

PMD Device Solutions AB



## **Company Description**

**prepared in connection with the change of name and business for Promore Pharma AB (publ) (under change of name to PMD Device Solutions AB) due to the acquisition of PMD Device Solutions AB and the continued listing on Nasdaq First North Growth Market Sweden.**

### **Nasdaq First North Growth Market Disclaimer**

Nasdaq First North Growth Market is a registered SME growth market, in accordance with the Directive on Markets in Financial Instruments (EU 2014/65) as implemented in the national legislation of Denmark, Finland, Iceland and Sweden, operated by an exchange within the Nasdaq group. Issuers on Nasdaq First North Growth Market are not subject to all the same rules as issuers on a regulated main market, as defined in EU legislation (as implemented in national law). Instead, they are subject to a less extensive set of rules and regulations adjusted to small growth companies. The risk in investing in an issuer on Nasdaq First North Growth Market may therefore be higher than investing in an issuer on the main market. All issuers with Shares admitted to trading on Nasdaq First North Growth Market have a Certified Adviser who monitors that the rules are followed. The respective Nasdaq exchange approves the application for admission to trading.

## IMPORTANT INFORMATION

### General

This Company Description does not constitute a prospectus and has therefore not been prepared in accordance with Regulation (EU) 2017/1129 of the European Parliament and of the Council (the "Prospectus Regulation") and has not been reviewed, registered or approved by the Swedish Financial Supervisory Authority. The Company Description has only been prepared in connection with the application for continued listing of the Company's shares on Nasdaq First North Growth Market and does not contain any offer to the public to subscribe for or otherwise acquire shares or other financial instruments in the Company, either in Sweden or in any other jurisdiction. The Company Description, or other material related to the Company Description, may not be distributed or published in any jurisdiction other than in accordance with applicable laws and regulations. The recipient of the Company Description is obliged to inform itself of and comply with these restrictions and may not publish or distribute the Company Description in violation of applicable laws and regulations. Actions in violation of these restrictions may constitute a breach of applicable securities legislation. Disputes arising from the content of the Company Description and related legal relationships shall be settled exclusively by Swedish courts. Swedish substantive law is exclusively applicable to this Company Description and related documents. This Company Description and the documents incorporated by reference are available in electronic form on the companies' websites, [www.promorepharma.com](http://www.promorepharma.com) and [www.pmd-solutions.com](http://www.pmd-solutions.com). The Company Description has been reviewed by Nasdaq Stockholm AB.

### Some definitions

In this Company Description, the following definitions apply unless otherwise stated. "PMD", the "Company" or the "Group" means, unless otherwise stated in the context, PMD Device Solutions AB with corporate registration number 556639-6809 (under name change from Promore Pharma AB after acquisition of PMD Device Solutions AB with corporate registration number 559305-4173), and, where applicable, the group of companies in which PMD Device Solutions AB is the parent company. "Promore" means Promore Pharma AB with corporate registration number 556639-6809 (before acquisition and name change to PMD Device Solutions AB). "Company Description" means this Company Description prepared in connection with the reverse acquisition between Promore and PMD and PMD's continued listing on Nasdaq First North Growth Market. "Certified Adviser" means Redeye AB, corporate identity number 556581-2954. "Eversheds Sutherland" means Eversheds Sutherland Advokat- byrå AB, corporate identity number 556878-2774. "Redeye" means Redeye AB, corporate identity number 556581-2954. "Fóla Partners" means Fóla Private Partners Limited incorporated in Ireland with registered number 532300. "Liquidator" means Lars-Henrik Andersson, attorney-at-law, Cirio Advokatbyrå AB. "First North" means Nasdaq First North Growth Market. "Euroclear" means Euroclear Sweden AB, corporate identity number 556112-8074.

### Forward-looking information

The Company Description contains certain forward-looking information that reflects PMD's current view of future events based on current conditions at the time of publication of the Company Description. Words such as "intended", "estimated", "expected", "may", "believe", "estimate" and "plan" and other expressions used to indicate that the information is to be considered as estimates and projections. Forward-looking information is always associated with both known and unknown uncertainties as it relates to and depends on events and circumstances beyond the Company's control. Therefore, no guarantee is given, either explicitly or implicitly, that the judgements made in the Company Description regarding forward-looking information are correct.

### Industry and market information

The company description contains industry and market information relating to the business of PMD and the market in which PMD operates. Unless otherwise stated, such information is based on the Company's analysis of multiple sources. Industry publications or reports generally state that information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information cannot be guaranteed. None of PMD, Redeye, Fóla Partners, or Eversheds Sutherland has verified the information, and therefore cannot guarantee the accuracy, of the industry and market information reproduced in the Company Description which has been taken from or derived from industry publications or reports. Such information is based on market research, which by its nature is based on sampling and subjective judgements, including judgements as to the type of products and transactions that should be included in the relevant market, both by those conducting the research and those surveyed.

The Company Description also contains estimates of market data and information derived therefrom that cannot be obtained from publications of market research institutions or any other independent sources. Such information has been prepared by the Company based on third party sources and the Company's own internal estimates. In many cases, there is no publicly available information and market data from, for example, industry associations, government agencies or other organisations or institutions. PMD believes that its estimates of market data and information derived therefrom are useful in providing investors with a better understanding of both the industry in which the Company operates and the Company's position within the industry. The third-party information has been accurately reproduced and, so far as PMD is aware and can ascertain from such information, no facts have been omitted which would render the reproduced information inaccurate or misleading.

### Certified Adviser

The Company has engaged Redeye AB as Certified Adviser to the Company. Redeye does not own any shares in the Company.

### Liquidity provider

The Company's liquidity provider is Erik Penser Bank AB.

### Presentation of financial information

PMD Device Solutions AB's audited annual accounts for the period 1 April 2022 - 31 March 2023 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as they have been adopted by the EU, the Swedish Annual Accounts Act (ÅRL) and the Swedish Financial Reporting Council. The annual report is incorporated by reference and forms part of the Company Description. Unless otherwise expressly stated, no financial information in the Company Description has been audited or reviewed by the Company's auditor. Financial information in the Company Description relating to the Company that is not included in the audited information or reviewed by the Company's auditor is derived from the Company's internal accounting and reporting system. Certain financial and other information presented in the Company Description has been rounded to make the information more accessible to the reader. Consequently, the figures in certain columns do not correspond exactly to the total amount stated. All financial amounts are stated in Swedish kronor ("SEK"), unless otherwise stated. The term "KSEK" stands for thousand Swedish kronor and "MSEK" stands for million Swedish kronor.

### Advisors

Redeye AB is the Company's Certified Adviser in connection with the continued listing process on First North and Eversheds Sutherland is acting as legal Adviser in connection with the Transaction and has assisted the Company in preparing the Company Description. Fóla Partners is acting as transaction adviser to PMD. Redeye is also acting as financial adviser in relation to a private placement as part of the Transaction. As all information in the Company Description regarding PMD originates from the Company, Redeye, Eversheds Sutherland, Fóla Partners disclaim all liability in relation to existing or future shareholders in PMD and regarding other direct or indirect financial consequences because of investment or other decisions based wholly or partly on information in the Company Description.

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### Important dates / Financial calendar

Event	Date
Interim report Jan-Dec 2023	29 February 2024
Annual Report 2023	26 April 2024
Interim Report Jan-March 2024	28 May 2024
Annual General Meeting	29 May 2024
Interim Report Jan-June 2024	22 August 2024
Interim Report Jan-Sept 2024	22 November 2024
Interim Report Jan-Dec 2024	26 February 2025

## DESCRIPTION OF THE TRANSACTION

### Description and rationale of the Transaction

On 29 November 2023, Promore Pharma AB (reg. no. 556639-6809) ("Promore") announced the proposed acquisition of all the shares in PMD Device Solutions AB (reg. no. 559305-4173) ("PMD") by making a payment to the shareholders of PMD Device Solutions AB in the form of newly issued shares in Promore (the "Transaction"). The Transaction constitutes a so-called reverse acquisition and is conditional on approval by Promore shareholders at an extraordinary general meeting to be held on 29 December 2023.

Since spring 2023, Promore has faced a very challenging market situation with a low market value in relation to the company's need for new investments. The company received the final results of the PHSU05 clinical trial, which showed that the treatment effect of Ensereptide was insufficient to justify further investments and the board subsequently decided to discontinue this development project. This resulted in Promore's market value being greatly reduced. Furthermore, the financial markets have been unstable. In general, it has created a difficult climate for Promore to carry out public share issues, which would be needed to finance the continued development of Promore's main asset, the drug candidate Ropocamptide. Following a decision at an extraordinary general meeting held on 5 October 2023, Promore entered into voluntary liquidation with effect from 12 October 2023. In light of the proposed Transaction, the basis for the voluntary liquidation will no longer exist. Against this background, it will be proposed that the extraordinary general meeting in Promore to decide on the Transaction will also decide to terminate the voluntary liquidation process.

PMD seeks to continue increasing its market share in the United Kingdom, with Germany and the United States to follow with initial market access activities. The board of PMD believes that a listing on First North will provide a quality stamp that contributes to confidence in discussions with potential customers and partners and an increased interest in PMD from the public, investors and other stakeholders. The Transaction will also enhance the conditions for creating shareholder value and gives PMD access to the capital market. The access to the stock market will also facilitate the implementation of the PMD's growth plans and ambition to expand the business into new markets globally.

As part of the Transaction, Promore will undergo a name change to PMD Device Solutions AB and will continue to operate PMD's business. Changes will also be made to the board of directors and senior executives. To achieve an appropriate number of shares, it will be proposed for Promore to undertake a reverse share split of 1:128.

Promore's current operations will be discontinued following the Transaction. The background for this is that (i) the runway of the remaining patent family is limited; (ii) the competitive challenge has increased in recent years; and (iii) the prior management, board and liquidator have exhausted all opportunities to monetize the remaining assets.

The Transaction is proposed to be carried out as an issue of 2,574,461,929 new shares in Promore directed to the shareholders of PMD as payment by way of non-cash contribution of all shares in PMD. The subscription price in the share issue corresponds to a valuation of PMD of approximately MSEK 153.5, which is the post-money valuation after the completion of the Private Placement in PMD. For more information on the private placement, please see "Private Placement" below.

Once the Transaction has been completed on 29 December 2023 and PMD Device Solutions AB is a wholly owned subsidiary of Promore, PMD Device Solutions AB would be dissolved by way of an upstream merger into Promore (then under change of name to PMD Device Solutions AB) to reduce the number of Swedish holding companies in the new group from two to one.

The current shareholders with an ownership of 5 per cent or more and the number of shares to be transferred in connection with the Transaction are presented below.

Shareholders	No. of shares to be transferred	Capital and votes
Myles Murray	9,050,716	40 %
Anne Dorney	2,169,982	9 %
John O'Sullivan	1,423,500	6 %

## Extraordinary General Meeting

Promore's acquisition of PMD is subject to approval by an extraordinary general meeting of Promore. Coespring New Technology AB, which is a current shareholder of Promore holding more than 10 per cent of the share capital (the "Requisitioner"), has requisitioned an extraordinary general meeting to be held on 29 December 2023 to approve the Transaction and all other matters required to complete the Transaction. This includes resolutions on termination of voluntary liquidation; issue of shares to shareholders in PMD with payment in kind (consisting of PMD shares); change of company name and articles of association; new board of directors; and reverse share split.

The Company has received binding commitments from the two largest shareholders in the Company with a combined share of the votes of 49.7 per cent to vote in favour of the Transaction and other matters proposed by the Requisitioner to complete the Transaction.

## Ownership structure

The proposed Transaction constitutes a reverse acquisition whereby payment for all shares in PMD will be made through a non-cash issue of new shares in Promore to the sellers of PMD. Following the Transaction, the current shareholders of PMD, taking into account the Private Placement, will hold approximately 97.7 per cent of the shares and votes in the Company and the current shareholders of the Company will hold approximately 2.3 per cent of the shares and votes of the Company. The Transaction entails an increase in the amount of shares in the Company from 60,713,936 to 2,635,175,865 and an increase in the Company's share capital from SEK 2,428,557.44 to SEK 105,407,034.60. Following the proposed reverse split of shares, the number of shares will be 20,587,314.

The ownership structure following the Transaction is presented in the table below.

Shareholders in the Company following the Transaction and the reverse split	Shares	Capital and votes
Myles Murray	8,081,910	39 %
Anne Dorney	1,937,703	9 %
John O'Sullivan	1,271,126	6 %
Other	9,296,575	45 %
<b>Total</b>	<b>20,587,314</b>	<b>100 %</b>

## Exemption from mandatory bidding

Myles Murray, the majority shareholder in PMD, will through the Transaction receive a shareholding in Promore corresponding to approximately 39 per cent of the votes for the total number of shares in Promore after the Transaction. Myles Murray has applied for and received a conditional exemption (AMN 2023:58) from the obligation to make a public takeover offer for all shares in Promore that he would otherwise be subject to under the Swedish Corporate Governance Board's takeover rules for certain trading platforms. The exemption is conditional upon the Transaction being approved by a general meeting of Promore with a two-thirds majority.

## Changes in the board of directors and management

As part of the Transaction, changes will be made to the board of directors and management of the Company. For information on the members proposed for election at the extraordinary general meeting on 29 December 2023 and the persons who will be appointed as senior executives in connection with the Transaction, see section "Board of directors, management and auditor".

## Name change

Following the Extraordinary General Meeting on 29 December 2023, it is proposed to change the name of the Company from Promore Pharma AB to PMD Device Solutions AB.

## Private Placement

For securing working capital to grow market share in the United Kingdom and to undertake market access activities in Germany and the United States, PMD has raised capital of approximately MSEK 26.5 through an issue of shares in PMD to certain existing shareholders and new investors in connection with the Transaction (the "Private Placement"). The investors include PMD's board member Christer Ahlberg (former CEO of Sedana Medical). PMD has engaged Redeye as financial adviser for the capital raise.

In addition to what is needed to cover the Company's working capital for the next 12 months and due to end-of-year time constraints, it will be proposed for the Extraordinary General Meeting on 29 December 2023 to resolve on a specific issue authorisation. The specific authorisation will be aimed at enabling the new board of directors of Company to carry out an additional capital raise, on the corresponding terms to the Private Placement up to an amount not exceeding MSEK 11.5 in order to accommodate further interest in participation in the Private Placement.

## RISK FACTORS

Before making an investment decision, it is important to carefully analyse the risk factors that may be relevant to an investment in PMD. This section describes the risk factors and important circumstances that are considered material to PMD's operations and future development. The assessment of the materiality of each risk factor is based on the probability of its occurrence and the expected magnitude of its adverse effects to convey clearly and concretely the assessment of risk realisation, the risk factors are described using a qualitative scale labelled low, medium and high. The risk factors listed below are limited to those risks that are specific to PMD and its shares and that are material to making an informed investment decision and do not claim to be comprehensive. The description below is based on information available as of the date of this Company Description. The risk factors currently considered most material are presented first in each category, while risk factors are presented in no particular order.

### Risks related to the Company's industry and its operations

#### Risks related to the ability to manage growth, launch in new markets, and market acceptance

PMD develops and sells medical products for respiratory monitoring. PMD's primary product is RespiraSense™, a solution used for monitoring respiratory rate to detect deterioration of a patient's general condition early and to avoid preventable respiratory failure and adverse patient outcomes. The Company is in a strong phase of growth and expansion and the Company may grow substantially, which may place demands on the Company's management, operational organisation and financial strength. As the Company's staff and operations grow, the Company needs to continuously adopt effective planning and management processes to implement its business plan effectively in an evolving market.

Today, RespiraSense™ is used in most of the major hospitals in Ireland. The use of RespiraSense™ varies between the hospitals, however, and none of the hospitals uses the system in all wards where it is relevant to monitor the respiratory rate. Overall, PMD sees good potential for continued growth in the Irish market and for the use of RespiraSense™ to monitor discharged patients in hospital-at-home care. The next market for PMD to expand in is the UK, and the Company further intends to launch its device in Germany and the US as well as other selected markets outside of the EU. In the EU, PMD will focus on markets considered to be digitally mature, that have adopted reimbursement systems for patient monitoring and that have clear national guidelines for respiratory monitoring. A launch in new markets will place demands on the Company's management, operational and financial capabilities. In addition, a successful launch in a new market will be dependent on the Company receiving a desired level of market acceptance from doctors, hospitals, patients, healthcare purchasers and the industry in general.

Furthermore, the Company intends to adopt a partner-oriented approach when entering the US market and other markets outside the EU. Such a strategy brings risks related to difficulties in developing partnerships on terms favourable to the Company or that some new partnerships may not develop as expected.

Should the Company encounter difficulties in managing the planned growth or the Company is unsuccessful in gaining the necessary market acceptance for the Company's products, there is a risk that this would result in delays in the planned expansion of the Company's business. This may lead to a loss of revenue and increased costs, which may have a significant adverse effect on the Company's operations, financial position and earnings.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, if materialised, would have a high impact on the Company.

#### Risks related to macroeconomic factors and political decisions relating to pricing and demand for medical devices

As PMD intends to market and sell its product in several parts of the world, the Company may be affected by general demand and the pricing of products for respiratory monitoring in relevant markets. Negative developments in financial markets economic and political economic downturn, or weak economic developments can lead to strains on the medical device market. This, in turn, may lead to increased pressure on hospitals,

governments and other purchasers of healthcare products to cut costs and potentially reduce willingness to pay for such products in general, including PMD's product. Such developments may be difficult for the Company to predict. If the risks described above become reality, they could have a significant adverse effect on the Company's operations, financial position and earnings.

PMD assesses the probability of the risk occurring as low. The Company estimates that the risk, if materialised, would have a high impact on the Company.

### Risks related to competition

PMD develops and sells medical products for respiratory monitoring. PMD's primary product is RespiraSense™, which, to the Company's knowledge, is the world's only continuous, motion-tolerant respiratory rate monitor delivering class-leading reliability in measuring respiratory rate. The medical device industry, however, is highly competitive and characterised by global competition, rapid technological development and substantial investments. The market for respiratory monitoring products is an emerging market with a competitive landscape. PMD is and will in the future be challenged by competition from, among others, technology and medical device companies, with significant financial resources, new entrepreneurs with innovative fast-growing businesses, and other companies active in the healthcare sector, where some of the competitors have larger financial resources and capacity to compete. The three main competitors that offer solutions focused on providing respiratory rate monitoring are Philips Respironics, Masimo and EarlySense. If competitors develop a similar product or other alternative technologies that prove to be equally successful as or even more successful than PMD's product, this could have significant adverse effect on the Company's ability to maintain and increase its market share and impact the Company's potential to grow revenue, improve its profitability, financial position of its business and prospects.

PMD assesses the probability of the risk occurring as low. The Company estimates that the risk, if materialised, would have a medium impact on the Company.

### Risks related to dependence on key individuals and qualified personnel

As of 30 September 2023, the Company had 25 employees, of which 19 were based in Ireland, 2 in the UK and 4 in Poland in the Company's engineering and development department. PMD is a relatively small organisation, and its future growth depends on the knowledge, experience and commitment of its management and other key people. There is a risk that the Company fails to retain these individuals' expertise and knowledge and fails to recruit additional qualified and talented employees on competitive terms to support its growth and sell its products in the future. Such a risk could have a significant negative impact on the Company's ability to develop and expand its business as planned, which would affect the Company's operations.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, if materialised, would have a medium impact on the Company.

### Risks related to suppliers and manufacturing

The Company uses subcontractors to produce its products. Production of RespiraSense™ lobes will be moved to the contract manufacturer Sanmina's facility in Örnsköldsvik, Sweden, which specialises in the production of advanced medical technology products, in the near term. Sensor patches are manufactured by a contract manufacturer of electronic components in China. PMD is currently and will continue to be dependent on subcontractors to produce the Company's products. Over time, the majority of PMD's revenue will come from the sale of sensor patches. Efficient and large-scale manufacturing is crucial for the Company's profitability potential.

There is a risk that one or more of the Company's suppliers and/or supply chain may not be able to continue the contractual relationship with the Company or that they may not be willing to continue the contractual relationship on competitive terms. Furthermore, there is a risk that the Company's suppliers will not meet the quality requirements set by the Company, by the FDA, EMA and relevant regulatory authorities. If PMD is required to replace such supplier in a timely and cost-effective manner, there is a risk that this would impact the supply chain and the Company's operations, costs and financial position. Additionally, there is a risk of global



shortage of supply of chips or other materials and components for manufacturing of the Company's technology. A general shortage of components may lead to the Company's product not being manufactured as planned resulting in the associated deliveries being delayed, or the orders may have to be cancelled. It may also require the Company to turn to alternative suppliers, which could result in significant costs, delays and transition issues.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, if materialised, would have a high impact on the Company.

## Legal and regulatory risks

### Risks related to the regulatory environment for medical devices

PMD develops and sells medical technology products for respiratory monitoring. The Company's primary product RespiraSense™ is a medical technology product for continuous respiratory rate monitoring that is subject to regulation worldwide and is monitored by various industry-specific government authorities. In any new national or regional market, the Company must maintain or obtain market approval or similar authorisations from the relevant authorities in the countries where the company markets and sells its product or intends to market and sell its products.

Within the EU for example, RespiraSense™ is, currently, CE marked as a Class IIb medical device. For class II and III medical devices to be marketed within the EU, a 'notified body' must first issue a certificate confirming that specified regulatory requirements have been met. Under the provisions of the Medical Devices Directive ('MDD'), the Company's current medical devices certificate is valid until 14 November 2026.

In January 2023, the EU parliament voted in favour of extending the deadlines of the MDR (EU) 2017/745 transition. This decision was mainly taken to avoid any medical device shortage on the European Market.

The approved text granted an automatic extension of the MDD certificate validity until 31 December 2027 for Class III & Class IIb implantable devices and 31 December 2028 for other devices. The following conditions, however, must be met:

- (i) devices continue to comply with the MDD;
- (ii) there are no significant changes in design and intended purpose;
- (iii) the devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, nor to other aspects of the protection of public health;
- (iv) manufacturers must have a quality management system compliant with MDR (EU) 2017/745 article 10(9) before 26 May 2024; and
- (v) manufacturers or their authorized representatives has lodged a formal application with a notified body before 26 May 2024 and a signed contract covering devices for transition before 26 September 2024 for the devices covered within the MDD certificate.

After that, the Company's certificate will need to be renewed in accordance with the new European Regulation for medical products ('MDR'). Because decisions taken by notified bodies are valid for a limited time, certificates must be renewed periodically and such renewal processes can be arduous.

PMD has also achieved regulatory approval in the United States through the FDA.

The costs of compliance with applicable legislation for market access on the Company's existing and future markets can be high. In addition, the regulatory environment in general has become more stringent and extensive over time. Failure to comply with regulatory requirements or failure to obtain market approval as planned could result in sanctions that could significantly increase the Company's costs, lead to delays in the development and commercialisation of the Company's product and materially impair its ability to generate planned revenues and achieve profitability. If these risks materialise, they could have a significant adverse effect on the Company's business and financial position.

PMD assesses the probability of the risk occurring as low. The Company estimates that the risk, if materialised, would have a high impact on the Company.

### **Risks associated with laws and regulations on data protection**

PMD collects significant amounts of anonymised data from patients with respiratory illnesses. The Company's processing of personal data is subject to regulations on data protection and data confidentiality, including Regulation (EU) 2016/679 of the European Parliament and of the Council ("GDPR"). GDPR affects, among other things, how the Company must manage, control and document the processing of the data. The Company also holds personal data on employees. The Company risks misinterpreting and thus misapplying laws and regulations, which involves a risk of extensive penalties in the event of non-compliance. Such a penalty may amount to the higher of four per cent of the Company's global annual turnover or EUR 20 million. Compliance with the GDPR regime requires resources that could otherwise be spent on the business. There is also a risk that one or more of the systems used by the Company may prove to be flawed and that hackers may break in, or that untrustworthy employees may misuse information. This can result in resource-intensive processes that take the focus away from operational matters and thus negatively impact the Company's business, which in turn can lead to a deterioration in its results and financial position and its reputational impact.

To mitigate risk PMD has secured its ISO 27001 certification, which covers data information security and is an important certification for medical device companies handling patient data.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, if materialised, would have a medium impact on the Company.

### **Risks related to the Company's ability to maintain and protect its intellectual property rights**

PMD has eight registered patents, including two in the US, two in China, two in Hong Kong, one in the EU and one in Japan with three divisional patents pending. PMD assesses that the patents are vital in assuring the protection of RespiraSense™. Therefore, patents and other intellectual property rights are key assets in PMD's business and any future successes are largely dependent on the Company's ability to maintain existing intellectual property rights. The Company also needs to obtain protection for filed and future patent applications. There is also a risk that the Company may be forced to defend its intellectual property rights in the form of patents and trademark protection against a potential competitor or that the Company may be inadvertently deemed to infringe another party's patents and/or other intellectual property rights. Infringement litigation of this type, like litigation generally, can be costly and time-consuming and, even if the outcome of such litigation is favourable to the Company, can have a material adverse effect on the Company's operations, financial position and earnings.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, if materialised, would have a medium impact on the Company.

### **Risks related to the Company's financing**

#### **Future financing**

The volume of resources required to implement PMD's business plan including the product development, expansion into new markets, and other investments depends on several factors that are unknown at present. Investments in product development or the roll out in new markets may be more costly and take longer time than anticipated. If the Company cannot obtain acceptable financing, it may limit the Company's ability to maintain its position in the market. PMD may also be forced to seek additional financing to continue with its operations. Such financing can be sought through external investors or existing shareholders and take place through public or private financing initiatives. There is a risk that new capital cannot be obtained when needed or, on acceptable terms, or that the capital obtained is not sufficient to finance operations according to established business planning and established objectives. If the risks associated with obtaining sufficient revenue or sufficient financing to maintain the Company's operations become reality, it could have a significant adverse effect on its operations and on the Company's ability to finance its growth plans.

PMD assesses the probability of the risk occurring as medium. The Company estimates that the risk, materialised, would have a high impact on the Company.

### Currency risk

The Company operates in various countries and will in the future report the financial statements and earnings, in their consolidated accounts, in SEK. The majority of PMD's costs and revenues are or will be in currencies such as EUR, USD and GBP. There is a risk that the Company may not be able to effectively manage its currency transactions and translation risks as desired, thus currency risks exist in the form of translation exposure. Such exposure and risk could have a negative effect on the Company's earnings and financial position.

PMD assesses the probability of the risk occurring as low. The Company estimates that the risk, if materialised, would have a medium impact on the Company.

## Risks relating to the securities

### Risks relating to dilution through future issues of new shares

PMD is in an expansion phase and the Company may, therefore, need to raise additional capital from existing shareholders and/or from new investors to finance its growth plans and/or accelerate or facilitate product development. If share issues are directed towards new investors other than existing shareholders, the shareholders' proportionate ownership and voting power in the Company, as well as earnings per share, is reduced. If issues of new shares are carried out at a low subscription price, for example because of unfavourable market conditions, or amount to large sums, the dilution for existing shareholders may be significant. Issues of new shares may also be carried out at a discounted price compared to the market price of the Company's shares, which may have a negative effect on the development of the share price.

### Risk of an illiquid market and price volatility

The share prices of publicly traded companies, including those listed on First North, can be highly volatile. Therefore, it is difficult to predict the amount of trading or the interest that may be shown in the shares. The price at which the Company's shares will be traded and the price which investors may realise for their shares will be influenced by many factors, some of which are specific to the Company and its business, while others are general for publicly traded companies and outside the Company's control. Prospective investors should be aware that the value of an investment in the Company and any income derived from it may go down as well as up. An investment in the Company's shares should therefore be preceded by a careful analysis of the Company, its competitors, general information about the industry, the general economic situation and other relevant information. The continued listing of the Company's shares on First North should not be interpreted as meaning that there will be a liquid market for the shares. There is a risk that the price of the shares will be highly volatile following the Transaction. If active and liquid trading does not develop or does not prove sustainable, this could make it difficult for shareholders to sell their shares and the market price could differ considerably from the price of the shares in the fundraising. Realisation of this risk would have a significant adverse effect on the share price for the Company's shares.

### Risks related to the Transaction

With the reverse acquisition there is some uncertainty for PMD as it does not know the full history of Promore. There is a risk that there is history, including potential liabilities, in the organisation that has not been revealed during the acquisition legal review. Although the shareholders of Promore have undertaken to vote in favour of the Transaction at the extraordinary general meeting of Promore, there is a risk that the Transaction will not be completed due to the required majority not voting in favour of the relevant resolutions at the extraordinary general meeting.

The Company believes that the probability of the risk being realised, in whole or in part, is low. The Company estimates that the risk, if materialised, would have a high impact on the Company.

### Risks related to future dividends

The Company's ability to pay dividends to its shareholders depends on the Company's future earnings, financial position, cash flows, working capital requirements, cost of investments and other factors. Accordingly, the

Company cannot make any assurances that dividends will be paid in the future. Should no dividends be paid, a shareholder's return will depend solely on the future development of the share price.

#### Risks related to the share's trading venue

The shares in the Company are planned to be continued trading on First North, an alternative trading venue operated by the various stock exchanges which is part of Nasdaq. Companies whose shares are traded on First North are not obliged to follow the same rules as companies whose shares are traded on a regulated market, but a less extensive set of rules adapted to preferably smaller companies and growth companies. An investment in a company whose shares are traded on First North may, therefore, hold higher risk than an investment in a company whose shares are traded on a regulated market.

#### Owners with significant influence

Myles Murray's ownership and voting rights in the Company will, following completion of the Transaction, amount to approximately 39 per cent in PMD and he can exercise significant influence on matters requiring shareholder approval at general meetings, including the appointment and removal of board members and any proposals for the acquisition or sale of assets and other corporate transactions. This influence may be to the detriment of shareholders whose interests differ from those of the said owner.

#### The sale of shares by existing shareholders may result in a negative share price development

The Company's share price may fall if there are extensive sales of the Company's shares, in particular sales by members of the board of directors, senior management or major shareholders. The Company's directors, senior executives and major shareholders have undertaken, with certain exceptions and for certain periods, not to sell shares or otherwise enter transactions with a similar effect. At the time when the lock-up period has expired, or before expiry with written consent, the shareholders affected by the lock-up will be free to sell their shares in the Company. The sale of many PMD's shares on the public market, or the perception that such a sale may take place, may adversely affect the Company's share price.

## BACKGROUND AND MOTIVATION

PMD develops and sells medical products for respiratory monitoring. Its primary product is RespiraSense™, a solution used for monitoring respiratory rate to detect deterioration of a patient's general condition early and to avoid preventable respiratory failure and adverse patient outcomes. RespiraSense™ is, to the Company's knowledge, the world's only continuous, motion-tolerant respiratory rate monitor delivering class-leading reliability in measuring respiratory rate. PMD received FDA approval for RespiraSense™ in 2022. RespiraSense™ is a novel technology and is currently used in 25 hospitals across UK and Ireland. The Company seeks to continue increasing its share of market in the UK, with Germany and the US to follow with initial market access activities.

Against this background, the boards of PMD and Promore announced the Transaction on 29 November 2023 aimed at listing PMD Device Solutions AB by way of the reverse acquisition. The board of PMD believes that a listing of the Company's shares on First North provides a quality stamp that contributes to confidence in discussions with potential customers and partners and an increased interest in the Company from the public, investors and other stakeholders.

A continued listing of PMD's shares makes it possible for the public to trade in the Company's shares, it also increases the conditions for creating shareholder value and gives the Company access to the capital markets. The access to the stock market will also facilitate the implementation of the Company's growth plans and ambition to expand the business into new markets globally.

As a result of the business change that the Transaction entails, the Company will undergo customary review by Nasdaq Stockholm AB for continued listing, which is the basis for the Company Description.

*We declare that, to the best of our knowledge, the information provided in the Company Description is accurate and that, to the best of our knowledge, the Company Description is not subject to any omissions that may serve to distort the picture the Company Description is to provide, and that all relevant information in the minutes of Board meetings, auditors' records and other internal documents is included in the Company Description.*

Stockholm, December 2023

**Promore Pharma AB (publ)**  
**(under change of name to PMD Device Solutions AB (publ))**

*Likvidator Lars-Henrik Andersson*

## A WORD FROM THE INCOMING CEO

It is with great pleasure that I introduce PMD to you. As a company, we have embedded our vision of #MakingEveryBreathCount in everything we do. It is a call to action to address the global clinical need for acute respiratory rate monitoring by developing industry leading inventions and commercialising them with the patient at the core.

Over 10 per cent of all hospital activity is driven by respiratory-related symptoms and during winter seasons, this presents a significant challenge for hospitals to delivery safe and efficient care. Respiratory compromise, an umbrella term for any condition that compromises the body's ability to respire, includes conditions such as Chronic Obstructive Pulmonary Disease, Pneumonia, Influenza, COVID, and other acute respiratory infections.

As there was no reliable solution previously available, the earliest sign of deterioration, respiratory rate, was considered a 'Lost Vital Sign'. Patients who presented with faster breathing, thereby compensating their other vitals such as blood oxygen levels as measured with a pulse oximeter, went unrecognised leading to preventable higher levels of care. PMD's innovations empower healthcare professionals to get accurate respiratory rate information to support efficient clinical decision making and to trigger the right care at the right time.

Our focus on Sweden has stemmed from our aspiration to list the company and support our ambition to become the industry leader for solutions in the prevention of respiratory failure. Having evaluated several growth markets over the years, we can see that Nasdaq in Stockholm has a strong culture of equity investment. Nasdaq itself is a strong affiliated exchange with our peers in patient monitoring and ventilation devices. Combined with our strategy of transferring manufacturing to an international supply chain provider with FDA approved site based in Sweden, it completes our selection of the right exchange for PMD to list on.

Carrying our vision forward as a listed company, we plan to expand our market share beyond Ireland and into the UK, Germany, and US; transforming outcomes for patients and delivering value for all stakeholders, including our shareholders.

PMD has the privilege to be part of an entire healthcare system in Ireland with the recommended solution for monitoring acute respiratory compromised admissions. Serving tens of hospitals and thousands of patients per year, we have a strong commercial foundation upon which to support operations and growth. With Determination and Simplicity being core values, we have demonstrated that our pragmatic approach to growing the Company has yielded great success. With this opportunity to become a listed company, this new element of our journey is the start of a new beginning and we will continue to bring those values forward in addition to our continued creation of innovation and partnership based approach to market access.

At this time, I would like to thank the team at Promore for their dedication and effort in developing innovations for the improvement of people's quality of life. It has been a pleasure to work with them during this transaction. Furthermore, to the team at PMD, I look forward to continue transforming patient outcomes, together. PMD believes that the innovations we create and commercialise not only affect individuals, but their families, friends, and the communities they are part of. We look forward to welcoming new shareholders to become part of this journey and to support, together, a shared ambition of #MakingEveryBreathCount.

**Myles Murray**

CEO, PMD Device Solutions AB

## DESCRIPTION OF ACTIVITIES

### Introduction

#### PMD Device Solutions AB's operations

Breathing is a vital biological function and one of the vital parameters used to assess a patient's general condition. Today, measurement and monitoring of the respiratory rate are usually done manually by healthcare professionals, which is a time-consuming and inaccurate method that is not practically possible to perform continuously. It is the Company's evaluation that, despite the importance of respiratory rate, there has been a complete lack of effective systems for accurate and reliable respiratory monitoring to date. Today, over 80 per cent of respiratory rate readings are inaccurate, leading to 41 per cent of patients' conditions being underestimated<sup>1</sup>. A solution for accurate monitoring of respiration would enable continuous measurement of the respiratory rate and, in turn, enable early warnings of patient deterioration and thus avoid deterioration and the need for intensive care.

PMD has developed RespiraSense™ which, to the Company's knowledge, is the world's first and only continuous and motion-tolerant system for monitoring of patient's respiratory rates. RespiraSense™ delivers both essential clinical benefits and reduced costs for the care provider. The Company assesses that RespiraSense™ can achieve the same fundamental importance for patient monitoring as the pulse oximeter, measuring blood oxygen saturation, got after its introduction in 1983<sup>2</sup>.

#### Promore Pharma AB (publ)'s current operations

Promore's current operations will be discontinued in connection with the Transaction. The background for this is that (i) the runway of the remaining patent family is limited; (ii) the competitive challenge has increased in recent years; and (iii) the prior management, board and liquidator have exhausted all opportunities to monetize the remaining assets.

### History

#### Promore Pharma AB (publ)

Promore Pharma is a biopharmaceutical company founded in 2002 and specialised in the development of locally administered first-in-category pharmaceuticals for indications with high unmet medical needs, where very few efficacious prescription pharmaceuticals are available. Today the group consists of Promore Pharma as the parent company and Pergamum AB and Pergasus AB as subsidiaries. Since spring 2023, Promore has faced a very challenging market situation with a low market value in relation to the company's need for new investments. The company received the final results of the PHSU05 clinical trial, which showed that the treatment effect of Ensereptide was insufficient to justify further investments, which is why the board subsequently decided to discontinue this development project. Following a decision at an extraordinary general meeting held on 5 October 2023, Promore entered into voluntary liquidation with effect from 12 October 2023. In light of the proposed Transaction, the basis for the voluntary liquidation will no longer exist. Against this background, it will be proposed that the extraordinary general meeting in Promore to decide on the Transaction will also decide to terminate the voluntary liquidation process.

#### PMD Device Solutions AB

PMD is an Irish medical technology company headquartered in Cork, Ireland. The Company was founded by Myles Murray in 2011, who was then working with a Professor of Emergency Medicine in Cork University Hospital on a project to measure patients' respiratory rate in a motion-tolerant and continuous manner.

PMD then developed RespiraSense™ to monitor a patients' respiratory rate. The first clinical trials of RespiraSense™ were initiated at Cork University Hospital during 2013 and the first version of RespiraSense™

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<sup>1</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. *Journal of Physiological Measurement*. In review PMEA-104030.R1, 23rd April 2021

<sup>2</sup> Katsuyuki Miyasaka et al. Tribute to Dr. Takuo Aoyagi, inventor of pulse oximetry. *Journal of Anesthesia*, 2021

launched during 2015. The third and current version of RespiraSense™ received CE marking in 2020, and was launched through a nationwide rollout in Ireland in 2021.

Today, RespiraSense™ is the standard of care in Ireland<sup>3</sup> and, to the Company's knowledge, the world's only continuous and motion-tolerant system for respiratory monitoring of patients.

## **PMD's vision, mission and targets**

### **Vision**

The Company's vision is to avoid preventable respiratory failure events by transforming the standard of care in patient monitoring.

### **Mission**

The Company's mission is to become the de facto standard of care for monitoring respiratory compromised patients in Europe and the US.

### **Financial and operational targets**

The Company's goal is to launch RespiraSense™ in selected progressive healthcare markets in the EU and the US in the coming years.

PMD's board of directors has adopted the following medium-term financial targets:

- Profitability: PMD's ambition is to achieve sufficient annual recurring revenue to realise profitability by the end of 2024;
- Expansion to new markets: PMD forecasts at least 10 pilots (i.e. trials that are paid for) launched between Germany and the US upto the end of 2025;
- Growth: PMD forecasts Year-on-Year compound Annual Growth Rates of greater than 30% from 2023 to 2026;
- Revenue Target: PMD forecasts an annual recurring revenue target of MESK 100 by the end of 2026; and
- Dividend Policy: PMD is focusing on pursuing growth through expanding its sales operations and does not anticipate paying any dividends in the near term.

PMD's financial and operational targets, as stated above, constitute forward-looking information. The financial and operational targets are based upon several estimates and assumptions relating to, among others, the development of PMD's industry, business, result of operations and financial position and are subject to risks and uncertainties. See "Risk factors" and "Important information" for more information.

## **Main challenge in expanding into UK, Germany and the US**

When launching RespiraSense™ into developed healthcare markets in the UK, Germany and the US over the coming years, the main challenge for PMD is to in create market awareness with key societies, payer organisations, and end-user medical facilities. This causes uncertainty, since healthcare markets around the world have a varying degree of acceptance of digital monitoring systems as well as divergent structures. The launch phase is relatively capital-intensive and achieving satisfactory market penetration will be of great importance for the Company's continued development.

PMD has selected markets where there is a significant scaling opportunity arising from regional or local pilot site(s), which will increase the probability for success. This is due to the scale and reach of the payer serving those healthcare facilities, particularly in the US. While in Germany, local success can unlock the beginning of

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<sup>3</sup> <https://www.hse.ie/eng/about/who/board-members/board-meetings/may-2022/5-1-b-final-ehealth-overview-may25-hse-board-redacted.pdf> page 15



an innovation pathway that leads to national reimbursement within 2-3 years of launching. Coupled with PMD's business model, this ensures that there is a high return on capital deployed for funding market access activities.

## Monitoring vital parameters - a critical part of healthcare

When assessing a patient's state of health, four vital parameters are usually measured: body temperature, heart rate, blood pressure and respiratory rate, all of which are related to a patient's general condition. These vital parameters are usually checked and documented when a person enters care and the decision as to how the patient should be prioritised in continued care is based on those measurements. The four parameters are considered vital because falling values can lead to death.<sup>4</sup> In addition, oxygen saturation in the blood is also usually counted as a vital parameter. The oxygen saturation in the blood is measured with a pulse oximeter which also measures the pulse.<sup>5</sup>

Several or all of the vital parameters are measured with a high frequency among patients admitted to hospital or in other care-related contexts. Deterioration of a patient's condition is often preceded by measurable changes in the vital signs, and measuring and monitoring the vital parameters is crucial to detect a clinical deterioration and intervention measures to prevent further deterioration. If impaired values are detected in time and effective measures are taken, then the patient can be stabilised and respiratory failure, cardiac arrest or other acute conditions can be avoided.<sup>6</sup> Early detection and preventive treatment, therefore, means that intensive care can be avoided leading to a significant cost saving for hospitals.

## Respiration - an important vital parameter

Breathing is a vital biological function where air is inhaled, blood is oxygenated and carbon dioxide is exhaled. An increased respiratory rate is a biological marker that the body is having difficulty in oxygenating the blood. By increasing the respiratory rate, the body works harder to maintain good oxygen saturation in the blood. The effect is evident during physical exertion, where the respiratory rate goes up to oxygenate the blood faster. A person with a weak general condition may have difficulty maintaining a sufficiently high respiratory rate to allow adequate blood oxygenation.<sup>7</sup>

Respiratory failure can occur for several reasons, including acute conditions such as pneumonia, pulmonary embolism (airway obstruction), pulmonary edema (fluid in the lungs), Covid-19 and acute exacerbation caused by chronic conditions such as asthma or obstructive pulmonary disease (COPD).<sup>8</sup>

The oxygen saturation in the blood is easy to measure with a pulse oximeter that warns when the oxygen saturation begins to decrease or reaches critical levels. By carefully monitoring the respiratory rate, however it is possible to predict in good time that the oxygen saturation in the blood **will** go down and thus take preventive measures.<sup>9</sup>

Measurement and monitoring of the respiratory rate today is usually done manually by healthcare professionals counting the number of breaths in one minute. Manual monitoring is a time-consuming and inaccurate method, and is not practically possible to perform continuously. Over 80 percent of respiratory rate readings are inaccurate, which leads to 41 percent of patients' conditions being underestimated.<sup>10</sup> With a solution for

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<sup>4</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

<sup>5</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

<sup>6</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

<sup>7</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

<sup>8</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

<sup>9</sup> <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>

<sup>10</sup> McCartan Et al. The Effectiveness of Continuous Respiratory Rate Monitoring in Predicting Hypoxic and Pyrexia Events: A Retrospective Cohort Study. Journal of Physiological Measurement. In review PMEA-104030.R1, 23rd April 2021

accurate respiratory monitoring, it is possible to take continuous measurements and highlight any deterioration at an earlier stage and thus avoid patient deterioration and the need for intensive care.

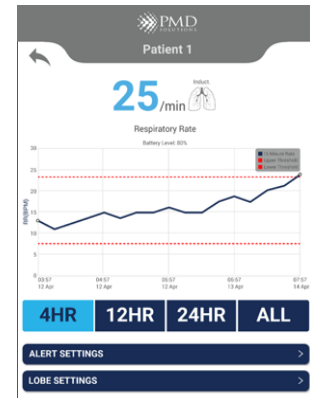
## RespiraSense™

### The sensor and lobe

PMD has developed RespiraSense™ which, to the Company's knowledge, is the world's first and only continuous and motion-tolerant system for monitoring of patient's respiratory rates. RespiraSense™ consists of a sensor and a processing and communication lobe, that is attached to the sensor.

The basis of RespiraSense™ is the patch that contains two sensors consisting of piezoelectric crystals that detect movements. The patch is attached to the side of the patient's chest wall so that one sensor is attached to the lower rib and the other sensor is attached to the abdomen. The dual sensors make it possible to measure movements in both the chest and abdomen, which increases the reliability of the measurement. The patch is a consumable that is used only once per patient.

PMD has placed great emphasis on user-friendliness when developing RespiraSense™. It is easy to apply the patch with the sensor to the patient and to apply the lobe. Furthermore, it is easy to connect the lobe to the software and add one or more additional lobes to the monitoring system on the tablet.



### The software, tablet and app

In addition to the sensor patch and lobe, RespiraSense™ includes software that controls the monitoring and manages all data that is available as an app on a tablet. In a hospital, data on the patient's breathing is transmitted wirelessly via Bluetooth to the tablet that the care staff can use to monitor the patient's breathing. The software registers the patient's breathing, and there are alarm functions that react if the patient's breathing pattern deviates. The software is intuitive with a visual presentation of patients' respiratory rate.

By providing a ready-made solution including a tablet for monitoring, PMD provides a complete solution that is easy to install and can be used alongside the hospital's other systems.

### Compatibility with digital patient monitoring solutions



*Caption: Tablet with software for patient monitoring where three patients are being monitored with RespiraSense™.*

The technical level and access to electronic patient monitoring systems vary between hospitals and wards. Many hospital wards lack digital patient monitoring and PMD's complete solution is well suited for this. Other hospitals already have digital solutions for patient monitoring where the other vital parameters are monitored and registered in a system. RespiraSense™ is compatible with the leading systems on the market and, therefore, the respiratory rate can be recorded together with other parameters in a central system as part of a larger patient monitoring system.

### RespiraSense™ as a patient monitoring solution

It is also possible to add functionality to RespiraSense™, which can then become a broader patient monitoring system. For example, PMD has carried out successful installations where pulse oximeters have been connected wirelessly to the lobe in RespiraSense™, which in turn transfers data to the software on the tablet. Furthermore, PMD has carried out tests where products for temperature monitoring were successfully integrated with RespiraSense™. By adding other vital parameter monitoring products, PMD can provide an efficient and easy-to-use patient monitoring solution.



*Caption: Monitoring image where one of the patients has a pulse oximeter connected to the RespiraSense™, and therefore, in addition to breathing, the heart rate and oxygen saturation in the blood can also be monitored.*

## Development and clinical validation

In 2019, the Company completed the third version of RespiraSense™, which while technically very similar to the second version was significantly improved in terms of usability, interoperability and how the lobe is attached to the patch. Great focus was placed on user-friendliness when it comes to handling the lobe and the patch. The software was also improved.

The fourth version, which will be launched in 2024, is identical in design but with a longer battery life and the addition of LTE cellular community. This was developed in partnership with the European Space agency by using their GNSS system for geolocating. The added usability enables patients with low connectivity to still benefit from remote monitoring devices. This enhancement is specifically focused on the hospital-at-home market segment.

RespiraSense™ has been tested and evaluated in nine clinical trials in several patient situations to validate the system's sensitivity and specificity. All clinical trials have been on alert and active patients in real-world hospital settings. The overall conclusion from the clinical studies conducted with RespiraSense™ is that the system works well and can measure the respiratory rate continuously with high accuracy while eliminating disturbances from the body's other movements.

## Areas of use for RespiraSense™

### Use in hospital

Monitoring of respiratory rate is relevant for a wide range of patients staying in hospitals, for example in post-operative respiratory care, emergency care and infection care. Furthermore, PMD considers that respiratory monitoring with RespiraSense™ is relevant for all types of chronically ill patients who require access to oxygen in some form.

One group of patients where monitoring of respiration is important is patients with respiratory and lung diseases such as Chronic Obstructive Pulmonary Disease (COPD), asthma, pneumonia, pulmonary fibrosis, etc.

Although wards that treat patients with respiratory and lung diseases are usually the first to adopt RespiraSense™ in a hospital, there are opportunities to expand its use to additional wards. The Company considers RespiraSense™ to be applicable to a broad range of diseases and debilitations in addition to lung diseases, such as cardiac arrest, sepsis, stroke and sleep apnoea amongst others.

### Use in hospital-at-home

PMD also sees significant potential for use for RespiraSense™ in the home setting (referred to as 'hospital-at-home'). For example, a patient who has undergone surgery or is recovering from infection, trauma or other conditions can be remotely monitored with RespiraSense™ and other products that monitor the vital parameters. A significant possibility for PMD is that patients who have had respiratory failure continue to use RespiraSense™ after leaving the hospital. By continuing to monitor the patient's respiratory rate after the patient has left the hospital, it is possible to see well ahead whether the patient's condition risks deteriorating and, therefore, whether to return the patient to the hospital or take other preventive measures.

To enable the use of RespiraSense™ in a hospital-at-home environment, PMD is introducing its fourth version of the product in 2024 that communicates via the cellular network. With the latest version, with built-in mobile capabilities, the hospital can easily continue to monitor the respiratory rate after the patient has left the hospital and is at home. The new version of RespiraSense™ does not need to be connected to a mobile phone or local Wi-Fi network. Instead, the communication takes place directly with the hospital via 2G, 4G and/ or 5G.

## Competing products

There are, according to the Company, two categories of competing respiratory rate monitoring methods:

- (i) manual respiratory rate monitoring methods; and
- (ii) emerging monitoring methods based on wearables that measure cardiac activity with added claims of measuring respiratory rate.

The most common method of assessing a patient's respiratory rate is to count the number of breaths per minute manually. The manual method may work at an initial assessment; however, it is imprecise and unsuitable for continuous monitoring of respiratory rate. Continuously measuring and monitoring the frequency of breathing is significantly more difficult than measuring heart rate, blood pressure, body temperature and oxygen saturation in the blood because the body's other movements make it difficult to distinguish those movements from breathing.

### Technical solutions for respiratory monitoring

Several international medical technology companies and smaller players have tried to develop effective products for respiratory monitoring. An example of a technical solution that has been used is the so-called impedance measurement, where the effect of respiration on the pulse is measured. In impedance-based measurement, the motion signal from breathing is small relative to motion signals caused by other body movements, which makes the signal-to-noise ratio challenging to measure. Another solution is to measure the sound in the throat caused by breathing or to use an accelerometer to record the breathing movements in the chest.

The products on the market today can, according to the Company's assessment, work well on patients who are anaesthetised and lying still. Difficulties arise, however, when breathing is to be monitored on a patient who is awake, moving, talking, eating or performing other activities. All types of activity create movements in the body, and all other technical solutions have difficulty distinguishing the breathing movements from other movements in the body. RespiraSense™ is, as far as the Company is aware, the only system on the market that can measure the respiratory rate continuously in an efficient and motion-tolerant manner.

## Main competitors

The Company has identified three main competitors offering solutions focused on providing respiratory rate monitoring, which are presented below. As of the date of the Company Description and to the knowledge of the Company, no other major market players are offering competing solutions to RespiraSense™.

### Philips Respironics

Philips Respironics is part of Philips Healthcare and is a global leader in the sleep and respiratory markets. The division provides solutions in sleep therapy and respiratory care. Within monitoring, Philips offers pulse oximetry and a respiratory rate monitor, BioSensor BX100, which received FDA clearance in 2020. The product is a wearable sensor that uses impedance signals from two ECG electrodes to calculate the respiratory rate. The device uses algorithms to filter out motion-related artefacts and Bluetooth to communicate with Philips other products for patient monitoring. The product has a similar scope as RespiraSense™, but according to PMD, BioSensor BX100 does not have the same accuracy and motion-tolerance as RespiraSense™, since it relies on impedance measurement, which is a less accurate method. The product is also, according to the Company's assessment, not applicable to all types of patients.

### Masimo

Masimo is a global medical technology company that develops and manufactures non-invasive patient monitoring technologies, medical devices and a wide array of sensors. Among other technologies, Masimo

provides solutions for respiratory rate monitoring. One solution is a continuous monitoring device that uses an acoustic sensor to listen to the sound of a patient's breathing. The sensor detects acoustic signals produced by the turbulent airflow in the upper airway during inhalation and exhalation, while signal processing algorithms convert the acoustic patterns into breath cycles to calculate the respiration rate. The device is connected through wires and does not allow for patient mobility. Masimo also offers a solution for Pulse Oximetry, including a lightweight, wearable fingertip sensor that monitors blood oxygen levels and alerts deteriorating levels through wireless communication to a mobile app. Like other technologies, Masimo's products are designed for either continuous monitoring in sedated patients (acoustic) or intermittent monitoring in general patients (pulse oximetry). In the latter case, PMD deems that there is weak evidence of the accuracy of measuring respiratory rate from pulse oximetry.

### EarlySense

EarlySense is an Israeli company with a presence in the US market, focusing on early detection of patient deterioration to trigger early intervention to reduce adverse events. EarlySense offers a contact-free, continuous monitoring system of the heart rate, respiratory rate and motion, called Contact-free Continuous Monitoring. A sensor is placed under the mattress in a hospital or at home and the device transmits patient data directly to clinical workstations and mobile devices. With this system, the sensor measures changes in pressure applied to it through the mattress and transmits the measurements to the software, which converts them to heart rate, breathing rate, and motion. With a sensor under the mattress, EarlySense's product does not work for patients that leave the bed and has difficulties when a patient sits up or shifts position in the bed. As the technology relies on motion detection from the body's pressure against the sensor, PMD deems that the signal-to-noise ratio is challenging and that the product thus has a low degree of motion-tolerance.

### RespiraSense™ - competitive advantages

RespiraSense™ is differentiated from competing respiratory rate monitoring solutions through its ability to continuously monitor respiratory rates with high motion-tolerance. Motion-tolerance and continuous monitoring are vital features to detect deteriorating patterns over time to avoid preventable adverse events. Motion-tolerance means that the patient can move around and be outside the hospital setting without disrupting the continuous respiratory rate monitoring. PMD's technology is, according to the Company, unique in this regard, with the ability to produce clear patterns of the patient's respiratory rate while eliminating disturbance from environmental noises, body movements and speech, appearing as noise in the monitoring pattern.

The Company's understanding is that competing solutions in the market suffer from alarm fatigue due to sensory overload of outside noise and disturbance and are unable to provide accurate continuous monitoring. As a result of the motion-tolerance and, in turn, accurate continuous monitoring features, RespiraSense's algorithms can rely on accurate data to predict respiratory patterns and provide early signs of patient deterioration. Due to this unique technology, RespiraSense™ is, besides the traditionally targeted emergency care, also applicable to both the general ward and hospital-at-home care as well as all groups of patients.

Competitors in the respiratory rate monitoring space have recently realised the long-term value of digital respiratory monitoring devices and are struggling to reach the same level of technological sophistication as RespiraSense™. As many competitors do not have accurate monitoring technology in place, PMD assesses the Company to have a substantial competitive advantage with several regulatory approvals already obtained and a product ready for large scale distribution.

### Product development

PMD will continue to invest significant resources in product development to develop RespiraSense™ further and the next step in the advancement is the launch of the fourth version that communicates via the mobile network and thus enables the use of the system outside the hospital, which opened a new and significant market segment for PMD.

RespiraSense™ delivers data to PMD's software, which means that the Company has access to comprehensive data on breathing patterns, which provides interesting opportunities for the Company. The availability of large

amounts of anonymised respiratory data can be used for further development of the algorithms, but also for progressing AI-based software for diagnostics. The more data PMD collates about respiration and other patient data, the better the understanding of the importance of respiration for the course of a disease. PMD sees potential in the future to integrate functionality for patient diagnosis in the RespiraSense™ system and thus increase the commercial potential of the system.

## Business model

### Hospital setting

The RespiraSense™ business model consists of several components that together create a complete delivery that generates attractive gross margins and recurring revenues. A sale of RespiraSense™ in a hospital setting rarely consists of a single system, but of a starter pack consisting of six RespiraSense™ Lobes with an associated charging station, a pre-configured tablet and a batch of sensor patches sufficient for around three months use. A starter pack can also include RespiraSense™ Air Hubs to ensure wireless coverage within the entire ward at the hospital.

A ward in a hospital using RespiraSense™ generates revenue for PMD as follows:

- (i) non-recurring revenue for the lobe including the charging station
- (ii) non-recurring revenue per department for Air Hubs;
- (iii) recurring revenue for the sensor patches; and
- (iv) a recurring annual license fee for the software.

The pricing of a starter pack is fixed below the EU thresholds for special budget processes for hospitals to be able to purchase the system. During the initial launch of RespiraSense™ in a new setting, non-recurring revenues from system sales (i.e., lobes and Air Hubs) account for a significant share of total revenue. As the installed base of RespiraSense™ increases over time; however, recurring sales of sensor patches are expected to account for most of the Company's revenue. In addition, recurring license revenues will be generated from the software. PMD estimates that the consumption of sensor patches amounts to about 72 patches per hospital bed per year. As hospitals become increasingly aware of the benefits of RespiraSense™, PMD believes that there is potential for the average use to be even higher.

Another revenue opportunity for PMD is to provide third-party products from suppliers of pulse oximeters and temperature sensors that can be configured with RespiraSense™ for a system.



*Caption: The lobes are placed on the charging plate, which fully charges the lobes in three hours.*

### Hospital-at-home setting

PMD has developed an end-to-end management service for patient monitoring in the hospital-at-home setting called 'RespiraSense Hub'. Each RespiraSense Hub will hold 30-beds per Hub with a typical stay of 1 month per patient. PMD's costs include the managed service personnel and equipment. PMD's end-to-end management service is limited to onboarding and offboarding patients and does not provide clinical management. PMD will typically equate one RespiraSense Hub ward to over six Hospital Wards for the purposes of calculating annual recurring revenue. PMD has one Hub already contracted in Ireland and this business line is expected to be a high growth business for PMD across UK and Ireland.

## Production and gross margins

Today, the production of RespiraSense™ lobes is located in Cork, Ireland. In 2024, PMD intends to move the production of RespiraSense™ lobes to Sanmina's facility in Örnsköldsvik, Sweden, which specialises in the production of advanced medical technology products and is FDA approved. PMD estimates that the gross margin for the lobe in time will amount to around 60–70 percent.

The sensor patches are manufactured by a global contract manufacturer of electronic components. Over time, the majority of PMD's revenue will come from the sale of sensor patches, and efficient and large-scale manufacturing is crucial for the Company's profitability potential. By using specialised subcontractors, the production chain is streamlined and, thus, a good gross margin is achievable. PMD estimates that the gross margin for the sensor patches in time will amount to 70–80 percent.

## Reimbursement system for RespiraSense™

There are currently many products for monitoring vital parameters (including products for respiratory monitoring) that are covered by reimbursement systems in both Europe and the US. However, the levels of reimbursement and acceptance of digital monitoring systems vary between EU countries, where some countries such as the UK, Germany, Italy, and the Nordic countries are ahead and have systems that encourage the use of digital and cost-effective systems. The Covid-19 pandemic showed the value of automated patient monitoring systems, which has significantly increased acceptance and interest for effective monitoring systems.

RespiraSense™ is a cost-effective system for healthcare. A health economic literature review has been carried out that illustrates that the use of RespiraSense™ could reduce healthcare costs by more than approximately EUR 250 per inpatient admission per day.<sup>11</sup> Clinical evidence demonstrating impact to outcomes also continues to be produced. PMD continues to build a rounded health technology assessment for third party payers in various geographical markets to review and critique with respect to a decision about reimbursement.

## Organisation

As of 30 September 2023, the Company had 25 employees, of which 19 were based in Ireland, 2 in the UK and 4 in Poland in the Company's development department.

For an overview of the Company's group structure, please see "Group structure" under the section "Legal matters and complementary information".

## Geographical markets

### National rollout in Ireland

In the Irish market, the Company has been the active party in dialogue with the health authorities and sold directly to the hospitals. In October 2020, the Irish healthcare authority ("HSE") decided to implement RespiraSense™ at national level and from the beginning of 2021, a national rollout was initiated covering all 26 major hospitals in Ireland. By the end of 2021, RespiraSense™ had been procured for 53 wards across the 26 hospitals, making Ireland the first country in the world to set continuous electronic monitoring of respiration as a standard of care procedure.

Initially used primarily for monitoring Covid-19 patients, the use of RespiraSense™ was extended to other patient groups as the burden of the pandemic on healthcare gradually reduced. All use of RespiraSense™ is recorded by the software, so PMD could monitor the use of the system in real-time and see that the broader use of RespiraSense™ offset the reduction of respiratory monitored Covid-19 patients.

The national implementation of RespiraSense™ in Ireland resulted in significant purchase orders for PMD at the beginning of 2021, when the Company sold equipment to the Irish hospitals. To ensure a continued high usage

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<sup>11</sup> Mehdi Javanbakht et al. – "Continues Monitoring of Respiratory Rate with Wearable Sensor in Patients Admitted to Hospital with Pneumonia Compared with Intermittent Nurse-Led Monitoring in the United Kingdom: A Cost-Utility Analysis". 2021

rate of sensor patches, HSE has placed replenishment orders of sensor patches since then, averaging MSEK 8.7 (EUR 750,000) per quarter up to and including Q4 2023.

Out of 53 procured wards in hospitals, 47 wards have been completely installed with the addition of one RespiraSense™ hub in a hospital-at-home setting.

### Expansion in Irish hospitals

While RespiraSense™ is used today in respiratory wards in most of the major hospitals in Ireland, its use varies between the hospitals and none yet uses the system in all wards where it is relevant to monitor the respiratory rate. PMD sees potential for growth, therefore, in the Irish market as the use of RespiraSense™ is extended to more wards and use-per-ward increases. Consequently, PMD assesses that it can increase coverage of hospital beds in Ireland from approximately 9 per cent today, up to 30 per cent.

### Expansion in hospital-at-home

Another significant opportunity in Ireland is the use of RespiraSense™ to monitor discharged patients as well as patients with chronic diseases, such as COPD, in hospital-at-home settings.

In December 2021, a pilot that was carried out in Ireland with twelve patients with severe COPD using RespiraSense™ in a home setting produced successful results and positions PMD well for respiratory monitoring of COPD patients in a hospital-at-home setting. By monitoring patients with severe COPD who have recently been discharged from hospitals, it is possible to detect signs of deterioration and take measures to prevent the patient from experiencing acute symptoms and having to return to the hospital. In Ireland, there are around 110,000 diagnosed patients with COPD<sup>12</sup> and of these, PMD estimates that 5,000 to 10,000 need recurrent hospital care, which are thus suitable for ongoing monitoring in a hospital-at-home setting.

PMD has now secured a 2-year contract for the supply of 20 virtual ward beds per month in a single RespiraSense™ hub for Letterkenny University Hospital. No further hubs have been announced yet and it is expected that the Irish healthcare services will evaluate Virtual Wards in 2024 for that year's winter flu preparations.

### The UK market

At the beginning of Q4 2021, a pilot was initiated at Nottingham Hospital which was part-funded by NHSx (a transformation agency of the NHS). In addition, several other hospitals are evaluating installations of RespiraSense™.

The launch strategy in the UK is based on two approaches:

- (i) direct access to individual hospitals, such as Nottingham Hospital; and
- (ii) access indirectly via the healthcare authorities, NHS (National Health Service).

The NHS is organised into approximately 220 so-called trusts, which are local organisations that run one or more hospitals each and, including private hospitals, there are a total of 1,229 hospitals in the country.<sup>13</sup> PMD, which is already an approved supplier to the NHS, estimates that the Company's initial target group consists of around 180 larger hospitals.

The UK market is, therefore, significantly larger than the Irish market. PMD currently has two employees in the UK, the Company's Head of Transformation who is responsible for managing existing sites in the UK and Ireland, while broadening the stakeholder network and a Clinical Change Specialist. The goal is to build a sales organisation that can address hospitals in the UK on a broader front.

To enhance the possibilities for addressing healthcare authorities centrally, PMD introduced RespiraSense™ to the National Institute for Health and Care Excellence ('NICE'), which is a UK Government agency. NICE provides

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<sup>12</sup> National Patient Safety Office (Ireland)

<sup>13</sup> A- Z List of All NHS Acute (Hospital) Trusts in England ([www.nhs.uk](http://www.nhs.uk))



both clinical guidelines and guidelines and recommendations in the UK regarding medical technology equipment. NICE published a MIB (Medtech Innovation Brief) which outlines what gaps RespiraSense™ must fill to qualify for guidance. This statement from NICE is important for PMD, as it provides validation for RespiraSense™ from a leading authority and is an essential reference in marketing to potential users of the system. Following the launch of RespiraSense™ in the UK, and once clinical experience and data are available, it is possible that NICE will include respiratory monitoring with RespiraSense™ in its national guidelines. This would be significant for PMD and open the potential for a national rollout of the system in the UK.

In addition, NICE further included RespiraSense Hub as part of the Early Value Assessment guidance for Virtual Wards managing Respiratory Infections for patients 16 years and older. This enables PMD to work with the NHS to fill the evidence gap to enable RespiraSense Hub to be considered for full guidance in the UK healthcare system.

PMD has also been awarded a place on the 17<sup>th</sup> Cohort of the Digital Health London Accelerator which will enable PMD to gain access to London based executives and stakeholders from each of the five London Integrated Care Boards. This is a 12-month programme that commenced in July 2023 and concludes in June 2024.

### Selecting Germany for the launch in the EU

Medical technology companies in the upscaling phase usually focus on the four largest markets in the EU, i.e., Germany, France, Italy and Spain. PMD will concentrate on Germany and then markets that have the best conditions for a successful launch of RespiraSense™ with a focus on:

- digital maturity - tendency to adopt innovative technical solutions in healthcare;
- reimbursement systems - patient monitoring systems are included in all reimbursement systems, but the time and resources required to be included in the systems vary between countries; and
- national guidelines - countries with clear guidelines for respiratory monitoring will be given priority.

As RespiraSense™ is a product that differs significantly from existing respiratory monitoring products, PMD believes that a dedicated sales effort will be required for a successful market introduction in Europe. The strategic choice to launch RespiraSense™ with a direct sales model in Europe means a higher demand for capital. It also means that the number of markets that can be addressed initially in parallel, will be limited. This makes the selection of the markets to be addressed important, and to be able to make an informed decision, PMD undertook a major market analysis in the autumn of 2021 and identified Germany for the launch of RespiraSense™ during 2024/ 25, in addition to continuing to grow Ireland and the UK.

### PMD's four step approach

PMD's strategy is to use a four steps approach when launching RespiraSense™ in new markets:

- Analysis Phase – market analysis to map structure, important hospitals/ clinics, key opinion leaders, reimbursement systems, etc. and identify suitable hospitals/ clinics for pilot installations;
- Pilot Phase – initial installations in one or two wards of a hospital. The purpose of the pilot is to create a local reference for how RespiraSense™ can create value;
- Sales Phase – establishment of direct sales organisation commencing with business development personnel and growing the team as the market evolves as well as accessing the local reimbursement system and converting the first pilot installations to ongoing customers; and
- Growth Phase – expansion of the local presence and marketing to many hospitals.

After the initial analysis is completed and an entry decision has been made, PMD will focus on being included in national clinical guidelines and start to arrange procurement frameworks. Those processes run in parallel from the pilot to the growth phase of the launch. Being included in national clinical guidelines has the potential to be a significant commercial breakthrough for the Company in that national market. Thus, PMD is keen to establish contact and early on seek to influence authorities setting the guidelines. An arrangement of the local

procurement framework is an essential parameter for the Company, to enable easy purchase and ordering of RespiraSense™.

### Partner focused strategy in the US

The United States is the world's largest healthcare market and accounts for about half of the global market in many segments. Having received FDA approval in October 2022, a launch in the US is a high priority for PMD.

The US market is large and divided into many regions. Furthermore, the healthcare system differs significantly from Europe in that private companies manage a large part of the healthcare sector. In the US healthcare system, the commercial aspects often weigh heavily, which favours PMD and RespiraSense™ since the system can contribute to significantly reduced costs for hospitals. Furthermore, there is a greater general acceptance of new and innovative technologies in healthcare in the US than in Europe.

A US market access strategy will encompass developing knowledge of the reimbursement systems and the key market players and their system priorities. A direct launch in the US would require a significant local organisation with the capacity to address the most important regions, requiring substantial investment and causing an increased level of risk for the Company.

PMD plans to undertake US market access via its acceptance onto the MassMEDIC IGNITE accelerator in Boston, Massachusetts. This is a 3-month programme that commenced in September 2023, it recently concluded in November 2023. PMD plans to scout for a possible pilot site to learn about the hospital governance, clinical workflow, patient pathway, procurement, and clinical guidance that will enable PMD to prepare a high effective sales strategy across the following months.

The clear health economic profile of RespiraSense™ means that the product should be attractive to the large integrated insurance and healthcare companies since its a monitoring system with both clear clinical benefits and cost-reducing features. PMD intends to begin dialogue with several of the most prominent integrated healthcare players in the US in 2024/25, with the aim of launching the system within these companies' organisations.

Once PMD has established cooperation with several local partners and launched RespiraSense™ in the US market, the Company will establish a larger local presence partly to support existing partners and partly to add additional partners to build a broader presence in the US market. PMD considers that the best strategy for the Company is to initially enter the US via partners to balance sales potential and risk.

### Additional opportunities in the rest of the world

PMD believes that RespiraSense™ is a product that is well suited for any country with a developed healthcare system. Success in Ireland has generated incoming inbound enquiries about RespiraSense™ from countries outside the EU. For example, the Company has contact with hospitals in Australia that plan to carry out a pilot installation in the coming year. Australia is a European-like market, and the Company is exploring the possibility of launching RespiraSense™ together with a local partner. PMD has also received inquiries from players in the Middle East, and the Company is currently investigating the possibilities of carrying out pilot installations in the region.

Launches outside Europe will take place together with local partners, as PMD does not have the capacity to address these markets on its own. In the Middle East and most countries in Asia, a local partner will be a prerequisite for a launch.

PMD is working with a market leader in high flow oxygen therapy by supporting their clinical trials with the aid of RespiraSense. Accurate and reliable respiratory rate has advantages when adjusting ventilation settings with precision to optimise therapy and outcomes. Trials are currently ongoing in Canada, New Zealand, and Australia. In addition, PMD is working with a global leading pharmaceutical company's digital technology group as part of their clinical trials group as a reference device for respiratory rate.

## Patents

PMD has patented the technical solution in RespiraSense™, including the use of multiple piezoelectric sensors and an accelerometer to record other body movements. Furthermore, the Company has patented the design of RespiraSense™ and the configuration of dynamic algorithms. In total, PMD has eight registered patents, including two in the US, two in China, two in Hong Kong, one in EU and one in Japan with three divisional patents pending. PMD considers that patents are an important part of ensuring competition protection for RespiraSense™. Overall, PMD believes that the Company has strong protection for its technologies and products.



### PMD SOLUTIONS - PATENTS REPORT

Reference	Title	Country	Patent No.
PMDD01/C/CN	A Method and Device for Respiratory Monitoring	CN	ZL2014809393.0
PMDD01/C/EP	A Method and Device for Respiratory Monitoring	EP	2958491
PMDD01/C/HK	A Method and Device for Respiratory Monitoring	HK	1216294
PMDD01/C/JP	A Method and Device for Respiratory Monitoring	JP	6401718
PMDD01/C/CND	A Method and Device for Respiratory Monitoring	CN	ZL201910422706.X
PMDD01/C/HKD	A Method and Device for Respiratory Monitoring	HK	40012716 B
PMDD01/C/EPD	A Method and Device for Respiratory Monitoring	EP	2958491
PMDD01/C/NL	A Method and Device for Respiratory Monitoring	NL	2958491
PMDD01/C/DK	A Method and Device for Respiratory Monitoring	DK	2958491
PMDD01/C/PL	A Method and Device for Respiratory Monitoring	PL	2958491
PMDD01/C/IT	A Method and Device for Respiratory Monitoring	IT	2958491
PMDD01/C/SE	A Method and Device for Respiratory Monitoring	SE	2958491
PMDD01/C/FR	A Method and Device for Respiratory Monitoring	FR	2958491
PMDD01/C/DE	A Method and Device for Respiratory Monitoring	DE	60 2014 083 884.7
PMDD01/C/GB	A Method and Device for Respiratory Monitoring	GB	2958491
PMDD01/C/IE	A Method and Device for Respiratory Monitoring	IE	2958491
PMDS1PUS01	Apparatus and method for detection for detection of dysfunctional breathing	U.S.A.	11172844 B2
PMDSP0101US	A Method and Device for Respiratory Monitoring	U.S.A.	11259716 B2
PMDSP0101US02CON	A Method and Device for Respiratory Monitoring	U.S.A.	Published

## Introduction to PMD's market

Due to the novelty of PMD's technology and its ability to potentially avoid preventable respiratory failures, the Company deems its addressable market to be emerging and the market penetration as low.

Accurate and well-documented vital signs are an indispensable part of emergency care and an important part of the monitoring of other patients in a hospital or other care facility. Several studies have shown that respiratory rate is the lead indicator of the onset of an adverse event.<sup>14, 15, 16, 17</sup>

When a patient becomes acutely unwell, time is critical in the prevention of irreversible deterioration and death.<sup>18</sup> In addition, causing increasing significant risk for the patient, deterioration of a patient's status after admission to hospital is also costly. Through good patient monitoring and timely interventions, admissions to critical care can be avoided and total length-of-stay reduced, thereby lowering the average cost per hospital admission.

## PMD's market

### A similar market – the pulse oximeter market

The pulse oximeter is a non-invasive instrument used to monitor pulse and oxygen levels. Due to its simplicity and accuracy, the pulse oximeter is used for various health conditions such as heart issues, respiratory problems and chronic obstructive pulmonary disorders (COPD) and is primarily used for patients that have reached an acute stage.

The pulse oximeter market, emerging in the 1980s, is a well-established reference market for PMD. The global pulse oximeter market was valued at approximately USD 2.7 billion as of 2021 and is expected to grow at a compounded annual growth rate (CAGR) of 8.0 percent from 2021–2026.<sup>19</sup> After the North American market, the European market is the second-largest market globally, with a market size of approximately USD 0.8 billion. The European market is expected to grow at a CAGR of 7.2% from 2021–2026.<sup>20</sup> The growth in the pulse oximeter market is expected to be underpinned by the high prevalence of respiratory diseases worldwide, the growing share of the elderly population and the increasing incidence of chronic diseases.<sup>21</sup>

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<sup>14</sup> C. J. H. K. e. a. Cretikos M, "The Objective Medical Emergency Team Activation Criteria: a case-control study.", 2007.

<sup>15</sup> H. M. H. C. e. a. Fiesemann JF, "Respiratory rate predicts cardiopulmonary arrest for internal medicine patients.", 1993.

<sup>16</sup> M. A. M. G. e. a. Goldhill DR, "A physiologically-based early warning score for patients: the association between score and outcome.", 2005.

<sup>17</sup> D. R. W. E. e. a. Subbe CP, "Effect of introducing the Modified Early Warning score on clinical outcomes, cardio-pulmonary arrests and intensive care utilisation in acute medical admissions.", 2003.

<sup>18</sup> Fiona McDaid et al. HSE Budget Impact Analysis – the National Early Warning System, 2018

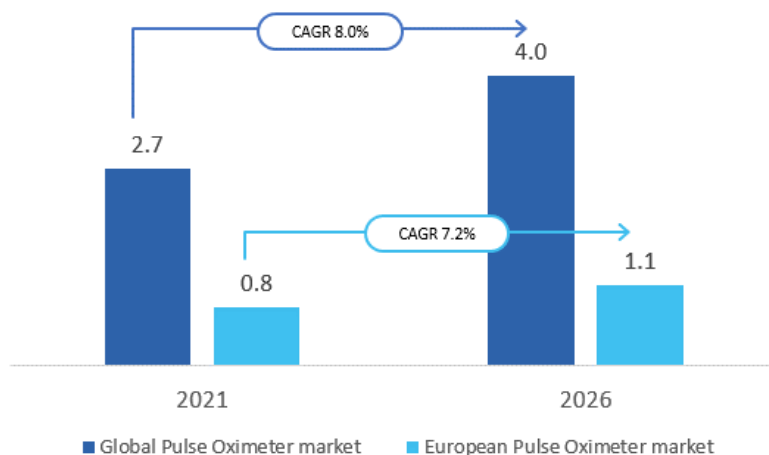
<sup>19</sup> Global Pulse Oximeter Market, Market Data Forecast research report, 2021

<sup>20</sup> European Pulse Oximeter Market, Market Data Forecast research report, 2021

<sup>21</sup> Pulse Oximeter Market, Markets and Markets research report, 2021

Figure: The pulse oximeter market

Market size, USD billion



### PMD's addressable market

As the pulse oximeter does not predict patient deterioration as early as changes in respiratory rate for patients entering respiratory failure, the pulse oximeter is mainly applicable to patients already in an acute stage. PMD, therefore, estimates that the Company's addressable market is significantly greater than the pulse oximeter market. The Company is seeing a new emerging market for continuous respiratory rate monitoring in the general ward. However, due to the novelty of PMD's technology and its broader field of use, it is difficult to assess the total addressable market with a degree of accuracy.

One disease, among others, to which RespiraSense™ is directly applicable is COPD. In 2018, the total number of COPD patients worldwide was approximately 64 million patients. According to Frost & Sullivan, the average reimbursement cost for COPD patients in the US added up to approximately USD 2,750 the same year, implying a total global COPD market of approximately USD 176 billion (assuming the US reimbursement rate being applicable worldwide). In the US market, approximately 10 per cent of total reimbursements for COPD patients reflects monitoring.<sup>22</sup> Using the corresponding monitoring rate on the global COPD market suggests a total COPD monitoring market of USD 17.6 billion. Based on established data for the average length of stay and the average cost per patient, PMD considers that approx. 15 - 35 per cent of the total COPD monitoring market is directly addressable for RespiraSense™ globally, implying an estimated global market value of USD 2.6 - 6.2 billion. The COPD patient group is only one of several to which RespiraSense™ is directly applicable, and the total COPD monitoring market should therefore, according to the Company, be viewed as one reference point in estimating the emerging total addressable market for the Company.

Also, there is a growing trend of hospital-at-home care and increasing demand for wearable devices. The Company projects that the future addressable market for RespiraSense™ is not limited to hospital care settings but will also include hospital-at-home care.

As of the date of the Company Description, the Company is primarily operating in the Irish market. With approximately 12,000 hospital beds, the Irish market is small compared to most other European markets. The largest market in Europe is Germany, with around 689,000 beds. The healthcare system in Germany relies on a high density of smaller regional hospitals, which is why the number of hospital beds per capita is among the highest in Europe. In total, the number of hospital beds in Germany is significantly higher than in other major European markets such as the UK and France. The graph below shows the total number of hospital beds for a select number of European countries and the US. As PMD executes its expansion pipeline, the addressable market for its solution is expected to increase significantly.

<sup>22</sup> Frost & Sullivan, [Respiratory Disorders Market in United States, Forecast to 2022](#)

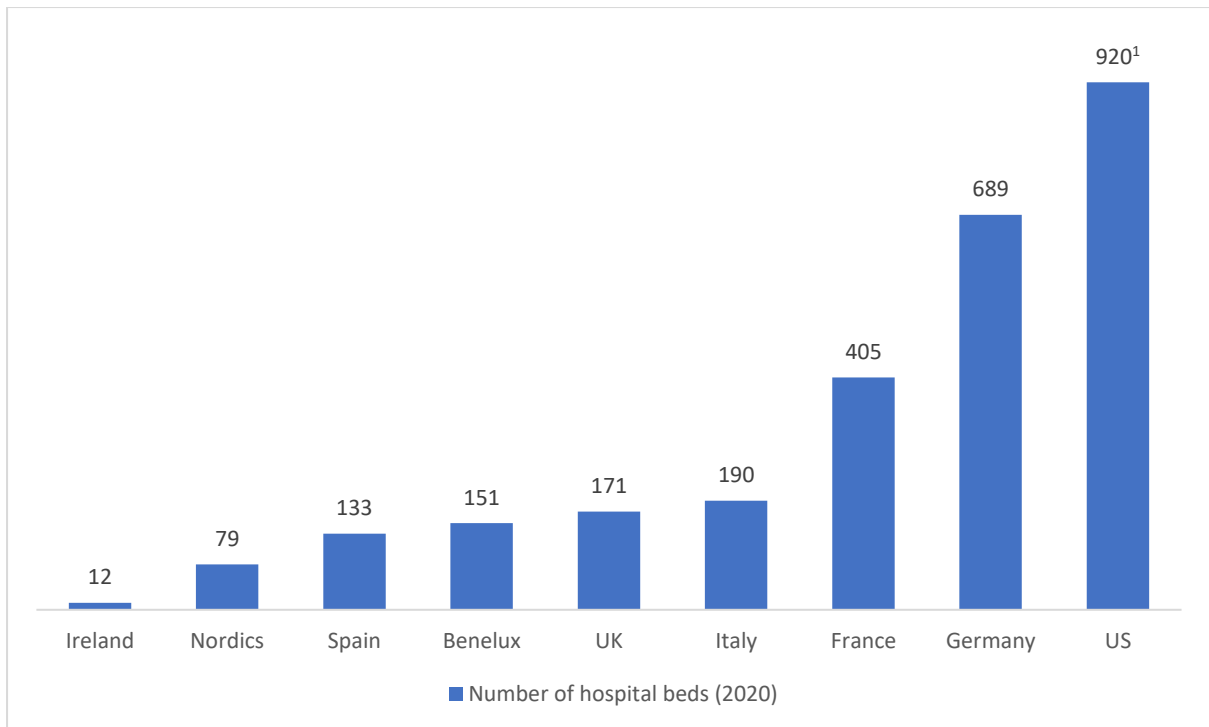


Figure: Number of hospital beds per country (thousands), 2020

## Market trends and outlook

The Company has identified several growth trends driving its addressable market, which are listed and described below:

- (i) Digital transformation;
- (ii) Electronic Health Records (EHR);
- (iii) Reimbursement for disruptive digital health solutions e.g., wearable medical devices;
- (iv) Value-based care; and
- (v) Big data analytics and predictive healthcare.

### Digital transformation

The Covid-19 pandemic has disrupted the healthcare sector with increasing acceleration in the adoption of digital healthcare, streamlined approval processes and reduced bureaucracy for digital health solutions.<sup>23</sup> New technology enables clinicians and hospitals to abandon outdated methods and trust that disruption in wearable medical devices, 5G mobile technology and AI-powered systems etc. will yield significant benefits through improved patient outcomes, reduced human error and lower costs.<sup>24</sup> PMD expects that digital transformation will continue to increase and raise demand for digital medical devices and automated processes, favouring the RespiraSense™ solution.

### Electronic Health Records (EHR)

In line with the digital transformation of the healthcare sector, hospitals internationally have increasingly implemented EHR systems, which are accepted as enablers of high-performing health systems today.<sup>25</sup> EHRs are real-time updated digital versions of patients' records, including information ranging from the patient's medical history and diagnoses to treatment plans and test results. A key feature of EHRs is that health

<sup>23</sup> Frost & Sullivan- "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>24</sup> Schell et al. "Essential Emergency and Critical Care: A consensus among global clinical experts", 2021

<sup>25</sup> Juliet Rumball-Smith et al. Late adopters of the electronic health record should move now | BMJ Quality & Safety, 2020

information can be created and managed in digital format, capable of being shared across several healthcare organisations.<sup>26</sup> The prevalence and growth in the use of EHRs is driving the need to capture and continuously monitor medical conditions and diagnoses digitally. RespiraSense™ provides continuous monitoring of a patient's respiratory rate in a digital format, thereby enabling records to be shared and stored in digital platforms.

### Wearable medical devices

The Covid-19 pandemic has accelerated the importance of solutions with remote functionality that enable decentralised and connected care and hospital-at-home models. Healthcare services at home are designed to meet the needs of patients by offering personalised assistance in the convenience of a patient's home and to reduce healthcare costs by reducing hospital readmissions. Technology-enabled remote care is growing in importance due to the increasing focus on value-based care, cost of care and patient outcome.<sup>27</sup> The global wearable medical devices market, including both diagnostic devices and therapeutic devices, such as monitoring devices for vital signs, sleep, and neurophysiology as well as electrocardiographs, pain management and respiratory therapeutic devices, is expected to grow with a CAGR of 24 percent until 2025.<sup>28</sup>

In April 2020, StartUS Insights analysed 173 start-ups focused on wearable solutions impacting remote healthcare during the Covid-19 pandemic and identified RespiraSense™ as one of the top five solutions globally.<sup>29</sup> PMD believes the Company to be well-positioned with its wearable and remote solution, RespiraSense™, which is applicable in both hospital and remote home care settings.

### Value-based care

The medical technology industry has experienced declining reimbursement rates and increasing pricing pressure, which has increased demand for innovative solutions that support value-based care. Value-based care is a healthcare delivery model in which providers, including hospitals and physicians, are reimbursed based on patient outcomes. Under value-based care model agreements, providers are rewarded for helping patients improve their health, reduce the effects and incidence of chronic disease, and live healthier lives in an evidence-based setting. Value-based care increases the emphasis on improving the patient outcomes across the care continuum, which is driving transformation within the medical technology industry, hence being a key driver for growth for innovative solutions and business models.<sup>30</sup>

PMD is well-positioned with its product RespiraSense™, which both improves patient outcomes and reduces cost-of-care. The Company expects to be able to capitalise on the value-based care trend with a compelling value proposition of cutting the average cost per hospital admission by SEK 2,560 and returning >3x returns to healthcare payers in respiratory populations.<sup>31</sup>

### Big data analytics and predictive healthcare

Like many other fields, healthcare is starting to take advantage of big data to provide predictive analyses. Predictive analyses deliver healthcare providers with forecasts of diseases and aim to anticipate and reduce risks based on current and historical patient data. Big data analytics in healthcare improves the quality of care by delivering more precise and personalised care and reducing healthcare costs.<sup>32,33</sup>

PMD's technology detects early signs of patient deterioration through digital monitoring. As a result, PMD collects significant amounts of anonymised physiological data from patients with respiratory illnesses from

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<sup>26</sup> What is an electronic health record (EHR)? | HealthIT.gov

<sup>27</sup> Frost & Sullivan - "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>28</sup> Global Wearable Medical Devices Markets Report 2021: Market (globenewswire.com)

<sup>29</sup> 5 Top Wearables Solutions To Use During The Coronavirus Pandemic (startus-insights.com), 2020

<sup>30</sup> Frost & Sullivan- "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>31</sup> Mehdi Javanbakht et al. - "Continues Monitoring of Respiratory Rate with Wearable Sensor in Patients Admitted to Hospital with Pneumonia Compared with Intermittent Nurse-Led Monitoring in the United Kingdom: A Cost-Utility Analysis", 2021

<sup>32</sup> Big Data in Healthcare Market Size Worth USD 78.03 Billion (globenewswire.com), 2020

<sup>33</sup> Healthcare Analytics Market - Global Forecast to 2026 | Markets and Markets, 2021

pneumonia to apnoea, which, according to the Company, supports the opportunities for predictive analysis through PMD's research.

## Regulations

### The European and UK regulations

The European medical technology landscape is tightly regulated and under the surveillance of the EU legislation. Before a medical technology can be introduced in the EU and affix a CE marking to its device, a manufacturer must comply with all applicable EU legislation.

Currently, RespiraSense™ is CE marked as a Class IIb medical device. It is also an ISO13485:2016 certified entity, meaning that it is an audited Quality Management System ('QMS'), which demonstrates the ability to provide medical devices and related services that consistently meet customers' and applicable regulatory requirements.<sup>34</sup>

RespiraSense™ thereby already satisfies the regulatory requirements of the EU's Medical Device Directive ('MDD') and also the regulatory requirements of the UK (pre-Brexit). The CE marking allows the sale and distribution of RespiraSense™ to countries of the European Economic Area without any regulatory barriers. The MDD directive was due to be replaced by the new EU Medical Device Regulation (MDR) in 2021; however, in January 2023, the EU parliament voted in favour of extending the deadlines of the MDR (EU) 2017/745 transition. PMD's MDD certificate has been extended to 14 November 2026 unless there are significant changes to the current product.

Subject to meeting certain criteria, there is an automatic extension of the MDD certificate validity until 31 December 2027 for Class III & Class IIb implantable devices and 31 December 2028 for other devices.

### US regulation

In the US, all medical technology devices require submission of a Premarket Notification under classification 510(k), mandated by the FDA before commercially distributing the device within the jurisdiction. PMD received FDA approval in October 2022.

### Rest of the World regulation

PMD is also pursuing MDSAP accreditation which is a harmonised certification combining US, Japanese, Australian, Brazil, and Canadian regulatory systems. This opens opportunities for distribution via third parties should the right partners present themselves.

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<sup>34</sup> Medtech Europe (2021)



## SELECTED FINANCIAL INFORMATION

### Introduction

This section presents selected condensed financial information for PMD and Promore. The financial information for PMD includes the financial years 2021-04-01–2022-03-31 and 2022-04-01–2023-03-31 as well as the interim periods 2022-04-01–2022-09-30 and 2023-04-01–2023-09-30. The financial information for Promore includes the financial years 2021-01-01–2021-12-31 and 2022-01-01–2022-12-31 as well as the interim periods 2022-01-01–2022-09-30 and 2023-01-01–2023-09-30.

PMD's financial information for the financial years 2021-2022 and 2022-2023 has been derived from the audited annual reports for each financial year. PMD's annual financial statements have been prepared in accordance with Swedish Law and the International Financial Reporting Standards as issued by the International Accounting Standards Board and adopted by the EU ("IFRS") and have been audited. PMD's financial information for the interim periods 2022-01-01–2022-09-30 and 2023-01-01–2023-09-30 is derived from PMD's interim report for the interim period ending on 30 September 2023. The interim report has been prepared in accordance with IFRS with application of IAS 34 on Interim Financial Reporting. The interim report has not been audited.

Promore's financial information for the financial years 2021 and 2022 has been derived from the audited annual reports for each financial year. Promore's annual financial statements have been prepared in accordance with Swedish law and BFNAR 2012:1 Annual Report and Consolidated Accounts (K3) and have been audited. Promore's financial information for the interim periods 2022-01-01–2022-09-30 and 2023-01-01–2023-09-30 is derived from Promore's interim report for the interim period ending on 30 September 2023. The interim report has been prepared in accordance with Swedish law and BFNAR 2012:1 Annual Report and Consolidated Accounts (K3). The interim report has not been audited.

The planned Transaction is expected to be completed on 29 December 2023. The transaction constitutes a so-called reverse acquisition, through which Promore acquires all shares in PMD while the shareholders of PMD becomes the majority owners of the new group. As a result of the Transaction, the Company will continue the operations of PMD Device Solutions AB. Promore's current operations will be discontinued following the Transaction.

The Company has not prepared any pro forma financial statements in the the Company Description due to the fact that Promore will not be conducting any business activities following the divestment of assets and the completion of the Transaction. Accordingly, PMD Device Solutions AB's historical financial information, which has been incorporated by reference, is what is deemed to be relevant to investors and provides a true and fair view of the of the business that will be conducted in the Company.

## Financial reports incorporated by reference

The following documents are incorporated into this Company Description by reference and thus form part of the Company Description.

### *PMD Device Solutions AB's interim report for the period 2023-04-01–2023-09-30*

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Link: [PMD Device Solution AB's interim report for 2023-04-01--2023-09-30](#)

### *PMD Device Solutions AB's annual report for the period 2022-04-01–2023-03-31*

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Link: [PMD Device Solutions AB's annual report for 2022-04-01--2023-03-31](#)

### *PMD Device Solutions AB's annual report for the period 2021-04-01–2022-03-31*

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Link: [PMD Device Solution AB's annual report for 2021-04-01--2022-03-31](#)

### *Promore Pharma AB (publ)'s interim report for the period 2023-01-01–2023-09-30*

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Link: [Promore Pharma AB \(publ\)'s interim report for 2023-01-01--2023-09-30](#)

### *Promore Pharma AB (publ)'s annual report for the period 2022-01-01–2022-12-31*

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Link: [Promore Pharma AB \(publ\)'s annual report for 2022-01-01--2022-12-31](#)

### *Promore Pharma AB (publ)'s annual report for the period 2021-01-01–2021-12-31*

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Link: [Promore Pharma AB \(publ\)'s annual report for 2021-01-01--2021-12-31](#)

## Consolidated income statement for PMD

Amounts in KSEK	Audited	Audited	Unaudited	Unaudited
	2022-04-01	2021-04-01	2023-04-01	2022-04-01
	2023-03-31	2022-03-31	2023-09-30	2022-09-30
<b>Operating income etc.</b>				
Net sales	18,407	12,245	18,469	4,637
Cost of goods sold	-4,022	-4,688	-3,887	-894
<b>Gross Profit</b>	<b>14 385</b>	<b>7 557</b>	<b>14 582</b>	<b>3 743</b>
<b>Operating expenses</b>				
Administration costs	-33,085	-43,700	-20,089	-13,527
Depreciation/amortisation	-4,442	-3,765	-2,579	-2,111
Other operating income	546	577	190	129
	<b>-36,981</b>	<b>-46,888</b>	<b>-22,478</b>	<b>-15,509</b>
<b>Operating loss</b>	<b>-22,596</b>	<b>-39,331</b>	<b>-7,896</b>	<b>-11,766</b>
<b>Profit from financial items</b>				
Financial costs	-13,883	-5,887	-4,263	-8,076
	<b>-13,883</b>	<b>-5,887</b>	<b>-4,263</b>	<b>-8,076</b>
<b>Loss after financial items</b>	<b>-36,479</b>	<b>-45,218</b>	<b>-12,159</b>	<b>-19,842</b>
<b>Loss before tax</b>	<b>-36,479</b>	<b>-45,218</b>	<b>-12,159</b>	<b>-19,842</b>
Income tax	0	0	0	0
<b>Loss for the year</b>	<b>-36,479</b>	<b>-45,218</b>	<b>-12,159</b>	<b>-19,842</b>
<b>Other comprehensive income</b>				
	Audited	Audited	Unaudited	Unaudited
	2022-04-01	2021-04-01	2023-04-01	2022-04-01
	2023-03-31	2022-03-31	2023-09-30	2022-09-30
<b>Report on total results</b>				
Loss for the period	-36,479	-45,218	-12,159	-19,842
<i>Items that may be reclassified to the income statement</i>				
Translation differences	-5,352	-282	-2,129	-3,212
<b>Other comprehensive income for the year</b>	<b>-5,352</b>	<b>-282</b>	<b>-2,129</b>	<b>-3,212</b>
<b>Total comprehensive income for the period</b>	<b>-41,831</b>	<b>-45,500</b>	<b>-14,288</b>	<b>-23,054</b>

## Consolidated balance sheet for PMD

Amounts in KSEK

ASSETS	Audited	Audited	Unaudited	Unaudited
	2023-03-31	2022-03-31	2023-09-30	2022-09-30
<b>Fixed assets</b>				
Intangible fixed assets	27,891	24,445	28,709	26,381
Tangible fixed assets	3,162	3,602	2,784	3,415
Right of use assets	3,964	2,339	3,440	3,066
<b>Total fixed assets</b>	<b>35,017</b>	<b>30,386</b>	<b>35,023</b>	<b>32,862</b>
<b>Current assets</b>				
<b>Current receivables and inventory</b>				
Inventory	4,937	2,229	1,367	4,494
Accounts receivable	64	656	2	104
Other receivables	271	901	1,648	4,737
Prepayments and accrued income	484	389	670	534
<b>Total current receivables and inventory</b>	<b>5,756</b>	<b>4,175</b>	<b>3,687</b>	<b>9,869</b>
<b>Cash and bank equivalents</b>				
Cash and bank equivalents	4,310	8,260	2,493	4,564
<b>Total current assets</b>	<b>10,066</b>	<b>12,435</b>	<b>6,180</b>	<b>14 433</b>
<b>TOTAL ASSETS</b>	<b>45,083</b>	<b>42,821</b>	<b>41,203</b>	<b>47,295</b>
<b>EQUITY AND LIABILITIES - GROUP</b>				
	Audited	Audited	Unaudited	Unaudited
	2023-03-31	2022-03-31	2023-09-30	2022-09-30
<b>Equity</b>				
Share capital	550	550	550	550
Other contributed capital	23,561	0	23,561	23,561
Reserve	-5,508	-156	-6,834	-3,181
Retained earnings including profit for the year	-113,506	-53,466	-125,665	-96,869
<b>Total equity</b>	<b>-94,903</b>	<b>-53,072</b>	<b>-108,388</b>	<b>-75,939</b>

<b>Long-term liabilities</b>				
Liabilities to credit institutions	257	542	81	363
Other liabilities	22,167	20,231	28,395	21,686
<b>Total long-term liabilities</b>	<b>22,424</b>	<b>20,773</b>	<b>28,476</b>	<b>22,049</b>
<b>Current liabilities</b>				
Convertible loans	27,281	25,500	24,942	31,460
Liabilities to credit institutions	510	496	379	483
Accounts payable	14,907	15,834	17,436	11,393
Other short term loans	9,882	-	10,331	110
Other liabilities	15,897	11,797	19,966	16,949
Accrued expenses and prepaid income	49,085	21,493	48,061	40,791
<b>Total current liabilities</b>	<b>117,562</b>	<b>75,120</b>	<b>121,115</b>	<b>101,185</b>
<b>TOTAL EQUITY AND LIABILITES</b>	<b>45 083</b>	<b>42 821</b>	<b>41 203</b>	<b>47 295</b>

## Consolidated cash flow statement for PMD

### CASH FLOW STATEMENT - GROUP

Amounts KSEK	Audited	Audited	Unaudited	Unaudited
	2022-04-01	2021-04-01	2023-04-01	2022-04-01
	2023-03-31	2022-03-31	2023-09-30	2022-09-30
<b>Cash flow from operating activities</b>				
Operating loss	-22,596	-39,331	-7,896	-11,766
Adjustments for items that are not included in cash flow	4,442	3,766	2,864	2,756
Tax paid	0	0	0	0
Interest paid	-4,131	-4,783	-4,263	-8,076
<b>Cash flow from operating activities before changes in working capital</b>	<b>-22,285</b>	<b>-40,348</b>	<b>-9,295</b>	<b>-17,086</b>
Cash flow from changes in working capital				
Decrease (+) / increase (-) of operating assets	-1,581	-619	2,198	-5,440
Decrease (-) / increase (+) of operating liabilities	28,752	24,776	2,238	20,499
<b>Total change in working capital</b>	<b>27,171</b>	<b>24,157</b>	<b>4,436</b>	<b>15,059</b>
<b>Cash flow from operating activities</b>	<b>4,886</b>	<b>-16,191</b>	<b>-4,859</b>	<b>-2,027</b>
<b>Cash flow from investing activities</b>				
Investment in intangible assets	-3,837	-3,703	-1,671	-1,782
Investment in tangible assets	-81	-3,212	-125	-0
Investments in leasing rights	-2,232	-	-	-970
<b>Cash flow from changes in working capital</b>	<b>-6,150</b>	<b>-6,915</b>	<b>-1,796</b>	<b>-2,752</b>
<b>Cash flow from financing activities</b>				
Issue of convertible debt	-	22,941	-	-
Repayment of convertible loans	-2,415	-	-2,528	-
Advance contributions from shareholders	-	-	6,259	-
Repayments of liabilities to credit institutions	-271	-2,135	-2,183	-2,052
Change in lease liabilities	-	-17	3,291	3,136
<b>Cash flow from financing activities</b>	<b>-2,686</b>	<b>20,789</b>	<b>4,839</b>	<b>1,084</b>
Change in cash and cash equivalents	-3,950	-2,317	-1,817	-3,696
Cash and cash equivalents at the beginning of the year	8,260	10,577	4,310	8,260
<b>Cash and cash equivalents at the end of the year</b>	<b>4,310</b>	<b>8,260</b>	<b>2,493</b>	<b>4,564</b>

## Comments on the historical financial development

### Income statements

Net sales in the last financial year to 31 March 2023 rose by 50% to MSEK 18.4 driven by higher replenishment orders for RespiraSense sensor. Gross profit rose by 90% to MSEK 14.3 due to higher revenues and a change in mix towards higher margin sensor sales. Consequently, gross profit percentage increased from 61.7% in 2022 to 78% in 2023.

The six months sales to 30 September 2023 at MSEK 18.4, were substantially higher than the same period in 2022 of MSEK 4.6. Gross profit margin fell slightly from 81% to 79% due to a change in mix of sales.

Administrative costs for the year fell by MSEK 10.6 from 2022 to 2023, largely due to an ongoing cost constraint programme and the once off costs incurred in 2022 relating to the cancelled listing in Q1 2022.

The Company's operating loss fell from MSEK 39m in 2022 to MSEK 22.5 in 2023 as revenues and product mix improved.

Financial costs increased from 2022 to 2023 as the Company took on more expensive loan facilities, which originally were put in place as a temporary bridging facility prior to the intended listing planned for early 2022. These were later renegotiated resulting in lower interest costs for the 6 months to 30 September 2023 compared to the same period in 2022.

Net loss after tax fell from MSEK 45 in 2022 to MSEK 36 in 2023. The six months loss to 30 September 2023 was 39% lower than the loss for the same period in 2022 primarily due to higher sales in 2023.

### Balance sheet

#### Assets

Fixed assets increased from MSEK 30 to MSEK 35 from 2022 to 2023 primarilyly due capitalisation of development costs relating to the next generation of RespiraSense.

#### Equity & liabilities

##### *Financial year 2022 vs 2023*

Negative equity increased from MSEK 53 to MSEK 94 in 2023 due to trading losses for the year. Prepaid income increased by MSEK 26. Loans and other liabilities increased by MSEK 11.3 mainly due to interest and facility costs incurred.

##### *March 2023 vs September 2023*

Negative equity increased from March to September 2023 based on the results for the 6 months to September 2023.

### Cash Flow

#### *Financial year 2022 vs 2023*

As of 31 March 2023, cash and cash equivalents amounted to MSEK 4.3 (MSEK 8.2), while cash flows from operating activities for the full year amounted to MSEK 4.9 (MSEK -16), due to improving revenues. Cash flows from financing activities decreased from MSEK 20.7 in 2022 to MSEK -2.6 in 2023 as the Company had received convertible loans in 2022, some of which were repaid in the following year.

#### *September 2023 vs September 2022*

As at 30 September 2023, cash and cash equivalents stood at MSEK 2.4 (MSEK 4.6), while cash flow from operating activities during the 6 months to 30 September 2023 amounted to MSEK -4.8m (MSEK -2m). v Cash flows from operating activities during the period is in line with management expectations. Cash flow from financing activities increased in 2023 due to raising additional funds (MSEK 6.3m) from shareholders up to 30 September 2023.

## Capital structure, indebtedness and other financial information

The tables below present the Company's equity, interest-bearing liabilities and net indebtedness as at 30 September 2023.

Equity and Liabilities (KSEK)	<i>Unaudited</i>
Share capital	550
Other contributed capital	23,561
Reserve	- 6,834
Retained earnings including loss for the period	-125,665
<b>Total equity</b>	<b>-108,388</b>
<b>Net Indebtedness</b>	
a) Cash and cash equivalents	2,493
<b>b) Total liquidity</b>	<b>2,493</b>
c) Convertible loans	24,942
d) Liabilities to credit institutions	379
e) Other short term loans	10,331
<b>f) Total current interest-bearing liabilities (c+d+e)</b>	<b>35,652</b>
<b>g) Net short-term debt (f-b)</b>	<b>33,159</b>
h) Long-term liabilities to credit institutions	81
i) Other interest bearing long term liabilities	20,376
<b>j) Total long-term interest-bearing liabilities (h+i)</b>	<b>20,457</b>
<b>k) Net Indebtedness (g+j)</b>	<b>53,616</b>



### Working capital statement

It is the Company's assessment that the current working capital is sufficient to meet PMD's needs for the coming twelve-month period. Working capital refers to the Company's access to liquid funds to fulfil its payment obligations after which they fall due for payment. PMD's ambition is to achieve sufficient annual recurring revenue to realise profitability by the end of 2024 and will not be dependent on any additional capital injections before then.

### Ongoing investments and commitments for future investments

The Company has not entered any firm commitments for significant future investments.

### Significant changes in the Group's financial position after 30 September 2023 up to and including the date of the of the Company Description

PMD has raised capital of approximately MSEK 26.5 through an issue of shares in PMD to certain existing shareholders and new investors in connection with the Transaction with the purpose of securing adequate working capital to grow market share in the United Kingdom and to undertake market access activities in Germany and the United States. The investors include PMD's board member Christer Ahlberg (former CEO of Sedana Medical). PMD has engaged Redeye as financial adviser for the capital raise. MSEK 11.6 of current indebtedness is being converted to equity.

In addition to what is needed to cover the Company's working capital for the next 12 months and due to end-of-year time constraints, it will be proposed for the Extraordinary General Meeting on 29 December 2023 to resolve on a specific issue authorisation. The specific authorisation will be aimed at enabling the new board of directors of Company to carry out an additional capital raise, on the corresponding terms as in the private placement up to an amount not exceeding MSEK 11.5 in order to accommodate further interest in participation in the Private Placement.

## PROPOSED BOARD, MANAGEMENT AND AUDITOR

According to the proposed articles of association, the board of directors shall consist of a minimum of three (3) and a maximum of ten (10) board members. The five individuals proposed for election as board members at the extraordinary general meeting on 29 December 2023 are presented below. The board members are proposed to be elected until the next annual general meeting. Regarding the board members' holdings, the holdings of each member in PMD after the completion of the Transaction and the reverse split (1:128) are presented. Own holdings refer to own and/ or related parties' holdings.

Name	Position	Member since	Independence* in relation to	
			Company and management	Major shareholders
Peter Donnelly	Chairman	2019	Yes	Yes
Magnus Christensen	Director	2019	Yes	Yes
Christer Ahlberg	Director	2019	Yes	Yes
Anne Dorney	Director and CCO	2019	No	No
Myles Murray	Director and CEO	2019	No	No

\*refers to independence in relation to the Company after the completion of the Transaction

### Peter Donnelly

Born in 1965. Chairman of the Board since 2021.

#### *Experience and relevant training*

Dr Peter Donnelly has a Bachelor of Engineering and a PhD degree in Electronics and Intelligent Adaptive Algorithms from Ulster University. For more than 30 years, Peter Donnelly has worked for blue-chip companies, new start businesses and research organisations in various industries. In addition to being the founder and CEO of BioBusiness Ltd, Peter has founded two medical device companies in the cardio-respiratory area and is the CEO and founder of Tapa Healthcare DAC. Peter is co-founder of MedZone Solutions. Furthermore, Peter has been involved in Northern Ireland government initiatives such as skills development and strategic economic foresight studies as well as operated as a UK Sector specialist to inform Government Departments and Agencies in Westminster. Peter has been director in PMD Device Solutions Limited since 2014.

#### *Ongoing appointments*

Other current appointments: Director and CEO of Tapa Healthcare DAC and director of MedZone Solutions.

#### *Holdings*

Holdings in the Company: 36,701 shares (following the completion of the Transaction and the reverse split (1:128)).

### Magnus Christensen

Born in 1974. Board member since 2021.

#### *Experience and relevant training*

Magnus Christensen has a Bachelor of Science degree from University of East Anglia. Christensen has extensive CFO experience of listed companies and has held the position of CFO at several large companies, including O'Leary's Trademark AB and Rebtel AB. Additionally, he has held the position of interim CEO of Medivir AB and Head of Business Control at ICA Sverige AB.

#### *Ongoing appointments*

CFO Medivir AB

#### *Holdings*

Holdings in the Company: -

## Christer Ahlberg

Born in 1971. Board member since 2021.

### *Experience and relevant training*

Christer Ahlberg holds a degree in economics from Örebro University. Christer has previously acted as CEO and Group CEO of Sedana Medical AB (publ). He has previous experience from the pharmaceutical industry as, inter alia, CEO within the Unimedica Group and CEO of Eisai AB. Christer has more than 10 years of experience of top positions in retail, marketing and market access in the pharmaceutical industry from companies such as AstraZeneca, Meda and Wyeth.

### *Ongoing appointments*

Director of FrostPharma AB and Prooxpharma AB, CEO of Cinclus Pharma Holding AB (publ), CEO and deputy board member in Waxholm by the sea aktiebolag.

### *Holdings*

Holdings in the Company: 157,350 shares (following the completion of the Transaction and the reverse split (1:128)).

## Myles Murray

See under "Senior management".

## Anne Dorney

See under "Senior management".

## SENIOR MANAGEMENT

As of the date of approval of the Company Description, the executive management of the Company consists of three persons. The following is a list of the Company's executive management with information regarding their year of birth, year of commencement, education and holdings in the Company. Holdings refer to own and closely related natural and corporate entities holding in the Company as of the date of this Company Description.

## Myles Murray

Born in 1986. Board member since 2021.

### *Experience and relevant training*

CEO and Founder of PMD. Myles Murray has a Bachelor of Engineering (Honours) degree in Mechanical Engineering from Cork Institute of Technology, as well as a post graduate certificate in Capital Markets. Myles has extensive experience within the medical technology industry and is a member of the Irish Medtech Association and a fellow of NHS Innovation Accelerator. Myles has been the CEO of PMD Device Limited since 2011.

### *Ongoing appointments*

None

### *Holdings*

Holdings in the Company: 8,081,910 shares (following the completion of the Transaction and the reverse split (1:128)).

## Anne Dorney

Born in 1958. Board member since 2021.

### *Experience and relevant training*

CCO and Executive Director of PMD. Anne Dorney is a Member of Compliance Institute Ireland and is a Certified Data Protection officer. A Qualified lender with the Institute of Banking Ireland. Former Bank Manager with AIB Bank. Anne has extensive management experience in Financials, Compliance, HR, Operations, Audit &

Business Development, Business planning and Strategy. Former consultant and mentor to several start-up companies and businesses. Anne held the position of CFO in PMD Device Solutions Limited from 2013 to 2021.

#### *Ongoing appointments*

None

#### *Holdings*

Holdings in the Company: 2,058,480 shares (following the completion of the Transaction and the reverse split (1:128)).

#### **Tom Meagher**

Born in 1967. CFO since 2021.

#### *Experience and relevant training*

Experience: Tom Meagher is a Chartered Accountant and has a bachelor's degree in Economics and Computer Studies from University College Cork. Tom has over 20 years' finance executive experience in Europe and the Middle East with multinational companies as well as SME companies, including senior roles at PwC, Trans Telecom, UPC and Saudi Specialized Laboratories.

#### *Ongoing appointments*

None

#### *Holdings*

Holdings in the Company: -

### **Other information relating to the Board of Directors and senior executives**

All directors and executive management can be contacted at the Company's office at Bishopstown House, Model Farm Road, Cork T12 T922, Ireland or the Company's address in Sweden, C/O Eversheds Sutherland Advokatbyrå AB, Box 14055, SE-104 40, Stockholm, Sweden.

There are no family ties between any directors and senior executives. Over the last five years none of the Company's members of the board of directors or executive management has (i) been convicted of any matter involving fraud, (ii) being bound by a crime and/or been subject to penalties for crime by a regulatory or supervisory authority (including recognised professional associations), or (iii) been prohibited by a court to be a member of an issuer's administration, or a management or supervisory body, or to person senior or leading functions at an issuer.

### **Auditor**

Finnhammars Revisionsbyrå Aktiefbolag (reg. no. 556358-0462), Videvägen 5, Box 194, 194 23 Upplands Väsby, Sweden is the Company's auditor for the period until the end of the next annual general meeting. Per-Olov Strand, authorised auditor, is the auditor in charge.

## Remuneration of the Board of Directors and senior executives

Remuneration to board members elected by the general meeting are resolved by the general meeting. It has been proposed that the extraordinary general meeting which is to be held on 29 December 2023 resolves that the remuneration to the Board of Directors shall be SEK 326,370 to the chairman of the Board of Directors and SEK 260,000 to board members who are not employees of the Company or a subsidiary to the Company. The Company has no accrued or pending amounts for pensions or similar benefits for board members or executive management upon their departure from service or positions.

The table below shows the remuneration to PMD's senior executives during the financial year 2022-04-01–2023-03-31.

Senior Executive	Salary MSEK	Pension MSEK	Total MSEK
Myles Murray	1,976.25	116.25	1,992.50
Anne Dorney	1,786.35	116.25	1,922.75
Tom Meagher	1,395.00	104.63	1,399.63

## CORPORATE GOVERNANCE

### General

The Company is a Swedish public limited company governed by Swedish law, primarily the Swedish Companies Act (2005:551). Subject to continued listing, the Company's shares will be admitted to trading on First North, whereby the Company applies the First North Rulebook for issuers. The Swedish Corporate Governance Code (the "Code") shall be applied by companies whose shares are admitted to trading on a regulated market. The Code does not currently need to be applied by companies whose shares are listed on First North and the Company has not voluntarily undertaken to comply with it. In addition to legislation, rules and recommendations, the Articles of Association form the basis for the governance of the Company's operations. The articles of association specify, among other things, where the board of directors has its registered office, the focus of the business, limits on share capital, number of shares and classes of shares, and the conditions for participation in general meetings. The Articles of Association that will be proposed to the extraordinary general meeting on 29 December 2023 (which will consider proposals for resolutions to approve the Transaction) are set out in full in the section "Articles of Association after the Transaction". The responsibility for governance, management and control of the Company is divided between the shareholders, the Board of Directors and the CEO, other members of the Company's management and the special committees and control bodies that the Board of Directors establishes from time to time.

### General meeting of shareholders

The general meeting is the Company's highest decision-making body and the shareholders' right to decide on the Company's affairs is exercised at the general meeting (annual general meeting and extraordinary general meeting). The Swedish Companies Act and the Articles of Association specify how notice of the AGM and EGM should be given and who is entitled to attend and vote at the AGM. The AGM shall be held within six (6) months of the end of the financial year. The AGM decides on the adoption of the income statement and balance sheet for the Company, the appropriation of the year's profit or loss according to the adopted balance sheet, the discharge of the board of directors and the CEO from liability for the financial year, the appointment of board members and auditors, the remuneration of board members and auditors, and decisions on certain other matters in accordance with the law and the articles of association.

Shareholders who wish to participate in a general meeting must be entered in the share register maintained by Euroclear on the record date for the general meeting and notify the Company of their participation no later than the time and date specified in the notice of the meeting. Shareholders may attend the general meeting in person or by authorised representative. Shareholders or proxies may be accompanied by a maximum of two assistants. Usually, shareholders can register for the general meeting in several different ways, which are specified in the notice of the meeting. Shareholders are entitled to vote for all the shares they hold in the Company. Shareholders whose shares are registered with a bank or other nominee must, in addition to informing the Company, request that their shares be temporarily registered in their own name in the share register maintained by Euroclear, to be entitled to participate in the general meeting. Shareholders should inform their nominees well in advance of the record date. Shareholders who wish to have a matter considered at the general meeting should request this in writing to the board of directors. The request must normally be received by the Board of Directors no later than one week before the earliest date on which the notice may be issued in accordance with the Swedish Companies Act. Each shareholder who notifies a matter with sufficient advance notice is entitled to have a matter dealt with at the general meeting.

### The board of directors

The board of directors is the Company's highest decision-making body after the general meeting. According to the Swedish Companies Act, the board of directors is responsible for the Company's organisation and management of the Company's affairs, which means that the board of directors is responsible for, among other things, establishing goals and strategies, ensuring procedures and systems for evaluating established goals, continuously evaluating the Company's results and financial position and evaluating the operational management. It is also the board of directors' responsibility to ensure that the right information is provided to the Company's stakeholders and that the Company's disclosure of information is characterised by transparency

and is correct, relevant and reliable, that the Company complies with laws and regulations and that the Company develops and implements relevant internal policies and guidelines. The board of directors is also responsible for ensuring that the annual accounts, consolidated accounts and interim reports are prepared in a timely manner and for appointing the CEO and determining his or her salary and other remuneration. The board members are elected annually at the annual general meeting of the Company for the period until the next annual general meeting. According to the Company's articles of association, the board of directors shall consist of a minimum of three and a maximum of ten members. The board members are presented in more detail under the section "Board of Directors, management and auditor". In addition to the Swedish Companies Act, the work of the board is regulated by rules of procedure adopted by the board. The rules of procedure must be revised annually and are adopted at the inaugural board meeting each year. The rules of procedure regulate, inter alia, the board's working methods, duties, decision-making procedures within the Company, the board's meeting procedures, the chairman's duties and the division of labour between the board and the CEO. The board shall also issue instructions for the CEO and instructions for financial reporting to the board. The board of directors meets according to an annual schedule and according to a programme set out in the rules of procedure, which includes fixed decision points and items as required.

## **The CEO and management**

The Company's CEO is accountable to the board of directors and is responsible under the Swedish Companies Act for the day-to-day management of the Company's affairs in accordance with the board's guidelines and instructions. The board of directors has adopted an instruction for the CEO that clarifies the CEO's responsibilities and powers. The board of directors shall continuously evaluate the performance of the CEO. According to the instruction, the CEO shall, among other things, provide the board of directors with the information and decision-making basis required for the board of directors to fulfil its task of being responsible for the management of the Company's affairs and continuously monitor the operations. The CEO shall, within the framework of the Swedish Companies Act and the business plan, budget and CEO instructions adopted by the board of directors, as well as other guidelines and instructions issued by the board of directors, make the decisions required in the Company's ongoing management. The CEO and senior executives, supported by various staff functions, are responsible for the Company's compliance with the overall strategy, financial and operational control, the Group's financing, capital structure and risk management. This includes preparation of financial reports, information to and communication with investors, etc.

## **Auditing**

As a public company, the Company is required to have at least one auditor to review the Company's and the Group's annual report and accounting records and the administration of the board of directors and the CEO. The company's auditors are elected by the general meeting in accordance with the Swedish Companies Act. An auditor in a Swedish limited company thus receives its assignment from, and reports to, the general meeting and may not be guided in its work by the board of directors or any senior executive. After each financial year, the auditor shall submit an audit report and, where applicable, a group audit report to the annual general meeting. According to the Company's proposed articles of association to be adopted at the extraordinary general meeting on 29 December 2023, the Company shall have a minimum of one and a maximum of two auditors or a registered accounting firm. Further information on the Company's auditor can be found under the heading "Auditor" in the section "Proposed board of directors, management and auditor". The provisions on the establishment of an audit committee are set out in the Swedish Companies Act and in this respect only apply to companies whose shares are admitted to trading on a regulated market. The provisions on the establishment of remuneration committees are set out in the Code, which is not mandatory for the Company. The board of directors has made the assessment that, considering the scope of the business and the size of the Company, it is currently not justified to establish special committees for audit and remuneration issues without these issues being dealt with by the board of directors. The Company has not established a special function for internal audit; the task is fulfilled by the board of directors. In the Company, the CEO is also responsible for ensuring the necessary control and follow-up.

# ARTICLES OF ASSOCIATION FOLLOWING THE TRANSACTION

The articles of association presented below are proposed to be adopted by the extraordinary general meeting to be held on 29 December 2023. The text in English is an unofficial translation of the Swedish original wording. If there are differences between the English translation and the Swedish original, the Swedish text takes precedence.

## **§ 1 Företagsnamn / Name of the company**

Bolagets företagsnamn är PMD Device Solutions AB. Bolaget är ett publikt bolag (publ).

*The name of the company is PMD Device Solutions AB. The company is a public company (publ).*

## **§ 2 Styrelsens säte / The registered office of the company**

Styrelsen har sitt säte i Stockholm.

*The registered office of the company is situated in Stockholm.*

## **§ 3 Verksamhetsföremål / Objects of the company**

Bolaget ska direkt eller indirekt genom dotterbolag bedriva forskning, utveckling och framtagning av medicintekniska produkter och utrustning och därmed förenlig verksamhet.

The company shall directly or indirectly through subsidiaries conduct research, development and production of medical devices and equipment and thereto related activities.

## **§ 4 Aktiekapital / Share capital**

Aktiekapitalet ska vara lägst 105 400 000 kronor och högst 421 600 000 kronor.

*The share capital shall be not less than SEK 105,400,000 and not more than SEK 421,600,000.*

## **§ 5 Antal aktier / Number of shares**

Antalet aktier ska vara lägst 20 580 000 och högst 82 320 000.

The number of shares shall be not less than 20,580,000 and not more than 82,320,000.

## **§ 6 Styrelse / Board of directors**

Styrelsen ska bestå av 3-10 ledamöter och högst 10 suppleanter.

*The board of directors shall comprise 3-10 directors and not more than 10 alternate directors.*

## **§ 7 Revisor / Auditor**

Bolaget ska utse en revisor samt högst en revisorssuppleant. Till revisor samt, i förekommande fall, revisorssuppleant, ska utses en auktoriserad revisor eller ett registrerat revisionsbolag.

*The company will elect one auditor and not more than one alternate auditor. The auditor, and where applicable the alternate auditor, will be an authorised public accountant or a registered accounting firm.*

## **§ 8 Kallelse till bolagsstämma / Notice of a general meeting**

Kallelse till bolagsstämma ska ske genom annonsering i Post- och Inrikes Tidningar och genom att kallelsen hålls tillgänglig på bolagets webbplats. Att kallelse skett ska annonseras i Svenska Dagbladet.

*Notice of a general meeting will be issued in the form of announcements in Post- and Inrikes Tidningar and on the company's web site. The fact that notice has been issued will be announced in Svenska Dagbladet.*

Aktieägare, som vill delta i bolagsstämma, ska anmäla detta till bolaget senast den dag som anges i kallelsen till stämman. Denna dag får inte vara söndag, annan allmän helgdag, lördag, midsommarafton, julafton eller nyårsafton och inte infalla tidigare än femte vardagen före bolagsstämman. Aktieägare som vill medföra ett eller två biträden vid bolagsstämman skall anmäla detta till bolaget inom ovan nämnda tid.

*A shareholder wishing to participate in the general meeting shall notify the company no later than the day stated in the notice of the general meeting. Last mentioned day may not be a Sunday, other public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve and may not occur earlier than the fifth weekday before the general meeting. A shareholder wishing to be accompanied by one or two advisors at a general meeting of shareholders shall notify the company of this fact within the above-mentioned period.*



### **§ 9 Ärenden på bolagsstämman / Matters on the annual general meeting**

På årsstamma ska följande ärenden förekomma till behandling:

*At the annual general meeting the following matters will be dealt with:*

1. val av ordförande vid stämman  
*election of the chairman to preside the meeting*
2. upprättande och godkännande av röstlängd  
*preparation and approval of the voting list*
3. godkännande av dagordning  
*approval of the agenda of the meeting*
4. val av en eller två justeringsmän  
*election of one or two people to approve the minutes*
5. prövning av om stämman blivit behörigen sammankallad  
*examination of whether the meeting has been duly convened*
6. framläggande av årsredovisningen och revisionsberättelsen, samt i förekommande fall av koncernredovisningen och koncernrevisionsberättelsen  
*presentation of the annual report and the auditor's report and, where applicable, the consolidated accounts and the auditor's report for the group*
7. beslut om  
*resolution on*
  - a) fastställelse av resultat- och balansräkningen, samt i förekommande fall av koncernresultat- och koncernbalansräkning  
*adoption of the income statement and the balance sheet and, where applicable, of the consolidated income statement and consolidated balance sheet*
  - b) dispositioner beträffande bolagets vinst eller förlust enligt den fastställda balansräkningen  
*disposition of the company's profit or loss according to the adopted balance sheet*
  - c) ansvarsfrihet gentemot bolaget för styrelseledamöterna och verkställande direktören  
*discharge from liability of the directors and the managing director*
8. fastställande av antalet ledamöter, suppleanter, revisor och revisorssuppleant som ska utses av bolagsstämman  
*determination of the number of directors, alternate directors, auditor and alternate auditor to be elected by the general meeting*
9. fastställande av arvoden åt styrelse och revisor  
*determination of fees for the board of directors and the auditor*
10. val av styrelseledamöter och revisor samt, i förekommande fall styrelsesuppleanter och revisorssuppleant  
*election of the directors and auditor and, where applicable, alternate directors and alternate auditor*
11. annat ärende som bolagsstämman enligt aktiebolagslagen eller bolagsordningen ska behandla  
*any other matter to be dealt with at the general meeting according to the Swedish Companies Act or the articles of association*

### **§10 Räkenskapsår / Financial year**

Bolagets räkenskapsår ska vara kalenderår.

*The financial year of the company will be calendar year.*

### **§11 Avstämningsförbehåll / Securities depository registration clause**

Den aktieägare eller förvaltare som på avstämningsdagen är införd i aktieboken och antecknad i ett avstämningsregister enligt 4 kap. lagen (1998:1479) om värdepapperscentraler och kontoföring av finansiella instrument eller den som är antecknad på avstämningskonto enligt 4 kap. 18 § första stycket 6-8 nämnda lag ska antas vara behörig att utöva de rättigheter som följer av 4 kap. 39 § aktiebolagslagen (2005:551).  
*The shareholder or administrator who, on the record day, is entered in the share register and in a securities depository register under Chapter 4 in the Swedish Central Securities Depositories and Swedish Financial Instruments Accounts Act (1998:1479) or entered in securities depository accounts under Chapter 4 Paragraph 18 First section 6-8 in above mentioned act, is assumed to be authorised to exercise the rights stated in Chapter 4 Paragraph 39 of the Swedish Companies Act (2005:551).*

### **§ 12 Fullmaktinsamling samt poströstning / Collection of proxies and postal voting**

Styrelsen får samla in fullmakter enligt det förfarande som anges i 7 kap. 4 § andra stycket aktiebolagslagen (2005:551).

*The Board of Directors may collect powers of attorney in accordance with the procedures specified in Chapter 7, Section 4, Paragraph 2 of the Swedish Companies Act (2005:551).*

Styrelsen får inför en bolagsstämma besluta att aktieägarna ska kunna utöva sin rösträtt per post före bolagsstämman.

*The Board of Directors may decide, prior to a general meeting of shareholders, that the shareholders be permitted to exercise their voting rights by post prior to the general meeting.*

**§ 13 Tvisters avgörande av skiljemän / Settlement of disputes through arbitration**

Skulle tvist uppkomma mellan bolaget och styrelsen, styrelseledamot, verkställande direktör, likvidator eller aktieägare, ska den hänskjutas till avgörande av skiljemän i enlighet med lagen (1999:116) om skiljeförfarande.

*In the event of a dispute between the company and the board of directors, a director, the managing director, a liquidator or a shareholder, the matter shall be determined by arbitrators in accordance with the Swedish Arbitration Act (1999:116).*

## SHARES, SHARE CAPITAL AND OWNERSHIP MATTERS

### General information on shares and share capital

According to the Articles of Association proposed to be adopted at the Extraordinary General Meeting on 29 December 2023, the share capital may not be less than SEK 105,400,000 and not more than SEK 421,600,000. As of 31 December 2022, Promore's share capital amounted to SEK 2,428,557.44 divided into 60,713,936 shares. Following the completion of the Transaction, the Company's share capital will amount to SEK 105,407,034.60. Following the completion of the Transaction and the implementation of the proposed reverse split, the number of shares will amount to 20,587,314. The Company has only one class of shares. The ISIN code for the Company's share is SE0009947740. The shares are denominated in SEK and each share will, following the reverse split, have a quota value of SEK 5.1. The shares in the Company have been issued in accordance with Swedish law. All issued shares are fully paid and paid and freely transferable.

### Changes in share capital

The table below shows the historical development of the the Company's share capital since its formation up to and including the the change in the number of shares and the share capital that will be will be implemented in connection with the Transaction and the continued listing.

Registration date	Event	Change in share capital (SEK)	Change in number of shares	Share capital after the change (SEK)	Number of shares after the change	Quotient value (SEK)	Subscription price
2003-01-29	Company formation	100,000.00	100,000	100,000.00	100,000	1.00	1.00
2004-02-06	Share issue	16,667.00	16,667	116,667.00	116,667	1.00	120.00
2004-05-10	Share issue	16,666.00	16,666	133,333.00	133,333	1.00	120.00
2004-11-16	Share issue	22,934.00	22,934	156,267.00	156,267	1.00	120.00
2005-03-15	Conversion of loan notes	3,333.00	3,333	159,600.00	159,600	1.00	120.00
2006-01-03	Share issue	54,424.00	54,424	214,024.00	214,024.00	1.00	113.00
2006-08-30	Share issue	35,398.00	35,398	249,422.00	249,422	1.00	113.00
2007-11-21	Share issue	61,947.00	61,947	311,369.00	311,369	1.00	113.00
2008-09-02	Share issue	70,798.00	70,798	382,167.00	382,167	1.00	113.00
2009-02-05	Share issue	61,947.00	61,947	444,114.00	444,114	1.00	113.00
2009-10-13	Share issue	48,159.00	48,159	492,273.00	492,273	1.00	52.48
2010-02-02	Share issue	57,143.00	57,143	549,416.00	549,416	1.00	52.50
2010-03-02	Share issue	57,143.00	57,143	606,559.00	606,559	1.00	52.50
2010-12-03	Share issue	151,879.00	151,879	758,438.00	758,438	1.00	65.95
2011-01-17	Share issue	75,815.00	75,815	834,253.00	834,253	1.00	65.95
2015-05-07	Reduction of share capital	784,197,82	-	50,055.18	834,253	0.06	-
2016-02-03	Share issue	1,323.60	22,060	51,378.78	856,313	0.06	225.00
2016-03-15	Share issue	151.02	2,517	51,529.80	858,830	0.06	225.00

2016-04-18	Share issue	1,363.62	22,727	52,893.42	881,557	0.06	200.00
2016-04-18	Share issue	681.78	11,363	53,575.20	892,920	0.06	200.00
2016-04-18	Share issue	681.78	11,363	54,256.98	904,283	0.06	200.00
2017-05-12	Bonus issue	488,312.82	-	542,569.80	904,283	0.60	-
2017-05-12	Share split (15:1)	-	12,659,962	542,569.80	13,564,245	0.04	-
2017-06-13	Warrant exercise	136,362.60	3,409,065	678,932.40	16,973,310	0.04	200.00
2017-06-27	Share issue	130,471.20	3,261,780	809,403.60	20,235,090.00	0.04	23.40
2019-12-03	Share issue	464,902.64	11,622,566	1,274,306.24	31,857,656.00	0.04	3.71
2019-12-11	Share issue	182,828.24	4,570,706	1 457 134,48	36,428,362.00	0.04	3.71
2021-07-15	Share issue	971,422.96	24,285,574	2,428,557.44	60,713,936.00	0.04	2.00
*	Share issue	102,978,477	2,574,461,929	105,407,034.60	2,635,175,865	0.04	0.05961
**	Share issue	13,08	327	105,407,047,68	2,635,176,192	0.04	0.04
***	Reverse share split (1:128)	-	2,614,588,878	105,407,047,68	20,587,314	5.12	-

\* Issue of consideration shares in connection with the closing of the Transaction, to be decided on the extraordinary general meeting to be held on 29 December 2023.

\*\* Equalisation issue in order to facilitate the reverse split of shares, to be decided on the extraordinary general meeting to be held on 29 December 2023.

\*\*\* Reverse split of shares to be decided on the extraordinary general meeting to be held on 29 December 2023.

## Authorisation for issues of shares, warrants and convertibles

On the annual general meeting of Promore held on 27 June 2023, it was decided to authorise the board of directors to, with or without deviation from the shareholders' preferential rights, for the period to the next annual general meeting and on one or several occasions, issue shares, convertibles and warrants with or without provisions of payment in kind, right of set-off and/or other conditions. The basis for the determination of the subscription price when disapplying from the shareholders' pre-emption rights will be the share's, the convertible's or the warrant's market value at the time of the respective issue, taking into account rebates in accordance with the market conditions, when applicable. The number of shares that the board shall be entitled to issue, the number of shares that convertibles may entitle to and the number of shares that may be subscribed for on account of warrants, shall totally amount to no more than 12,142,787 new shares, corresponding to a dilution of approximately 20 per cent.

It is proposed for the extraordinary general meeting to be held on 29 December 2023 to decide to authorise the board of directors to, on one or more occasions during the period from the authorisation been registered by the Swedish Companies Registration Office up and until 15 January 2024, resolve to issue new shares at the same conditions as applied for in the directed issue of shares in PMD prior to the reverse acquisition and the issue in kind announced through a press release on 29 November 2023 with the heading "Promore Pharma AB intends to carry out a reverse acquisition of PMD Device Solutions AB". The purpose of the authorisation is to enable the Board of Directors to satisfy further interest in participating in a capital raising also after the completion of the reverse acquisition. The authorisation may be used for one or more issues corresponding in total to a maximum raise of MSEK 11.5.

## Lock up agreements

All current shareholders in PMD with a holding greater than 1.0 per cent will enter a lock up for 12 months following completion of the Transaction.

All current shareholders in Promore with holdings of 10 per cent or more of the Promore shares will enter in a stepwise lock-up with 1/3 free from restriction after 6 months from the Transaction, another 1/3 free from restriction after 9 months of the Transaction and the balance free from restriction after 12 months from the Transaction.

## Warrants

The extraordinary general meeting held on 31 December 2021 in PMD decided on an issue of warrants to CEO Myles Murray and CCO Anne Dorney. The warrants were issued without consideration. The total number of outstanding warrants amounts to 929,102. The warrants can be exercised to subscribe for new shares from the date when the resolution was registered with the Swedish Companies Registration Office (9 February 2022) until 31 December 2024, at a subscription price of SEK 6.81 SEK per share. The warrants are subject to customary recalculation terms.

To ensure that PMD remains a wholly-owned subsidiary of the Company after the completion of the Transaction, the outstanding warrants in PMD, upon the option holders' exercise of the subscription options, will entitle them to new shares in the Company instead of new shares in PMD. In a warrant agreement between the warrant holders and the Company, each holder will undertake towards the Company and PMD that if the warrants in PMD are exercised, they will transfer the newly subscribed shares in PMD to the Company in exchange for newly issued shares in the Company. In the warrant agreement, the Company will undertake towards the warrant holders that, upon the exercise of the warrants, it will, to the best of its ability, ensure that the Company resolves on a new issue of shares to be paid with non-cash assets to facilitate the warrant holders' subscription of shares in the Company upon the exercise of the warrants in PMD. In the event that such a resolution on a new issue in the Company is not made, the warrants holders have the right to receive cash compensation for the shares in PMD instead of newly issued shares in the Company.

## Shareholders' agreements

To the best of the proposed board of directors' knowledge, there are no shareholder agreements or other agreements between the Company's shareholders aiming at joint influence over the Company. As far as the proposed board of directors' of the Company is aware, there are no other agreements or equivalent agreements that which aim at joint influence over the Company or which may lead to lead to a change or prevention of control over the Company.

## Dividend policy

The Company does not have a dividend policy in place and has per the date of the Company Description never paid any dividends to its shareholders. The Company is currently in an expansion phase and plans to re-invest any profits in continued Company development. Therefore, no dividend is expected to be paid in the near term.

## Shareholders' rights

### General information

The Company's shares have been issued in accordance with Swedish law and the rights associated with the Company's shares, including those pursuant to Company's articles of association, can only be amended in accordance with the procedures set out in the Swedish Companies Act.

### Voting rights

Each share in the Company entitles the holder to one (1) vote at shareholder's meetings and each shareholder is entitled to cast votes equal in number to the number of shares held by the shareholder in the Company.

## Preferential rights

If the Company issues new shares, warrants or convertibles in cash issue or set-off issue, the shareholders shall, as a general rule, have preferential rights to subscribe for such securities proportionally to the number of shares held prior to the issue.

## Right to dividends, share in the company's profits and proceeds of liquidation

All shares give equal rights to dividends and the Company's assets and possible surpluses in the event of liquidation. Resolutions regarding dividends are passed by shareholder's meetings. All shareholders registered as shareholders in the share register maintained by Euroclear Sweden on the record date adopted by the shareholders' meeting shall be entitled to receive dividends. Dividends are normally distributed to shareholders as a cash payment per share through Euroclear Sweden but may also be paid out in manner other than cash (in-kind dividend). If shareholders cannot be reached through Euroclear Sweden, such shareholders still retain their claims on the Company to the dividend amount, subject to a statutory limitation of ten years. Upon the expiry of the period of limitations, the dividend amount shall pass to the Company. There are no restrictions on the rights to dividends for shareholders domiciled outside Sweden.

## Central securities depository

The Company's shares are registered in a securities register in accordance with the Swedish Central Securities Depository and Financial Instruments Accounts Act (Sw. lagen (1998:1479) om värdepapperscentraler och kontoföring av finansiella instrument). The register is operated by Euroclear Sweden (Euroclear Sweden AB, P.O. Box 191, SW-101 23 Stockholm, Sweden). No share certificates have been issued for the shares in the Company.

## Information on public takeover bids and redemption of minority shares

The Takeover Rules for certain trading platforms (the "Takeover Rules") apply to public takeover offers and the decisions and rulings of the Swedish Securities Market Board regarding the interpretation and application of the Takeover Rules and, where applicable, the decisions and rulings of the Swedish Securities Market Board regarding the interpretation and application of the previous "Rules on Public Takeover Offers on the Stock Market" of the Swedish Business Exchange Committee apply to the offer. If the board of directors or the CEO, on the basis of information originating from the person intending to make a public takeover offer for shares in the Company, has reasonable grounds to believe that such an offer is imminent, or if such an offer has been made, the Company may only take measures, so-called defensive measures, which are likely to impair the conditions for the making or implementation of the offer, after a decision by the general meeting. However, this does not prevent the Company from seeking alternative offers.

The Takeover Rules for certain trading platforms also contain provisions on mandatory takeover bids, which, in summary, set out the following rights and obligations of shareholders. The offer must cover all shares in the Company and include a consideration option whereby all shareholders are entitled to receive cash payment. The offeror is obliged to treat all holders of shares with identical terms and conditions equally. The acceptance period for shareholders must not be less than three weeks.

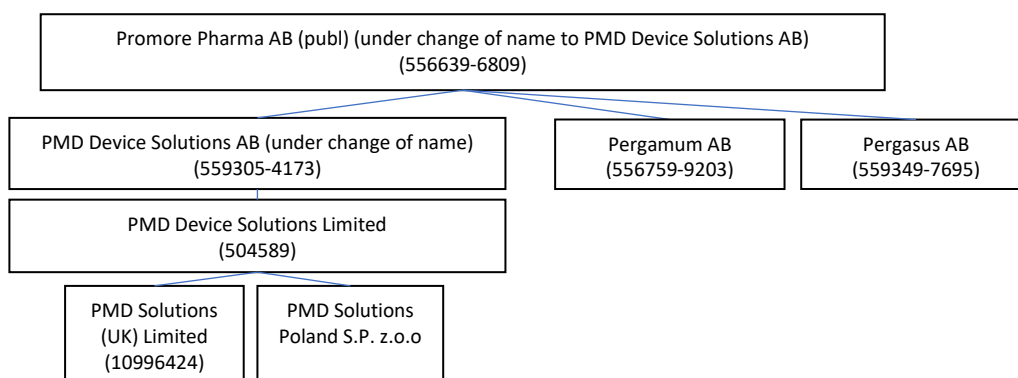
The redemption of shares is not regulated in the articles of association but is governed by the rules of the Swedish Companies Act, which, in summary, sets out the following rights and obligations of shareholders. A shareholder holding more than nine-tenths of the shares (the majority shareholder) has the right to redeem the remaining shares from the other shareholders of the Company. Anyone whose shares are redeemable has the right to have his shares redeemed by the majority shareholder. If the redemption amount is in dispute, the redemption amount shall be determined so as to correspond to the price of the share that can be charged in a sale under normal circumstances. Where a request for redemption of a share has been preceded by a public offer to acquire all the shares not already held by the offeror and where that offer has been accepted by the holders of more than nine-tenths of the shares to which the offer relates, the redemption price shall be equal to the consideration offered, unless special reasons justify otherwise. The Company's shares are not subject to any offer made pursuant to a mandatory bid, right of redemption or obligation to redeem. There have been no public takeover bids for the Company's shares during the current or previous financial year.

## LEGAL MATTERS AND COMPLEMENTARY INFORMATION

### Group structure

The Company is a public limited company formed and registered under under Swedish law with the company name Promore Pharma AB (publ), under change of name to PMD Device Solutions AB. The Company's registered office is in Solna. The registered office will be changed to Stockholm in connection with the Transaction. The Company's form of association is governed by, and its shares have been issued under, the Swedish Companies Act. The Company was incorporated in Sweden on 19 February 2002 and was registered with the Swedish Companies Registration Office on 29 January 2023.

The group structure after the completion of the Transaction is shown below. All subsidiaries in the group structure are directly or indirectly owned to 100 per cent by PMD.



Once the Transaction has been completed on 29 December 2023 and PMD Device Solutions AB is a wholly owned subsidiary of Promore, PMD Device Solutions AB would be dissolved by way of an upstream merger into Promore Pharma AB (publ) (under change of name to PMD Device Solutions AB) to reduce the number of Swedish holding companies in the new group from two to one. The operations of the subsidiaries Pergamum AB and Pergasus AB will be discontinued following the Transaction.

### Related-party transactions

During the period covered by the historical financial information included in the Company Description, there has not been any transactions between either Promore and its related parties or PMD and its related parties that have affected the group's position, apart from the transactions described below and the remuneration to the Board of Directors and senior executives. The Company believes that all transactions with related parties have been carried out on market terms.

Promore has a consulting agreement with the consulting company Arexela AB, wholly owned by Margit Mahlapuu, under which Margit has provides services as Chief Scientific Officer in Promore. The remuneration amounted to KSEK 2,880 during the financial year 2021, KSEK 2,781 during the financial year 2022, and KSEK 2,630 during the financial year 2023 up to the date of this Company Description.

Promore has a consulting agreement with the consulting company Råderik AB, wholly owned by Erik Magnusson, under which Erik has provided services as Chief Financial Officer in Promore. The remuneration amounted to KSEK 1,981 during the financial year 2021, KSEK 1,517 during the financial year 2022, and KSEK 1,394 during the financial year 2023 up to the date of this Company Description.

PMD has entered into a financing agreement with board member Christer Ahlberg. For more information, see "Financing agreements" under section "Material agreements" below.

## Material agreements

### Customer agreements

At the beginning of Covid 19, PMD received a purchase order from the Health Service Executive (HSE) dated 2 February 2020, which details the products and services the HSE purchased from the Company. The Purchase Order is subject to the HSE Standard Terms for Services and Suppliers available at [www.hse.ie](http://www.hse.ie).

The Company continues to supply replacement sensors to the HSE every 3 months since January 2020 for EUR 750k. A public procurement process is expected to be set up in 2024, but there is no firm date for this process. The annual value amounts to approximately MSEK 34.8.

The HSE awarded PMD a further contract for Community Virtual Ward (Hospital-at-Home ) This is a two year contract, from 1 November 2023 renewable for a further two years, for the supply of a managed service from Letterkenny Hospital to support patients in the home. This contract carries an annual value of approximately MSEK 6.4.

An agreement between the Company and the UK NHS Nottingham is in place since 2 November 2022. This allows for a pilot research project carried out over 12 months. Useage of RespiraSense has since extended to additional wards in Nottingham University hospital.

PMD is an Approved NHS Supplier under HSSF Framework agreement 30 July 2020.

Since 2020, an agreement has been in place with the European Space Agency to develop a world's first patient wearable using 5G technology. The project is expected to be completed within next 3 months. The Project involves PMD showcasing a working home care device including hardware, software and documentation with enhanced connectivity.

### Supplier agreements

PMD have ongoing contracts with different suppliers providing PMD with Piezo electric sensors, plastic housing and the lobe (printed circuit board assembly) for RepiraSense. All supplier contracts are rolling with no expiry date.

### Financing agreements

PMD has entered into a loan agreement with Buntel AB ("Buntel"), of which its latest amendment is dated 10 October 2023 (transfer of debt from an original loan agreement with Modelio AB originally dated 15 December 2021). The loan has a fixed interest rate of 1.5 percent per month. As per the date of this Company Description, the outstanding debt under the loan agreement amounts to MSEK 3.5. The Remaining part of the loan is to be repaid within 30 days of a capital markets transaction of not less than MSEK 15 or 31 March 2024 at the latest.

PMD has entered into a loan agreement with Chirp AB ("Chirp") of which its latest amendment was entered into in December 2023 (originally entered into in December 2021). The loan has a fixed interest rate of 1.5 percent per month. The loan has been repaid to an amount of MSEK 7.5 through set-off within the Private Placement conducted by PMD prior to the Transaction. As per 31 December 2023, the total outstanding debt to Chirp amounts to approximately MSEK 19.5. The Remaining part of the loan is to be repaid on 31 January 2025 at the latest. The loan may be repaid by way of set-off against Chirp's undertaking to pay the subscription price in an issue in PMD of shares or other financial instruments in which Chirp is entitled to participate. PMD undertakes to pledge to Chirp all its shares in its Irish subsidiary PMD Device Solutions Limited as security for its payment obligations under the loan agreement.

On 12 January 2022, the Christer Ahlberg subscribed for 1,500,000 dematerialised convertible debentures (Sw. konvertibler) in the total amount of MSEK 1.5 issued by PMD. The convertible debentures fell due for repayment in full on 30 June 2022. The Parties agreed to cancel the Convertible Debentures and substitute the aggregate convertible debt with a loan agreement on 30 September 2022. On 29 March 2023 the Company and Christer Ahlberg entered into an amendment and restatement agreement in which the loan was extended until the 31



December 2023. The loan has a fixed interest rate of 1.5 percent per month. The loan has been repaid to an amount of MSEK 1.20 through set-off within the private placement conducted by PMD prior to the Transaction.

### **Intellectual property rights**

Please refer to "Patents" under the section "Description of activities".

### **Trends and prospects**

Other than the tendencies and trends set out in the section "Market overview" and what is stated in the section "Risk factors", PMD is not aware of any uncertainties, potential claims or other demands, commitments or events that could have a material impact on the Company's business prospects. PMD is currently not aware of any information about public, economic, tax policy, monetary policy or other political measures that may, directly or indirectly, significantly affect the Company's operations or business prospects during the current financial year. To the best of the PMD's knowledge, there are no known trends, uncertainties, potential material claims or other requirements, commitments or events, other than those described in this Company Description, that can be expected to have a material impact on the Company's prospects.

### **Insurances**

The Company has taken out customary business insurances and property insurances. The Group has also taken out liability insurance for the Board of Directors and the CEO covering the Company. The Company believes that its insurance coverage is in line with the insurance coverage of other companies in the same industry and that the insurance coverage is sufficient for the risks that the business is usually associated with. However, PMD cannot provide any guarantees that the Company will not incur losses beyond what is covered by these insurance policies.

### **Legal proceedings and arbitration**

Neither PMD nor Promore is, and has not been, subject to any regulatory or legal proceedings or arbitrational proceedings (including pending or threatened proceedings) during the last twelve months, which have materially affected, or could materially affect, the Company's financial position or profitability. The Company and its board of directors have confirmed that they are not aware that any such proceedings could arise.

### **Conflicts of interest**

There are no conflicts of interest or potential conflicts of interest between the directors' and senior executives' commitments to PMD and their private interests and/or other commitments (however, several proposed board members and senior executives have certain financial interests in PMD due to their direct or indirect share and warrant holdings in the Company). None of the members of the board of directors or the senior executives have been elected or appointed as a result of an agreement with major shareholders, customers, suppliers or other or other parties.

### **Advisor's interest**

The Company believes that there are no significant conflicts of interest due to the Company's continued listing on First North .

### **Certain tax issues**

Investors should note that the tax regulation in the investor's home country and in the country where the Company is registered can affect the eventual return made on a share investment in the Company. Taxation of an eventual dividend, and taxation on capital gain and rules regarding capital losses in sales of securities, depend on each individual shareholder's specific situation. Specific tax rules apply to certain types of taxpayers and certain types of investments. Hence, investors are advised to consult a tax consultant regarding any tax consequences that may arise on their particular case, including the applicability and effect of foreign tax rules.

## **Termination of voluntary liquidation process and continued listing on Nasdaq First North**

On 12 October 2023, Promore entered into voluntary liquidation, following a decision made at an extraordinary general meeting held on 5 October 2023. The Swedish Companies Registration Office appointed the lawyer Lars-Henrik Andersson from Cirio Advokatbyrå AB as the liquidator. The reason for the decision on voluntary liquidation was that there was deemed to be no acceptable alternative to a decision on voluntary liquidation to avoid a bankruptcy situation in the event that a structural transaction could not be implemented. However, in light of the Transaction, the basis for the voluntary liquidation is no longer deemed to exist. Against this background, it has been proposed that the extraordinary general meeting in Promore, scheduled for 29 December 2023, decides on the termination of the voluntary liquidation process.

The liquidator of the Company has, as part of the Transaction, decided to apply for continued listing of the Company's shares for trading on Nasdaq First North following the extraordinary general meeting and the closing of the Transaction on 29 December 2023.

### **Available documents**

This Company Description, documents incorporated by reference and the articles of association is available in electronic form on the Company's website. Upon request, the Company's registration certificate may be obtained from the Company.

## ADDRESSES

### **PMD Device Solutions AB**

C/o Eversheds Sutherland Advokatbyrå AB  
Box 14055, 104 40 Stockholm, Sweden

### **Promore Pharma AB (publ)**

C/o Ciro Advokatbyrå AB  
Box 3294, 103 65 Stockholm, Sweden

### **Certified Adviser**

Redeye AB  
Mäster Samuelsgatan 42, 10 tr  
Box 7141, 103 87 Stockholm, Sweden

### **Transaction advisor**

Fóla Private Partners  
The Tree House, 12 Beechurst, Bray, Co Wicklow  
A98 TW32 Ireland

### **Legal advisor**

Eversheds Sutherland Advokatbyrå AB  
Sveavägen 20  
Box 14055, 104 40 Stockholm, Sweden

### **Auditor**

Finnhammars Revisionsbyrå Aktiebolag  
Videvägen 5  
Box 194, 194 23 Upplands Väsby, Sweden