



## INFORMATION MEMORANDUM

Invitation to Subscribe for Shares with preferential rights in PMD Device Solutions AB  
Subscription period 19 August – 2 September 2024

PLEASE NOTE THAT THE SUBSCRIPTION RIGHTS ARE EXPECTED TO HAVE ECONOMIC VALUE.

To avoid losing the value of the subscription rights, the holder must either:

- exercise the subscription rights to subscribe for shares no later than 2 September 2024; or
- sell the subscription rights no later than 28 August 2024.

Please note that shareholders with nominee-registered holdings should contact their nominee for instructions on how to subscribe and make payment.

DISTRIBUTION OF THIS INFORMATION MEMORANDUM AND SUBSCRIPTION FOR NEW SHARES ARE SUBJECT TO LIMITATIONS IN CERTAIN JURISDICTIONS, SEE "IMPORTANT INFORMATION".

## IMPORTANT INFORMATION

### General information

This information memorandum (the "**Memorandum**") has been prepared in connection with PMD Device Solutions AB's new issue of shares with preferential rights for the company's existing shareholders (the "**Rights Issue**" or the "**Offering**"). In this Memorandum, "**PMDS**", the "**Company**" or the "**Group**" means, depending on the context, PMD Device Solutions AB with reg. no. 556639-6809, the group of which PMD Device Solutions AB is the parent company or a subsidiary of the group. Stockholm Corporate Finance AB ("**SCF**") is PMDS' financial advisor in connection with the Offering and Nordic Issuing AB ("**Nordic Issuing**") is acting as issuing agent. Eversheds Sutherland Advokatbyrå AB ("**Eversheds Sutherland**") is acting as legal advisor to the Company in connection with the Offering. Redeye AB is the Company's Certified Adviser. "**Euroclear**" refers to Euroclear Sweden AB. The Company's liquidity provider is Erik Penser Bank AB.

This Memorandum 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**") or Commission Delegated Regulation (EU) 2019/980. Nor has the Memorandum been approved by or registered with the Swedish Financial Supervisory Authority under the Prospectus Regulation.

PMDS has not taken and will not take any measures to allow a public offering in any jurisdiction other than Sweden. Consequently, the offering is not directed to, and no new shares, subscription rights, or paid subscribed shares ("**BTA**") may be offered, subscribed, sold, or transferred, directly or indirectly, within or to the United Kingdom, the United States, Australia, Belarus, Canada, Hong Kong, Japan, New Zealand, Russia, Switzerland, Singapore, South Africa, South Korea, or any other jurisdiction where such distribution requires a prospectus, registration, or other measures beyond those required by Swedish law or would otherwise be in violation of the rules of such jurisdiction or cannot be conducted without the application of an exemption from such measures. Accordingly, the memorandum may not be distributed to or within any jurisdiction where distribution or the offering requires such measures or contravenes the rules of such jurisdiction. Subscription for securities in violation of the aforementioned restrictions may be invalid. Individuals receiving copies of the memorandum, or who wish to invest in PMDS, must inform themselves of and comply with these restrictions. Actions in violation of the restrictions may constitute a breach of applicable securities laws. PMDS reserves the right, at its sole discretion, to invalidate any subscription application that PMDS or its advisors deem to potentially involve a breach or violation of laws, rules, or regulations in any jurisdiction. No shares or other securities issued by PMDS have been or will be registered under the United States Securities Act of 1993, or the securities laws of any state or other jurisdiction in the United States.

### Forward-looking statements

The Memorandum contains certain forward-looking information. Forward-looking information consists of statements and opinions regarding the future that do not relate to historical facts and include expressions such as "believes", "intends", "assesses", "expects", "may", "will", "plans", "potential", "forecasts", "could", or similar phrases, aimed at identifying statements that indicate, estimate, or predict future developments or trends. This applies, in particular, to statements and opinions in the Memorandum concerning future financial returns, plans, and expectations for PMDS' operations and governance, future growth and profitability, as well as the general economic and legal environment and other matters affecting PMDS. Forward-looking statements are based on current calculations and assumptions made on the basis of what the Company knows at the time of the Memorandum's publication. Such forward-looking statements are inherently subject to both known and unknown risks and uncertainties and do not constitute a guarantee of future results or developments. Therefore, actual results, including the Company's cash flow, financial position, and operating results, may differ significantly from those expressed in such forward-looking statements, not meet the expectations, or be less favorable than those explicitly or implicitly assumed or described in these statements. Potential investors should not place undue reliance on these forward-looking statements and are encouraged to read the Memorandum carefully, including the detailed descriptions of risk factors that may affect PMDS' operations and the market in which the Company operates (see the "Risk Factors" section). Neither the Company nor SCF guarantees the accuracy of the presented forward-looking information or whether the predicted developments will actually occur. Forward-looking information derived from third-party studies referred to in the Memorandum may prove to be incorrect. Actual results, implementation, or events may differ significantly from what is indicated in such information. Following the publication of the Memorandum, neither the Company nor SCF, unless required by law or the Nasdaq First North Growth Market's ("**First North**") regulations, undertakes to update forward-looking statements or adapt these forward-looking statements to actual events or developments.

### Industry and Market Information

The Memorandum contains industry and market information related to PMDS' operations and the market in which PMDS operates. Unless otherwise indicated, such information is based on the Company's analysis of various sources. Industry publications or reports usually state that the information reproduced therein has been obtained from sources deemed reliable, but the accuracy and completeness of such information cannot be guaranteed. Neither PMDS nor SCF has verified the information and, therefore, cannot guarantee the accuracy of the industry and market information contained in the Memorandum that has been obtained from or derived from industry publications or reports. Such information is based on market surveys, which by nature are based on samples and subjective assessments, including assessments of which types of products and transactions should be included in the relevant market by both those conducting the surveys and those surveyed. In addition to information from external sources, the Company also makes certain internal assessments and assumptions regarding PMDS' market. These have not been verified by independent experts, and the Company cannot guarantee that a third party or any of the Company's competitors using different methods of data collection, analysis, or market data calculations will obtain or generate the same results. Such information has been prepared by PMDS based on third-party sources and the Company's own internal estimates. In many cases, there is no publicly available information, and such market data from sources such as industry organizations, authorities, or other organizations and institutions. PMDS believes that these market data estimates and the information derived from them are useful for providing investors with a better understanding of both the industry in which PMDS operates and PMDS' position within the industry. The Board ensures that information from these sources in the Memorandum has been accurately reproduced and that – so far as the Company is aware and can ascertain by comparing it with other information published by the relevant party – no facts have been omitted that would make the reproduced information inaccurate or misleading. The Memorandum also describes the leading companies and products that the Board of PMDS has assessed as close competitors to PMDS' operations. The account does not claim to be exhaustive.

### 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 Memorandum. Unless otherwise expressly stated, no financial information in the Memorandum has been audited or reviewed by the Company's auditor. Financial information in the Memorandum 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 Memorandum 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.

### 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.

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### The Offering in brief and preliminary timetable

Offering price	SEK 4.40 per share
Subscription period	19 August – 2 September 2024
Trading in subscription rights	20 August – 28 August 2024
Preferential right	Those who are registered as shareholders on the record date of 15 August 2024 will receive one (1) subscription right for each one (1) share held on the record date. Ten (10) subscription rights will entitle to subscription of three (3) newly issued shares.
Maximum number of issued shares	6,254,559 shares
Issue volume	SEK Approximately SEK 27.5 million
Record date	15 August 2024
Announcement of outcome	Around 5 September 2024

### Financial calendar

Interim Report Jan-Sept 2024	22 August 2024
Interim Report Jan-Dec 2024	26 February 2025

### Other information

The shares ticker	PMDS
The shares ISIN code	SE0021513645

## RISK FACTORS

Before making an investment decision, it is important to carefully analyse the risk factors that may be relevant to an investment in PMDS. This section describes the risk factors and important circumstances that are considered material to PMDS' 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 PMDS 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 Memorandum. 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

PMDS develops and sells medical products for respiratory monitoring. PMDS' 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. In April 2024, the Company entered into a transfer agreement with the Trustee of Coala-Life Group AB to purchase its US subsidiary Coala Life Inc. and its intellectual property and technology portfolio, including the product Coala Heart Monitor. PMDS 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, PMDS 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 PMDS 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, PMDS 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.

PMDS 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 PMDS 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 PMDS' 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.

PMDS 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

The medical device industry 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. PMDS 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 PMDS' 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.

PMDS 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

PMDS 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.

PMDS 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 RespiSense™ products. Production of RespiSense™ lobes will be moved to the contract manufacturer Sanmina's facility in Örnköldsvik, 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. PMDS is currently and will continue to be dependent on subcontractors to produce the Company's products. Over time, the majority of PMDS' 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 PMDS 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.

PMDS 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

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.

PMDS 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.

PMDS 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

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

PMDS 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

PMDS assesses that its patents are vital in assuring the protection of RespiraSense™. Therefore, patents and other intellectual property rights are key assets in PMDS' 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.

PMDS 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 PMDS' 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. PMDS 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.

PMDS 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 PMDS' 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.

PMDS 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

PMDS 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. 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 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 admitted to 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

The Company's largest shareholder, Myles Murray, holds approximately 38,76 per cent of the shares and votes in PMDS 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.

### Unsecured underwriting commitments

Within the framework of the Rights Issue, the Company has received underwriting commitments totalling approximately 80 per cent of the Offering. The Company has not received or requested security from the parties who have undertaken to subscribe for shares in the Offering based on subscription commitments. The underwriting commitments have not been secured by way of advance transactions, bank guarantees or similar measures. Therefore, there is a risk that parties who have entered into underwriting commitments may not fulfil their obligations towards the Company.

## BACKGROUND AND MOTIVE FOR THE OFFERING

### Introduction

PMDS was incorporated in 2011 to develop and sell 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. PMDS received FDA approval for RespiraSense™ in 2022. RespiraSense™ is a novel technology currently used across the UK and Ireland.

In April 2024, PMDS started a Rights issue process to support the company's restructuring following its recent acquisition of a US-based remote patient monitoring company. In addition, the company is preparing to scale its UK sales operation and improve its balance sheet. The acquisition supported the accelerated market entry of the company into the US while also diversifying its revenue sources by both market segment and geography.

Upon full subscription of the Rights Issue, the Company will receive approximately SEK 27.5 million before deduction of issue costs. The issue costs are estimated to amount to approximately SEK 5.8 million, assuming that all issue guarantors choose cash compensation. The costs for the guarantee commitments in such a case amount to approximately SEK 3.3 million. In the event that all issue guarantors instead choose compensation in shares, the issue costs can amount to a total of approximately SEK 2.5 million at most, since the Company's direct costs for issue guarantors in such a case amount to SEK 0. The assessment is that the Company's working capital needs during the next twelve months will be met by the issue proceeds from the forthcoming Rights Issue.

The Company has received subscription and guarantee commitments in the Offer of approximately SEK 22.0 million, which corresponds to 80 percent of the Rights Issue. However, these measures have not been secured by bank guarantees, blocking funds, pledges or the like, so there is a risk that the commitments, in whole or in part, will not be met.

### Use of proceeds

The net proceeds from the Rights Issue of approximately SEK 21.7 million are intended to be distributed according to the order of priority below:

Supporting US operations	20% (MSEK 4.3)
Support scaling of UK sales activities	6% (MSEK 1.3)
Supporting group operations	14% (MSEK 3.0)
Support balance sheet improvements, including repayment of bridge loans	60% (MSEK 13.0)

Provided that the Rights Issue is fully subscribed, it is the Board's assessment that the net cash covers the Company's liquidity needs during at least the coming twelve-month period. If the Offer, despite the underwriting agreements and subscription commitments entered into, is not subscribed to a sufficient extent, the Company may be compelled to seek alternative financing options such as additional capital raising or loan financing, or alternatively carry out cost reductions or be compelled to conduct operations at a lower rate than estimated until additional capital can be raised.

*The Board of Directors of PMDS is responsible for this Memorandum and has taken reasonable measures to ensure that the information provided, to the best of its knowledge, is in accordance with the facts and that nothing has been omitted which could likely affect the assessment of the Company. This document has not been reviewed and approved by the Swedish Financial Supervisory Authority.*

Stockholm, 16 August 2024  
PMD Device Solutions AB  
The Board of Directors

# BUSINESS AND MARKET OVERVIEW

## Introduction

As the healthcare industry tries to meet the demands of an ageing population and cost-effectively address the increasing complexity of care with patients having more than one chronic disease, a move towards two key trends is occurring:

- Deploying digital preventive solutions to both Acute and Chronic conditions
- Shifting more complex care back into the community setting

Since its formation in 2011, PMD Device Solutions AB (PMDS) has evolved into a digital healthcare company, offering value-based services to acute and community healthcare systems for the prevention of decline in patients with either acute (Pneumonia or Influenza) and chronic (COPD or Heart Failure) diseases. Applying PMDS over a decade of experience designing and selling respiratory monitoring medical devices has positioned the company as a provider of turnkey value-based service. Uniquely having them underpinned by proprietary and innovative medical devices for preventative monitoring of acute and chronic patients in the Hospital or Home setting. Increasing market share through organic and acquisition strategies to include **remote patient monitoring (RPM)** and **Chronic Care Management (CCM)** services in the US, **Virtual Ward** services in Europe, and in-patient acute monitoring technology solutions globally.

The combined serviceable market opportunity for PMDS products and services is estimated to be more than **117bn SEK<sup>1</sup> in annual recurring revenue** with an expected growth rate of between 14-25 percent<sup>2</sup>.

## History

PMD Device Solutions AB (PMDS), incorporated in 2011, started its journey by designing and launching a revolutionary approach to respiratory rate monitoring with the product RespiraSense™. 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 percent of respiratory rate readings are inaccurate, leading to 41 percent of patients' conditions being underestimated<sup>3</sup>. This gives healthcare systems an advantage in the early intervention of patient decline in either the hospital or home setting. 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>4</sup>.

Headquartered in Cork, Ireland, PMDS founder Myles Murray developed RespiraSense™ to monitor a patient's respiratory rate in a motion-tolerant way. The first clinical trials of RespiraSense™ were initiated at Cork University Hospital in 2013, and the first version of RespiraSense™ launched in 2015. The third and current version of RespiraSense™ received CE marking in 2020 and was launched through a nationwide rollout in Ireland in 2021 as the standard of care in Ireland<sup>5</sup> and expanded to the English NHS in 2023.

In 2022, PMDS began to evaluate the development of a new business model to address the growing need for Hospital-at-Home (HaH) services in Ireland. This 'managed service' involved using continuous respiratory rate as a key parameter for triggering early intervention in communication where needed. Furthermore, it supported clinical staff by removing technology and logistical burdens and managing the onboarding of patients, ensuring patients take their measurements daily, and off-board patients upon discharge. The impact has been a 100

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<sup>1</sup> Estimated 41bn SEK Respiratory rate hospital sales and 76bn SEK in remote patient monitoring services. All of these are based on recurring revenue based on either consumable replenishments or monthly service delivery.

<sup>2</sup> Medi-Tech Insights. 2023 Remote Patient Monitoring Market Size, Share & Growth Opportunities by 2026. <https://meditechinsights.com/remote-patient-monitoring-market>.

<sup>3</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>4</sup> Katsuyuki Miyasaka et al. Tribute to Dr. Takuo Aoyagi, inventor of pulse oximetry. Journal of Anesthesia, 2021

<sup>5</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

percent reduction in preventable hospitalisations for patients with severe chronic respiratory diseases and a 300 percent return on investment. This service has now been implemented into clinical operations and is a flagship product of our proposition of releasing bed capacity and improving the quality of life for patients<sup>6</sup>.

In April 2024, the Company entered into a transfer agreement with the Trustee of Coala-Life Group AB to purchase its US subsidiary Coala Life Inc. and its intellectual property and technology portfolio for the price of 3.6 MSEK with operational control passing to CEO Myles Murray.

In July 2024, PMDS incorporated the US company Remote Care Connect Inc., a full-service RPM company focused on safeguarding health and simplifying care by monitoring every beat, breath, and level. This new addition to PMDS included a revenue-generating asset, including the Remote Patient Monitoring Company in the US, a novel cardiology device for intermittently monitoring cardiac activity for patients with heart failure or suspected heart disease, and a Web-based Patient Monitoring clinical platform. The acquired company previously reported 39.8 MSEK in revenue for the first 9 months of 2023, with a gross margin of 81 percent. The customer base included 44 US clinics and a monthly billable patient activity level of 4,400 patients. It was understood that cashflow resulted in operational challenges which led to the sale of the assets. Upon acquiring the company, all clinics and operations were evaluated during Q2. The operational overhead was reduced by over 75 percent and the number of clinics reduced to those 14 that had the potential to bring the business into positive cashflow. Most importantly, the company's operations were reorganised to ensure a patient-centric approach while minimising insurance denials from non-conforming documentation or removing ineligible patients before enrolling them into the service. The synergy between this acquisition and PMDS growth strategy was in the accelerated market entry into the US while also bolstering its range of preventive solutions for both acute and chronic management of patients in the hospital and home setting. By June 2024, the company had 1,700 patients on service with approximately 70 percent compliance with 14 clinics across 8 US states.

In July 2024, PMDS incorporated the US company Remote Care Connect Inc., a full-service RPM company focused on safeguarding health and simplifying care by monitoring every beat, breath, and level.

By June, 1,700 patients on service with ~70 percent compliance with 14 clinics across 8 US states; **Compliance** is a term to indicate patients eligible for billable activity per month.

In May 2024, PMDS entered into a head of terms with the original inventor of the cardiac technology that was acquired in the acquisition of Coala Life Inc. While PMDS is committed to transforming patient outcomes with reliable respiratory rate monitoring, it sees synergy in partnering to license the European sale of the device and the ability to develop upon it while receiving an annual license fee and royalty payment on all revenues of the cardiac device. PMDS maintains the ownership of the intellectual property and supply chain with the option for the partner to buy out the rights to all assets for a note of SEK 1 million and 5x royalty payment based on the last 12 months of sales.

## Vision, mission and targets

### Vision

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

<sup>6</sup> <https://www.gavinpublishers.com/article/view/community-virtual-ward-cwcr-proof-of-concept-examining-the-feasibility-and-functionality-of-partnership-based-alternate-care-pathway-for-copd-patients-empowering-patients-to-become-partners-in-their-disease-management>

### 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. In addition to scaling its Remote Patient Monitoring business in the US.

PMDS board of directors has adopted the following medium-term financial targets:

- Profitability: PMDS ambition is to achieve sufficient annual recurring revenue to realise profitability by the end of 2024;
- Expansion to new markets: PMDS forecasts at least 10 pilots (i.e. trials that are paid for) launched between Germany and the US up to the end of 2025;
- Growth: PMDS forecasts Year-on-Year compound Annual Growth Rates of greater than 30 percent from 2023 to 2026;
- Revenue Target: PMDS forecasts an annual recurring revenue target of MESK 260 by the end of 2026 (increased in June 2024 from MSEK 100); and
- Dividend Policy: PMDS is focusing on pursuing growth through expanding its sales operations and does not anticipate paying any dividends in the near term.

PMDS 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 PMDS industry, business, result of operations and financial position and are subject to risks and uncertainties. See "Risk factors" and "Important information" for more information.

### Key Success Factors

Based on a decade of experience, PMDS has a strong product and commercial validation foundation across Europe and the US. This foundation enables the company to target profitability and diversify its revenues across several geographies and key product/service lines.

#### Strong Clinical Evidence

PMDS prides itself on its patient-centric research, development, and operations approach. The RespiraSense™ technology has been proven in nine clinical trials and over 500 patients in emergency departments, post-anaesthetic care units, respiratory wards, and homecare monitoring. Furthermore, its managed service model has been developed in partnership with the healthcare systems procuring the service. Deploying design thinking methodologies to develop and sustain a transformative clinical care pathway for HaH. Through this, PMDS have the knowledge to develop class-leading technology designed for the real world and constructively transform healthcare providers' workflows in a change management framework to demonstrate value.

The Coala device is based on three accurate clinical trials involving 1,207 patients with confirmed heart failure and palpitations, and the Karolinska Institute in Sweden undertook research.

Evidence continues to be collected from real-world data on the continued impact of the company's products and services to supporting healthcare systems, improving bed capacity, and reducing readmissions and unplanned episodes of care.

#### Differentiated Technology

All technology within the company is protected by granted patents across the major geographies including US, EU, China, and Japan. These markets collectively make up over 95 percent of the total market. Today, the company has 53 patents covering the mechanical design, algorithms, features, inventions, and methods for both the RespiraSense™ and Coala devices.

#### Market Leader Advantage

The respiratory rate monitoring and remote patient monitoring markets are emerging and PMDS is the market leader in the former and a fast follower for the latter. RespiraSense™ has been a revolution in the monitoring of acutely unwell patients and its design has been refined over almost a decade of market feedback and real-world validation. Likewise, in the US, remote patient monitoring has only been reimbursed since 2019, and market

entrants emerged around this time. With the largest multi-state provider having a self-reported 104K patients on service, it is a feasible ambition to be a fast follower and become one of the US's leading RPM companies through both organic and inorganic revenue growth.

#### Blue-ocean Emerging Markets

From the 2020s, new start-ups and specifications for respiratory monitors in hospital tenders have emerged. This is encouraging as it adds investment into the marketing of respiratory rate monitoring technology. As the market is still emerging, there is an advantage for the more mature companies. Those with superior technology readiness, internal governance, and an existing customer base to reference from have the greater opportunity to capture market share faster.

Likewise, for RPM in the US, with a target on smaller clinics, it has been evident that the opportunity to outsource RPM is not yet widely known. Therefore, like with the respiratory market, it is an opportunity for mature companies to land grab market share through the strength of their technology readiness and reference sites.

#### Large Serviceable Market

The US/EU market opportunity for respiratory rate monitoring in acute and HaH care is >79bnSEK per annum. Likewise, the RPM business generally has an equal level of opportunity. This gives mature companies a distinct advantage as the marketing spent per customer acquisition will be reasonable.

#### Double-digit market growth rates

The respiratory rate market is estimated to have a compound annual growth rate (CAGR) of 14 percent. Meanwhile, the RPM market in the US is reported to have a CAGR of 25 percent. This further implies the investments being made by healthcare providers to adopt these services is fuelling demand.

#### Market: Value-based solution to transforming patient outcomes

##### 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 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>7</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>8</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 detecting 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>9</sup> Early detection and preventive treatment, therefore, means that intensive care can be avoided, leading to significant cost savings 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

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<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> 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

person with a weak general condition may have difficulty maintaining a sufficiently high respiratory rate to allow adequate blood oxygenation.<sup>10</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 Chronic obstructive pulmonary disease (COPD).<sup>11</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>12</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>13</sup> With a solution for 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.

#### *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 PMDS. 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>14</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 percent from 2021–2026.<sup>15</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>16</sup>

#### *Chronic disease burdens healthcare services*

##### *Pulmonary Disease*

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. PMDS, 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 PMDS technology and its broader field of use, it is difficult to assess the total addressable market with a degree of accuracy.

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<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

<sup>11</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>12</sup> <https://www.fda.gov/medical-devices/safety-communications/pulse-oximeter-accuracy-and-limitations-fda-safety-communication>

<sup>13</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>14</sup> Global Pulse Oximeter Market, Market Data Forecast research report, 2021

<sup>15</sup> European Pulse Oximeter Market, Market Data Forecast research report, 2021

<sup>16</sup> Pulse Oximeter Market, Markets and Markets research report, 2021



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, of which 14 million patients were recorded in the US in 2021<sup>17</sup>. According to Frost & Sullivan, the average reimbursement cost for COPD patients in the US added up to approximately USD 2,750 in the same year, implying a total global COPD market of approximately USD 176 billion (assuming the US reimbursement rate is applicable worldwide). In the US market, approximately 10 per cent of total reimbursements for COPD patients reflect monitoring.<sup>18</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, PMDS considers that approx. 15 - 35 percent 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.

In 2021, the US Serviceable Attainable Market for COPD patients was approximately 14 million patients.

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 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 PMDS executes its expansion pipeline, the addressable market for its solution is expected to increase significantly.

### Cardiovascular Disease

Chronic diseases are usually defined as diseases that last over a person's lifetime or for a very long time. The U.S. National Center for Health Statistics classifies chronic disease as a disease that lasts for three months or longer<sup>19</sup>. In Sweden, 80–85 percent of healthcare resources are allocated to the care and treatment of chronic diseases<sup>20</sup>. In Sweden, almost one in two adults has at least one chronic disease, and in the under-20 age group, one in five suffers from a chronic disease. In the US, more than 120 million patients are affected by chronic cardiovascular disease<sup>21</sup>, many with a potential need for monitoring different clinical markers in the home. According to the WHO, unhealthy lifestyles cause around 80 percent of all cases of heart disease and stroke, and 30 percent of all cancers. Preventative efforts focused on a healthy lifestyle can prevent or improve about 90 percent of the morbidity associated with chronic diseases<sup>22</sup>. In the EU and US, the cost to society of cardiovascular disease totals EUR 210 Bn and USD 330 Bn, respectively, each year, including both direct and

US Serviceable Attainable Market is more than 120 million patients are affected by chronic cardiovascular disease

<sup>17</sup>[https://www.cdc.gov/mmwr/volumes/72/wr/mm7246a1.htm#:~:text=An%20estimated%2014.2%20million%20\(6.5,1999%E2%88%922019%20\(4\).](https://www.cdc.gov/mmwr/volumes/72/wr/mm7246a1.htm#:~:text=An%20estimated%2014.2%20million%20(6.5,1999%E2%88%922019%20(4).)

<sup>18</sup> Frost & Sullivan, Respiratory Disorders Market in United States, Forecast to 2022

<sup>19</sup> Stöppler, Melissa. Medical Definition of Chronic disease. MedicineNet. [https://www.medicinenet.com/chronic\\_disease/definition.htm](https://www.medicinenet.com/chronic_disease/definition.htm)

<sup>20</sup> HFS (The Swedish Health Promoting Healthcare Network). 2015. Preventing chronic diseases through a healthy lifestyle - a way to optimize healthcare

<sup>21</sup> European Heart Network. 2017. European Cardiovascular Disease statistics 2017. <https://ehnheart.org/cvd-statistics.html>

<sup>22</sup> The National Board of Health and Welfare The National Board of Health and Welfare National Guidelines – Evaluation 2014 Methods for disease prevention. <https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/nationella-riktlinjer/2015-1-1.pdf>

indirect costs. Patients, hospital staff and healthcare systems stand to benefit from the obvious advantages of more efficient monitoring and diagnostics methods for cardiovascular disease<sup>23</sup>.

#### Heart palpitations & self-management (Cardiac Monitoring Europe)

Palpitations are a less serious but common form of chronic heart disease. This common symptom means that the individual feels their own heartbeat. The causes of this can vary. In most cases, the discovery is benign and may be due to changes in the heart's autonomous tonus, which may originate from mental stress, physical exertion, or pregnancy. It may also be caused by harmless extra heartbeats, which all individuals experience to varying degrees, although most are unaware. Palpitations can also be a symptom of an underlying non-cardiac disease, such as high blood pressure, hyperthyroidism or other metabolic disorders. To a lesser extent, palpitations are likely caused by clinically significant arrhythmia such as atrial fibrillation or other supraventricular arrhythmia, and to an even lesser extent by ventricular arrhythmia in addition to ventricular extra beats.

Palpitations are common and often cause associated symptoms such as worry, anxiety and feelings of panic. The psychological symptoms are often caused by fears of having an underlying serious heart condition or that the heart will stop, causing sudden death. Palpitations burden healthcare services and lead to long waiting lists. In the US, over 73 million people visit primary healthcare providers for palpitation symptoms each year, and it is the second most common reason for a referral to a cardiologist<sup>24</sup>.

It is often difficult to use traditional ECG techniques (Holter registration, where ECG is registered continuously over one or two days) to capture episodes of palpitation, which usually occur sporadically in daily life.

In the so called RedHeart study, completed by researchers from Karolinska University Hospital in 2018, almost 1,000 Swedish women were included. The aim of the study was to investigate whether ECG registration with the Coala Heart Monitor could contribute to improving the quality of life and reducing palpitations and psychological symptoms in women experiencing palpitations. The study also investigated whether the Coala Life Heart monitor could map arrhythmia in palpitation symptoms that occur sporadically in women in daily life.

The published results indicate that the women experienced reduced palpitations and an improved quality of life as a result of using Coala Heart Monitor. Of the just under 300,000 registered ECG readings in the study, 95 percent were entirely normal or indicated harmless extra heartbeats. Undiagnosed atrial fibrillation or atrial tachycardia was discovered in 4 percent of participants. Carina Carnlöf, PhD and clinical research nurse at Karolinska Institute, concluded that "Immediate analysis of ECG with Coala in connection with palpitations with an unclear cause reduced symptoms, worry, anxiety, depression and improved quality of life."<sup>25</sup>

Coala Heart Monitor engages the individual and patient, and allows them to record ECG when symptoms arise, thereby improving the prospects for providing an immediate response and calming information. If arrhythmia such as atrial fibrillation is discovered, the patient can quickly be offered appropriate therapeutic care.

#### The shift to tele and remote medicine from the pandemic

Telemedicine was first introduced as a form of healthcare provision at the end of the 1960s, driven by NASA's need to monitor astronauts remotely. Its implementation in general healthcare services has met a number of obstacles over the past fifty years. Financial, regulatory and technical challenges have led to difficulties in progressing the shift towards telemedicine.

However, broadband, smartphones, new reimbursement models, simplified regulatory frameworks, and new operators have led to extensive market growth in the segment. Partly driven by COVID-19, US healthcare

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<sup>23</sup> European Heart Network. 2017. European Cardiovascular Disease statistics 2017. <https://ehnheart.org/cvd-statistics.html>

<sup>24</sup> Markets and Markets. 2022. Remote patient monitoring market by product –Global forecast to 2027. <https://www.marketsandmarkets.com/Market-Reports/remote-patient-monitoring-market-77155492.html>.

<sup>25</sup> Carnlöf, Carina, et al. 2021. Instant electrocardiogram feedback with a new digital technique reduces symptoms caused by palpitations and increases health related quality of life (the RedHeart study). *European Journal of Cardiovascular Nursing*, Volume 20, Issue 5, June 2021, Pages 402–410. <https://academic.oup.com/eurjcn/article/20/5/402/6162694>.

insurers now reimburse telemedicine visits at the same amount as in-person visits, accelerating the shift towards remote medicine.

Coala Heart Monitor is well adapted to the transition to tele- and remote medicine. The product is easy to prescribe directly to the patient, and digital healthcare providers are able to follow up on parameters remotely. Examples of areas of use include heart and lung rehabilitation. For example, the Home Rehab Network, based in Baltimore, US, delivers Coala Heart Monitor as part of its 3 - 6 month-long virtual rehabilitation program.

#### Remote Patient Monitoring (RPM)

RPM is a relatively new US healthcare model introduced in the US in 2019 that enables remote monitoring of patients in the home. RPM allows healthcare providers to utilize connected, patient-centred technology that facilitates interaction between clinics and patients in the home. RPM differs from telemedicine as RPM includes connected medtech products and aims to provide better care between visits, detect complications at an early stage and prevent them from deteriorating.

During the respiratory pandemic (COVID), the acceleration of investment into remote monitoring and hospital services at home for both acute and chronic disease management transformed the future of digital healthcare. US healthcare provider Kaiser Permanente provides an example of the successful implementation of telemedicine, and as early as 2015 the company reported that over 50 percent of its 110 million patient interactions took place as e-visits via smartphones, kiosks, video conferences and through other digital methods<sup>26</sup>. The US was more prepared, as it began to reimburse remote patient monitoring as early as 2019. In Europe, countries like England and Germany launched their remote monitoring programmes as a result of the 2020 pandemic. Although there is still fragmentation on the singular definition of HaH, it is largely applied to patients of multiple pathways, including Respiratory, Cardiology, Nephrology, Oncology, Surgical, and Facility.

The US Center for Connected Health Policy (CCHP) defines RPM as follows: “RPM can help keep people healthy and allow older and disabled individuals to live at home longer and avoid having to move into skilled nursing facilities. RPM can also serve to reduce the number of hospitalizations, readmissions, and lengths of stay in hospital—all of which help improve quality of life and contain costs”.

The regulatory frameworks governing RPM require the prescription of FDA-approved medtech equipment to patients, and automatic data reporting to healthcare providers via the cloud. Normally, RPM systems automatically raise the alarm when there is an indication that patient data falls outside the set parameters or guidelines. Typical products used in RPM systems include connected blood pressure monitors, ECG, scales and heart rate monitors.

In November 2018, Centers for Medicare & Medicaid Services (CMS) officially approved a regulatory framework and a number of new CPT reimbursement codes for RPM. These CPT codes now form the basis for reimbursement from all major insurers in the US, including Medicare (i.e. the publicly financed healthcare system in the US). The average RPM reimbursement to healthcare providers is approximately USD 150-200 per patient and month, depending on geography, technology and time allocated to monitoring the patient in the home. Average primary care doctors in the US can generate more than USD 400,000 in extra revenue each year by running an RPM program to complement conventional operations.

The pandemic has increased market demand for RPM programs that reduce travel and direct contact between patients and healthcare providers. In 2021, CMS expanded the potential of RPM further and extended the regulatory framework to include patients with acute conditions and chronic diseases.

Coala Life has developed a complete platform with software and hardware that is well suited to remote monitoring of patients and also uses another platform through a licensing agreement. The company's two systems are currently used in a number of clinics in the US and are covered by the aforementioned CPT codes. The company currently also has several customers who use Coala Care and Coala Heart Monitor in RPM programs.

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<sup>26</sup> Wicklund, Eric. 2016. Kaiser CEO: Telehealth Outpaced In-Person Visits Last Year. *mHealthIntelligence*, <https://mhealthintelligence.com/news/kaiser-ceo-telehealthoutpaced-in-person-visits-last-year>.

## Innovative medical devices – a unique differentiator

### RespiraSense™

#### *The Sensor Patch and Lobe*

PMDS has developed RespiraSense™, which, to the Company's knowledge, is the world's first and only continuous and motion-tolerant system for monitoring patient's respiratory rates. RespiraSense™ consists of a 'Sensor Patch' and a data processing 'Lobe' attached to the Sensor Patch. The term Lobe is taken from the description of the lobes of the lung.

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 to the abdomen. The dual sensors make measuring movements in both the chest and abdomen possible, increasing the measurement's reliability. The Sensor Patch is a consumable that is used only once per patient.

PMDS 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.



#### *RespiraSense™ App*

In addition to the Sensor Patch and Lobe, RespiraSense™ includes software that controls the monitoring and manages all data available as the RespiraSense™ App on a smart device. In a hospital, data on the patient's breathing is transmitted wirelessly via Bluetooth to a smart device with the RS Application, which the care staff can use to monitor the patient's breathing. The software registers the patient's breathing, and an alarm function reacts if the patient's breathing pattern deviates. The software is intuitive and visually describes patients' respiratory rate.



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

#### *RespiraSense™ Air & interoperability*

The digital maturity level and access to electronic patient monitoring systems can vary between hospitals. Many hospital wards lack centralised digital patient monitoring, and PMDS's complete solution is well-suited. RespiraSense™ Air is a gateway system comprising a Bluetooth to Internet Gateway and a cloud-hosted server. Information flows from the Lobe to the Gateway via Bluetooth. Thereafter, the Gateway validates the data and pushes it to the cloud. All terminals for the data then have the data pushed. This approach allows RespiraSense™ to be integrated with any hospital IT system or adjacent vital sign monitoring equipment.

#### *RespiraSense™ as a patient monitoring solution*

It is also possible to add monitoring functionality to RespiraSense™, which can become a broader patient monitoring system to measure more than respiratory rate. For example, PMDS has successfully installed pulse oximeters connected wirelessly to the Lobe in RespiraSense™, which transfers data to the software on the RS Application. Furthermore, PMDS has carried out tests where products for temperature monitoring were successfully integrated with RespiraSense™. By adding other vital parameter monitoring products, PMDS can provide an efficient, easy-to-use, and adaptable patient monitoring solution.

### Coala Heart Monitor

The Coala Heart Monitor is a small handheld, intermittent-use monitor that records the cardiac activity of the heart in addition to an acoustic recording of heart sounds. The standard configuration is that the patient first makes a chest ECG recording for 30 seconds, followed by a thumb ECG recording for 30 seconds. In total, the measurement takes about 60 seconds. The ECG measurement is made using integrated stainless steel electrodes that capture a high-resolution ECG with 24-bit DC, coupled directly to digitising conversion and 1,000 Hz sampling rate. Signal performance with diagnostic quality is in accordance with IEC 60601-2-25.

Heart sounds are also recorded synchronously during the chest measurement using a digital, patented piezoelectric stethoscope. The sound recording is done with 24-bit resolution, 4,000 Hz sampling rate and sound sensor with a frequency range of 20 - 1,500 Hz. The stethoscope function can also be used to record lung sounds.



Coala Heart Monitor's digital stethoscope is built on a patented high-sensitivity piezoelectric membrane. The stethoscope is developed with the Littman 3200 as a reference and can be compared in performance. The stethoscope is based on a robust and durable design, which makes it particularly suitable for recording low-frequency heart sounds remotely and in the patient's home environment. In the standard configuration of the Coala Heart Monitor, there is a synchronous and simultaneous recording of heart sounds and ECG, which are presented together after the completion of the measurement. The simultaneous recording of heart sounds and ECG by Coala Heart Monitor is done to reinforce an unexpected or difficult-to-interpret detection in the ECG curve.

The system architecture in Coala's Heart Monitor is based on a SaaS solution<sup>27</sup> with standardised interfaces, which provides good conditions for collaboration and development of functionalities with other suppliers. The company endeavours to be at the forefront of the development of new technologies. In addition, Coala's Heart Monitor has an internal rechargeable lithium polymer battery that guarantees at least 40 recordings per charge, and the product comes with a charging station that is charged via USB-C. Thus, no external batteries or other devices are required. Thus, no external batteries or other disposable products are required. The product also has no need for servicing or calibration. There is no storage of data or information in the product.

### Coala Life App

The Coala Life App can be downloaded free of charge on the patient's phone and is available for both Apple iOS-based smartphones (Coala App iOS) and Android-based smartphones (Coala Life App Android).

The Coala Heart Monitor connects wirelessly via Bluetooth to the Coala Life App. In the Coala Life App, the patient can start their registrations and follow instructions for taking measurements. Perceived symptoms or well-being can be registered in connection with the measurement, which is also presented to the carer and the results. Immediately after completing the measurement, the patient can access the results that have been automatically analysed. In the Coala Life App, the results are stored under "My journal". "My journal" can also benefit from two-factor authentication via Mobile BankID.

A simplified overview of the ECG signal is displayed in the Coala Life App with playback of the audio recording. A PDF of the ECG from the measurement is generated and can be viewed and saved on the patient's phone. The app also includes "My Inbox", where the carer can send messages and notifications via the Coala Care Portal. The patient cannot reply to the messages.

The Coala App provides the main user interface via the patient's own compatible smartphone. The Coala App interfaces with the Coala Heart Monitor and the Coala Care Portal. Communication with the Coala Heart Monitor is via a Bluetooth wireless link, allowing the Coala App to receive data from physical signals (ECG and audio). Communication with the Coala Care Portal is via the phone's data communication (e.g. WiFi or 3G/4G/5G).

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<sup>27</sup> SaaS solution refers to a type of cloud service that provides software over the internet (software as a service, SaaS).

mobile network), thus storing recordings and detection of cardiac arrhythmias via an ECG analysis software package available in the Coala Cloud.

### Qora Care Portal

Qora Care Portal is a web-based portal/auditing software that is accessed through a web browser and no special software is needed. The portal is used to manage patients and to analyse and review ECG results and generate reports. The portal gives the user a quick overview of the most recently received ECG recordings. Furthermore, ECG recordings can be noted and analysed with different tools, such as a so-called calliper. This enables the user to make a detailed analysis. In addition to ECG-specific functions, the user is given the opportunity to flag and filter measurements and create notes. This simplifies the workflow and communication between colleagues and different professional categories. The portal also supports login with BankID and SITHS cards<sup>28</sup>. The system offers a number of different access modules, which means that access to data and functions can be individualised based on the user's needs.

Coala Cloud consists of a validated software package on a Microsoft Azure® platform for analysing and identifying arrhythmias for Coala Heart Monitor measurements. ECG measurements performed with Coala Life Heart Monitor are transmitted by Coala Life App via the data communication capabilities of a smartphone to Coala Cloud for analysis. The results of the analysis are brought back to the Coala Life App using the same data communication capabilities and presented in the Coala Life App.

The implementation in the Coala Heart Monitor follows the American Heart Association's guidance and is an FDA-approved product (DXH, DPS, DQD, DQC product codes for both ECG and electronic stethoscope and Phonocardiograph) that also complies with the requirements of HIPAA (the US federal Health Insurance Portability and Accountability Act of 1996). The usability has been validated in the so-called RedHeart study (see more below under "Heart palpitations affect almost everyone at some point").



Currently, the Coala Heart Monitor supports the following languages: English, German, Dutch, Italian, French and Swedish according to the product's instructions for use.

## Development and clinical validation

### RespiraSense™

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 connectivity. It was developed in partnership with the European Space Agency 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 to validate the system's sensitivity and specificity in several patient situations. All clinical trials have been on alert and active patients in real-world

<sup>28</sup> SITHS is an electronic identity document used for logging in, signing, secure access to - and communication between - organisations - national health systems and services.

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.

### Coala Life™ Solution

Coala Heart Monitor enables clinical studies of the heart. The product simplifies the conduct of studies by allowing participants to perform examinations at home, making it easier to collect large amounts of ECG and heart sound data in geographically distributed groups. The performance of the product has been clinically evaluated and is based on research results presented at several national and international research conferences. The Company believes that Coala Heart Monitor is the first and only integrated smartphone-based system where the product detects atrial fibrillation by analysing both P-wave and RR variability in the ECG recording in accordance with clinical guidelines, see further description under "Product portfolio". The system also automatically detects several other types of arrhythmias and the high accuracy is achieved by recording both chest and thumb ECGs. PMDS partners also continue to develop the system so that more physiological and pathophysiological processes within the heart and vessels can be recorded and evaluated.

The company conducts the main product development with internal competencies from the head office in Uppsala. Product development is focused on algorithms, cloud services, software platforms and user interfaces. Resources are continuously invested in expanding the intended use to broader application areas. Future initiatives include in-depth development efforts in artificial intelligence (AI) and the prediction of heart and lung diseases.

### Clinical applications

Area of Use	In-Patient Hospital Care	General Hospital-at-Home / RPM care	Chronic Disease Management
<i>RespiraSense™</i>	✓	✓	In-Development
<i>Coala Life</i>	x	✓	✓

### Hospital Care

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, PMDS 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 for whom monitoring respiration is important is patients with respiratory and lung diseases such as Chronic Obstructive Pulmonary Disease (COPD), asthma, pneumonia, and pulmonary fibrosis. To manage or prevent an acute stage of the chronic condition.

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

### Hospital-at-Home Care

PMDS 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 an infection, trauma or other conditions can be remotely monitored with RespiraSense™ and other products that monitor the vital parameters. A significant possibility for PMDS is that patients who have had respiratory failure continue to use RespiraSense™ after leaving the hospital. By monitoring 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, PMDS is introducing its fourth version of the product in 2024, which 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. The Coala Heart Monitor is equally useful in managing patients with heart failure or heart disease.

### Competing products

#### Technical solutions for respiratory monitoring

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.

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.

#### Competitive Factors for Coala Life Heart Monitor

Many players are offering solutions for remote monitoring of chronically ill patients in the US market, some of the most relevant of which are listed below. The company believes that most of these players, however, only offer services with tools for monitoring patients (including a platform and equipment for measuring vital parameters, such as scales, blood pressure monitors, ECGs, etc.) and do not offer the comprehensive solution with actual monitoring and management of billing services to insurance companies corresponding to that offered by PMDS.

There are many players offering remote solutions in cardiac monitoring and ECG monitoring. The main companies are American and in the American market the transition to new wireless and digital solutions has also been established faster than in Europe, for example.

Over the last five years, Patch ECG technology has gained significant market share from traditional Holter ECG, see further description under "Limitations of available products for remote monitoring of cardiovascular patients".

Consumer ECGs have experienced rapid growth in recent years, which is in line with the trend that consumers increasingly want to monitor their health parameters via connected products. The challenge for healthcare is that these products rarely generate data of diagnostic quality, have a high number of false positive indications and are not reimbursed by insurance systems. One market trend is that consumer ECG companies have begun to move towards the healthcare market with further developed solutions.



### Competitive factors for Remote Patient Monitoring

Across Europe and the US, there are emerging market leaders with first mover advantage; however, one key weakness – they are tech companies selling a technology-centric solution. Across Europe, there are a handful of companies that offer a full ‘Virtual Ward’ a.k.a. Hospital-at-Home platform and device solution. These solutions are bought through tenders and are procured by socially funded healthcare systems. The United Kingdom and Ireland are actively looking to scale virtual wards and are only limited by the organisation’s ability to tender and available budgets.

Conversely, in the US, Remote Patient Monitoring Services, a.k.a. Hospital-at-Home, are in growing demand as they offer increased revenue for clinics and hospitals, with negligible increases in overheads. There is no limiting factor here as every healthcare group can make their own purchasing decisions as Medicare and Commercial private insurers reimbursement for standardised services – including Remote Patient Monitoring.

### 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. PMDS 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™ 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, PMDS assesses the Company to have a substantial competitive advantage with several regulatory approvals already obtained and a product ready for large-scale distribution.

### RPM - competitive advantages

One of the most important differentiators is the Patient-centric approach that PMDS has when designing its service and offering. Most of the competitors are technology companies selling into the healthcare market, often relying on clinics to implement the service. In contrast, patient-centric design is embedded in the processes within PMDS. Furthermore, the following are additional advantages:

- Novel medical devices with a particular focus on Respiratory Rate
- Clinically trained account managers become part of the team to support the transition and management of the service
- Billing expertise ensures we can support clinics to minimise denials and maximise reimbursement potential by sharing our expertise with Medicare and Commercial billing
- Inhouse software that is optimised to maximise billing potential, automatic repetitive workflows, efficiently produce reimbursement reporting for clinics, and demonstrate to clinics how the service is performing.

### Leading Product development

PMDS 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 PMDS.

RespiraSense™ delivers data to PMDS 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 PMDS collates about respiration and other patient data, the better the understanding of the importance of respiration for the course of a disease. PMDS 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

### Product Sales to Hospitals

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 PMDS 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. PMDS 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™, PMDS believes that there is potential for the average use to be even higher.

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

### Service Sales for Hospital-at-Home - Europe

PMDS 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. PMDS costs include the managed service personnel and equipment. PMDS end-to-end management service is limited to onboarding and offboarding patients and does not provide clinical management. PMDS will typically equate one RespiraSense™ Hub ward to over six Hospital Wards for the purposes of calculating annual recurring revenue. PMDS has one Hub already contracted in Ireland and this business line is expected to be a high growth business for PMDS across UK and Ireland.

### Remote Patient Monitoring Sales - US

Remote patient monitoring is an umbrella term for any patient monitoring. Today, PMDS support the following types of service:

- **RPM:** Remote Patient Monitoring – daily monitoring of vital signs such as heart rate or body weight
- **CCM:** Chronic Care Management – a monthly review of patient symptoms and medication where the patient has two or more chronic diseases e.g. diabetes and hypertension
- **PCM:** Principle Care Management – this is the same as CCM but for patients with only one chronic disease.

The service is paid for by Medicare (80-90 percent) and Private (10-20 percent) insurance i.e. co-pay. The price per service is broken into 'CPT' codes and each code has a set price. The business model is fundamentally based

on recurring revenues through revenue share business models. The volume of the reimbursement per code will vary state by state due to the Physician Fee Schedule.

The devices initially needed to set up a new patient are shipped to the patient and are included in the reimbursement fees, i.e. they are not separately reimbursed. Devices are considered 'sold' to the patient when shipped. Other cost of goods would include IT administrative fees which are negligible.

The service will maximise clinical time by coupling patients who are eligible for multiple service types. Whereas only one CPT is based on a formal report, all other codes are based on the amount of clinical time spent in coordinating care for the patient.

## **Production and gross margins**

### **PMDS Combined**

The combined gross margin between product and service sales is estimated to be approximately 70 percent. The majority of sales are attributed to RespiraSense™ Sensor Patches and Hospital-at-Home services.

### **RespiraSense™ Product Sales**

#### *RespiraSense™ Lobe*

Today, the production of RespiraSense™ lobes is located in Cork, Ireland. PMDS intends to move the production of RespiraSense™ Lobes to a facility in Örnsköldsvik, Sweden, which specialises in the production of advanced medical technology products and is FDA-cleared. PMDS estimates that the gross margin for the lobe in time will amount to around 60–70 percent.

#### *RespiraSense™ Sensor Patch*

The sensor patches are manufactured by a global contract manufacturer of electronic components. Over time, the majority of PMDS 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. PMDS estimates that the gross margin for the sensor patches in time will amount to 70–80 percent.

### **Coala Heart Monitors**

All manufacture of Coala Life Heart Monitor currently takes place in Estonia. PMDS will consolidate manufacturing to a single location, namely to the same facility as the RespiraSense™ Lobes. The gross margin on the monitor itself is estimated to be 70 percent.

### **Hospital-at-Home services**

#### *Europe*

The European market for Hospital-at-Home (Virtual Ward) services is based on a fixed fee for virtual beds or a unit fee per admission. On average, the gross margin of a virtual ward service is estimated to be 60-70 percent. The variance is attributed to the volume of patients per month, where higher volumes improve margins, but operations do not scale linearly with demand.

#### *US*

The US market for Hospital-at-Home (Remote Patient Monitoring) services is based on a fixed fee but variable based on the amount of clinical time required to coordinate patient care. The operating model is better suited to evaluate the Net Profit of this business unit. However, the gross margin has a negligible cost of sales and, as such, is estimated to have a 95 percent gross margin.

## **Reimbursement**

### **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, significantly increasing 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>29</sup> Clinical evidence demonstrating impact to outcomes also continues to be produced. PMDS 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.

#### Remote Patient Monitoring

RPM has been developed over time, and there are six CPT codes that cover RPM: CPT® 99453, CPT® 99454, CPT® 99457/8, CPT® 99426/7, CPT® 99439/90, CPT® 93268. There is no time limit to how long a patient can be included in an RPM program, as this is governed by clinical need.

The following patient examples qualify for RPM and may, therefore, benefit PMDS services and products:

- Chronically ill heart patients.
- Patients with high blood pressure and obesity.
- Patients with type I and type II diabetes.
- Patients with irregular heartbeat, palpitations or suspected atrial fibrillation.
- Patients undergoing heart and lung rehabilitation.
- Patients requiring post-operative follow-up, e.g. after heart surgery or stroke.
- Patients undergoing treatment with pharmaceuticals with a potential adverse effect on the heart.

## Organisation

As of 30 June 2024, the company had 36 employees, 19 based in Ireland, 1 based in Stockholm, 2 based in the UK, 4 in Poland and 10 in the US.

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

## Geographical markets

PMDS has a strong base in the Irish hospital market, where the use of its primary product, RespiraSense™, is the standard of care for respiratory-compromised admissions. The following other geographies and market segments are now the focus for future growth.

### The NHS England market

#### Foundation

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).

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<sup>29</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

### *Scale of opportunity*

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>30</sup> PMDS, 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. PMDS 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.

### *Guidance*

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

PMDS has also been awarded a place on the 17th Cohort of the Digital Health London Accelerator which will enable PMDS 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.

## **The US Remote Patient Monitoring Market**

### *Foundation*

PMDS today supports 14 clinics and monitors approximately 1,700 patients per month. These clinics are spread across 8 US states and mostly support cardiac patients.

### *Scale of opportunity*

Within the current capacity of existing clinics, there is the potential to expand beyond 2,300 patients per month, which is a break-even point for the business unit. The pipeline for new clinics has the near-term potential to reach over 4,000 patients per month. PMDS has a sales team operating in Texas and Virginia and is evaluating new sales professionals for Florida. There are at least 7,000 cardiology practices in the US, with an estimated average of 2,500 patients eligible for remote patient monitoring per clinic. For context, PMDS' three largest clinics have an average volume of 1,200 eligible patients per provider and an average of 3 providers per practice.

### *Guidance*

As the US is primarily driven by reimbursement criteria, the guidance is easier to follow than in Europe.

### **Irish expansion into 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 PMDS well for respiratory monitoring

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<sup>30</sup> A- Z List of All NHS Acute (Hospital) Trusts in England ([www.nhs.uk](http://www.nhs.uk))

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>31</sup> and of these, PMDS estimates that 5,000 to 10,000 need recurrent hospital care, which are thus suitable for ongoing monitoring in a hospital-at-home setting.

PMDS 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.

#### Expansion within 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. PMDS 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, PMDS assesses that it can increase coverage of hospital beds in Ireland from approximately 9 percent today, up to 30 percent.

#### 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. PMDS 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, PMDS 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, PMDS 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.

#### PMDS four step approach

PMDS 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, PMDS 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. Including these in national clinical guidelines can be a significant commercial breakthrough for the company in that national market. Thus, PMDS is keen to establish contact and,

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<sup>31</sup> National Patient Safety Office (Ireland)

early on, seek to influence authorities in 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™.

#### Additional opportunities in the rest of the world

PMDS 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. PMDS has also received inquiries from players in the Middle East, and the Company is currently investigating the possibility of carrying out pilot installations in the region.

Launches outside Europe will take place together with local partners, as PMDS 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.

PMDS 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, PMDS 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

PMDS has a portfolio of patents covering the device innovations of the RespiraSense™ and Coala Heart Monitor, in addition to several method and approach patents covering novel techniques and clinical diagnostic features.

Patent family "A Method and Device for Respiratory Monitoring"			
patent number	Status	Valid until	Region
ZL2014809393.0	Authorised		China
2958491.00	Authorised		EPO
1216294.00	Authorised		Hong Kong
6401718.00	Authorised		Japan
ZL201910422706.X	Authorised		China
40012716 B	Authorised		Hong Kong
2958491.00	Authorised		EPO
2958491.00	Authorised		Netherlands
2958491.00	Authorised		Denmark
2958491.00	Authorised		Poland
2958491.00	Authorised		Italy
2958491.00	Authorised		Sweden
2958491.00	Authorised		France
60 2014 083 884.7	Authorised		Germany
2958491.00	Authorised		Great Britain
2958491.00	Authorised		Ireland
11259716 B2	Authorised		USA
Patent family "Apparatus and method for detection for detection of dysfunctional breathing"			
patent number	Status	Valid until	Region
11172844 B2	Authorised		USA

Patent family "Stethoscope"			
patent number	Status	Valid until	Region
2006215644.00	Authorised	15/02/2026	Australia
P10606865-0	Authorised	15/02/2026	Brazil
ZL200680005558.2	Authorised	15/02/2026	China
602006026673.10	Authorised	15/02/2026	Germany
ES2379478	Authorised	15/02/2026	Spain
1850758.00	Authorised	15/02/2026	France
1850758.00	Authorised	15/02/2026	United Kingdom
278439.00	Authorised	15/02/2026	India
276297.00	Authorised	15/02/2026	Mexico
0500397-5	Authorised	21/02/2025	Sweden
8634570.00	Authorised	21/01/2028	USA

Patent family "Sensor"			
Patent/application number	Status	Valid until	region
2013229493.00	Authorised	07/03/2033	Australia
2822470.00	Authorised	07/03/2033	Belgium
112014019692-3	Authorised	07/03/2033	Brazil
ZL201380012131.5	Authorised	07/03/2033	China
602013004642.50	Authorised	07/03/2033	Germany
2822470.00	Authorised	07/03/2033	Denmark
2822470.00	Authorised	07/03/2033	Finland
2822470.00	Authorised	07/03/2033	France
2822470.00	Authorised	07/03/2033	United Kingdom
407484.00	Authorised	07/03/2033	India
5781245.00	Authorised	07/03/2033	Japan
10-2027614	Authorised	07/03/2033	South Korea
2822470.00	Authorised	07/03/2033	The Netherlands
2822470.00	Authorised	07/03/2033	Norway
13710325.50	Authorised	07/03/2033	Sweden
9498181.00	Authorised	07/03/2033	USA

Patent family "Electrode cleaning"			
Patent/application number	Status	Valid until	Region
201880029246.8 ((publ. no. 110785121)	Application Submitted	29/03/2038	China
18781037.9 ((publ. no. 3606419)	Application Submitted	29/03/2038	EPO
201947044130.00	Application Submitted	29/03/2038	India
6814896.00	Authorised	29/03/2038	Japan
2218577.00	Authorised	29/03/2038	South Korea
1750413-5	Authorised	04/04/2037	Sweden

Patent family "Classifying heart sounds"			
patent number	Status	Valid until	region
60 2014 071 510.9	Authorised	27/06/2034	Germany
3019077.00	Authorised	27/06/2034	France



3019077.00	Authorised	27/06/2034	United Kingdom
Patent family "ECG and phonogram system"			
Patent/application number	Status	Valid until	Region
201880043667.6((publ. no. 110831494)	Application Submitted	28/06/2038	China
18822591.6 ((publ. no. 3644850)	Application Submitted	28/06/2038	EPO
201947053856 (publ. no. 201947053856)	Application Submitted	28/06/2038	India
6929975.00	Authorised	28/06/2038	Japan
10-2295361	Authorised	28/06/2038	South Korea
16/620640 (publ. nr 2020-0163575)	Application Submitted	28/06/2038	USA
Patent family "Evaluating multiple ECG readings"			
Patent/application number	Status	Valid until	Region
201980008314.7 (publ. no. 111601548)	Application Submitted	24/01/2039	China
19744364.1 (publ. no. 3742966)	Application Submitted	24/01/2039	EPO
202047035911 (publ. no. 202047035911)	Application Submitted	14/01/2039	India
6986161.00	Authorised	24/01/2039	Japan
216/960493(publ. nr 2020/0375474)	Application Submitted	24/01/2039	USA
Patent family "Electrode extension assembly"			
Patent/application number	Status	Valid until	Region
201980042204.2 (publ. no. 112334069)	Application Submitted	18/06/2039	China
202147003392 (publ nr 202147003392)	Application Submitted	18/06/2039	India
7258921.00	Authorised	18/06/2039	Japan
1850808-5	Authorised	29/06/2038	Sweden
Patent family "Vacuum sealed patch"			
Patent/Application number	Status	Valid until	Region
2050692-9	Authorised	11/06/2040	Sweden
18/001301	Application Submitted	07/06/2041	USA

## Introduction to PMDS market

Due to the novelty of PMDS 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>32, 33, 34, 35</sup>

When a patient becomes acutely unwell, time is critical in the prevention of irreversible deterioration and death.<sup>36</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.

<sup>32</sup> C. J. H. K. e. a. Cretikos M, "The Objective Medical Emergency Team Activation Criteria: a case-control study.", 2007.

<sup>33</sup> H. M. H. C. e. a. Fiesemann JF, "Respiratory rate predicts cardiopulmonary arrest for internal medicine patients.", 1993.

<sup>34</sup> M. A. M. G. e. a. Goldhill DR, "A physiologically-based early warning score forward patients: the association between score and outcome.", 2005.

<sup>35</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>36</sup> Fiona McDaid et al. HSE Budget Impact Analysis – the National Early Warning System, 2018

## 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>37</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>38</sup> PMDS 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>39</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 information can be created and managed in digital format, capable of being shared across several healthcare organisations.<sup>40</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>41</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>42</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>43</sup> PMDS 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.

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<sup>37</sup> Frost & Sullivan- "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>38</sup> Schell et al. "Essential Emergency and Critical Care: A consensus among global clinical experts", 2021

<sup>39</sup> Juliet Rumball-Smith et al. Late adopters of the electronic health record should move now | BMJ Quality & Safety, 2020

<sup>40</sup> What is an electronic health record (EHR)? | HealthIT.gov

<sup>41</sup> Frost & Sullivan - "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>42</sup> Global Wearable Medical Devices Markets Report 2021: Market (globenewswire.com)

<sup>43</sup> Frost & Sullivan- "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

### 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>44</sup>

PMDS 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>45</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>46, 47</sup>

PMDS technology detects early signs of patient deterioration through digital monitoring. As a result, PMDS collects significant amounts of anonymised physiological data from patients with respiratory illnesses from pneumonia to apnoea, which, according to the Company, supports the opportunities for predictive analysis through PMDS 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>48</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. PMDS 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.

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<sup>44</sup> Frost & Sullivan- "Innovative Business Model Unleash Growth Opportunities in the MedTech Industry", 2021

<sup>45</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>46</sup> Big Data in Healthcare Market Size Worth USD 78.03 Billion (globenewswire.com), 2020

<sup>47</sup> Healthcare Analytics Market - Global Forecast to 2026 | Markets and Markets, 2021

<sup>48</sup> Medtech Europe (2021)

#### 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. PMDS received FDA approval in October 2022.

#### Rest of the World regulation

PMDS 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.

## WORKING CAPITAL

Due to PMDS having decided to increase investments in its revenue-generating activities, e.g., UK and US operations, it is the Company's assessment that the existing working capital, prior to the Rights Issue, is not sufficient for the current needs during the coming twelve-month period. As of 31 March 2024, the Company's cash and cash equivalents amounted to approximately SEK 2.9 million. Based on future revenues from the US and European businesses, and the expected position on positive cashflow by 31 December 2024, the Company assess its working capital to be SEK 11.3 million for the coming twelve-month period.

Upon full subscription of the Rights Issue, the Company will receive approximately SEK 27.5 million before deduction of issue costs. The issue costs are estimated to amount to approximately SEK 5.8 million, assuming that all issue guarantors choose cash compensation. The costs for the underwriting commitments in such a case amount to approximately SEK 3.3 million. In the event that all issue guarantors instead choose compensation in shares, the issue costs can amount to a total of approximately SEK 2.5 million at most, since the Company's direct costs for issue guarantors in such a case amount to SEK 0. The assessment is that the Company's working capital needs during the next twelve months will be met by the issue proceeds from the forthcoming Rights Issue.

The Company has entered into underwriting agreements and subscription commitments amounting to approximately SEK 22.0 million, corresponding to 80 per cent of the Rights Issue's total volume. However, entered guarantee commitments or subscription commitments are not secured via advance transactions, bank guarantees, blocking funds, pledges or similar arrangements. Consequently, there is a risk that one or more parties will not meet their respective obligations.

If the Offer, despite the underwriting agreements and subscription commitments entered into, is not subscribed to a sufficient extent, the Company may be compelled to seek alternative financing options such as additional capital raising or loan financing, or alternatively carry out cost reductions or be compelled to conduct operations at a lower rate than estimated until additional capital can be raised.

# TERMS AND CONDITIONS FOR THE OFFERING

## Pre-emption right to subscription

Those who, on the record date the 15 of august 2024, are registered as shareholders in the Company's share register held by Euroclear, have pre-emption right to subscribe for shares in the Rights Issue in relation to their shareholdings, whereby one (1) existing share entitles to one (1) subscription right. Ten (10) subscription rights entitle to subscription of three (3) new shares.

## Issue volume

The Offer comprises not more than 6,254,559 new shares. The total issue volume amounts to not more than approximately SEK 27.5 million before transaction costs.

## Subscription price

The subscription price is SEK 4.40 per share. No brokerage fee will be charged.

## Record date

Record date with Euroclear Sweden AB ("Euroclear") for the right to participate in the Offer was on 15 august 2024. The last day for trading with the Company's shares including the right to participate in the Offer was on 13 August 2024. The first day of trading in the Company's share without right to participate in the Offer was on 14 August 2024.

## Subscription period

Subscription of new shares with the support of subscription rights, shall take place during the period from and including 19 August until and including 2 September 2024. The Board of Directors of the Company reserves the right to extend the subscription period. A possible extension will be announced by the Company through a press release no later than 2 September 2024.

## Subscription rights

Shareholders in the Company receive one (1) subscription right for each share held on the record date. Ten (10) subscription rights give the right to subscribe for three (3) new shares.

## Trading with subscription rights

Subscription rights will be traded at Nasdaq First North Growth Market during the period from and including 20 August 2024, until and including 28 August 2024. Shareholders shall contact their bank or other nominee with the necessary permission to purchase and sell subscription rights. Subscription rights acquired during the above-mentioned trading period provide the same right to subscribe for new shares as subscription rights that shareholders receive based on their shareholdings in the Company on the record date.

## Unutilized subscription rights

Subscription rights that have not been sold on 28 August 2024 or exercised to subscribe for new shares in the Offer on 2 September 2024, will be deregistered from the respective shareholder's VP account. No notification will be sent regarding the deregistration of subscription rights.

## Pre-printed payment forms and subscriptions forms

Shareholders directly registered in the share register held by Euroclear  
Shareholders or representatives of shareholders, who on the record date 15 August 2024, were directly registered in the share register held by Euroclear, receives a preprinted issue statement with an attached payment form. The Memorandum can be downloaded on Nordic Issuing's web page ([www.nordic-issuing.se](http://www.nordic-issuing.se)) and on the Company's web page ([www.pmd-solutions.com/](http://www.pmd-solutions.com/)). Shareholders who are included in a separate list of pledgees and trustees will not receive issue statement but will be notified separately. No notification regarding registration of subscription rights on the VP account will be sent.

## Subscription with subscription rights

Subscription of shares with the support of subscription rights shall be made by way of cash payment not later than 2 September 2024. Subscription by cash payment must be made either with the pre-printed subscription form attached to the issue statement or in accordance with the payment instructions on the subscription form with support of subscription rights in accordance with the following two options:

1. Preprinted payment form (issue statement)

If all subscription rights allotted on the record date are exercised, only the preprinted payment form shall be used as documentation for subscription by way of cash payment.

2. Subscription form with support of subscription rights

If a different number of subscription rights than what is stated on the pre-printed payment form shall be exercised, for example, if subscription rights are acquired or sold, subscription with subscription rights should be made on Nordic Issuing's platform on the following website; <https://minasidor.nordic-issuing.se/> and be used as basis for subscription through cash payment. The shareholder must log in on the platform and state the total number of subscription rights to be exercised, the number of shares to be subscribed for, and the amount that is being paid. The subscription is binding. Nordic Issuing reserves the right to disregard subscription forms sent by regular mail, as it cannot be guaranteed that the subscription form will be Nordic Issuing at hand before the subscription period has ended.

## Information to banks/managers regarding subscription

On the first day of the subscription period, Nordic Issuing will send an e-mail containing the Memorandum, short summary about the offer and subscription forms with and without rights that can be used by banks and investors.

Nordic Issuing reserves the right to disregard registration forms received by post, as it cannot be guaranteed that they will be received before the last day of the subscription period if they are mailed.

## Nominee registered shareholdings

Shareholders whose holdings of shares in the Company are nominee registered with a bank or other nominee do not receive a preprinted payment form or subscription form. Subscription and payment should instead be made in accordance with instructions from the respective bank or nominee. Please note that if the use of subscription rights takes place via a bank or a nominee, this should be done early in the subscription period, as the respective bank/nominee may set different deadlines for the last subscription date.

## Subscription without subscription rights

Subscription of shares without subscription rights shall be made during the same period as subscription of shares with subscription rights, from and including 19 August 2024 up to and including 2 September 2024. The Board of Directors of the Company reserves the right to extend the subscription period and the time for payment under any circumstances. Such an extension must be announced no later than the last day of the subscription period and published by the Company.

An application for subscription of shares without subscription rights shall be made through Nordic Issuing's platform on the following website, <https://minasidor.nordic-issuing.se/>.

Nominee-registered shareholders, who wish to subscribe for shares without subscription rights, must coordinate such a subscription with the account-holding bank or nominee in accordance with instructions from the respective account-holding bank or nominee, or if shares are registered at several different nominee-registered accounts, from each of these account-holding banks or nominees. In order to be able to proclaim subsidiary subscription rights, it is required that the subscription is carried out via the nominee, otherwise there is no possibility of identifying a particular subscriber who has subscribed for shares both with and without the support of subscription rights.

Incomplete or incorrectly filled out subscription forms may be disregarded. It is only permissible to submit one (1) subscription form without subscription rights. If more than one such subscription form is submitted, only the

one last received will be considered, and other such subscription forms will be disregarded. The subscription form must be Nordic Issuing at hand no later than 2 September 2024. The subscription is binding. Nordic Issuing reserves the right to disregard subscription forms sent by regular mail, as it cannot be guaranteed that the subscription form will be Nordic Issuing at hand before the subscription period has ended.

### **Subscription from accounts subject to specific rules**

Note that shareholders or other investors who have an account with specific rules for securities transactions, such as an investment savings account (Sw.: Investeringssparkonto) or endowment account (Sw.: Kapitalförsäkring), must check with the account holding bank or nominee, whether, and if so, the subscription of securities in the Rights Issue is possible. The subscription shall in that case be made in accordance with instructions received from the account-holding bank or nominee.

### **Subscription above EUR 15,000**

If the subscription amounts to, or exceeds, EUR 15,000.00 a money laundering form shall be completed and sent to Nordic Issuing in accordance with the Swedish Act (2017:630) on measures against money laundering and terrorist financing. The form is found on Nordic Issuing's platform on the following website, <https://minasidor.nordic-issuing.se>. Please observe that Nordic Issuing cannot distribute any securities, even if payment has been received, before the money laundering form has been received by Nordic Issuing.

### **Shareholders residing outside of Sweden**

Shareholders who reside outside of Sweden (with the exception of shareholders residing in the United States, Australia, Belarus, Canada, Hong Kong, Japan, New Zealand, Russia, Switzerland, Singapore, South Africa, South Korea or other countries in which participation in the Rights Issue may require supplementary prospectus, further registration or other measures than those which are required by Swedish legislation) who have pre-emption right in the Rights Issue can contact Nordic Issuing for further information about subscription and payment.

Due to restrictions in the legislation regarding securities in the United States, Australia, Belarus, Canada, Hong Kong, Japan, New Zealand, Russia, Switzerland, Singapore, South Africa, South Korea and other countries in which participation may require supplementary prospectus, further registration or other measurements than those which are required by Swedish legislation, subscription rights through Euroclear will not be issued to shareholders with registered addresses in any of these countries. Accordingly, no offer is made to subscribe for shares in the Company to shareholders residing in these countries.

Notwithstanding any other provision of this document, the pre-printed issue statements or the subscription forms, the Company reserves the right to permit any person to subscribe in the Rights Issue if the Company, in its sole and absolute discretion, is satisfied that the transaction in question is exempt from, or not subject to, the legislation or regulations giving rise to the restrictions in question.

### **Allotment in case of subscription without subscription right**

If not all shares in the Rights Issue are subscribed for with subscription rights, the Board shall decide on allotment of shares within the limits of the maximum amount of the Rights Issue to shareholders or other investors that have subscribed for shares without subscription rights.

Firstly, allotment of shares subscribed for without subscription rights shall be made to shareholders or other investors who have also subscribed for shares with subscription rights, regardless of if the subscriber was a registered shareholder on the record date or not. In case the Rights Issue is oversubscribed, allotment shall be made in relation (pro rata) to the quantity of subscription rights exercised for subscription of shares in the Rights Issue, and to the extent this is not possible, by drawing of lots.

Secondly, allotment of shares which are subscribed for without preferential right shall be made to other investors than the above mentioned, who have subscribed for shares without subscription rights. In case of oversubscription, allotment shall be made in relation (pro rata) to the number of subscribed shares without subscription rights in the Rights Issue, and to the extent this is not possible, by drawing of lots.



Thirdly, allocation of shares subscribed without the support of subscription rights shall be made to the issue guarantors in relation to the size of the guaranteed commitments, and to the extent that this cannot be done, by lottery.

### **Notification of allotment of shares subscribed for without preferential rights**

Notification of allotment of shares without preferential rights will be made via a settlement note via email. Settlement notes are expected to be sent out as soon as possible after the subscription period, and payment must be made in accordance with the payment instructions on the settlement note. Payment is due within three (3) Swedish business days from the date the settlement note was distributed. Note that payment for any allotted shares will not be drawn from the specified book-entry account. If payment is not received in due time, the subscribed shares may be assigned to another party. Should the price by such an assignment be lower than the subscription price in the Rights Issue, the subscriber who initially was allotted these shares may have to pay for all or a part of the difference. Shareholders or other investors that are not allotted any shares will not receive any notification.

### **Publication of the outcome of the rights issue**

Publication of the outcome in the Rights Issue is planned for 5 September 2024 or as soon as possible after the subscription period ends. The Company will publish the result of the Rights Issue through a press release.

### **Paid and subscribed for share (BTA)**

Subscription with support of subscription rights is registered with Euroclear as soon as feasible, which normally means a few banking days after payment is made. Thereafter, the subscriber will receive a securities depository account notification confirming that the registration of paid subscribed shares has occurred in the subscriber's securities depository account. Subscribed for and paid shares ("Betald Tecknad Aktie" or "BTA") are entered as BTAs in the securities account until the new shares in the Rights Issue has been registered with the Swedish Companies Registration Office.

Shareholders who have their holdings in a custodian account at a bank or nominee will receive information from their respective bank/nominee.

### **Partial registration**

The rights issue may be partially registered at the Swedish Companies Registration Office. If partial registration is used, several series of BTA will be issued, whereby the first series is called "BTA 1" in the VPC system. BTA will be converted into shares as soon as a first possible partial registration has taken place. A second series of BTA ("BTA 2") will be issued if shares could not be included in the first partial registration and will be converted into shares as soon as the second part of the Rights Issue is registered with the Swedish Companies Registration Office. Only BTA 1 will be admitted to trading on the Nasdaq First North Growth Market.

### **Trading in BTA**

Trading in BTA will take place on Nasdaq First North Growth Market from 19 August 2024 until the Rights Issue is registered at the Swedish Companies Registration Office (Sw. Bolagsverket). Paid and subscribed for shares are entered as BTA in the securities depository account until the Rights Issue has been registered with the Swedish Companies Registration Office, which is expected to take place around week 38, 2024.

### **Delivery of shares**

As soon as the Rights Issue has been registered with the Swedish Companies Registration Office, which is estimated to take place around week 38, 2024, BTAs are converted into shares without special notification from Euroclear. For those shareholders who have their shareholdings registered as trustees, information comes from the respective trustees.

Please note that the issue may be partially registered at the Swedish Companies Registration Office.

## Trading in the share

The shares of the Company are listed on Nasdaq First North Growth Market. The shares are traded under the short name "PMDS" and have the ISIN code SE0021513645. The new shares are admitted to trading in connection with the conversion of BTA into shares.

## Applicable legislation

The shares are issued under the Swedish Companies Act (2005:551) (Sw. aktiebolagslagen) and are governed by Swedish legislation.

## Right to dividend

The new shares give right to dividend for the first time on the first record date for dividend, appearing after the new shares have been registered in the shareholder register maintained by Euroclear. The new shares give the same right to dividend as the existing shares.

## Dilution

The offer results in a full subscription that the number of shares in the Company increases by 6,254,559 shares, which corresponds to a dilution of approximately 23 percent of the total number of shares and votes in the Company.

## Subscription that entails the obligation to notify investments according to the FDI Act

The Foreign Direct Investment Review Act (2023:560) ("FDI Act") applies to the Company's operations. In the event that the signing of documents would result in one of the investor's holdings exceeding the limit values of 10, 20, 30, 50, 65 or 90 percent of the votes in the Company, the investor needs to notify his investment in accordance with the FDI Act. This notification obligation does not apply if the investor subscribes for shares with preferential rights in relation to the number of shares that the investor owns on the record date of August 15, 2024.

## Information about LEI and NCI number

According to the securities trading regulations that came into effect on January 3, 2018, all investors need to have a global identification code in order to carry out securities transactions. These requirements mean that legal entities need to apply for registration of a so-called Legal Entity Identifier (LEI) and natural persons find out their National Client Identifier (NCI) in order to be able to subscribe for shares in the Offer. Please note that it is the legal status of the signatory that determines whether an LEI code or NCI number is required, and that Nordic Issuing may be prevented from executing the transaction for the person concerned if the LEI code or NCI number (as applicable) is not provided. Legal entities that need to obtain an LEI code can turn to one of the providers on the market. Instructions for the global LEI system can be found at [gleif.org](http://gleif.org). For physical persons who only have Swedish citizenship, the NCI number consists of the designation "SE" followed by the person's social security number. If the person in question has several citizenships or something other than Swedish citizenship, the NCI number can be some other type of number. Those who intend to subscribe for shares in the Offer are encouraged to apply for the registration of an LEI code (legal entities) or find out their NCI number (physical persons) in good time in order to have the right to participate in the Offer and/or be able to be allocated new shares that are subscribed for.

## Other

The Board of Directors of the Company does not have the right to cancel, revoke or temporarily withdraw the offer to subscribe for new shares in the Company in accordance with the terms of the Memorandum.

In the event that an excessive amount has been paid in by a subscriber for subscribed shares, Nordic Issuing will see to it that the excess amount is refunded. In such a case, Nordic Issuing will contact the subscriber for information about a bank account to which Nordic Issuing can repay the amount. No interest will be paid on excess amounts. Amounts below SEK 100 are only refunded on request.

## SELECTED FINANCIAL INFORMATION

### Financial reports incorporated by reference

PMDS financial reports for the financial years 2022-04-01 – 2023-03-31 and 2023-04-01 – 2023-12-31 (9 months) and the interim report 1 January – 31 March 2024 form part of the Memorandum and should be read as a part thereof. These financial statements can be found in PMDS annual accounts for the financial years 2022/2023 and 2023 (9 months) and the interim report 1 January – 31 March 2024, where references are made as follows:

- The annual report 2022/2023: income statement (page 4), balance sheet (pages 5-6), change in equity (page 7), cash flow statement (page 8), notes (pages 14–41) and auditor’s report (pages 43-44).
- The year-end-report 2023 (9 months): Income statement (page 49), balance sheet (pages 50-51), change in equity (page 52), cash flow statement (page 53), notes (pages 60–88) and auditor’s report (pages 90-92).
- Interim report 1 January – 31 March 2024: income statement (page 18), balance sheet (page 19) and cash flow statement (page 21).

Other than the Company’s audited reports for the financial years 2022/2023 and 2023, no information in the Memorandum has been reviewed or audited by the Company’s auditor. The parts of the financial information that have not been incorporated by reference are either not relevant to investors or can be found elsewhere in the Memorandum.

### Accounting principles

PMDS 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”). PMDS financial information for the interim period 2024-01-01–2024-03-31 is derived from PMDS interim report for the interim period ending on 31 March 2024. The interim report has been prepared in accordance with IFRS with application of IAS 34 on Interim Financial Reporting.

### Consolidated income statement

#### Consolidated Income statement

(kSEK)	Jan-Mar	9-months	12 Months
	2024	Apr 23-Dec23	Apr 22-Mar 23
Net sales	11 059	28 623	18 407
Cost of sales	-2 349	-6 120	-4 022
<b>Gross profit</b>	<b>8 710</b>	<b>22 503</b>	<b>14 385</b>
Operating expenses	-10 666	-38 932	-33 085
Depreciation and amortisation	-1 207	-3 840	-4 442

Other income	367	217	546
<b>Operating loss</b>	<b>-2 796</b>	<b>-20 052</b>	<b>-22 596</b>
Financial costs	-3 561	-9 042	-13 883
<b>Loss on ordinary activities before taxation</b>	<b>-6 357</b>	<b>-29 094</b>	<b>-36 479</b>
Taxation	-	-	-
<b>Loss for the financial period</b>	<b>-6 357</b>	<b>-29 094</b>	<b>-36 479</b>

## Consolidated statement of comprehensive income

### Consolidated Statement of Comprehensive Income

(kSEK)	Jan-Mar	9-months	12 Months
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<b>Loss on ordinary activities before taxation</b>	<b>-6 357</b>	<b>-29 094</b>	<b>-36 479</b>
Taxation	-	-	-
<b>Loss for the financial period</b>	<b>-6 357</b>	<b>-29 094</b>	<b>-36 479</b>
Other comprehensive income:-	-	-	-
Exchange difference on translation of foreign operations			-5 352
<b>Total comprehensive loss for the period</b>	<b>-6 357</b>	<b>-29 094</b>	<b>-41 831</b>

## Consolidated balance sheet

(kSEK)	31-Mar	31-Dec	31-Mar
	2024	2023	2023
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets	28 708	27 810	27 891
Tangible assets	2 469	2 550	3 162
Right of use assets	2 817	3 022	3 964
<b>Total non-current assets</b>	<b>33 994</b>	<b>33 382</b>	<b>35 017</b>

### Current assets

Inventory	1 334	1 216	4 937
Trade and other receivables	1 813	3 597	819
Cash and cash equivalents	2 856	1 284	4 310
<b>Total current assets</b>	<b>6 003</b>	<b>6 097</b>	<b>10 066</b>
<b>TOTAL ASSETS</b>	<b>39 997</b>	<b>39 479</b>	<b>45 083</b>

### EQUITY AND LIABILITIES

#### Current liabilities

Trade payables	21 341	20,065	14 907
Convertible loan notes	-	-	27 281
Deferred revenue	39 883	38 801	40 401
Other short term loans	26 983	3,000	9 882
Liabilities to credit institutions	275	355	510
Leased creditor	1 377	1 371	1 509
Other liabilities and accruals	35 294	33 182	23 072
<b>Total current liabilities</b>	<b>125 153</b>	<b>96 774</b>	<b>117 562</b>

#### Non-current liabilities

Leased creditor	1 383	1 707	2 680
Warehoused tax liabilities	18 244	17 655	17 903
Other long term liabilities	1 339	22,113	1 584
Liabilities to credit institutions	-	-	257
<b>Total non-current liabilities</b>	<b>20 966</b>	<b>41 476</b>	<b>22 424</b>
<b>TOTAL LIABILITIES</b>	<b>146 119</b>	<b>138 248</b>	<b>139 986</b>

<b>TOTAL EQUITY</b>	<b>-106 122</b>	<b>-98 670</b>	<b>-94 903</b>
<b>TOTAL LIABILITIES AND EQUITY</b>	<b>39 997</b>	<b>39 479</b>	<b>45 083</b>

## Consolidated cash flow statement

### Consolidated cash flow statement

(kSEK)	Jan-Mar	9-months	12-months
	2024	Apr 23-Dec23	Apr 22-Mar 23
<b>Cash-flows from operating activities</b>			
Operating Loss for the financial period	-2 796	-20 052	-22 596
Adjusted for:			
Depreciation and amortisation	1 207	3 840	4 442
Interest paid	-142	-9 042	-4 131
Decrease (+)/ increase (-) of operating receivables	1 828	1 738	1 127
Decrease (+)/ increase (-) of operating liabilities	891	9 642	27 234
<b>Net cash inflow/(outflow) from operating activities</b>	<b>988</b>	<b>-13 874</b>	<b>6 076</b>
<b>Cash flows from investing activities</b>			
Payment to acquire tangible fixed assets	-193	-119	-3 837
Payments to acquire intangible & ROU fixed assets	-513	-2 493	-2 313
Net cash received from acquisition of Promore Group	-	1 071	-

<b>Net cash received/(used) in investing activities</b>	<b>-706</b>	<b>-1 541</b>	<b>-6 150</b>
<b>Cash flow from financing activities</b>			
Repayments of liabilities to credit institutions	-288	-401	-271
Movement on convertible loan notes & other loans	-	-5 000	-2 415
Movement in leases	-421	-1 054	1 518
Proceeds from shareholders	1 946	19 070	-
<b>Net cash inflow/(outflow) from financing activities</b>	<b>1 237</b>	<b>12 615</b>	<b>-1 168</b>
Net increase/(decrease)			
in cash and cash equivalents during the period	1 519	-2 800	-3 950
Cash and cash equivalents at the beginning of the period	1 294	4 310	8 260
FX differences	43	-226	-
<b>Cash and cash equivalents at the end of the period</b>	<b>2 856</b>	<b>1 284</b>	<b>4 310</b>

### Significant changes in PMDS financial position after the last reporting period

There have been no significant changes regarding PMDS financial position after 31 March 2024 up to the date of publication of the Memorandum.



## BOARD AND SENIOR MANAGEMENT

According to the Company's articles of association, the board of directors shall consist of a minimum of three (3) and a maximum of ten (10) board members. The board of directors currently consists of five (5) board members.

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

### 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 PMDS 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

### 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.

### **Myles Murray**

See under "Senior management".

### **Anne Dorney**

See under "Senior management".

## **SENIOR MANAGEMENT**

As of the date of approval of the Memorandum, 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 Memorandum.

### **Myles Murray**

Born in 1986. Board member since 2021.

### *Experience and relevant training*

CEO and Founder of PMDS. 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: 8,081,909 shares.

### **Anne Dorney**

Born in 1958. Board member since 2021.

### *Experience and relevant training*

CCO and Executive Director of PMDS. 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: 1,937,703 shares.

### **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.

## Remuneration of the Board of Directors and senior executives

Remuneration to board members elected by the general meeting are resolved by the general meeting. The annual general meeting held on 28 June 2024 resolved on a total board fee of SEK 844,800 shall be paid, of which SEK 316,800 to the Chairman of the Board and SEK 264,000 each to the Board members Christer Ahlberg and Magnus Christensen. 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 PMDS' senior executives during the Company's previous financial year.

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). The Company's shares are 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 current Articles of Association can be found on the Company's website. 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 general meetings should be given and who is entitled to attend and vote at the general meetings. The annual general meeting shall be held within six (6) months of the end of the financial year. The annual general meeting 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 Articles of Association, the Company shall have a minimum of one and a maximum of two auditors or a registered accounting firm. 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.

## SHARES, SHARE CAPITAL AND OWNERSHIP MATTERS

### General information on shares and share capital

According to the Company's Articles of Association the share capital may not be less than SEK 105,400,000 and not more than SEK 421,600,000. As of the date of this Memorandum, the share capital amounts to SEK 106,744,473.60, divided into 20,848,530 shares. 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 have a quotient value of SEK 5.12. The shares in the Company have been issued in accordance with Swedish law. All issued shares are fully paid and paid and freely transferable.

### Ownership structure

The table below shows the Company's ten largest shareholders as of 26 June 2024.

Name	Number of shares	Capital and votes
Myles Murray	8,081,909	38.76 %
Anne Dorney	1,937,703	9.29 %
Tom O'Brien	1,019,461	4.89 %
Gentian Health LTD	851,347	4.08 %
Mohammed Al Amoudi & company	766,068	3.67 %
Chirp AB	605,368	2.90 %
Christopher Martin	507,795	2.44 %
Hurley Conor	370,640	1.78 %
Sullivan Donal	333,877	1.60 %
Thrasherstown Farm LTD	281,687	1.35 %
Other	6,092,675	29.22 %
Total	20,848,530	100,00 %

### Changes in share capital

The table below shows the historical development of the Company's share capital since its formation.

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
2024-01-12	Share issue	102,978,477	2,574,461,929	105,407,034.60	2,635,175,865	0.04	0.05961
2024-01-15	Share issue	13,08	327	105,407,047,68	2,635,176,192	0.04	0.04
2024-01-15	Reverse share split (1:128)	-	2,614,588,878	105,407,047,68	20,587,314	5.12	-
2024-02-02	Share issue	1,337,425.92	261,216	106,744,473.60	20,848,530	5.12	7.63



## **Authorisation for issues of shares, warrants and convertibles**

On the annual general meeting of the Company held on 28 June 2024, it was decided to authorise the board of directors to resolve, on one or more occasions during the period until the next Annual General Meeting, to issue new shares, convertibles and warrants with or without derogation from the shareholders' preferential rights. New issues of shares, as well as issues of warrants and convertibles, may be made with or without deviation from the shareholders' preferential rights and with or without provision for contribution in kind, set-off or other conditions.

Issues with or without derogation from the shareholders' preferential rights may be made to the extent permitted by the current Articles of Association, or by any other Articles of Association that the shareholders may adopt by the required majority during the period up to the next Annual General Meeting.

The issue decided by virtue of the authorisation shall be made at the market subscription price, subject to the market issue discount, if any. The issue decided by virtue of the authorisation shall be made in order to provide the Company with working capital, to increase the Company's financial flexibility and to enable acquisitions by payment in shares.

## **Warrants**

The extraordinary general meeting held on 31 December 2021 in PMD Device Solutions Sweden AB 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 PMDS remains a wholly-owned subsidiary of the Company after the completion of the reverse acquisition between PMD Device Solutions Sweden AB and Promore Pharma AB that took place in December 2023, the outstanding warrants in PMD Device Solutions Sweden AB, upon the option holders' exercise of the subscription options, will entitle them to new shares in the Company instead of new shares in PMD Device Solutions Sweden AB. Each holder will undertake towards the Company that if the warrants in PMD Device Solutions Sweden AB are exercised, they will transfer the newly subscribed shares the Company in exchange for newly issued shares in the Company. 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 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 Device Solutions Sweden AB 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 Memorandum 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

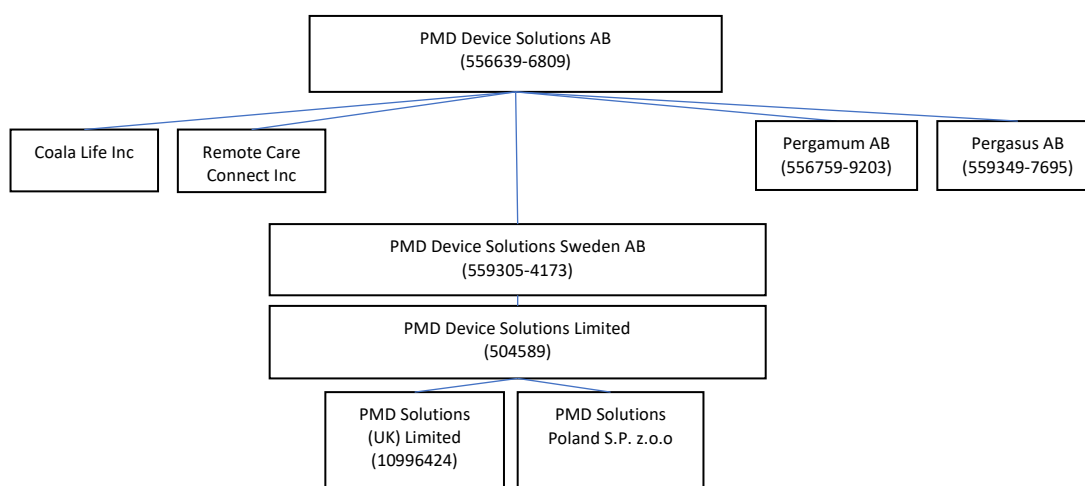
remaining shares from the other shareholders of the Company. Anyone whose shares are redeemable has the right to have his shares redeemed by the majority shareholder. If the redemption amount is in dispute, the redemption amount shall be determined so as to correspond to the price of the share that can 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 Swedish law with the company name PMD Device Solutions AB. The Company's registered office is in Stockholm. The Company's form of association is governed by, and its shares have been issued under, the Swedish Companies Act.

The Company's group structure is shown below. All subsidiaries in the group structure are directly or indirectly owned to 100 per cent by PMDS.



The reverse acquisition of Promore Pharma AB and PMD Device Solutions Sweden AB was completed on 29 December 2023. The operations of the former Promore subsidiaries Pergamum AB and Pergasus AB will be discontinued.

### Related-party transactions

During the period covered by the historical financial information included in the Memorandum, there has not been any transactions between PMDS and its related parties that have affected the group's position.

PMDS 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, PMDS 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 approximately 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 PMDS 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.

PMDS 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 involves PMDS showcasing a working home care device including hardware, software and documentation with enhanced connectivity.

#### Supplier agreements

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

#### Financing agreements

PMDS 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 PMDS 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 PMDS of shares or other financial instruments in which Chirp is entitled to participate. PMDS 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.

To support UK sales and the restructuring of the US company until the Rights Issue has been completed, the Company has raised bridge loans of SEK 12.0 million in total from Fenja Capital I A/S, Råsunda Förvaltning AB and Gerhard Dal. As compensation for the loans, a commitment fee of 5.00 percent and an interest of 2.00 percent per month or part thereof is charged. The loans are to be repaid no later than 30 September 2024. The lenders have the right, but not the obligation, to set off all or part of the loans, including accrued interest, against issued shares in the Rights Issue, provided that the lenders are allocated shares in the Rights Issue.

#### Other

In April 2024, the Company entered into a transfer agreement with the Trustee of Coala-Life Group AB to purchase its US subsidiary Coala Life Inc. and its intellectual property and technology portfolio for the price of 3.6 MSEK.

## Underwriting commitments regarding the Rights Issue

The Rights Issue is partially covered by underwriting commitments to 80 percent. The underwriting commitments have been provided by a consortium of external investors. For underwriting commitments, an underwriting compensation of fifteen (15) percent of the underwritten amount is paid in cash, or twenty (20) percent of the underwritten amount in newly issued shares. In the event of a directed share issue to underwriters, it has been agreed, following negotiations with the underwriters with support of advisors, that the subscription price will be the same as in the Rights Issue. Underwriting commitments have not been secured by way of advance transactions, bank guarantees or similar measures.

#### Summary of underwriting commitments

Name	Underwriting commitment (SEK)	Share of the Rights Issue
Life Science Invest Fund 1 ApS	6 999 999,60	25,44%
Tuvedalen Ltd	1 999 998,00	7,27%
Fenja Capital I A/S	1 999 998,00	7,27%
Fredrik Lundgren	1 333 019,60	4,84%
Wilhelm Risberg	1 333 019,60	4,84%
AD94 Holding AB	999 996,80	3,63%
Meriti Neutral	999 996,80	3,63%

Råsunda Förvaltning AB	999 996,80	3,63%
Gerhard Dal	999 996,80	3,63%
Myacom Investment AB	999 996,80	3,63%
Jens Miöen	999 996,80	3,63%
Ghanem Chouha	599 997,20	2,18%
Göran Källebo	499 998,40	1,82%
Niclas Löwgren	249 999,20	0,91%
Stefan Hansson	249 999,20	0,91%
Birger Jarl 2 AB	249 999,20	0,91%
Hemo Spray & Pump AB	249 999,20	0,91%
Dariush Hosseinian	249 999,20	0,91%
<b>Sum</b>	<b>22 016 007,20</b>	<b>80,00%</b>

## 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", PMDS 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. PMDS 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 PMDS' knowledge, there are no known trends, uncertainties, potential material claims or other requirements, commitments or events, other than those described in this Memorandum, 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 Company 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, PMDS cannot provide any guarantees that the Company will not incur losses beyond what is covered by these insurance policies.

## Legal proceedings and arbitration

PMDS 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 PMDS and their private interests and/or other commitments (however, several proposed board members and senior executives have certain financial interests in PMDS 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.

## 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.

### **Available documents**

This Memorandum, 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.