situation with focus on its three technologies: (i) Measuring volume via contactless sensors, (ii) Sippsense[®], measuring sensor degradation and hence biofilm onset and (iii) Sippcoat[®], the use of silicone oil as biofilm prevention properties in both urology and other bodily fluid systems. There are currently 44 approved patents in key countries and territories. The Company's subsidiary Observe Medical Aps is the registered owner of all of the Group's patents.

Type and registration year	Patent number	Description	Regions	Expiration date
Urosense	EP2445408	Protects the system design of;	Brazil, France, India, Italy,	Year 2030
Patent (IP1)	US10182747	the base unit, disposable unit	Japan, China, Netherlands,	
June 2009		and interaction between units	Russia, Spain, UK, Sweden,	
			Turkey, Germany, USA, EPO and PCT	
Urosense II	CN103959020B	Detection of a degenerated	Brazil, India, Japan, China,	Earliest Year 2031
Patent (IP2)	JP6078549	sensor surface – Sippsense [®]	Russia, Sweden, USA, EPO	Latest Year 2032
November 2011	RU2618089		and	
	US10145813		РСТ	
Sippcoat®		Protection relating to the	PCT, EPO, USA and China	Year 2033
Patent Application		patient activated silicone oil		
(IP3)		capsule - Sippcoat [®]		
March 2013				
Urosense III	CH105120752B	Sterile release of encapsulated	Brazil, France, India, Italy,	Earliest Year 2034
Patent (IP4)	EP2967464	oil mixture (ETO & Radiation)	Japan, China, Netherlands,	Latest Year 2035
September 2014	JP6416796		Russia, Spain, UK, Sweden,	
	US10188339		Turkey, Germany, USA, EPO	
			and PCT	
Urosense IV	EP3193947	Administration of silicone oil	Brazil, India, Japan, China,	Earliest Year 2034
Patent application	RU2693473	into urine collection system in	Russia, Sweden, Brazil, EPO	Latest Year 2035
(IP5)	SE538635C2	general	and PCT	
March 2016	US9861715			

The table below provides an overview of the Group's five patent families:

6.12 Material contracts

Other than the Demerger and the Debt Conversion (see Section 6.2.2 "The Demerger establishing the Groupand the Loan Agreement (see Section 7.9.1 "Loan Agreement"), no company in the Group has entered into any material contracts outside the ordinary course of business for the two years prior to the date of this Registration Document. Further, no company in the Group has entered into any other contract outside the ordinary course of business which contains any provision under which any member of the Group has any material obligation or entitlement.

6.13 Dependency on contracts, patents and licenses

The Group owns all the intellectual property rights that protects the technology behind the Sippi[®] family of products as listed in Section 6.11 "The Group's intellectual property rights" above. The Group also owns all the key tools and rigs for manufacturing of the products. The manufacturing and assembly of the products are contracted out, but there are no manufacturing or assembly step that could not be moved to another contractor should that be necessary.

At the date of this Registration Document, the Group's current operations are dependent on the Loan Agreement (see Section 7.9.1 "Loan Agreement" for more information) and for retaining and obtaining CE certification and other regulatory certifications when entering into markets outside the EU (e.g. the Group's FDA registration).

Other than the above, it is the Company's opinion that the Group's existing business or profitability is not materially dependent on any patents or licenses, industrial, commercial or financial contracts.

6.14 Employees

As at the date of this Registration Document, the Group has seven employees.

The table below shows the development in the number of employees in the Group for the years ended 31 December 2019, 2018 and 2017 and as of 31 March 2020.

Position	As of 31 March 2020	As of 31 December 2019	As of 31 December 2018	As of 31 December 2017	
Management	2	2	1	1	
R&D	4	4	3	3	
Sales	1	2	2	1	
Total	7	8	6	5	
Country	As of 31 March 2020	As of 31 December 2019	As of 31 December 2018	As of 31 December 2017	
Norway	1	1	0	0	
Sweden	6	7	6	5	
Total	7	8	6	5	

6.15 Regulatory and environmental matters

Each main market around the world has its own regulations to ensure the safety and performance of medical devices ("**MD**") throughout their lifetime. In EU, medical devices are regulated by the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), repealing Council Directive 93/42/EEC (MDD).* This legislation states e.g. the requirements of which the legal manufacturer must conform to in order to make a medical device available on the European market. This includes CE-mark requirements needed for each device. In the U.S., the Medical Device Regulation Act regulates the safety and effectiveness of medical devices intended for human use. Both in the U.S. and EU medical devices are categorized into classes (Class I-III) depending on the intended purpose and the inherent risk of the MD. Simply explained, a higher class represents devices with a higher inherent risk, e.g. devices intended for long duration of use; devices intended to be invasive or implantable; devices intended to actively support or sustain human life. The requirements for documentation and/or approval increases with each step of class.

Observe Medical AB has been certified according to ISO 13485:2016 and the existing product, i.e. Sippi[®], is certified and valid until January 25, 2022, according to *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD).* In accordance to EU regulations Sippi[®] can continue to be sold throughout the EC certificate validity. However, Observe Medical AB transition to MDR is planned for 2021 well in advance before certificate expiry date. In the U.S., Observe Medical AB and Sippi[®] has been registered with the FDA since 2015 as a Class II device. The Group will continuously update the current EU certifications accordingly. Observe Medical AB will also ensure conformance with regulations in each new territory (outside EU) before making Sippi[®] available on that specific market.

Changes in environmental regulations may affect the Group's ability to deliver its products to the market. Changes in approved plastics or ingredients (e.g. PVC) that are integral parts in the Group's products may affect the Group's stock of products.

6.16 Insurance

The Group's insurance coverage covers risks connected with the Group's business and activities, including occupational injury liability, travel insurance and public and product liability.

The Company considers the Group to be adequately covered with regard to the nature of the business activities of the Group and the related risks in the context of available insurance offerings and premiums. Management regularly reviews the adequacy of the insurance coverage. However, no assurance can be given that the Group will not incur any damages that are not covered by its insurance policies or that exceed the coverage limits of such insurance policies.

6.17 Legal proceedings

The Group is not, nor has it been, during the course of the preceding 12 months prior to the date of this Registration Document, involved in any legal, governmental or arbitration proceedings which may have, or has had in the recent past, significant effects on the Group's financial position or profitability, and the Company is not aware of any such proceedings which are pending or threatened.

7 OPERATING AND FINANCIAL REVIEW

This operating and financial review should be read together with the Financial Information and related notes included therein. The Financial Information has been incorporated by reference, see Section 12.3 "Incorporated by reference".

7.1 Presentation of Financial Information

The 2019 Financial Statements have been prepared in accordance with IFRS. The comparative information in the 2019 Financial Statements prior to the Demerger on 31 October 2019 is labelled as "consolidated" in the 2019 Financial Statements and is derived from the carve-out financial statements up to and including 30 June 2019, and from Navamedic's internal consolidation system for the remaining period up to and including 31 October 2019.

The Carve-out Annual Financial Statements have been prepared in accordance with IFRS and interpretations by IASB, as adopted by the EU to the extent appropriate since IFRS does not provide explicit guidance for the preparation of carve-out financial information.

The Q1 Financial Presentation has not been prepared in accordance with IFRS or IAS 34, however, when the Company prepared the Q1 Financial Presentation it applied the same measurement principles and recognition criteria as applied in the 2019 Financial Statements.

The 2019 Financial Statements and the Carve-out Annual Financial Statements have been audited by KPMG, as set forth in their audit report included therein. The Q1 Financial Presentations has not been audited.

The Financial Information is presented in NOK (presentation currency).

The Company's auditor, KPMG, made the following emphasis of matter in their auditor's report to the Carve-out Annual Financial Statements regarding the basis for preparation:

"Without modifying our opinion, we draw attention to Note 1 and 2 to the carve-out financial statements, which explains the basis of preparation, including the approach to and the purpose for preparing them. The carve-out financial statements were prepared in connection therewith, and for no other purpose. Our opinion is not modified in respect of this matter."

Furthermore, in connection with the 2019 Financial Statements, KPMG, made the following emphasis of matter in their auditor's report to the 2019 Financial Statements regarding material uncertainty related to going concern:

"We draw attention to Note 3 in the financial statements and the Board of Directors' report, which indicates that there is substantial risk associated with the Company's liquidity in 2020. The Group currently is in an early phase of commercialization and development process of its products. Based on updated cash flow forecasts for next 12 months, the Group will at some stage require additional funds in order to execute and complete its commercialization and growth strategy, or for other purposes. There is a risk that adequate sources of funds may not be available, or available at acceptable terms and conditions, when needed."

7.2 Significant factors affecting the Group's results of operations and financial performance

The Group's operations and results of operations have been, and may continue to be, affected by a range of factors. The factors that Management believes have had a material effect on the Group's results of operations during the periods under review, as well as those considered likely to have a material effect on its results of operations in the future, are described in the following.

7.2.1 Revenues

The Group has had insignificant amounts of revenues in the financial periods covered by the Financial Information. This is because the Group has developed its products and just recently started its commercialisation of the Sippi[®] product family. Subject to successful launch and market uptake of the products and technology offered by the Group, revenues are gradually expected to increase, even though no guarantees can be made.

7.2.2 Cost of materials

Cost of materials have been higher than revenues in many of the periods covered by the Financial Information. This is due to materials used in the pre-and early commercialisation phase for the development and commercialisation of the Sippi[®] product family. Cost of materials has also been affected by write-downs, and reversal of write-downs, of inventory.

Subject to successful launch and market uptake of the products and technology offered by the Group, cost of materials are expected to increase, but at a point in time it is expected that revenues will be higher than cost of materials.

7.2.3 Payroll expenses and other operating expenses

Payroll expenses and other operating expenses mainly follow the level of activity in operations. The mix between own employees and hired consultants in certain financial periods covered by the Financial Information affects the proportion of total costs for each type of operating cost. In 2019, cost of services delivered from Navamedic has increased due to the Company's listing process on Oslo Axess.

7.2.4 Depreciation, amortization and impairment

Depreciation, amortization and impairment for the periods presented in this Registration Document are primarily related to amortization of the fair value adjustment of technology asset that arose on the acquisition of OMI in 2015. Amortisation is calculated to write off the cost of intangible assets less their estimated residual values using the straight-line method over their estimated useful lives, and is generally recognized in profit or loss. Goodwill is not amortised. In connection with the acquisition in 2015 the useful lives was estimated to 10 years. Amortisation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate. The review of estimated useful lives at 31 December 2019 concluded that estimated remaining useful lives is 10 years from 1 January 2020. Change in estimated remaining useful lives was concluded after an assessment of the time of patent expiry, as well as assessment of competitors, the market and technological development. Amortization of capitalized development expenses has also contributed to the amortization charge. No impairment charges have been recognized for the periods presented in this Registration Document.

7.2.5 Change in Contingent Consideration

On 4 August 2015, Navamedic acquired all of the shares and votes in OMI, where the Contingent Consideration was part of the purchase price agreed in the SPA (see Section 7.9.2 "The Contingent Consideration" for more information). The Contingent Consideration is recognised as a financial liability. Change in estimated fair value, which includes calculated interest, is recognized through profit or loss as part of financial income or financial expenses. During the periods presented, the change in fair value has been affected by accrued interest on the liability and changes in the probabilities related to the milestone payments and royalties.

7.3 Recent developments and trends

The outbreak of the COVID-19 pandemic, which emerged during Q1 2020 has a serious impact on all aspects of the global society, specifically the healthcare system and patients, and thus on the Group as well. As the Group is in a launch phase with the next generation of Sippi[®], the Group is highly dependent on dialogue with current and potential customers and other stakeholders. The current situation, however, with national travel restrictions and a healthcare system, and healthcare providers, fully occupied with acute handling of COVID-19, provides constraints to the launch efforts for Sippi[®], with some of the sales projects and other projects being slowed down or stalled. Despite these circumstances, the Group operates at full capacity and works according to plan and focus particularly on the international launch and sales of Sippi[®], and the Group monitors its value chain closely.

Other than this and except as set out in 6.7 "Market Launch", the Group has not experienced or has any information about significant trends in production, sales and inventory, costs and selling prices, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on the Group's prospects for the current financial year.

Except for the information provided in Section 7.11 "Significant changes", the Group has not experienced any significant changes in the financial performance of the Group since 31 March 2020 and until the date of this Registration Document.

7.4 Results of operations

7.4.1 Summarised result of operations information

The following table summarizes data of the Group's historical results of operations, and is extracted from the unaudited Q1 Financial Presentation for the interim period ended 31 March 2020 with comparative interim financial information for the same period in the prior financial year, and from the audited 2019 Financial Statements as of and for the year ended 31 December 2019 and the audited Carve-out Annual Financial Statements as of and for the years ended 31 December 2018 and 2017.

In NOK thousand	F		Years ended 31 December		
	2020	2019	2019	2018	2017
Total revenue	32	27	177	106	198
Operating expenses	4,442	2,768	11,678	7,929	11,187
Depreciation and amortization	779	1,043	4,285	3,901	3,981
Operating result	-5,189	-3,784	-15,787	-11,724	-14,970
Change in contingent consideration	-567	-557	-221	14,009	-2,618
Net other financial items	5,332	250	-909	-11	219
Net profit / loss (-)	-424	-4,091	-16,917	2,274	-17,370

Results of operations for the three months' period ended 31 March 2020 compared to the three months' period ended 31 March 2019

Revenues were TNOK 32 for the three months' period ended 31 March 2020, at the same level as the comparable period for the three months' period ended 31 March 2019 when the revenues were TNOK 27. Operating expenses increased from TNOK 2,768 for the three months' period ended 31 March 2019 to TNOK 4,442 for the three months' period ended 31 March 2020. The increase is related to increased headcount and increased other operating expenses related to build-up functions as a standalone listed company. Depreciation and amortization decreased from TNOK 1,043 for the three months' period ended 31 March 2019 to TNOK 779 for the three months' period ended 31 March 2020. The decrease is related to review of useful life time of intangible assets. From 1 January 2020 the estimated useful life time was extend from 2025 to 2029 for intangible assets related to Sippi[®]. Net other financial items amounted to TNOK 5,332 for the three months' period ended 31 March 2020, compared to TNOK 250 for the three months' period ended 31 March 2019 due to currency adjustments on internal loans.

Results of operations for the year ended 31 December 2019 compared to the year ended 31 December 2018

Revenues were TNOK 177 in the year ended 31 December 2019, compared to TNOK 106 in year ended 31 December 2018. Operating expenses increased from TNOK 7,929 as of 31 December 2018 to TNOK 11,678 as of 31 December 2019. The increase in the operating expenses was mainly due to expenses in connection with the incorporation of the Company, the Demerger and the Listing on Oslo Axess. In addition, operating expenses were affected by higher cost of materials due to write-downs of inventories in 2019. Depreciation and amortization increased from TNOK 3,901 in 2018 to TNOK 4,285 in 2019. The increase is related to higher amortization of technology development (Sippi[®] and related proprietary technologies) and depreciation of lease right of use after implementation of IFRS 16 from 1 January 2019. In 2019 there was a finance cost related to change in contingent consideration of TNOK 221, compared to a finance income at TNOK 14,009 in 2018. The finance income in 2018 was related to change in estimated fair value of the Contingent Consideration (as defined in Section 7.9.2) as a result of the likelihood of milestone payments in the purchase agreement of OMI in 2015. Net other finance expenses in the year ended 31 December 2019 were TNOK 909 and were related to interest of borrowings that more than offset net currency gain. In the year ended 31 December 2018, net other finance expenses came in at TNOK 11.

Results of operations for the year ended 31 December 2018 compared to the year ended 31 December 2017

Revenues were TNOK 106 in the year ended 31 December 2018, compared to TNOK 198 in the year ended 31 December 2017. The operating expenses decreased from TNOK 11,187 in 2017 to TNOK 7,929 in 2018. The decrease was mainly due to decreased cost of materials and personnel benefit expenses. In 2017, part of the inventories was older than estimated shelf life of three years and the Group conducted write-down of the inventories on this basis. In 2018, Navamedic (at the time prior to the Demerger when Navamedic was the parent company of the Group) and Research Institutes of Sweden conducted tests that determined that the shelf life was 5 years. Based on these tests, the Group reversed the write-down from 2017 of NOK 606,247. In addition, the Group had one less employee in 2018 compared to 2017 and this resulted in decreased payroll expenses. The change in contingent consideration changed from a finance expense in 2017 at TNOK 2,618 to a finance income in 2018 at TNOK 14,009. In 2018, the expected payments to the former owners of OMI (the Contingent Consideration) were adjusted downwards, which reduced the estimated liability by NOK 14.0 million. The change was primarily a result of changes to the probabilities of milestone payments and royalties in the SPA. At year-end 2018, the Group estimated that revenue from sales of the Group's products will be realised at later points in time than assumed when OMI was acquired by Navamedic in 2015. However, the potential revenue and expected realisations remain unchanged and have only been postponed. Net other financial items was in 2018 an expense at TNOK 11 related to interest of borrowings that more than offset other finance income. In 2017 there was a net finance income of TNOK 219 related to currency gain and other finance income more than offset interest of borrowings.
7.5 Consolidated statement of financial position

7.5.1 Summarised consolidated statement of financial position data

The following table shows summarized historical consolidated statement of financial position data related to the Group's activities, and is extracted from the unaudited Q1 Financial Presentation for the interim period ended 31 March 2020 with comparative interim financial information for the same period in the prior financial year, and from the audited 2019 Financial Statements as of and for the year ended 31 December 2019 and the audited Carve-out Annual Financial Statements as of and for the years ended 31 December 2018 and 2017.

In NOK thousand	As	of		As of		
	31 M	31 March		31 December		
	2020	2019	2019	2018	2017	
Total non-current assets	56,325	51,567	51,670	54,731	58,459	
Total current assets	4,918	3,145	3,663	4,100	5,578	
Total assets	61,243	54,712	55,333	58,831	64,037	
Total equity	14,641	11,497	14,542	16,823	11,394	
Non-current lease liabilities ¹	45	-	78	-	-	
Contingent Consideration	12,965	12,734	12,398	12,177	26,186	
Non-current interest bearing loan ²	29,353	-	25,413	-	-	
Total current non-interest bearing liabilities	4,239	1,731	2,902	4,799	3,652	
Total current interest bearing liabilities ²	-	28,750	-	25,032	22,805	
Total liabilities	46,602	43,215	40,791	42,008	52,643	
Total equity and liabilities	61,243	54,712	55,333	58,831	64,037	

1: IFRS 16 – Leases, implemented from 1 January 2019..

2: The Group entered into the Loan Agreement with Navamedic in September 2019 and the Loan Agreement is classified as noncurrent liabilities. The Loan Agreement refinanced the former loan from the Navamedic group.

Consolidated statement of financial position data as of 31 March 2020 compared to as of 31 March 2019

The Group had assets of TNOK 61,243 as of 31 March 2020, compared to TNOK 54,712 as of 31 March 2019. The increase is primarily related to currency adjustments and investments in intangible assets. Total equity increased from TNOK 11,497 as of 31 March 2019 to TNOK 14,641 as of 31 March 2020. The increase is mainly related to the Debt Conversion of TNOK 16,000 in connection with the Demerger from Navamedic as at 31 October 2019 that more than offset the negative result in the period. The Group had total non-current interest bearing loan of TNOK 29,353 as of 31 March 2020, compared to TNOK 0 as of 31 March 2019 due to the Loan Agreement (as defined in Section 7.9.1) entered into in September 2019. Contingent Consideration liabilities was TNOK 12,965 as of 31 March 2020, compared to TNOK 12,734 as of 31 March 2019. The increase is due to calculated interest on the liability (see Section 7.9.2 for more information about the Contingent Consideration). Total current non-interest bearing liabilities as of 31 March 2020 amounted to TNOK 4,239, compared to TNOK 1,731 as of 31 March 2019. The increase is mainly related to increased trade payables due to higher other operating expenses and purchase of materials for sale. At 31 March 2019 the Company had interest bearing current liabilities at TNOK 28,750 and this was related to loans from Navamedic group. In September 2019 the Company entered into the Loan Agreement and this was classified as non-current liabilities while the previous loan agreement was classified as current liabilities.

Consolidated statement of financial position data as of 31 December 2019 compared to as of 31 December 2018

The Group had assets of TNOK 55,332 as of 31 December 2019, compared to TNOK 58,831 as of 31 December 2018. At year-end 2019, the Group had current assets of TNOK 3,663, mainly related to inventories. In 2018, the Group had current assets of NOK 4,100 and the decrease is mainly related to decreased other receivables. The Group had equity of TNOK 14,542 as of 31 December 2019, compared to TNOK 16,823 as of 31 December 2018. In the period between the Company's incorporation in June 2019 and the date of the Listing, the Company completed a share capital increase related to the Debt Conversion. The Group had total non-current interest bearing loan of TNOK 25,423 as of 31 December 2019 compared to TNOK 0 as of 31 December 2018. The increase is related to interest bearing liabilities to Navamedic of TNOK 25,413, as a result of the Loan Agreement entered into in connection with the Demerger. Contingent Consideration liabilities was TNOK 12,398 as of 31 December 2019, compared to TNOK 12,177 as of 31 December 2018. The increase is due to calculated interest more than offset the decrease of liability related to postponed estimated revenues (see Section 7.9.2 for more information about the Contingent Consideration)Total current liabilities as of 31 December 2019 amount to TNOK 2,901, compared to TNOK 29,831 as of 31 December 2018. The decrease is related to

the new Loan Agreement from 2019 classified as non-current liabilities, while the loan agreement in 2018 was classified as short-term agreement.

Consolidated statement of financial position data as of 31 December 2018 compared to as of 31 December 2017

Total equity amounted to TNOK 16,823 as of 31 December 2018 compared to TNOK 11,394 as of 31 December 2017. The increase in equity is primarily due to group contribution received. In addition, the Group received further debt financing from the Navamedic group, which caused the increase in total current interest bearing liabilities. Decrease in total non-current assets is primarily due to amortization of intangible assets. Decrease in total current assets is primarily related to the decrease in bank deposits that more than offset the increase in trade receivables and other receivables. The reduction in non-current liabilities was due to the decrease in the Contingent Consideration.

7.6 Liquidity and capital resources

7.6.1 Sources and use of cash

The Group launched its new main product Sippi[®]BLE in the fourth quarter of 2019, and in order to be able to launch the product in the global market, the Group will have to continue to focus and invest in business development and growth going forward.

The Group's primary source of liquidity has been cash from its borrowing arrangements (see Section 7.9.1 "Loan Agreement" for more information about the Group's borrowing arrangements). As at 31 March 2020, the Group had approximately NOK 460,000 available in cash and cash equivalents and except for the increased loan from Navamedic there have been no material changes outside regular business in the Group's cash situation since 31 March 2020 and until the date of the Registration Document. The Group's future principal source of liquidity will still be cash generated from financing, equity and debt, in addition to net cash flows generated from sales. Consequently, any shortfall of cash generated from operations management will have to be covered through such additional financing in order to secure the ability to continue as a going concern. As the Company itself is a non-operative entity, the main portion of the Group's cash balance is and will be held at subsidiary level to cover the daily liquidity requirements of the operating subsidiaries. The following table shows the Group's net interest bearing debt:

In NOK thousand	As of 31 March		As of 31 December		
	2020	2019	2019	2018	2017
Current interest bearing debt	0	28,750	0	25,032	22,805
Non-current interest bearing debt	42,363	12,734	37,889	12,177	26,186
Total interest bearing debt	42,363	41,484	37,889	37,209	48,991
Bank deposits	460	1,264	485	621	2,059
Net interest bearing debt (NIBD)	41,903	40,220	37,404	36,588	26,932

The following table shows the Group's debt-to-equity ratio:

In NOK thousand	As of		As of			
	31 March		31 December			
	2020	2019	2019	2018	2017	
Non-current liabilities	42,363	12,734	37,889	12,177	26,186	
Current liabilities	4,239	30,481	2,902	29,831	26,457	
Total liabilities	46,602	43,215	40,791	42,008	52,653	
Equity	14,641	11,497	14,542	16,823	11,394	
Debt-to-Equity ratio (D/E)	3.18	3.76	2.81	2.50	4.62	

7.6.2 Treasury policies

The Group's operations have historically been, and are currently, financed with loans and contributions from the Navamedic group. The Group has not had cash and cash equivalents for alternative use than finance of short term operations, and current liquidity has been kept in short bank deposits in local currency for each group company.

7.7 Cash flows

7.7.1.1 Summarised cash flow information

The following table summarizes the Group's historical cash flows, and is extracted from the unaudited Q1 Financial Presentation for the interim periods ended 31 March 2020 and 2019, and from the audited 2019 Financial Statements

as of and for the year ended 31 December 2019 and the audited Carve-out Annual Financial Statements as of and for the years ended 31 December 2018 and 2017.

In TNOK	Three months' period ended 31 March		Years ended 31 December		
	2020	2019	2019	2018	2017
Cash flow from operating activities	-4,408	-4,503	-13,972	-8,364	-9,828
Cash flow from investing activities	-404	645	-2,141	-1,949	-1,569
Cash flow from financing activities	4,752	4,524	16,187	9,558	11,810
Exchange rate fluctuations	36	-23	-210	-683	-1,859
Net change in cash and cash equivalents	-25	643	-136	-1,438	-1,446
Cash and cash equivalents at end of period	460	1,264	485	621	2,059

7.7.1.2 Cash flows from operating activities

Three months' period ended 31 March 2020 compared to the three months' period ended 31 March 2019

Cash flow from operating activities for the three months' period ended 31 March 2020 was -4,408, compared to TNOK - 4,503 for the three months' period ended 31 March 2019. The increase is primarily related to increased current liabilities, that more than offset the increased inventories and increased operating expenses compared to same period last year.

Year ended 31 December 2019 compared to year ended 31 December 2018

Cash flow from operating activities was negative TNOK 13,972 in 2019, compared to negative TNOK 8,364 in 2018. The decrease is primarily related to the increased operating expenses and negative change in working capital, mainly due to decreased trade payables.

Year ended 31 December 2018 compared to year ended 31 December 2017

Net cash outflow from operating activities for the year ended 31 December 2018 was TNOK 8,364 compared to a net cash outflow of TNOK 9,828 for the year ended 31 December 2017. The improvement is primarily related to decreased operating expenses in 2018 mainly due to one less employee.

7.7.1.3 Cash flows from investing activities

Three months' period ended 31 March 2020 compared to the three months' period ended 31 March 2019

Cash flow used in investing activities for the three months' period ended 31 March 2020 was TNOK 404, compared to TNOK 645 for the three months' period ended 31 March 2019. The change is related to periodic differences on the development of Sippi[®].

Year ended 31 December 2019 compared to year ended 31 December 2018

The Group used TNOK 2,141 for investing activities in 2019, an increase from TNOK 1,949 in 2018. As in 2018, the cash flow used in investing activities in 2019 was related to investments in Sippi[®] products.

Year ended 31 December 2018 compared to year ended 31 December 2017

Net cash used in investing activities for the year ended 31 December 2018 was TNOK 1,949 compared to TNOK 1,568 for the year ended 31 December 2017, an increase of TNOK 381 due to higher level of investment in intangible and tangible assets as a result of investments in Sippi[®].

7.7.1.4 Cash flows from financing activities

Three months' period ended 31 March 2020 compared to the three months' period ended 31 March 2019

Cash flow from financing activities for the three months' period ended 31 March 2020 was TNOK 4,752, compared to TNOK 4,524 for the three months' period ended 31 March 2019. The increase is related to share issue in the first quarter 2020 in connection with exercise of share options as described in Section 10.4 "Share options".

Year ended 31 December 2019 compared to year ended 31 December 2018

In 2019, net cash flow from financing activities was TNOK 16,187 due to cash flow from increased interest-bearing debt. In 2018, net cash flow from financing activities was TNOK 9,558 and related to group contribution and increased debt.

Year ended 31 December 2018 compared to year ended 31 December 2017

Net cash flows from financing activities for the year ended 31 December 2018 was TNOK 9,558 compared to TNOK 11,810 for the year ended 31 December 2017, a decrease of TNOK 2,252 primarily due to lower level of group contribution that more than offset higher level of net interest bearing debt towards Navamedic group to finance operations in Observe Medical.

7.8 Investments

The Company's investments are related to the development of Sippi[®]. Investments have been financed through interest bearing debt and with equity contribution.

Net cash flow used in investing activities:

Amounts in NOK thousands	Three months' period ended 31 March		Year ended 31 December		
	2020	2019	2019	2018	2017
Development of intangible assets	-404	645	-2,141	-1,949	-1,568

The Group is now in an important launch phase for the next generation Sippi[®] (Sippi[®]BLE) and the Group's related investments to the development of this product have in all material respect already been incurred. During the launch phase, the investments will mainly be related to connectivity to PDMS systems. The Group has established connectivity with two of the proprietary systems (GE and iMDsoft) and is in development stages with two more. The Group will continue to strive to have all six PDMS systems connected before the end of 2020. Remaining investments related to connectivity to the four PDMS systems are estimated to a lower level than investments in previous periods. The Company is also in the process of developing SippBridge[™], a stand-alone wireless receiver. Estimated remaining investment in SippBridge[™] is NOK 800,000. The Company will finance the investments related to connectivity to the PDMS systems and SippBridge[™] as mentioned above with existing cash, borrowing agreements and equity. The Group does not have any other material investments that are in progress or for which firm commitments have already been done.

In the Financial Information, the accounting principles set out in IAS 38 have been used to recognise research and development expenditures. External expenditures for the development of SippbagTM, wireless connection to PDMS and related functionality have been capitalised in the consolidated statement of financial position. Development activities have so far mainly been performed in-house, but can as well be performed in projects that are outsourced to external parties. Such development expenditures together with expenditures related to patent registration are the only development expenditures that have been capitalised in the consolidated statement of financial position in the Financial Information. Internal expenditures have not been capitalised in the consolidated statement of financial position as all the requirements set out in IAS 38.57 were not satisfied.

7.9 Borrowings and other contractual obligations

7.9.1 Loan Agreement

On 27 September 2019, the Company (as the borrower) entered into a subordinated convertible loan agreement with Navamedic (as the lender) for a loan of an aggregate amount of NOK 32,000,000 (the "**Loan Agreement**") to refinance existing loan of NOK 19,000,000 and to obtain additional liquidity loan of NOK 13,000,000. The Loan Agreement is structured as a bullet loan.

The Loan Agreement consists of the two following facilities:

- A subordinated convertible term loan facility in the amount of NOK 19,000,000 (the "Facility A"); and
- A subordinated convertible term loan facility in the maximum amount of NOK 13,000,000 (the "Liquidity Facility").

The purpose of the Facility A was to use the net proceeds from such facility to refinance the debt the Company had to Navamedic as at 30 June 2019 and additional loan provided by Navamedic to the Company in the period from 1 July 2019 and until the completion date of the Demerger limited to an aggregate amount of NOK 19,000,0000. On 30 September 2019, the Company became the debtor of the previous loans that the Navamedic group had provided to the Group companies and Navamedic became the creditor of such loans, in order to achieve a structure where the Company is the borrower and Navamedic is the lender under the Loan Agreement.

The purpose of the Liquidity Facility was to provide the Group with liquidity for its general corporate purposes for the 12 months' period following the Listing date.

The facilities given under the Loan Agreement constitute direct, unsecured and fully subordinated obligations of the Company, and rank at least pari passu with all other existing and future unsecured and subordinated obligations of the Company (other than in respect of any obligations preferred by mandatory provisions of applicable law), and rank ahead of all amounts payable in respect of the share capital of the Company.

The Facility A was made available to the Company on the completion date of the Demerger, while the Liquidity Facility is paid in portions within the first 12 months following the Listing date. As at the date of this Registration Document, drawdowns on the Liquidity Facility for a total amount of NOK 12,000,000 have been made.

Each loan given under the facilities accrue interest at a fixed interest rate of 8.00% per annum. Interest will be computed from (and including) the first day the relevant loan has been paid out until the last day of an interest period of three months, on the actual number of days elapsed in a 360-day year. Accrued interest shall on the last day of the three months' interest period be capitalised and added to the aggregate principal amount of the loans outstanding under the Loan Agreement.

The Company shall on the date falling 36 months after the date of the Loan Agreement repay to Navamedic the aggregate amount of each loan then outstanding together with all accrued but unpaid interest. The Company may at any time prepay any loan outstanding in part or in full. Any amount repaid or prepaid may not be re-borrowed.

The table below illustrates the maturity structure of the Loan Agreement, assuming that the debt is not converted and that the Company chooses not to prepay any loan amount or interest in cash before maturity:

Maturity structure non-current interest bearing loan and interest

(Amounts in NOK millions)

	0 ¹ - 12 months	12 - 24 months	24 - 36 months	Total
Non-current interest bearing loan	0.0	0.0	32.0	32.0
Interest of non-current interest bearing loan	0.0	0.0	8.3	8.3
Total	0.0	0.0	40.3	40.3

1 Starting date is the date of the Loan Agreement.

Navamedic has the right to, following the date falling 12 months after the completion date of the Demerger (i.e. on 31 October 2020), request that all, but not parts of, the loan outstanding is converted into Shares (the "**Conversion Right**"). Following the disbursement of a written notice to the Company informing about the exercise of the Conversion Right, the Company has the optionality to either (i) accept the Conversion Right or (ii) reject such Conversion Right by settling the loans in full in cash or settling parts of any loans in cash and the remainder through conversion. The Company has in the two months' period following receipt of the written notice the right to take all actions necessary to obtain sufficient funding, either by debt capital transactions or equity capital transactions or otherwise at its sole discretion, for the purpose of enabling the Company to repay the loans.

The subscription price in a conversion shall be equal to the volume weighted average share price of the Shares on the Oslo Axess (or any other exchange having replaced Oslo Axess as the market place for the Shares at the time of the conversion) for the last ten days prior to the conversion date, but in no event be less than the nominal value of each Share.

The number of Shares to be issued upon completion of the Conversion Right shall be determined by dividing (x) the principal amount of the outstanding loans (with accrued but unpaid interest) by (y) the conversion price. The number of Shares to be issued shall be rounded down to the nearest whole share. The Conversion Right cannot be separated from the loans under the facilities.

The Loan Agreement includes market standard default and termination rights for Navamedic.

7.9.2 The Contingent Consideration

In the share purchase agreement entered into between Navamedic (as the buyer) and the sellers of OMI on 3 August 2015 for the acquisition of the shares in OMI (the "**SPA**"), the parties agreed an "earn out" towards the sellers of OMI (the "**Contingent Consideration**"), whereby Navamedic subject to OMI's achievement of certain revenue levels for the Sippi[®] product in the period up until the end of 2023 shall pay the sellers an additional purchase price to be determined based on the achieved level of revenues for the product.

The Contingent Consideration was estimated to NOK 25.6 million by Navamedic at the date of the acquisition (in 2015) and was set with a book value of NOK 12.4 million as at 31 December 2019 in the Group's financial statements for the financial year 2019. The estimated fair value of the Contingent Consideration involves discounting expected future payments. Discounting is carried out based on a discount rate of 18.3%, which is the same that was used in the purchase price allocation to value the identified intangible assets in the business combination in 2015.

The maximum amount of the Contingent Consideration is as follows:

- For the period 2016-2023, a royalty may be paid to the former shareholders of OMI, based on the following: A royalty of 7% based on annual operating revenue from sales of the Sippi[®] product in excess of NOK 7.5 million, increasing to a 15% royalty for operating revenue in excess of NOK 100 million per annum.
- (ii) In addition to this, six milestone payments may be made to the former shareholders of OMI based on set sales targets for the product. These sales targets must be achieved by the end of 2023, with the last by the end of 2026. Total potential milestone payments cannot exceed NOK 125 million, in addition to royalties. The six potential milestone payments will be triggered as follows:
 - a) NOK 6 million of accumulated operating revenue in excess of NOK 50 million;
 - b) Plus, NOK 6 million of accumulated operating revenue in excess of NOK 75 million;
 - c) Plus, NOK 6 million of accumulated operating revenue in excess of NOK 100 million;
 - d) Plus, NOK 13 million of accumulated operating revenue in excess of NOK 300 million;
 - e) Plus, NOK 34 million of accumulated operating revenue in excess of NOK 600 million;
 - f) Plus, NOK 60 million of accumulated operating revenue in excess of NOK 900 million.

In 2018, the expected payments to the former owners of OMI were adjusted downwards, which reduced the estimated liability by NOK 14.0 million, and resulted in a book value of NOK 12.2 million as at 31 December 2018. The change was primarily a result of changes to the probabilities of milestone payments and royalties in the purchase agreement. At year-end 2019, the Group estimated that revenue from sales of the Group's products will be realised at a later point in time than previously assumed. However, the potential revenue and expected realisation remain unchanged and have only been postponed. The increased Contingent Consideration liabilities of NOK 0.2 million in 2019 is due to calculated interest that more than offset the decrease of liability related to postponed estimated revenues.

7.9.3 Restrictions on use of capital

There are currently no restrictions on the use of the Group's capital resources that have materially affected or could materially affect, directly or indirectly, the Group's operations. The Group does not have any debt covenants, and is therefore not in breach, and does not expect to be in breach, of any such covenants. The Group does not believe that there are significant obstacles or barriers to transfers of funds to it from its subsidiaries.

7.10 Financial risk management

The Group's operations expose it to various types of financial risk such as market risk (including currency risk, interest risk, and price risk), credit risk, liquidity and going concern risk.

Management of currency risk

The Group has at the date of this Registration Document not adopted specific currency hedging strategies in relation to its operations.

Management of liquidity and going concern risk

The Group currently is in phase of its commercialisation and development process of Sippi[®]. The ongoing COVID-19 situation with national travel restrictions and a healthcare system, and healthcare providers, fully occupied with acute handling of COVID-19, provides constraints to the launch efforts for Sippi[®], with some of the sales projects and other

projects being slowed down or stalled. In this phase the Group has limited with revenues and its main source of liquidity is still cash generated from financing, equity and debt. The economic impact of the current global response to the COVID-19 outbreak is expected to adversely impact the Group's liquidity risk in terms of risk of delays in forecasted revenues compared by original budgets. The impacts of the COVID-19 outbreak are dependent upon the extent and duration of the outbreak. If markets served by the Group are impacted further and/or do not recover quickly, the Group's liquidity risk will increase further.

The Group will require additional funding in order to execute and complete its commercialisation and growth strategy. Management performs on a regular basis cash flow projections to evaluate whether it will be in a position to cover the liquidity needs for the 12 months' period and to comply with terms of existing and future financing agreements. In developing estimates of future cash flows, the management makes assumptions about revenue and revenue growth, cost of materials, payroll and operating expenses, capital expenditure, loan repayments and interest charges. The assumptions applied are based on historical experience and future expectations.

Until the Group generates sufficient cash flow from operations, the Group will depend on longer term financing in form of debt and/or equity issuance. Such financing may not be available to the Group, or available at acceptable terms and conditions, when needed.

Interest rate risk management

The Group has effectively hedged the main part of its variable interest rate risk by entering into a fixed interest rate under the Loan Agreement. The Group has limited bank deposits and change in variable interest rate will have limited effect. The Group has not hedged its interest rate exposure.

Management of capital

The Group has so far not had any expressed goals or requirements in relation to management of capital. Focus in the short term will be to ensure continued operations to further develop and commercialise Sippi[®]. In the longer term, goals will include securing returns for its shareholders, and to maintain an optimal capital structure in order to reduce capital expenses. At the date of this Registration Document, the Group has not had any debt with financial covenant restrictions.

7.11 Significant changes

There have been no significant changes in the financial or trading position of the Group since 31 March 2020.

8 BOARD OF DIRECTORS, MANAGEMENT AND CORPORATE GOVERNANCE

8.1 Introduction

The general meeting of the Company is the highest decision-making authority of the Company. All shareholders of the Company are entitled to attend and vote at general meetings of the Company and to table draft resolutions for items to be included on the agenda for a general meeting.

The overall management of the Company is vested with the Board of Directors and the Management. In accordance with Norwegian law, the Board of Directors is responsible for, among other things, supervising the general and day-to-day management of the Company's business ensuring proper organization, preparing plans and budgets for its activities ensuring that the Company's activities, accounts and assets management are subject to adequate controls and undertaking investigations necessary to perform its duties.

The Board of Directors have appointed an audit committee and a nomination committee in accordance with the Corporate Governance Code (as defined below). See Sections 8.5 "Audit committee" and 8.6 "Nomination committee" below for more information on these committees.

The Management is responsible for the day-to-day management of the Company's operations in accordance with Norwegian law and instructions set out by the Board of Directors. Among other responsibilities, the Company's chief executive officer (the "**CEO**"), is responsible for keeping the Company's accounts in accordance with existing Norwegian legislation and regulations and for managing the Company's assets in a responsible manner. In addition, the CEO must according to Norwegian law, brief the Board of Directors about the Company's activities, financial position and operating results at a minimum of one time per month.

8.2 The Board of Directors

8.2.1 Overview

The Articles of Association provide that the Board of Directors shall consist of between three and seven board members, as elected by the Company's shareholders. The current Board of Directors consist of four Board Members, as listed in the table below.

All Board members are independent of the Company's executive management and no members of the Company's executive management serves on the Board of Directors. Except for Terje Bakken and Kathrine Gamborg Andreassen who are not considered independent from the Company's larger shareholders and material business associates, all Board Members are independent of the Company's larger shareholders (shareholders holding more than 10% of the Shares) and material business associates.

8.2.2 The Board of Directors

The Company's registered business address, Henrik Ibsens gate 90, 0255 Oslo, Norway, serves as business address for the members of the Board of Directors in relation to their directorship in the Company. The names and positions and current term of office of the Board Members, in addition to their number of Shares and options held in the Company, as at the date of this Registration Document are set out in the table below.

Name	Position	Served since	Term expires	Shares	Options
Terje Bakken ¹	Chairperson	13 June 2019	AGM 2021	-	-
Kathrine Gamborg Andreassen ²	Director	13 June 2019	AGM 2021	541,668 ³	125,000 ³
Kristin Nyberg	Director	13 June 2019	AGM 2021	-	-
Thomas Grünfeld	Director	1 October 2019	AGM 2021	-	-

1: Bakken represents the large shareholders, Ingerø Reiten Investment Company AS and Navamedic ASA, at the Board of Directors.

2: Gamborg Andreassen represents the large shareholder and material business contact, Navamedic ASA, at the Board of Directors.

3: The Shares owned by Gamborg Andreassen are owned through her privately held company, Soleglad Invest AS. Additionally, Gamborg Andreassen holds 125,000 options (Series B options).

8.2.3 Brief biographies of the Board Members

Set out below are brief biographies of the Board Members. The biographies include each Board Member's relevant management expertise and experience, an indication of any significant principal activities performed by them outside the Company and names of companies and partnerships of which a Board Member is or has been a member of the administrative management or supervisory bodies or partner in the previous five years (not including directorships and executive management positions in subsidiaries of the Company).

Terje Bakken, Chair

Terje Bakken, born in 1966, is a partner with the investment company Reiten & Co AS and has been chairman of the board of the Company since its incorporation. Mr. Bakken has been with Reiten & Co AS since 1998. Mr. Bakken has extensive experience as a board member in public listed and private companies, including Navamedic ASA, Webstep ASA, Questback Holding AS and Grilstad Holding AS. Mr. Bakken holds a Master of Science in Financial Economics and Bachelor of Business and Administration degrees from the Norwegian School of Management. Bakken is a Norwegian citizen and resides in Oslo, Norway.

Current directorships and senior management positions.....

Reiten & Co AS (board member), Navamedic ASA (chairman), Questback Holding AS (chairman) and Questback AS (chairman).

Previous directorships and senior management positions last five vears

Blueway AS (board member), Webstep ASA, Grilstad Holding AS (board member) and Grilstad AS (board member).

Kathrine Gamborg Andreassen, Board Member

Kathrine Gamborg Andreassen, born in 1966, has been CEO of Navamedic ASA since December 2018. Gamborg Andreassen is a seasoned and experienced executive who has held various management positions in Consumer Health and Fast-moving Consumer goods companies. Previously she held the position as CEO of the public listed company Weifa ASA, until the company was acquired by Karo Pharma AB in November 2017, and prior to that she was VP Consumer Health at Weifa AS. She has several years of experience as a consultant in strategy and marketing research. Gamborg Andreassen is also co-owner and chair of the board of directors of Novicus Pharma AS. Gamborg Andreassen studied Business Administration (BBA) at Handelsakademiet/ Oslo Business School and holds a MSc in Business Strategy & Marketing from the University of Wisconsin, Madison. Gamborg Andreassen is a Norwegian citizen and resides in Drøbak, Norway.

Current directorships and senior management positions Navamedic ASA (CEO), and Soleglad Invest AS (chairman). Previous directorships and senior management positions last five

years

Weifa ASA (CEO) and Weifa AS (VP Consumer Health), Novicus Pharma AS (chair), Vistin Pharma ASA (board member)

Kristin Nyberg, Board Member

Kristin Nyberg, born in 1966, has been Country Manager Nordic in Photocure ASA since January 2020. Before that she held the position as Country Director of Biogen Norway AS, a position she held for 12 years. Nyberg is an experienced pharma industry leader. She has held various roles in small, medium sized and big pharma companies for 26 years, such as sales representative in Leo Pharmaceutical AS, sales representative in MSD (Norge) AS, product manager in Roche Norge AS, AbbVie and product manager in Photocure ASA. She holds a MSc degree in Molecular Cell Biology from the University of Oslo and several internal leadership programs from the Pharma Industry at INSEAD, IESE and Henley. Nyberg is a Norwegian citizen and resides in Fjellhamar, Norway.

Current directorships and senior management positions..... N/A Previous directorships and senior management positions last five Biogen Norway AS (Country Director) years ..

Thomas Grünfeld, Board Member

Thomas Grünfeld, born 1964, recently comes from the position as CEO of Labrida AS, a dental medical device company with international sales a position he held since 2012. He has also managed major public projects implementing personalized medicine in Norway, and is at the Board of Faculty of health sciences, Oslo Metropolitan University. Grünfeld has wide experience in business development, technology and finance from the health care sector. He has served as engagement manager at McKinsey & Co, CEO of Interagon AS (a spin-off from FAST Search and Transfer), CEO of Sarsia Life Science management (A life Science VC fund), Investment manager at Kistefos AS, and various board positions in health care and consulting companies. By education, Grünfeld is a medical doctor (OBgy and surgery), and holds a master in health economics and administration. Grünfeld is a Norwegian citizen.

Current directorships and senior management positions	Grynt Holding AS (chairman), NIM Supplement AS (board member) and Med-Storm Innovation AS (Board member).
Previous directorships and senior management positions last five years	Labrida AS (CEO), Faculty of health sciences, Oslo Metropolian University (board member), Labrida AS (Head of finance and supply chain management),

8.3 Management

8.3.1 Overview of Management

The Group's Management consists of two individuals. The names of the members of Management and their respective positions, in addition to their holding of Shares and options in the Company, are presented in the table below. The Company's registered business address, Henrik Ibsens gate 90, Oslo, Norway, serves as business address for all members of Management in relation to their positions with the Company.

Name	Position	since	Shares	Options
Björn Larsson	Chief Executive Officer	16 December 2019	-	120,000
Per Arne Nygård	Chief Financial Officer	1 December 2019	-	-

8.3.2 Brief biographies of the members of Management

Set out below are brief biographies of the members of Management. The biographies include the members of Management's relevant management expertise and experience, an indication of any significant principal activities performed by them outside the Company and names of companies and partnerships of which a member of Management is or has been a member of the administrative, management or supervisory bodies or partner the previous five years (not including directorships and executive management positions in subsidiaries of the Company).

Björn Larsson, Chief Executive Officer

Björn Larson is an experienced marketing and business development professional, who has held various senior positions within medical technology (Dentsply (previously Astra Tech), Medtronic, Mentice), pharmaceuticals (AstraZeneca, Novo Nordisk) and biotechnology. He has comprehensive experience from commercialisation of life science start-ups, in both operational roles and in board positions. Prior to joining the Company, Björn Larsson holds the position as Director, Corporate Communications at ABIGO Medical, a Swedish pharmaceutical and medtech company. He is also Chairman of the Board at Alzinova, a Swedish biotech company listed on Nasdaq First North, Sweden, developing a vaccine for the treatment of Alzheimer's disease. Björn Larsson holds an MSc in Engineering from Chalmers University of Technology, Gothenburg, Sweden. Larsson resides in Västra Frölunda, Sweden.

Current directorships and senior management positions	Director, Corporate Communications at ABIGO Medical AB, chairman of the board in ALZINOVA AB and deputy chairman of IML (a trade organisation for Swedish SMEs within life science)
Previous directorships and senior management positions last five years	N/A

Per Arne Nygård, Chief Financial Officer

Per Arne Nygård has experience from finance functions in various industries. The last 12 years he has worked in listed companies as Veidekke and Multiconsult. Per Arne Nygård joined Navamedic as consultant in August 2019 and participated in the listing of Observe Medical in November 2019. Per Arne Nygård holds an bachelor degree in audit from Molde University College and resides in Oslo, Norway.

 Current directorships and senior management positions
 N/A

 Previous directorships and senior management positions last five years
 Group accounting manager at Multiconsult ASA

8.4 Remuneration and benefits

8.4.1 Remuneration of the Board of Directors

At the extraordinary general meeting of the Company held on 1 October 2019, the following remuneration was resolved to the members of the Board of Directors: The chairperson of the board of directors shall receive NOK 250,000 and all other board members shall receive NOK 175,000. No remuneration was paid to the members of the Board of Directors for the financial year 2019.

The members of the Board of Directors have not been awarded share options or any other form of incentive-based remuneration, in their sole role as members of the Board of Directors for the financial year 2019. Kathrine Gamborg Andreassen was granted 250,000 options in Navamedic in 2019 and as part of completion of the Demerger these options

were split and as a result, she received 250,000 options in the Company, 125,000 of which are not exercised as at the date of this Registration Document (see Section 10.4 "Share options").

8.4.2 Remuneration of Management

The table below sets out the remuneration paid to members of the Management for the financial year of 2019 (in NOK):

Name	Position	Salary	Bonuses	Benefits	Pension	Total
Björn Larsson	CEO	54,201	-	-	6,486	60,687
Per Arne Nygård	CFO	83,000	-	-	-	83,000
Total					-	143,687

8.4.3 Benefits upon termination

In the event the CEO's employment is terminated by the Company subject to prior notice, the CEO shall be entitled to severance pay equivalent to six times the monthly base salary which the CEO had at the expiry of the employment.

Other than this, no employee, including any member of Management, has entered into employment agreements which provide for any special benefits upon termination. None of the Board Members or the members of the nomination committee has a service contract and none will be entitled to any benefits upon termination of office.

8.4.4 Loans and guarantees

The Company has not granted any loans, guarantees or made any other similar commitments to any of its Board Members or members of Management.

8.4.5 Pension and retirement benefits

The Group has defined contribution pension schemes. The CEO has an occupational pension insurance scheme where the Company pays premium calculated as 4.5% of paid base salary up to the amount to 7.5 income basic amounts (one basic amount is SEK 64.400) and 30% of paid salary components (basic and variable salary) which exceed an amount equivalent to 7.5 income basic amounts. For 2019, the total amount accrued for pension was NOK 6,486 (see the table in Section 8.4.2 "Remuneration of Management" above).

8.5 Audit committee

The Board of Directors has established an audit committee comprising Thomas Grünfeld (chair), Kathrine Gamborg Andreassen and Terje Bakken. All three members have relevant qualifications within accounting/auditing and Thomas Grünfeld is independent of the Company.

The primary purpose of the audit committee is to act as a preparatory and advisory committee for the Board of Directors in monitoring the Group's internal control of the risk management and financial reporting. This includes but is not limited to:

- all critical accounting policies and practices;
- quality, integrity and control of the Group's financial statements and reports;
- compliance with legal and regulatory requirements;
- qualifications and independence of the external auditors; and
- performance of the internal audit function and external auditors.

The audit committee reports and makes recommendations to the Board of Directors, but the Board of Directors retains responsibility for implementing such recommendations.

8.6 Nomination committee

The Articles of Association provide for a nomination committee composed of two or three members. The current members of the nomination committee are Bernt Olav Røttingsnes (chair) and Grete Hogstad.

The nomination committee is responsible for nominating candidates for the election of shareholder-elected members and chairperson to the Board of Directors and for nominating members to the nomination committee, as well as making recommendations for remuneration of these.

8.7 Corporate governance

The Company has adopted and implemented a corporate governance regime which in all material respects complies with the Norwegian Code of Practice for Corporate Governance last updated 17 October 2018 (the **"Corporate Governance Code**"). The Company complies in all material respects with the Corporate Governance Code, except for that:

- (i) the composition of the Board of Directors does not comply with the requirement set out in section 8 of the Corporate Governance Code of having a majority of its members independent of the Company's material business associates, as the Board Members Terje Bakken and Kathrine Gamborg Andreassen are not considered independent of Navamedic (who is considered a material business associate of the Company because of the Loan Agreement and the TSA). The reason for the deviation was that the Loan Agreement and the TSA was entered after the Board Members were elected;
- (ii) the authorisations given by the Company's general meeting to the Board of Directors to increase the share capital of the Company (see Section 10.7 "Authorisation to increase the share capital and to issue Shares" for more information) and to acquire treasury shares (see Section 10.6 "Authorisations to acquire treasury shares" for more information) have been given for a period until the annual general meeting in 2021, which is not the next annual general meeting of the Company which is recommended in the Corporate Governance Code section 3. The reason for the deviation is because the authorisations were given at a time considered close to the next annual general meeting of the Company. Neither the Board of Directors nor the general meeting have adopted any resolutions which are deemed to have a material impact on the Group's corporate governance regime.

8.8 Conflict of interests etc.

No Board Member or member of Management has, or had, as applicable, during the last five years preceding the date of the Registration Document:

- any convictions in relation to fraudulent offences;
- received any official public incrimination and/or sanctions by any statutory or regulatory authorities (including designated professional bodies) or was disqualified by a court from acting as a member of the administrative, management or supervisory bodies of a company or from acting in the management or conduct of the affairs of any company; or
- been declared bankrupt or been associated with any bankruptcy, receivership or liquidation in his or her capacity as a founder, member of the administrative body or supervisory body, director or senior manager of a company.

Except for as stated in Section 8.2.1 above, there are currently no other actual or potential conflicts of interest between the Company and the private interests or other duties of any of the members of the Management and the Board of Directors, including any family relationships between such persons.

9 RELATED PARTY TRANSACTIONS

9.1.1 Introduction

This Section provides information about certain transactions which the Company is a party to with its related parties for the periods covered by the Financial Information and up until the date of this Registration Document. For the purpose of the following disclosures of related party transactions, "related party transactions" are those transactions that are set out as such in accordance with the Regulation (EC) No 1606/2002 of the European Parliament and of the Council.

Transactions and shared costs have historically been charged from the Navamedic group to the Group, and consequently recognised in the Financial Information. Navamedic AB has also provided group contributions to the Group, to utilize parts of the tax losses carried forward in the Group.

In addition to the Navamedic group, the Group's related parties are members of Management and the Board of Directors, and their close associates in accordance with the Norwegian Public Limited Companies Act Section 1-5. Besides the remuneration of the Board of Directors as further described in Section 8.4.1 "Remuneration of the Board of Directors", the remuneration of the Management as further described in Section 8.4.2 "Remuneration of Management" and the issue of options to the CEO as further described in Section 10.4 "Share options", the Group has not had any transactions with such persons for the period covered by the Financial Information.

The companies within the Group (which prior to the Demerger were owned by Navamedic) are also considered related parties, but transaction and balances are eliminated in the Financial Information, and are not disclosed in this Section.

9.1.2 Transactions and balances with the Navamedic group

Transactions and balances within the Group are eliminated in the Financial Information and are not disclosed therein. The Group had the following transactions and balances with the Navamedic group in the period covered by the Financial Information:

Amounts in TNOK		' period ended Iarch	Year ended 31 December		
	2020	2019	2019	2018	2017
Revenues	-	-	53	-	-
Expenses	205	252	2,141	935	1,047
Finance income	-	-	0	96	241
Finance expenses	538	-	1,154	416	315
Group contributions received	-	-	0	5,614	12,992
Receivables	-	-	66	-	1,716
Liabilities	29,353	28,750	25,777	26,792	23,661

Expenses are primarily related management fee (to cover costs and activities as finance and management support), rent of office space and expenses related to the Demerger and listing at Oslo Axess in 2019. Finance expense is interest on interest bearing loan towards Navamedic.

By completing the Debt Conversion (see Section 6.2.2 "The Demerger establishing the Group") and by entering into the Loan Agreement (see Section 7.9.1 "Loan Agreement"), the Group refinanced its previous liabilities towards the Navamedic group.

9.1.3 The Transitional Services Agreement

The Company entered into a transitional services agreement with Navamedic on 1 October 2019 (the **"TSA**"), which became effective on the completion date of the Demerger. The TSA provides for certain services being provided by Navamedic to the Company in a transitional period ending on 31 December 2020 on which date the services provided under the TSA shall automatically terminate. The Company has the right, at its sole discretion, to terminate any of the services delivered pursuant to the TSA, by giving one months' prior written notice to Navamedic.

As at the date of this Registration Document no services under the TSA are being delivered to the Company.

10 CORPORATE INFORMATION AND DESCRIPTION OF THE SHARE CAPITAL

The following is a summary of certain corporate information and material information relating to the Shares and share capital of the Company and certain other shareholder matters, including summaries of certain provisions of the Articles of Association and applicable Norwegian law in effect as of the date of this Registration Document. The summary does not purport to be complete and is qualified in its entirety by the Articles of Association and applicable law.

10.1 Company corporate information

The Company's legal and commercial name is Observe Medical ASA. The Company is a public limited company organised and existing under the laws of Norway pursuant to the Norwegian Public Limited Companies Act. The Company was incorporated on 13 June 2019 and has its registered office at Henrik Ibsens gate 90, Oslo, Norway. The Company's registration number in the Norwegian Register of Business Enterprises is 822 907 822 and its LEI code is 9845005F38B74FFJ1B65.

The Company's Shares are registered in book-entry form with the VPS under ISIN NO 0010865009. The Company's register of shareholders in the VPS is administrated by DNB Bank ASA with address at Dronning Eufemiasgate 30, 0191 Oslo, Norway (the "**VPS Registrar**").

The Group's website can be found at www.observemedical.com. The information on the website is not incorporated by reference to this Registration Document, nor does it in any other manner constitute a part of this Registration Document.

10.2 Legal structure

The Company is the parent of the Group, owning 100% of the shares in its subsidiary OMI, which is the owner of 100% of the shares in Observe Medical ApS which is the owner of 100% of the shares in Observe Medical AB.

Company	Domicile	Activity	Shareholder	Ownership interest
Observe Medical International AB	Sweden	Operating company	Observe Medical ASA	100%
Observe Medical ApS	Denmark	Operating company	Observe Medical International AB	100%
Observe Medical AB	Sweden	Operating company	Observe Medical Aps	100%

As at the date of this Registration Document, the Company is of the opinion that its holdings in all of its direct and indirect subsidiaries, as listed in the table above, are likely to have a significant effect on the assessment of the Company's own assets and liabilities, financial condition and profit or loss.

10.3 Share capital and share capital history

As at the date of this Registration Document, the Company's share capital is NOK 3,989,094.98 divided into 15,342,673 Shares, each with a par value of NOK 0.26. All the Shares have been created under the Norwegian Public Limited Companies Act, and are validly issued and fully paid up.

The Company has one class of shares. Neither the Company nor any of its direct or indirect subsidiaries own Shares in the Company.

The table below shows the development in the Company's share capital from its incorporation in June 2019 and up to the date of the Registration Document:

Date of registration	Type of change	Change in share capital (NOK)	New share capital (NOK)	Nominal value (NOK)	New number of total issued Shares	Subscription price per share (NOK)
17 June 2019	Incorporation	1,000,000	1,000,000.00	1.00	1,000,000	1.00
31 October 2019	Redemption of Shares	(1,000,000)	0.00	1.00	0	-
31 October 2019	Demerger	3,085,594.98	3,085,594.98	0.26	11,867,673	3. 92413
1 November 2019	Debt Conversion	832,000	3,917,594.98	0.26	15,067,673	5.00
28 February 2020	Exercise of share options	71,500	3,989,094.98	0.26	15,342,673	3.12

Other than the share capital increase of NOK 3,085,594.98 and the related issuance of 11,867,673 demerger consideration shares completed in connection with the Demerger and the Debt Conversion (see Section 6.2.2 "The Demerger establishing the Group" for more information), no share capital increases in the Company have been paid for with assets other than cash.

Other than the share options described below and the Conversion Right for Navamedic included in the Loan Agreement as approved by the extraordinary general meeting of the Company (see Section 7.9.1 "Loan Agreement" for more information), there are no share options or other right to subscribe for or acquire Shares in the Company.

10.4 Share options

Upon completion of the Demerger, the 467,500 share options issued under Navamedic's long-term incentive program (400,000 options, where 275,000 Series A options and 125,000 Series B options) and other employee share option programs (67,500 options) were "mirrored" and split so that these options were transferred to the Company, resulting in the Company having 467,500 share options issued upon completion of the Demerger. The terms and conditions applicable to the options in Navamedic were also applied for the Company, however so that the exercise price for the options issued in the Company was amended to 26% of the initial exercise price of the options in Navamedic to reflect the exchange ratio in the Demerger. Each option gives the holder the right to subscribe for one Share. The options were granted without consideration.

For the Series A options, all of the options vested in the third quarter of 2019 because Navamedic's share price exceeded a certain threshold for a period. On 21 January 2020, all 275,000 Series A options were exercised.

For the Series B options, 100% of the options vested on the day of grant. Initially, the date of expiration for the 125,000 Series B options was set to 31 March 2020. However, to adapt the COVID-19 situation, the Board of Directors decided to postpone the expiry date for these share options with six months, i.e. until 30 September 2020.

On 9 January 2020, the Company's CEO was granted 120,000 options in the Company as part of a long-term incentive plan. Half (60,000) of the options are Series A options that will vest with 1/3 every 12 months after the day of grant and shares issued upon exercise will be subject to a lock-up period of 12 months after exercise. Series A options that have not been exercised will lapse three and a half years after the date of grant. The other 60,000 options are Series B options which vested on the day of grant and the shares issued upon exercise will be subject to a lock-up period of 24 months after exercise. Series B options that have not been exercised will lapse three and a half years issued upon exercise will be subject to a lock-up period of 24 months after exercise. Series B options that have not been exercised will lapse on 1 January 2021. The options were granted without consideration and each option gives the right to acquire one share in the Company.

The table below sets out key information about the options the Company has in issue at the time of this Registration Document:

Number of options	Exercise price	Vested / Vesting date	Expiry date
67,500	NOK 2.444	Yes	6 June 2021
125,000 (Series B) ¹	NOK 3.12	Yes	30 September 2020
20,000 (Series A) ²	NOK 11.09	9 January 2021	9 July 2023
20,000 (Series A) ²	NOK 11.09	9 January 2022	9 July 2023
20,000 (Series A) ²	NOK 11.09	9 January 2023	9 July 2023
60,000 (Series B) ¹	NOK 11.09	Yes	1 January 2021

1: Shares issued upon exercise of the Series B options are subject to a 24 month's lock-up period.

2: Shares issued upon exercise of the Series A options are subject to a 12 month's lock-up period.

10.5 Major shareholders

Shareholders owning 5% or more of the Shares have an interest in the Company's share capital which is notifiable pursuant to the Norwegian Securities Trading Act. Pursuant to the Company's shareholders' register as at 11 June 2020, no shareholders other than Navamedic (3,200,000 Shares, approx. 20.86%), Ingerø Reiten Investment Company AS (2,916,667 Shares, approx. 19.01%), UBS Switzerland AG (1,420,522 Shares, approx. 9.26%) and Ro, Lars (1,300,010 Shares, approx. 8.47%) hold more than 5% of the Company's Shares.

There are no differences in voting rights between the shareholders.

To the extent known to the Company, there are no persons or entities that, directly or indirectly, jointly or severally, exercise or could exercise control over the Company. The Company is not aware of any arrangements the operation of which may at a subsequent date result in a change of control of the Company.

The Articles of Association do not contain any provisions that would have the effect of delaying, deferring or preventing a change of control of the Company. The Shares have not been subject to any public takeover bids during the current or last financial year.

10.6 Authorisations to acquire treasury shares

The Company's extraordinary general meeting held on 1 October 2019, granted the Board of Directors with an authorisation to purchase treasury shares for a maximum aggregate nominal value of NOK 391,750. The highest amount that can be paid per share is NOK 100 and the lowest amount that can be paid per shares is NOK 0.26. The authorisation to acquire treasury shares may be used, *inter alia*, as an instrument to optimize the Company's capital structure or as full or partial consideration in connection with acquisitions. The authorisation is valid until the Company's annual general meeting in 2021, but no longer than to and including 30 June 2021.

10.7 Authorisation to increase the share capital and to issue Shares

At the Company's extraordinary general meeting held on 24 October 2019, the Board of Directors was granted an authorisation to increase the share capital of the Company with up to NOK 200,000 in order to enable the Company to settle the options which were issued in connection with the completion of the Demerger and other options to be issued under the Company's long-term incentive program or otherwise. The authorisation may not be used in connection with share capital increases with share contributions in other assets than cash nor with share capital increases in connection with mergers. The authorisation is valid until the Company's annual general meeting in 2021, but no longer than to and including 30 June 2021. On 21 January 2020, in relation to the share option exercise, the Board of Directors made use of the authorisation to increase the share capital by NOK 71,500. Following the increase, the Board of Directors has NOK 128,500 remaining from the authorisation granted on 24 October 2019.

At the Company's extraordinary general meeting held on 1 October 2019, the Board of Directors was granted an authorisation to increase the Company's share capital with up to NOK 391,750 in order to give the Board of Directors financial flexibility in connection with financing further growth of the Group. The authorisation may be used in connection with share capital increases with share contributions in other assets than cash and in connection with mergers. The authorisation is valid until the Company's annual general meeting in 2021, but no longer than to and including 30 June 2021.

The preferential rights of existing shareholders to subscribe for new Shares pursuant to section 10-4 of the Norwegian Public Limited Companies Act may be deviated from with respect to the existing authorisations mentioned above.

10.8 Other financial instruments

Except for the share options described in Section 10.4 "Share options" and the Conversion Right included in the Loan Agreement as described in Section 7.9.1 "Loan Agreement", neither the Company nor any of its subsidiaries have issued any options, warrants, convertible loans, subordinated debt or other instruments or transferrable securities that would entitle a holder of any such instrument to subscribe for shares in the Company or its subsidiaries.

10.9 Shareholder rights

The Company has one class of shares in issue, and in accordance with the Norwegian Public Limited Companies Act, all shares in that class provide equal rights in the Company. Each of the Shares carries one vote.

10.10 The Articles of Association

Below is a summary of provisions of the Articles of Association as of 21 January 2020 valid at the date of this Registration Document.

10.10.1 Objective of the Company

Pursuant to section 3 of the Articles of Association, the objective of the Company is to develop, produce, market and sell medical technical equipment and related products, provide connected consulting services and invest in related business.

10.10.2 Registered office

Pursuant to section 2 of the Articles of Association, the Company's registered office is in the municipality of Oslo, Norway.

10.10.3 Share capital and par value

Pursuant to article 4 of the Articles of Association, the Company's share capital is NOK 3,989,094.98 divided into 15,342,673 Shares, each Share, each with a par value of NOK 0.26.

10.10.4 Board of Directors

Pursuant to article 5 of the Articles of Association, the Board of Directors shall consist of between three and seven members. The board of directors is elected for a term of two years, unless otherwise decided by the general meeting in connection with the election.

10.10.5 Signature rights

Pursuant to article 6 of the Articles of Association, the chairperson of the Board together with one board member jointly have the right to sign for and on behalf of the Company.

10.10.6 Restrictions on transfer of Shares

The Articles of Association do not provide for any restrictions on the transfer of Shares, or a right of first refusal upon transfer of the Shares, nor does any such restrictions follow by applicable Norwegian law. Share transfers are not subject to approval by the Board of Directors.

10.10.7 General meetings

Documents concerning matters to be considered by the Company's general meeting, including documents which by law shall be included in or attached to the notice of the general meeting, do not need to be sent to the shareholders if such documents have been made available on the Company's website. A shareholder may nevertheless request that documents which relate to matters to be considered by the general meeting are sent to him/her.

The annual general meeting shall consider the following matters:

- Approval of the annual accounts and the annual report.
- The proposal of the board regarding dividends or other distributions.
- Other matters, which pursuant to law or the Articles of Association shall be considered by the general meeting.

Shareholders may give cast their votes in writing, including through electronic communication, in a period prior to the general meeting. The Board of Directors may establish guidelines for such advance voting. It must be stated in the notice of the general meeting which guidelines have been set out.

The Board of Directors may resolve that shareholders who wants to participate at the general meeting have to notify to the Company about this by a deadline which shall not be less than three days prior to the general meeting.

10.11 Shareholders agreement

To the Company's knowledge, there are no shareholders' agreements related to the Shares

11 SELLING AND TRANSFER RESTRICTIONS

The Shares may, in certain jurisdictions, be subject to restrictions on transferability and resale and may not be transferred or resold except as permitted under applicable securities laws and regulations. Investors should be aware that they may be required to bear the financial risks of this investment for an indefinite period of time. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

Receipt of this Registration Document shall not constitute an offer for Shares and this Registration Document is for information only and should not be copied or redistributed. Accordingly, if an existing shareholder receives a copy of this Registration Document, the existing shareholders should not distribute or send the same, or transfer the Shares to any person or in or into any jurisdiction where to do so would or might contravene with local securities laws or regulations. If an existing shareholder forwards this Registration Document into any such territories (whether under a contractual or legal obligation or otherwise), the existing shareholder should direct the recipient's attention to the contents of this Section 11 "Selling and transfer restrictions".

The Shares may not be offered, sold, resold, transferred or delivered, directly or indirectly, in or into, any jurisdiction in which it would not be permissible to offer the Shares and this Registration Document shall not be accessed by any person in any jurisdiction in which it would not be permissible to offer the Shares.

Neither the Company nor its representatives, are making any representation to any purchaser of Shares regarding the legality of an investment in the Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser.

The information set out in this Section 11 "Selling and transfer restrictions" is intended as a general guide only. If you are in any doubt about any of the contents of these restrictions, or whether any of these restrictions apply to you, you should obtain independent professional advice without delay.

12 ADDITIONAL INFORMATION

12.1 Independent auditor

The Company's independent auditor is KPMG AS (KPMG), with company registration number 935 174 627, and registered business address Sørkedalsveien 6, 0369 Oslo, Norway. The partners of KPMG are members of The Norwegian Institute of Public Accountants (Nw.: Den Norske Revisorforening). KPMG has been the Company's auditor since the Company's incorporation in 2019.

The 2019 Financial Statements, incorporated by reference hereto, see Section 12.3 "Incorporated by reference, have been audited by KPMG, as stated in their report also incorporated by reference hereto. KPMG's report contains an additional paragraph describing a material uncertainty related to going concern, cf. Section 7.1 "Presentation of Financial Information" above.

The Carve-out Annual Financial Statements, incorporated by reference hereto, see Section 12.3 "Incorporated by reference, have been audited by KPMG, as stated in their report also incorporated by reference hereto. KPMG's report contains an emphasis of matter paragraph for the basis of preparation of the Carve-out Annual Financial Statements, cf. Section 7.1 "Presentation of Financial Information" above.

12.2 Documents available

Copies of the following documents will be available for inspection at the Company's offices at Henrik Ibsens gate 90, Oslo, Norway during normal business hours from Monday to Friday each week (except public holidays) and on the Company's website www.observemedical.com for a period of twelve months from the date of this Registration Document:

- the Company's certificate of incorporation and Articles of Association; and
- all reports, letters, and other documents, historical financial information, valuations and statements prepared by any expert at the Company's request any part of which is included or referred to in this Registration Document.

12.3 Incorporated by reference

The information incorporated by reference in this Registration Document should be read in connection with the cross reference table set out below. Except as provided in this Section 12.3, no information is incorporated by reference into this Registration Document.

Section in the Registration Document	Disclosure requirement	Reference document and link	Page of reference document
Section 3.3.1	Annex 1, item 18.1	Annual Report 2019: https://observemedical.com/wp- content/uploads/2020/04/Observe-Medical-ASA-Annual- Report-2019.pdf	Page 41 – 84 (Accounts and notes)
Section 3.3.1	Annex 1, item 18.1	Auditor's report 2019: https://observemedical.com/wp- content/uploads/2020/04/Observe-Medical-ASA-Annual- Report-2019.pdf	Page 103-108
Section 3.3.1	Annex 1, item 18.1	Carve-out Annual Financial Statements https://observemedical.com/wp- content/uploads/2020/05/Carve-out-financial- statements-full-year-2016-2018-Observe-Medical- Group.pdf	Page 2-34 (Accounts and notes)
Section 3.3.1	Annex 1, item 18.1	Auditor's report on Carve-out Annual Financial Statements <u>https://observemedical.com/wp-</u> <u>content/uploads/2020/05/Carve-out-financial-</u> <u>statements-full-year-2016-2018-Observe-Medical-</u> <u>Group.pdf</u>	Page 36 - 38
Section 3.3.1	Annex 1, item 18.2	Q1 Financial Presentation: https://mb.cision.com/Main/19175/3109187/1245967.p df	Page 9 – 14

13 DEFINITIONS AND GLOSSARY

In the Registration Document, the following defined terms have the following meanings:

APMs	Alternative performance measures.
Articles of Association	The Company's articles of association.
Board Members	The members of the Board of Directors.
BD	Becton, Dickinson and Company.
Board of Directors	The board of directors of the Company.
Carve-out Annual Financial Statements	Carve-out financial statements for the years ended 31 December 2016, 2017 and 2018, prepared for the Group from Navamedic's audited consolidated financial statements.
CAUTI	Catheter Associated Urinary Tract Infections.
CEO	Chief Executive Officer.
CFO	Chief Financial Officer.
Company	Observe Medical ASA, a public limited company incorporated under the laws of Norway with company registration number 822 907 822.
Contingent Consideration	The earn-out obligation (a contingent consideration) to the sellers of Observe Medical International AB related to Navamedic's acquisition of Observe Medical International AB in 2015, which was transferred to the Company as part of the Demerger.
Conversion Right	Navamedic's right, pursuant to the Loan Agreement, to, following the date falling 12 months after the completion date of the Demerger (i.e. on 31 October 2020), request that all, but not parts of, the loan outstanding is converted into shares in the Company.
Corporate Governance Code	The Norwegian Code of Practice for Corporate Governance.
Debt Conversion	The share capital increase in the Company resolved by the extraordinary general meeting of the Company on 1 October 2019, issuing 3,200,000 Shares to Navamedic at a subscription price of NOK 5.00 per share.
Demerger	The demerger completed on 31 October 2019 whereby all of Navamedic's shares in Observe
	Medical International AB were transferred to the Company together with a contingent consideration and a relevant portion of the share options issued in Navamedic.
DKK	Danish krone, the lawful currency of Denmark.
EEA	The European Economic Area.
ER	Emergency room.
EU	The European Union.
EU Prospectus Regulation	Regulation (EU) 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 Text with EEA relevance.
EUR	The lawful common currency of the EU member states who have adopted the Euro as their sole national currency.
ESMA	The European Securities and Markets Authority.
Facility A	A subordinated convertible term loan facility, part of the Loan Agreement, in the amount of NOK 19,000,000
Financial Information	The 2019 Financial Statements, the Q1 Financial Presentation and the Carve-out Annual Financial Statements, collectively.
General Meeting	The general meeting of the shareholders in the Company.
Group	The Company taken together with its consolidated subsidiaries.
HAI	Hospital Associated Infections.
IAS 34	International Accounting Standard 34 "Interim Financial Reporting" as adopted by the EU.
ICU(s)	Intensive Care Unit(s)
IFRS	International Financial Reporting Standards as adopted by the EU.
KPMG	KPMG AS.
LEI	Legal Entity Identifier.
Liquidity Facility	A subordinated convertible term loan facility, part of the Loan Agreement, in the maximum amount of NOK 13,000,000.
Listing	The listing of the Company's shares on Oslo Axess on 4 November 2019.
Loan Agreement	The subordinated convertible loan agreement entered into on 27 September 2019 between the Company (as the borrower) and Navamedic (as the lender) for a loan of an aggregate amount of NOK 32,000,000.
Management	The senior management team of the Company.

OBSERVE MEDICAL ASA - REGISTRATION DOCUMENT

N/A	Not applicable.
Navamedic	Navamedic ASA, a public limited company incorporated under the laws of Norway with company registration number 985 012 059.
Net interest bearing debt	Non-current and current interest bearing debt deducted cash deposits.
NOK	Norwegian Kroner, the lawful currency of Norway.
Norwegian Corporate Governance Code	Norwegian Code of Practice for Corporate Governance dated 17 October 2018.
Norwegian FSA	The Financial Supervisory Authority of Norway (Nw.: Finanstilsynet).
Norwegian Public Limited	
Companies Act	The Norwegian Public Limited Companies Act of 13 June 1997 no. 45 (Nw.: allmennaksjeloven).
Norwegian Securities Trading Act.	The Norwegian Securities Trading Act of 29 June 2007 no. 75 (Nw.: verdipapirhandelloven).
Observe Medical	The Company together with its consolidated subsidiaries, or the Group.
OEM	Original Manufacturer Equipment
ОМІ	Observe Medical International AB, a subsidiary of OMASA.
Operating result	Result before net financial items and income tax expenses/income.
Oslo Axess	Oslo Axess, a Norwegian stock exchange operated by Oslo Børs.
Oslo Stock Exchange	Oslo Børs ASA, or, as the context may require, Oslo Børs, a Norwegian regulated stock exchange operated by Oslo Børs ASA.
PDMS	Patient data management systems.
Q1 Financial Presentation	The Company's unaudited consolidated interim financial presentation as of and for the three month period ended 31 March 2020 including comparative interim financial information for the same period in the prior financial year.
R&D	Research and development.
Registration Document	This Registration Document dated 18 June 2020.
RoW	Rest of the World.
SEC	U.S. Securities and Exchange Commission.
SEK	Swedish Kroner, the lawful currency of Sweden.
Share(s)	Means the shares of the Company, each with a nominal value of NOK0.26, or any one of them.
SPA	The share purchase agreement entered into between Navamedic (as the buyer) and the sellers of OMI on 3 August 2015 for the acquisition of the shares in OMI.
TSA	The transitional services agreement the Company entered into with Navamedic.
UK or United Kingdom	The United Kingdom.
U.S. or United States	The United States of America.
USD	United States Dollars, the lawful currency of the United States of America.
UTI	Urinary Tract Infection.
VPS	The Norwegian Central Securities Depository (Nw.: Verdipapirsentralen).
VPS Registrar	DNB Bank ASA.
2019 Financial Statements	The Company's audited consolidated financial statements as of and for the year ended 31 December 2019.

REGISTERED OFFICE AND ADVISORS



Observe Medical ASA Henrik Ibsens gate 90 0255 Oslo Norway

Legal Advisor to the Company Advokatfirmaet Thommessen AS Haakon VIIs gate 10 N-0161 Oslo Norway