# ISOFOL

# **ANNUAL REPORT 2024**

Isofol issues all its reports in Swedish language and this report has been translated into English. In the event of differences between the two, the Swedish version shall apply.

# ARFOLITIXORIN

Н

OH

OH

A DRUG CANDIDATE FOR TREATMENT OF COLORECTAL CANCER



# **CONTENTS**

Vision, goal and strategy	3
The year in brief	4
Message from the CEO	5
About Colorectal cancer	8
About arfolitixorin - evidence platform	10
About the phase Ib/II-study	12
Market overview	13
Strategy	14
Statement - Charité-Universitätsmedizin Berlin	15
Organization and partners	16
Comment from the chairman	18
lsofol's history	19
Isofol's share	20
Administration Report	22
Corporate Governance Report	27
Financial information	36
Notes	41
Certification	53
Auditor's report	54
Calendar	57
Glossary	58



"We have gained a good picture of how arfolitixorin should be administered to maximize its effect."



"The authorities have validated and approved our study design, strengthening our hope of achieving our



"There is a critical need for innovative treatment options as arfolixorin."

Professor of Medicine

# ABOUT **ISOFOL MEDICAL AB (PUBL)**

Isofol Medical AB (publ) is a research-based biotechnology company working to improve the prognosis for patients with severe forms of cancer. The company's drug candidate arfolitixorin aims to increase the effect of first-line standard treatment for several forms of solid tumors and is currently being studied in colorectal cancer, the world's third most common cancer, where the medical need for better treatments is high. A phase Ib/II study is now being conducted with a new dosing regimen that are expected to optimize the effect of the drug candidate. Isofol Medical AB (publ) is traded on Nasdag Stockholm.

# VISION

Isofol's vision is for arfolitixorin to improve the prognosis for hundreds of thousands of patients with severe forms of cancer by replacing current folate drugs in 5-FU-based treatments.

# now well positioned to continue the clinical development of arfolitixorin. The goal is clear: to improve cancer treatment for millions of patients and thereby create significant value for shareholders, employees and society at large. A new and exciting phase in the company's development has just begun. **STRATEGY** THE MAIN ELEMENTS OF THE COMPANY'S STRATEGY FOR 2025 ARE TO: Drive clinical development forward and generate new efficacy data for arfolitixorin by conducting the phase lb/ll study in an efficient and time-optimized manner in collaboration with leading clinical experts; and lay a solid foundation for continued development and regulatory approval processes. Maximize the potential of Isofol's collaborations by nurturing established commercial and scientific collaborations; and identifu and establish collaborations

GOAL

Maximize the potential of Isofol's collaborations by nurturing established commercial and scientific collaborations; and identify and establish collaborations with additional clinical experts and partner companies to strengthen the further clinical development and commercialization of arfolitixorin.

The goal is to make arfolitixorin available worldwide and thereby improve the prognosis for cancer patients treated with the 5-FU-based therapies that constitute standard treatment for many cancers. As a first step, we are working to get

second leading cause of cancer-related deaths worldwide. With only a 14 per-

cent five-year survival rate, there is an urgent need to improve treatment out-

require conversion and metabolization in the body before it becomes active,

ners, and the knowledge and experience available in the organization, Isofol is

which is expected to lead to significant efficacy benefits.

Today, 5-FU is combined with a folate to increase the treatment effect. Arfolitixorin is a new form of folate that, in contrast to current drugs, does not

Based on the evidence and knowledge about arfolitixorin generated to date,

**Build trust in Isofol as a company** and enable continued financing through transparent and open communication with shareholders, potential investors and partners, maintaining a high standard of regulatory compliance, and good cost control where value-creating activities are prioritized.

THE YEAR IN BRIEF

2024

# TSEK 0

Net revenue amounted to TSEK 0 (721) and other operating revenue to TSEK 0 (0)

# MSEK -43.5

Result before tax amounted to MSEK -43.5 (-37.1)

# SEK -0.27

Earnings per share amounted to SEK -0.27 (-0.23)

# MSEK 96.2

Cash and cash equivalents at year-end amounted to MSEK 96.2 (138.1)

4

# THE YEAR IN BRIEF

# JANUARY-MARCH

• At the extraordinary general meeting held on January 4, Jan-Eric Österlund was appointed chairman of the board, Lars Lind, Alain Herrera, Helena Taflin and Sten Nilsson as board members, all of whom are newly elected. In connection with this, all former members of the board left their positions in the company.

• On January 9, the board appointed Petter Segelman Lindqvist as the new Chief Executive Officer.

• On January 10, Magnus Hurst was appointed as new Chief Financial Officer.

• On February 14, the company announced that they are starting the planning of new clinical studies with the aim of maximizing the opportunities to take arfolitixorin further to-wards a potential commercialization.

• On March 19, the company presented the preliminary framework for a phase I/II clinical study of arfolitixorin as a first-line treatment in combination with 5-FU-based chemotherapy in patients with metastatic colorectal cancer. This with the aim of generating both efficacy and safety data using a new dose regimen.

• On March 19, announced that the company's collaboration partner, the Japanese pharmaceutical company Solasia Pharma K.K., has confirmed its continued strong commitment in the development of arfolitixorin. Solasia will contribute with its expertise and participate in defining the detailed design of the clinical development program.

# **APRIL-JUNE**

 On May 24, announced that the company has signed a collaboration agreement with the world-leading academic hospital Charité
 Universitätsmedizin Berlin and Professor Sebastian Stintzing, for the further clinical development of arfolitixorin.

# JULI-SEPTEMBER

On July 5, announced that an external committee of experts has performed a post hoc per protocol analysis of the clinical Phase III AGENT study that shows new results in favor of arfolitixorin.

On July 16, announced results of two further preclinical studies conducted by Oncosyne AS in collaboration with Akershus University Hospital in Oslo; and at the Surgical Oncology Laboratory (SOL) at Sahlgrenska University Hospital in Gothenburg, respectively. Both studies show that increased doses of arfolitixorin in combination with 5-FU lead to significantly higher efficacy and thus support the dose-response relationship of arfolitixorin.

• On July 30, announced that Margareta Hagman had been appointed as Chief Financial Officer and would assume the position on August 13.

• On September 17, announced the positive outcome of a preliminary patentability report on a new international product patent application for arfolitixorin, submitted under the Patent Cooperation Treaty (PCT).

# OKTOBER-DECEMBER

• On October 23, the company announced that a Late Breaking Abstract regarding the drug candidate arfolitixorin was to be presented as a poster at ENA 2024 in Spain. The poster describes dose-dependent cytotoxic effects and increased activity of arfolitixorin at higher doses in combination with 5-FU.

• On November 20, the company presented an operational update during the investor meeting that took place in Gothenburg, and which was also available digitally via link. The company presented the evidence platform that forms the basis for the upcoming clinical study, the intended study design for the phase lb/II study, and an update on the commercial potential of arfolitixorin.

On November 21, the company announced that the investigator-initiated Modelle study, which evaluated the effect of arfolitixorin at the tissue level, has been published in the scientific journal BJC Reports. The study showed dose-dependent TS inhibition with arfolitixorin.

• On December 18, it was announced that the company's Japanese partner Solasia Pharma K.K. has made a strategic decision to include Japanese patients in the Phase II part of the upcoming Phase Ib/II clinical study of arfolitixorin in patients with metastatic colorectal cancer.

# EVENTS AFTER THE END OF THE YEAR

• On March 21, 2025, announced that the regulatory authority in Germany, BfArM, has given their final approval for the initiation of the new clinical trial of the company's drug candidate arfolitixorin. The study will initially be conducted in Germany.

# "FULL FOCUS ON THE NEW CLINICAL STUDY IN 2025"

Throughout 2024, we have worked intensively on preparations for initiating our clinical study designed to evaluate arfolitixorin as a potential new treatment for metastatic colorectal cancer. The final approval in March 2025 of our study design i from the German regulatory authority, BfArM, validates our development plans. For 2025, our focus will be on conducting the clinical study, advancing business development, and discussing our continued development strategy with regulatory authorities and prospective partners.

During the past year, Isofol has strengthened the evidence behind the company's drug candidate arfolitixorin and completed the necessary preparations to initiate a new clinical study with an optimized dose regimen. We have gained a clear understanding of how arfolitixorin should be administered to maximize its efficacy and have strengthened our own conviction about the drug's potential. This confidence has also spread to existing and potential new partners, who are contributing with enthusiasm and commitment to its continued development.

## Study initiation approved

During the first quarter of 2025, we received approval from the German regulatory authority, BfArM, to initiate our clinical Phase Ib/ Il study. The approval is a crucial validation of our development strategy for arfolitixorin and indicates that the study can begin shortly. As previously announced, the study will be conducted at the prestigious Charité - Universitätsmedizin Berlin hospital led by the renowned Professor Sebastian Stintzing.

The first part of the study aims to evaluate increasing doses of our drug candidate to determine which doses will be used in the second phase of the study, where efficacy evaluation is the primary focus.

## Study expansion to Japan planned for 2026

The year concluded with our Japanese partner Solasia announcing a strategic decision to actively participate in the Phase II part of the clinical study. In parallel with the initiation of the first part of the study at Charité - Universitätsmedizin Berlin, Isofol and Solasia are beginning joint preparations for phase II, with the goal of including patients in Japan by 2026. Expanding the study to Japan will not only increase the total number of patients but also enhance the diversity of the patient population, which together creates better conditions for future regulatory processes, both in Japan and in other markets. Preparations for expanding into Japan include identifying and establishing agreements with the clinical research organization (CRO) with which we will collaborate alongside Solasia, as well as engaging in dialogue with the Japanese pharmaceutical authority PMDA.

# Enhanced patent protection through product development

To strengthen and extend the international patent protection for arfolitixorin, we have expanded the existing collaboration with our substance partner Merck during the year to focus more on product development and the creation of new drug formulations. Continuous development of the substance in new formulations and compositions aims to generate new patents and strengthen long-term commercial potential. In parallel, we are working to develop new patents related to the new dose regimen currently being tested.



For 2025, our focus will be on conducting the clinical study, advancing business development, and discussing our continued development strategy with regulatory authorities and prospective partners.

> Petter Segelman Lindqvist, Chief Executive Officer

In September, we received a positive preliminary assessment regarding new patents for arfolitixorin's substance formulation which, if granted final approval, could result in a new substance patent valid until the mid-2040s in Isofol's key markets: the United States, Europe and Japan. A new substance patent could significantly extend arfolitixorin's lifecycle and therefore holds great commercial value both for us and our partners.

### Sustained market potential

During an investor meeting in November, we presented an updated overview of arfolitixorin's market potential based on a new market analysis conducted by an external consulting firm. According to this analysis, the global market for metastatic colorectal cancer treatment is projected to reach SEK 80 billion by 2032<sup>1</sup>. The current standard of care – consisting of 5-FU-based chemotherapy in combination with folates such as arfolitixorin - is expected to remain the foundation of first-line treatment for the foreseeable future; consequently, the need for a drug candidate like arfolitixorin persists. The analusis confirmed Isofol's previous estimate that arfolitixorin could achieve blockbuster gross sales <sup>1</sup> (SEK ≥10 billion) in metastatic colorectal cancer in the U.S. market alone following a potential market launch. On top of this, we see additional opportunities across multiple indications and geographical markets where arfolitixorin can deliver significant improvements to current standard treatments.

### Substantial evidence for arfolitixorin

Throughout 2024, new analyses and results have strengthened our conviction that arfolitixorin has the potential to make a difference in first-line treatment. Our evidence platform gathers comprehensive data from previously completed preclinical and clinical studies, as well as new preclinical studies and analyses conducted during the year.

Based on this evidence platform, we can conclude that arfolitixorin already has shown efficacy in a large phase III clinical study, that higher doses of arfolitixorin administered in a new manner are expected to yield even better efficacy, and that these higher doses likely can be administered without compromising the safety profile. All these conclusions are addressed in the new study design and increase the probability of success.

# Presence in both scientific and investment arenas

Throughout the year, we have participated in numerous scientific conferences and partnering meetings, ranging from ASCO in Chicago and ENA in Barcelona to BIO-Europe, which was held in Stockholm this year. In early 2025, we attended the JP Morgan Healthcare Conference in San Francisco, a comprehensive and informative investor meeting that connects global pharmaceutical companies, fast-growing innovative businesses, and investors. Additionally, an abstract summarizing the positive findings from the post-hoc analysis of the completed Phase III AGENT study was presented at ASCO-GI, which took place in San Francisco, USA.

During the first months of 2025, we have also participated in several investor meetings. In March, Isofol was presented to a substantial group of investors at the Life Science Day in Gothenburg, Stora Aktiedagarna in Stockholm, and the international investor conference Swiss Nordic Bio in Zurich, Switzerland. Further participation in events and meetings is planned for the upcoming period.

### **Reinforced organization**

This summer, Margareta Hagman was recruited as our Chief Financial Officer. Margareta has extensive experience from various biotech and pharmaceutical companies, and we are delighted to welcome her to our team. We have also strengthened our organization by rehiring Roger Tell as Chief Medical Officer. Roger has been a crucial driving force within the company since 2019, serving in various roles, and has been working on a consultancy basis for the past few years.

We are now prepared for the company's next phase as we reintroduce arfolitixorin into clinical development. We look to the future with confidence and work tirelessly toward our goal: bringing arfolitixorin to market and thereby improving the prognosis for hundreds of thousands of patients with severe cancer.

Petter Segelman Lindqvist CEO, Isofol Medical AB (publ)

Source: 1) Market research and analysis conducted by Back Bay Life Science Advisors on behalf of Isofol in 2024.

# Need

# High medical need

# Potential

Arfolitixorin has the potential to significantly improve outcomes

# Market

High market potential

120.00

# ABOUT COLORECTAL CANCER

Colorectal cancer (CRC) is caused by uncontrolled cell growth. The disease usually progresses slowly over several years, starting as a raised growth of tissue, called a polyp, that originates from the lining of the colon and subsequently grows into the lumen of the colon. Polyps can be cancerous, meaning they can develop into cancer if not removed. Eventually, the cancer can break through the colon wall and spread to other organs, a condition known as metastatic colorectal cancer (mCRC).



# COLORECTAL CANCER – THIRD MOST COMMON FORM OF CANCER

Colorectal cancer is the third most common form of cancer globally after lungand breast cancer and the second most deadly. Despite several medical advances in cancer research, the mortality rate for metastatic colorectal cancer remains high – 86 percent of patients with disseminated disease die within five years.

Colorectal cancer is the collective name for colon and rectal cancer, a form of cancer that arises from uncontrolled cell growth in the colon or rectum.

Colon cancer is equally common in men and women, while rectal cancer is slightly more common in men. Colorectal cancer mainly affects older people, with the majority developing the disease after the age of 70. The incidence in younger people (aged 25-49) is increasing, while it is stable in older age groups. The global incidence (number of new patients diagnosed annually) for the cancer was just over 1.9 million patients in 2022, while approximately 0.9 million people died from the disease in the same year <sup>1</sup>.

Colorectal cancer usually occurs as uncontrolled cell division in the glands of the intestinal mucosa, which form polyps in the intestine that can develop into cancer after a while. When a cancerous tumor grows through the intestinal wall, the cancer cells can spread to other organs, so-called metastatic colorectal cancer, mCRC.

# The causes are partly environmental and hereditary

As with most other cancers, there is no known

single trigger for colorectal cancer. Hereditary factors and diet composition are considered to influence the risk. Smoking and lifestyles that cause obesity also increase the risk.

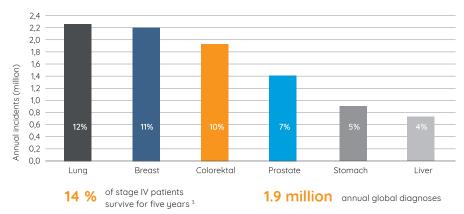
## High mortality rate when detected late

Colorectal cancer is the second most common cause of cancer-related deaths globally after lung cancer. However, the prognosis for survival is good if diagnosed early. Through health checks, so-called screening, where blood is checked in the stool, colorectal cancer can be detected at an early stage, which reduces mortality. Patients who are detected at a late stage, when the cancer has spread to other organs and formed metastases, face a worse prognosis and a significantly higher mortality rate. Around 86 percent of patients with metastatic colorectal cancer, mCRC, are no longer alive five years after diagnosis <sup>2</sup>.

## Current standard treatment

Today's standard treatment for metastatic colorectal cancer is based on 5-FU – one of the world's most widely used cancer drugs – and is given in combination with both folate and other chemotherapy, such as oxaliplatin or irinotecan, as well as biological drugs such as bevaci-

zumab and cetuximab. These combinations have been applied since 2004 and are variants of the current standard treatment in first and second line. However, current folate-based drugs require metabolic activation that occurs in several steps. Despite combination treatment with several drugs, fewer than half of patients with metastatic colorectal cancer respond to treatment with current folate-based drugs. Immune and targeted therapy are also included in today's standard treatment for certain groups of patients who have specific mutations.



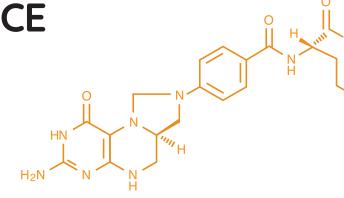
### 10% OF THE FORMS OF CANCER DETECTED ANNUALLY ARE CRC<sup>2</sup>

Source: 1) https://pressroom.cancer.org/Colorectal-Cancer-Cases-Surge-Globally 2) Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). Global Cancer Observatory: Cancer Today (version 1.1). Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.who.int/today, accessed [27 March 2024]. 3) American Society of Clinical Oncology (ASCO) Cancer.Net. Accessed 12 March 2024.

https://www.cancer.net/cancer-types/colorectal-cancer/statistics.

# ARFOLITIXORIN A DRUG CANDIDATE THAT CAN ENHANCE THE EFFECT OF CHEMOTHERAPY

Isofol's folate-based drug candidate arfolitixorin ([6R]-MTHF) has the potential to be established as a key component in today's standard treatment of several forms of solid tumors. A clinical study in patients with colorectal cancer is now being conducted as a first step. To optimize the efficay of the first-line treatment, 5-FU-based chemotherapy, it is administered together with folate-based drugs that, after degradation in the body, are converted to the active metabolite [6R]-MTHF. This active metabolite increases the tumor cell-killing effect of 5-FU and simultaneously reduces the production of one of the building blocks that tumor cells need to multiply. The body's conversion of currently available folate-based drugs to the active metabolite in its pure form, eliminating the need for conversion, could therefore bring significant benefits.



Isofol's patented drug candidate arfolitixorin, composed of the active metabolite [6R]-MTHF, is the world's first and only direct-acting folate-based drug candidate.

In a comparative clinical study in the early development phase (ISO-CC-002), Isofol has statistically verified that patients with colorectal cancer showed at least three to four times higher levels of [6R]-MTHF in the tumor when treated with arfolitixorin compared to current folate-based treatments. When arfolitixorin was administered together with 5-FU in the treatment of colorectal cancer, the tumor-killing effect was enhanced and more cancer cells died.

# The Evidence Platform support continued development

# Phase III study AGENT

Arfolitixorin has previously been evaluated in the randomized, controlled global, multicenter phase III study AGENT, which compared the efficacy and safety of arfolitixorin with the current folate-based drug leucovorin. Both substances were used in combination with 5-FU, oxaliplatin and bevacizumab in patients with metastatic colorectal cancer in first-line treatment. The study, which was initiated in 2018, was the first in approximately 20 years to evaluate a meaningful alternative to today's standard treatment for the vast majority of patients with metastatic colorectal cancer and included around 90 clinics in the



See how arfolitixorin functions in cancer cells Follow the link above or use the QR code.

US, Canada, Europe, Australia and Japan and a total of nearly 490 patients.

In August 2022, top-line results from the AGENT study were presented, showing that arfolitixorin was not statistically significantly superior to the control arm, and the study was subsequently halted.

# Conclusions from the AGENT study

OH

When data from the AGENT study were analyzed, it was found that:

- The selected dose and administration regimen consisting of two 60 mg bolus likely resulted in a blood concentration of arfolitixorin that was too low to deliver a sufficiently high amount of active substance into the tumor.
- The selected dose was lower than that used in the standard treatment control group, which compromised the validity of the comparison between the groups.
- The dose of arfolitixorin was administered late in relation to 5-FU. An earlier dose would likely maximize the potential for arfolitixorin to act synergistically with 5-FU and thereby provide greater efficacy.

Furthermore, in 2024, an external expert group conducted a post hoc, per-protocol analysis of the AGENT study, commissioned by Isofol. It was noted that compliance with the study protocol was low, mainly with regard to the time interval between the administration of 5-FU bolus and arfolitixorin and the duration of the 5-FU injections, which may have affected the outcome.

Results from the analysis, where the expert committee excluded patients who

were not treated according to the study protocol, show that arfolitixorin, even with the suboptimal dose regimen used in the AGENT study, provided better efficacy than standard treatment in most of the regions <sup>1</sup>.

In addition, pharmacokinetic modeling and a review of available safety data showed that it is likely feasible to administer arfolitixorin at a higher dose than in the AGENT study and that a different dose and administration regimen could probably improve the efficacy of the drug candidate.

### Positive assessment of the data collected

To summarize the conclusions in the extensive data package available for arfolitixorin, the following can be mentioned:

- Arfolitixorin has already shown efficacy at a level comparable to the control group in the extensive global phase III AGENT study.
- The dose-response relationship shown in previous preclinical studies indicates that higher doses may lead to better efficacy based on. Furthermore, an adjustment of the dosing time should be able to further optimize the efficacy as it increases the possibilities for synergistic effects between arfolitixorin and 5-FU.
- According to PK simulations and safety data from previously conducted clinical studies, higher doses can probably be administered without affecting the safety profile.

Based on these conclusions, a new study program is now being conducted where a new dosage regimen is tested and protocol compliance is optimized. The design of the new program is based on the large data package generated so far, which constitutes a strong evidence platform that strengthens lsofol's confidence in being able to show positive results.

## New clinical study in 2025

To demonstrate the clinical potential of arfolitixorin, Isofol will conduct a new phase Ib/II study, with the aim of determining the optimal dosage regimen with regard to tolerability and efficacy.

The study design was approved in March 2025 and will include patients with advanced (metastatic) colorectal cancer and will initially be conducted in collaboration with the leading academic hospital Charité - Universitätsmedizin Berlin, Germany.

In parallel with the first part of the study being conducted at Charité, Isofol and its license partner Solasia will carry out joint preparations for the second part of the study with the goal of recruiting patients in Japan in 2026. The inclusion of Japanese patients not only expands the study with additional participants but also enhances the diversity of the patient population, creating a stable foundation for subsequent regulatory processes in Japan and other geographic markets.

# Patent portfolio

The intellectual property protection for arfolitixorin currently comprises a combination of substance patents (owned by Merck) and clinical use patents (owned by Isofol), which together provide robust protection and market exclusivity in key global markets. In parallel with arfolitixorin's clinical development, efforts continue to further expand the scope and extent of intellectual property protection.

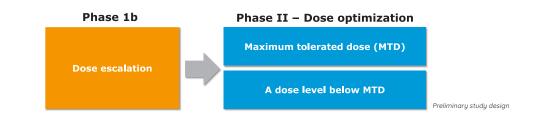
The substance arfolitixorin is patent-protected until 2037 in the U.S. and until 2034 in other markets. Additionally, the European Patent Office has issued a positive preliminary opinion regarding a new international substance patent that could extend protection until 2043, pending approval by national patent authorities. Furthermore, the new dosage regimen currently under testing could lead to additional patents providing exclusivity until 2045 if granted, and potentially beyond if patent term extensions are approved.

Working with leading patent experts, the company continuously evaluates opportunities to file new patents based on potential discoveries emerging from ongoing development work, which could further extend exclusivity protection and potentially increase the value of the company's pharmaceutical projects even more.

Source: 1) Poster ASCO-GI 2025; Titel "The Importance of treatment handling and compliance on overall response rate in a phase III study of metastatic colorectal cancer: Post-hoc per protocol analyses of the AGENT trial". Author; Pivodic et al, 2025

# NEW STUDY DESIGN INCREASES THE PROBABILITY OF ACHIEVING THE GOALS IN THE CURRENT PHASE Ib/II STUDY

Based on the extensive knowledge base from previously conducted preclinical and clinical studies, Isofol is now working on a time- and cost-effective phase Ib/II study to confirm the clinical benefits of arfolitixorin compared to traditional folates.



# The study design thus addresses all the main findings in the new evidence platform:

- Higher dose > expected higher efficacy with an intact safety profile
- Different administration regimen > optimizes conditions for synergistic interaction with 5-FU and decreases the need for precision
- Stricter protocol adherence > better outcomes

The study will begin with a phase lb part where increasing doses of arfolitixorin are evaluated to ensure safety and tolerability, while some efficacy assessments are performed. The phase II part of the study aims to evaluate the highest tolerated dose and a selected lower dose. Primary endpoints will be tolerability and safety, as well as objective tumor response (ORR). Secondary endpoints are progression-free survival (PFS) and overall survival (OS).

The study will initially be conducted at Charité – Universitätsmedizin Berlin.

# Expansion of the study to Japan

Isofol and the Japanese license partner Solasia are mutually strongly committed to the development of arfolitixorin as a potential new treatment for colorectal cancer. In parallel with the first part of the study (phase Ib), which is being conducted at Charité – Universitätsmedizin Berlin, Isofol and Solasia will conduct joint preparations for the second part of the study (phase II) with the goal of recruiting patients in a separate expansion cohort in Japan in 2026. The inclusion of Japanese patients expands the study numerically with additional patients and strengthens the diversity of the patient population, creating a solid foundation for subsequent regulatory processes both in Japan and other geographic markets.

The joint preparations in 2025 include activities such as initiating cooperation with a clinical research organization (CRO) and conducting discussions with the Japanese drug regulatory authority PMDA.

Isofol is now conducting a new clinical phase Ib/II study, with the aim of determining the optimal dosage regimen regarding tolerability and efficacy of arfolitixorin.

BOUT THE PHASE ID/II-STUD

Roger Tell, <u>Chief</u> Medical Officer

# SIGNIFICANT MARKET POTENTIAL FOR ARFOLITIXORIN

The already substantial market for colorectal cancer treatment is projected to expand further, and the need for improved treatments for metastatic disease is critically important. Current 5-FU-based chemotherapy will remain the first-line standard treatment of care for the foreseeable future, and the best opportunity to enhance patient prognosis therefore lies in optimizing this treatment – which is the purpose of arfolitixorin.

The global market for metastatic colorectal cancer treatment is projected to reach SEK 80 billion by 2032<sup>1</sup>. The standard treatment – 5-FU-based chemotherapy in combination with folates (such as arfolitixorin) – is expected to remain the foundation of first-line treatment for the foreseeable future.

At the forefront of cancer drug research are numerous innovative drug candidates, yet these are primarily intended either as add-ons to 5-FU+folate regimens or for use in later lines of therapy. Arfolitixorin stands as one of the few innovations with the potential to significantly enhance the efficacy of firstline treatment.

# Significant commercial potential in the U.S. market

A market analysis recently conducted by external consultant firm Back Bay Life Sci-

ence Advisors confirms Isofol's previous estimates and indicates that arfolitixorin has the potential to achieve blockbuster status<sup>1</sup> (more than SEK 10 billion) in metastatic colorectal cancer in the U.S. market alone.

The analysis is based on calculations of an addressable population between 60,000-70,000 patients <sup>1</sup> annually in the U.S., projecting a market penetration of 50-70%. Furthermore, the market analysis indicates a substantial medical need and high willingness to pay for an improved treatment concept in first-line therapy for metastatic colorectal cancer.

# Further markets and indications may be added

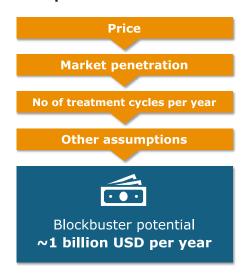
Beyond the U.S. market potential, arfolitixorin offers additional leverage in other geographic regions as well as potential expansion of indications. Japan, Canada and Europe represent other significant markets beyond the United States.

Arfolitixorin's therapeutic applications could also be extended to additional indications within colorectal cancer, potentially as adjuvant or neoadjuvant treatment.

Folate treatments are often employed in other cancer diseases and solid tumors where arfolitixorin may enhance therapeutic efficacy as a supplement to 5-FU-based chemotherapy. Pancreatic, breast, and head/neck cancers are notable therapy areas where arfolitixorin may contribute significant clinical value.

If arfolitixorin proves efficacy in clinical studies, the drug candidate represents one of the few innovations in first line treatment and will have a crucial role to play.

# Indicates large commercial potential in the US



Source: 1) Market research and analysis conducted by Back Bay Life Science Advisors on behalf of Isofol in 2024.

# THE PATH FORWARD FOR ISOFOL AND ARFOLITIXORIN

The key components of Isofol's strategic plan for value creation include strengthening the evidence platform with new clinical data while advancing arfolitixorin toward registration, maximizing the potential of the company's collaborations and partnerships, and continuing to build trust among investors and other stakeholders.

Building on the evidence and knowledge of arfolitixorin generated to date, the strong partnerships established with both clinical experts and collaborators, and the expertise and talent available within the organization, lsofol is now well-positioned to continue the clinical development of arfolitixorin. The goal is clear: to improve cancer treatment for millions of patients and thereby create significant value for shareholders, employees, and society at large.

The main elements of the company's strategy for 2025-2027 are to:

## Generating new efficacy data

Based on the comprehensive evidence platform that gathers all previously generated clinical and preclinical data for arfolitixorin, along with analyses and calculations, Isofol is conducting a Phase Ib/II clinical study. The aim of this study is to identify an optimal dosing regimen that is both safe and effective for treating metastatic colorectal cancer. The Phase Ib/II study begins with a Phase I part in which escalating doses of arfolitixorin are evaluated to ensure safety and tolerability, while simultaneously performing preliminary efficacy assessments. Patients are treated in cohorts receiving different doses, all higher than in the AGENT study. The Phase II part of the study aims to evaluate both the highest tolerated dose and a lower dose in two separate study arms. Endpoints include objective tumor response, progression-free survival, and overall survival.

The results of the study will establish a solid foundation for decisions on further clinical development and potential future regulatory approval processes.

# Maximizing the potential in Isofol's partnerships

During the continued clinical development of arfolitixorin, Isofol will leverage its existing partnerships and collaborations. These include Merck, the company's strategic partner for substance development; Charité Universitätsmedizin, which is conducting the study and serving as partner for the broader clinical development program; and Solasia, the development and commercialization partner for the Japanese market. During 2020, Solasia acquired exclusive rights to arfolitixorin (SP-05 in Japan) for the Japanese market and participated in conducting the AGENT Phase III clinical study. In late 2024, Solasia decided to actively participate in the planned second part of the Phase Ib/II clinical study with the aim of enrolling Japanese patients in 2026. Isofol will collaborate with Solasia to prepare for the study's expansion to Japan while simultaneously initiating the study at Charité. The inclusion of Japanese patients not only increases the study's numerical size but also diversifies the patient population, creating a solid foundation for subsequent regulatory processes both in Japan and other geographic markets. In addition to Solasia, Isofol has established a commercialization partnership with Paladin Pharma Inc. for the Canadian market.

Isofol will continue to build upon established partnerships and expand relationships with leading clinical experts while laying the foundation for collaborations with additional partner companies. To maximize Isofol's potential, the company is actively working to build and strengthen relationships for new, strategic partnerships through various channels and initiatives. An important example of this work is the participation in international conferences and industry meetings, such as ASCO, ENA, BIO-Europe, and other key industry forums, where the company actively seek and develop new collaborative opportunities.

# Continuing to build trust

Isofol builds trust for the company and secures ongoing financing through transparent and open communication with the stock market, maintaining high standards of regulatory compliance, and implementing effective cost control that prioritizes value-creating activities.

The company's values are *care, integrity, urgency and cooperation.* We work together within the company and with our partners to bring our drug candidate to market as quickly as possible, without compromising safety or integrity and with great concern for patients. The sooner arfolitixorin becomes approved, the sooner the common goal can be achieved: to help improve the prognosis for all those affected by gastrointestinal cancer.

# "THERE IS A CRITICAL NEED FOR INNOVATIVE TREATMENT OPTIONS"

Sebastian Stintzing is heading the Department of Hematology, Oncology and Cancer Immunology at Charité - Universitätsmedizin in Berlin and serves as the principal investigator of the Isofol clinical study. His research is dedicated to optimizing current treatment options and improving the prognosis for patients living with gastrointestinal cancer.

## What does clinical daily life look like at Charité?

"Our research group specializes in clinical research on gastrointestinal cancer, with a specific emphasis on optimizing treatment for patients with metastatic colorectal cancer. Currently, 95 percent of colorectal cancer patients receive 5-FU-based chemotherapy in combination with leucovorin, paired with either oxaliplatin or irinotecan. Treating metastatic colorectal cancer remains a persistent challenge, and there is a critical need for innovative treatment options to improve patient prognosis".

# What role could arfolitixorin potentially play in the treatment of cancer patients?

"Today's cancer research is highly focused on precision oncology, developing targeted treatments for specific patient subgroups. Initial clinical studies in this field explored chemotherapy-free treatment regimens, but researchers are now investigating precision medicine approaches in combination with the current standard of care, 5-FU-based chemotherapy. Preliminary results from these combination studies demonstrate remarkable efficacy, suggesting that the integration of precision oncology with 5-FU-based chemotherapy will become the standard treatment for these patient populations. This approach ensures that 5-FU-based chemotherapy will remain the primary treatment for the vast majority of patients. If arfolitixorin can be used to enhance the effectiveness of the standard treatment, it would represent a significant breakthrough in cancer care.

When discussing 5-FU and colorectal cancer, it is crucial to emphasize that 5-FU and folate are not only employed in metastatic disease, which affects approximately 1.9 million patients globally each year, but also serve as a standard adjuvant therapy.

Colorectal and gastrointestinal cancers collectively account for around 25 percent of all malignant cancers worldwide, of which colorectal cancer represents 12.5 percent. I believe that enhancing the efficacy of 5-FU has the potential to significantly improve the prognosis for a broad majority of patients. Consequently, we are very excited to participate in the new Isofol study, which aims to optimize the effectiveness of 5-FU".

# Could you tell us about the study?

"The study we are conducting with Isofol is not a typical Phase I study because we already have data from the previously completed Phase III AGENT study, involving hundreds of patients. This study demonstrated that a lower dose of arfolitixorin gave an effect comparable to leucovorin. Our current objective is to increase the dosage and modify the administration timing, as preclinical data suggest that arfolitixorin may be more effective at higher doses. Furthermore, since higher doses have been previously administered to patients, we do not anticipate any unexpected toxicity issues".

## What about other cancer types?

"Colorectal cancer is not the only gastrointestinal cancer where 5-FU and leucovorin are currently used. Gastric cancer, which is particularly common in the Asian population but also occurs in Europe, represents another key indication. In gastric cancer, 5-FU in combination with leucovorin remains the standard of care across first, second and subsequent lines of treatment. Similarly, in lung and breast cancer, the focus is on TS inhibitors, suggesting significant potential for arfolitixorin if it can demonstrate superior efficacy compared to existing standard treatments".



Sebastian Stintzing, Professor of Medicine, Head of the Department of Hematology, Oncology and Cancer Immunology (CCM) at Charité - Universitätsmedizin Berlin.

# STRONG PARTNERSHIPS PROVIDE A SOLID FOUNDA-TION FOR THE DEVELOPMENT OF ARFOLITIXORIN

Isofol has established a comprehensive network with expertise in fields such as oncological research, clinical studies, manufacturing, patent issues, and commercialization. Together, these partnerships create favorable conditions for advancing the development of arfolitixorin.

Isofol is led by individuals with extensive experience in pharmaceutical and business development. The company operates in a cost-effective manner, utilizing a well-established network of leading experts in the field who are engaged on a consultancy basis. This approach provides Isofol access to essential expertise in areas including research, production (CMC), quality assurance (QA), patent matters, clinical drug development and business development.

With support from highly competent, quality-focused, and flexible partners, active knowledge exchange in external networks, and collaborations with academic institutions, the work to improve current cancer treatments continues.

# Board and management

The Board of Directors consists of Chairman Jan-Eric Österlund and members Dr. Alain Herrera, Dr. Helena Taflin, Lars Lind, and Professor Sten Nilsson. Several board members have been involved in earlier phases of the company's development and combine medical expertise with deep knowledge of business development. Petter Segelman Lindqvist serves as the Chief Executive Officer, Margareta Hagman holds the position of Chief Financial Officer, and Dr. Roger Tell is the Chief Medical Officer. For more information about the Board of Directors and management, please refer to page 30 and 33.

## External advisors

Isofol maintains close dialogue with clinical experts worldwide to discuss the design of the arfolitixorin study program and the overall development process. The company's clinical advisory board serves as a notable example, consisting of leading oncologists and colorectal cancer experts from the United States, Europe and Japan:

 Heinz-Josef Lenz, MD, professor, Associate Director for Clinical Research and Co-Leader of the Gastrointestinal Cancers Program at the USC Norris Comprehensive Cancer Center, Professor of Medicine and Preventive Medicine, Section Head of GI Oncology in the Division of Medical Oncology and Co-Director of the Colorectal Center at the Keck School of Medicine of the University of Southern California, USA.

- Sebastian Stintzing, MD professor, Head of the Department of Hematology, Oncology and Cancer Immunology (CCM) at Charité -Universitätsmedizin Berlin, Germany.
- Takayuki Yoshino, MD, PhD, Chairman of the Japan Society of Clinical Oncology, Deputy Hospital Director, Head of the Division for the Promotion of Drug and Diagnostic Development, Chief of the Department of Gastrointestinal Oncology, National Cancer Center Hospital East, Japan.

In addition to the clinical advisory board, Isofol also has a network of additional advisors. The network includes professor Frits Peters, professor emeritus at the Laboratory Medical Oncology, Amsterdam University Medical Center, professor at the Medical University of Gdansk, Poland, and honorary professor at Amity University in Noida, India.

Isofol's founder and the initiator of the clinical development of arfolitixorin, Professor Bengt Gustavsson, MD, PhD, Professor of Surgery, is also affiliated with the company as a senior advisor. He is one of the originators behind the positive effect of leucovorin on 5-FU, which is the mainstay of almost all colorectal cancer treatments.

# **Commercial partners**

Isofol has established collaborations with various partners to commercialize arfolitixorin. Some of these include:

# Solasia Pharma K.K.

Isofols has established a regional license agreement for Japan, the world's second largest pharmaceutical market, with Solasia Pharma K.K. The agreement has a total value of 100 million dollars, consisting of initial payments and future milestone payments linked to clinical development, regulatory processes and sales. Additionally, Isofol is entitled to an incremental double-digit royalty based on the future net sales. This agreement provides insight into the potential value that licensing in other regions of the world, or alternatively a divestment of the project, could generate.

In March 2024, Solasia announced their continued strong commitment to the development of arfolitixorin, and in August, the company confirmed their readiness to finance potentially upcoming studies in Japan. Solasia contributes with their expertise on an ongoing basis and participates in shaping the details of the clinical development program. By the end of 2024, Solasia announced their intention to expand the Phase II portion of the upcoming study to include Japanese patients in 2026. This inclusion significantly increases the study size and enhances diversity in the patient population, creating a solid foundation for subsequent regulatory processes in both Japan and other geographic markets.

### Endo Inc. and Paladin Pharma Inc.

Additionally, Isofol has a license agreement with Paladin Pharma Inc. covering commercialization in the Canadian market, which will also generate royalty income from future sales. As the clinical development program advances, discussions will be initiated with additional potential partners for other regions of the world, regarding both further clinical development and commercialization.

### Other partnerships

Merck – experts in the processing of substance Isofol maintains a strategic research and development partnership with Merck Life Science KGaA, Germany, and its Swiss subsidiary Merck & Cie. This partnership, formalized through a global licensing agreement, offers numerous synergies. Isofol contributes with specialized knowledge in the development and application of arfolitixorin for cancer treatments, while Merck & Cie provides expertise in synthesizing of a stable API (active pharmaceutical ingredient) of [6R]-MTHF as well as formulating a stable and sustainable drug.

## Charité – Universitätsmedizin Berlin – one of Europe's leading cancer hospitals

Isofol has established a collaboration with Charité - Universitätsmedizin Berlin, Germany, and its Department of Hematology, Oncology and Cancer Immunology (CCM) headed by Professor Sebastian Stintzing, MD. The collaboration focuses on the further development of the drug candidate arfolitixorin for colorectal cancer and other solid tumors. Under this agreement, Isofol and Charité - Universitätsmedizin Berlin will jointly conduct the Phase Ib/ II clinical study. Professor Stintzing serves as the coordinating investigator of the study.

## Link Medical – CRO

Link Medical is Isofol's primary CRO (Clinical Research Organization) that manages the clinical study on behalf of and in collaboration with Isofol.

## Recipharm - commercial manufacturer

Recipharm in Wasserburg, Germany has been a partner for the manufacturing of Isofol's product, arfolitixorin, since 2015. A large-scale production process is in place and Isofol has a close dialogue with Recipharm to secure manufacturing and deliveries in connection with the clinical studies.

## Other partnerships

In addition to the above mentioned partners, Isofol maintains close collaborations with advisors and experts in regulatory affairs, statistical planning and analysis, intellectual property and patents, legal matters, and other fields.

# About arfolitixorin

Isofol's drug candidate arfolitixorin, the folate [6R]-MHTF, has the potential to become a key component in the treatment of several cancers where 5-FU chemotherapy is the standard treatment, including colorectal cancer. Folate has long been a standard component in the treatment of metastatic colorectal cancer and has been shown to enhance the effect of 5-FU. However, the body's conversion of folate to the active metabolite occurs in several steps, and there are advantages in treating patients with the metabolite in its pure form.

Arfolitixorin is the world's first and only direct-acting folate-based drug candidate that does not require conversion and thus has the potential to more effectively improve the effect of 5-FU in first-line treatment. To date, 490 patients have been treated with arfolitixorin in clinical trials and a new clinical trial is now being prepared based on a new dosage regimen that is expected to optimize the effect of the drug candidate.



22

For a biotechnology company without its own revenue, our financing is always an important issue for the board.

> Jan-Eric Österlund Chairman of the Board

# "IF WE SUCCEED IT WILL BE A MAJOR BREAKTHROUGH IN CANCER TREAT-MENT"

Isofol's Chairman of the Board, Jan-Eric Österlund, shares his perspective on the past year and outlines the board's priorities for 2025. The focus is on gaining clearer insights into regulatory authorities' recommendations for designing future registration studies, as well as creating favorable conditions for additional partnerships to advance the development and commercialization of arfolitixorin.

# How would you summarize 2024?

"The year brought three significant advances for Isofol. The first was that we obtained evidence suggesting arfolitixorin gave better effect than leucovorin, even at the dose administered in the AGENT study – given the study protocol was followed. This insight became an important validation for us and our existing partners.

We also obtained preclinical evidence demonstrating that a higher dose of arfolitixorin yields better efficacy. This has been shown in the Modelle study, published in 2024, that was conducted at the Surgical Oncology Laboratory (SOL) at Östra Hospital in Gothenburg, Sweden, and in the organoid studies completed during the year. The SOL study demonstrated not only that a higher dose of arfolitixorin provided better inhibition of the crucial enzyme thymidylate synthase, but also that a higher dose of leucovorin did not improve efficacy.

The third important advancement is the establishment of a strong management team

through the recruitment of Petter Segelman Lindqvist as CEO, Margareta Hagman as CFO, and the reinstatement of Roger Tell as CMO shortly after year-end. Additionally, we have received external validation of our drug candidate through the collaboration with Charité and renewed commitment from our Japanese partner, Solasia".

# What role could arfolitixorin play in future cancer treatment?

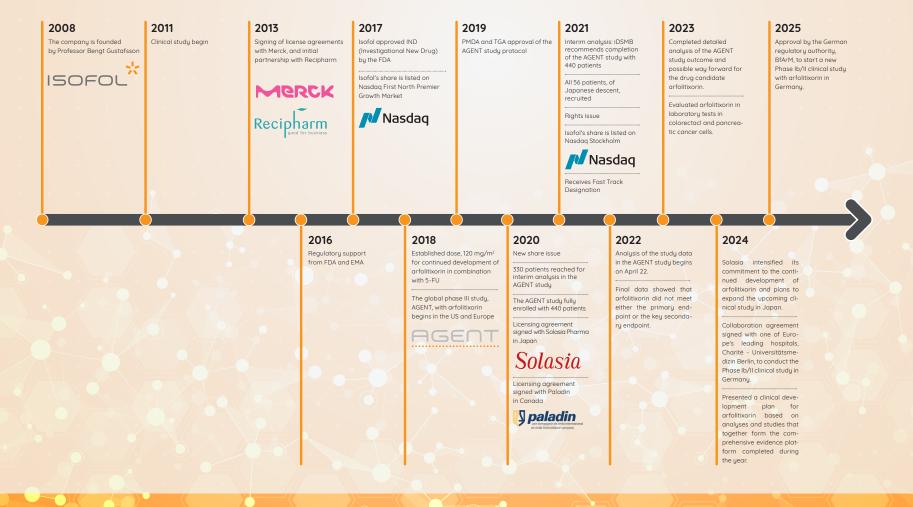
"Extensive resources are devoted to cancer research, but almost all projects focus on adjuvant therapies and development projects for later-line treatments. The cornerstone of first-line cancer treatment today and for the foreseeable future is 5-FU, and there is surprisingly little development in this area, perhaps because it is so challenging. If we succeed with arfolitixorin, it will be a major breakthrough in cancer treatment with immediate benefits for the majority of patients.

The development of arfolitixorin is currently focused on improving the prognosis for colorectal cancer patients, but our long-term ambition is to establish arfolitixorin as an adjuvant treatment, thereby enabling us to cure cancer in more patients, including those with tumor types beyond colorectal cancer".

# What are Isofol's biggest challenges moving forward, and how is the board addressing them?

"We aim to discuss the next steps for arfolitixorin with regulatory authorities well in advance of reviewing the Phase II results, enabling us to bring it to market as quickly as possible. For a biotech company without revenue, financing remains a critical priority for the board. Another challenge is identifying the right partners who can commercialize arfolitixorin to market beyond Japan and Canada. Alongside the development of arfolitixorin, we are engaging in discussions with other potential partners to prepare for future commercialization".

# **ISOFOL'S HISTORY**



# THE SHARE

Isofol Medical 's (publ) share has been listed on Nasdaq Stockholm under the ticker ISOFOL since 2021. The share was previously listed, since 2017, on Nasdaq First North Premier Growth Market.

# Share capital

As of December 31, 2024 the share capital of Isofol Medical amounted to SEK 4,945,253, distributed between 161,515 440 shares (161,515,440) with a nominal value of SEK 0.0306 (00306). All of Isofol's outstanding ordinary shares entitle the holder to one vote. The number of shareholders as of December 31, 2024 was approximately 14,000 (10,200).

# Share price trend and liquidity

On December 31, 2024 the share price was SEK 2.22 per share, an increase of 204 percent compared to the closing price as of December 31, 2023. The OMX Stockholm Pharmaceuticals & Biotechnology PI-index rose by 6 percent during the same period.

At year-end 2024, Isofol's market capitalization was mSEK 358.6 (117.9) based on the closing price. The highest closing price during the period was SEK 4.54 and the lowest quote during the period was SEK 0.57.

# Trading volume

425.9 million (268.5) Isofol shares were traded during the year, corresponding to a turnover rate of 264 percent (166).

# Dividend policy and dividend

Isofol is a biotech company and there are no plans to pay dividends in 2024 or the next coming years. Dividend may be paid in the future when the Group's results and financial position so permit.

## **Contact Investor Relations**

Petter Segelman Lindqvist, CEO Margareta Hagman, CFO

# Largest shareholders

Isofol's largest shareholders based on information from Euroclear Sweden AB and Monitor as of December 31, 2024.

## Largest Shareholders as of December 31, 2024

Shareholder	Number of Shares	Share capital/votes
Avanza Pension	14,368,280	8.90%
Swedbank Försäkring	7,911,911	4.90%
Christian Haglund	7,636,506	4.73%
Göran Gustafsson*	6,003,489	3.72%
Mats Franzén med närstående*	5,952,393	3.69%
Hans Enocson	4,555,236	2.82%
Handelsbanken Fonder	4,386,104	2.72%
Bengt Gustafsson	3,749,459	2.32%
Claes Ekman	3,302,511	2.04%
Futur Pension	2,135,150	1.32%
10 largest shareholders	60,001,039	37.15%
Other shareholders	101,514,401	62.85%
TOTAL	161,515,440	100.00%

\* Own or related natural or legal person's holding of shares (direct and indirect) in the company.

Source: Monitor of Modular Finance AB, Compiled and processed data from sources including Euroclear, Morningstar and the Swedish Financial Supervisory Authority.

# FINANCIAL INFORMATION AND CORPORATE GOVERNANCE REPORT

Administration Report	22
Corporate Governance Report	27
Financial information	36
Notes	41
Certification	53
Auditor's report	54
Calendar	57
Glossary	58

# ADMINISTRATION REPORT

The Board of Directors and CEO of Isofol Medical AB (publ) (Isofol), corporate identity number 556759-8064, hereby present the annual report for the 2024 financial year.

## **OPERATIONS**

Isofol's registered office is in Gothenburg. Isofol divested its subsidiary in December 2023, and the Group consequently also ceased to exist. All comparative figures are therefore now those of the company and not the Group.

Isofol is a research-based biotechnology company working to improve the prognosis for patients with severe types of cancer. The company's drug candidate arfolitixorin is intended to enhance the efficacy of standard first-line treatment for several types of solid tumors and is now being studied in colorectal cancer, the world's third most common type of cancer, where there is a great medical need for better treatments. A phase Ib/II study is now being conducted with new dose regimens that are expected to optimize the efficacy of the drug candidate.

### SIGNIFICANT EVENTS DURING THE YEAR

 At an Extraordinary General Meeting held on January 4, 2024, a new Board of Directors was elected consisting of Jan-Eric Österlund (Chairman), Dr Alain Herrera, Dr Helena Taflin, Lars Lind and Professor Sten Nilsson. Several members of the Board have a background in earlier phases of the company's development and combine medical experience with in-depth knowledge of business development. The new Board appointed Petter Segelman Lindqvist as the new Chief Executive Officer and Magnus Hurst as the new Chief Financial Officer. Roger Tell, who had previously served as acting CEO, returned to the role of Chief Medical Officer.

- In March 2024, the preliminary framework for a phase I/II clinical trial of arfolitixorin in first-line treatment, in combination with 5-FU-based chemotherapy in patients with metastatic colorectal cancer, was presented. This was done for the purpose of generating both efficacy and safety data with a new dosage regimen.
- In March 2024, it was also announced that the company's partner, the Japanese pharmaceutical company Solasia Pharma K.K., has confirmed its continued strong commitment to the development of arfolitixorin. Solasia will contribute its expertise and participate in the work of formulating the details of the clinical development program.
- In the second quarter, the company announced that a collaboration agreement has been signed with the world-leading teaching hospital Charité – Universitätsmedizin Berlin, and Professor Sebastian Stintzing, for the further clinical development of arfolitixorin.
- On July 5, the company announced that an external expert committee had conducted a post hoc per-protocol analysis of the phase III clinical trial AGENT showing new results in favor of arfolitixorin.
- Later in July, the company presented results from two additional preclinical studies conducted by Oncosyne AS in collaboration with Akershus University Hospital in Oslo, and at the Surgical Oncology Laboratory (SOL) at Sahlgrenska University Hospital in Gothenburg. Both studies show that in-

creased doses of arfolitixorin in combination with 5-FU lead to significantly higher efficacy, thus substantiating the dose-response relationship of arfolitixorin.

- In August, Margareta Hagman took over as CFO, replacing Magnus Hurst.
- In September, the company announced that a positive preliminary opinion had been issued on the patentability of a new international application for a substance patent for arfolitixorin filed with the PCT (Patent Cooperation Treaty).
- In October, the company announced that a Late Breaking Abstract on the drug candidate arfolitixorin would be presented as a poster at ENA 2024 in Spain. This poster describes the dose-dependent cytotoxic effect and increased activity of arfolitixorin at higher doses in combination with 5-FU.
- Also in October, the investigator-initiated Modelle study, which has evaluated the efficacy of arfolitixorin at tissue level, was published in the scientific journal BJC Reports. The study showed dose-dependent TS inhibition with arfolitixorin.

# In December, it was announced that the company's Japanese partner Solasia Pharma K.K. had made a strategic decision to include Japanese patients in the phase II part of the upcoming phase Ib/II clinical trial.

# SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

 In March 2025 announced that the company has received approval from the regulatory authority in German, BfArM, to initiate the new clinical study of the drug candidate arfolitixorin. The study will initially be conducted in Germany.

# THE COMPANY'S KEY PERFORMANCE INDI-CATORS MULTI-YEAR OVERVIEW

As a development company whose drugs are still at the development stage, Isofol has limited revenue from licensing agreements and has no revenue to recognize for drugs, but has significant research and development costs.

# Five-year summary

	2024	2023	2022	2021	2020
Net revenue (kSEK)	0	721	12,797	22,407	37,119
Operating result (kSEK)	-47,209	-41,683	-167,543	-204,583	-186,635
Result after financial items (kSEK)	-43,488	-37,071	-159,793	-200,280	-188,989
Total assets (kSEK)	98,417	140,597	209,890	400,004	145,450
Equity ratio (%)	79.2	86.4	75.5	79.6	45.8
Average number of employees	4.3	4.8	14	13	12

# THE SHARE AND OWNERSHIP STRUCTURE

The share capital of Isofol Medical AB (publ) amounts to kSEK 4.945. Isofol's shares have been admitted to trading on Nasdag Stockholm since 2021. As of December 31, 2024, the total number of shares and votes in the company is 161,515,440. All shares are ordinary shares and carry equal entitlement to the company's profit, and each share entitles the holder to one vote at an Isofol general meeting of shareholders. At a general meeting of shareholders, each voting member may vote for the full number of shares owned or represented without restriction on the number of votes. At the end of 2024, the company had approximately 14.050 (10.200) shareholders. and the ten largest shareholders owned 37.2 percent (36.8) of the outstanding shares and other shareholders owned 62.8 percent (63.2).

## SALES AND RESULT

Sales in 2024 amounted to kSEK 0 (721). Other external costs during the year amounted to kSEK -38,734 (-35,136). The costs are mainly attributable to start-up costs for the upcoming study related to a clinical CRO, advice and consultancy resources regarding drug development and administration, and other ongoing operating costs. Other external costs in the previous year were dominated by costs related to discontinuing activities and analytical work related to the AGENT study in accordance with the strategy presented at that time.

Personnel costs in the company amounted to kSEK -8,480 (-7,424), representing a increase of kSEK -1,056. The number of employees was five (three) at the end of December 2024.

The result after financial items was kSEK -43,488 (-37,071). The company has no tax costs since it did not report any profit during the year.

### LIQUIDITY AND FINANCIAL POSITION

As of December 31, 2024, cash and cash equivalents amounted to kSEK 96,157 (138,148). No loans had been raised as of December 31, 2024 or have been raised since that date. Working capital amounted to kSEK 78,593 (122,341). The Board of Directors and management believe that the company has adequate funding to pursue its planned operations in 2025.

# CASH FLOW AND INVESTMENTS

Cash flow from operating activities during the year amounted to kSEK -41,986 (-52,536), representing a change of kSEK 10,550. The negative cash flow is mainly attributable to startup costs for the upcoming study related to a clinical CRO, advice and consultancy costs for development and administration, and other ongoing operating costs. Cash flow from investing activities amounted to kSEK 0 (101). Cash flow from financing activities amounted to kSEK 0 (0). Cash flow for the year amounted to kSEK -41,986 (-52,435), representing a change of kSEK 10,449.

### **EMPLOYEES**

At the end of the year, the number of employees in the company amounted to five (three), of which one man and four women, all employed at the company's headquarters in Gothenburg, Sweden. The average number of employees in 2024 was 4.3 (4.8). In addition, the company has a number of consultants in key positions who work full-time or nearly full-time for Isofol.

# GUIDELINES FOR REMUNERATION OF SENIOR EXECUTIVES

In accordance with the Swedish Companies Act, the general meeting of shareholders has to resolve upon guidelines for remuneration of the CEO and other senior executives. Guidelines for remuneration of senior executives were adopted at the Annual General Meeting held on May 19, 2022, to apply until the end of the 2026 Annual General Meeting. No deviations from these guidelines have taken place. The following guidelines were adopted at the 2022 Annual General Meeting:

### Scope

These guidelines encompass the executive management of Isofol Medical AB (publ) and the company's Board members to the extent that remuneration other than that resolved by the Annual General Meeting is paid to Board members. The term "executive management" refers to the CEO, Deputy CEO and other members of the executive management" refers to members of the management. "Other members of the executive management" refers to members of the management team and managers who report directly to the CEO. Managers reporting directly to the CEO in 2024 were the Chief Medical Officer and the Chief Financial Officer.

The guidelines are forward-looking and are to be applied to agreed remuneration and changes made to already agreed remuneration, after the guidelines were adopted by the 2022 Annual General Meeting. The guidelines do not cover remuneration resolved upon by the general meeting of shareholders.

For employment relationships that fall under regulations other than Swedish regulations, appropriate adaptations may be made to comply with such regulations or established local practice, the overall aim of the guidelines being met as far as possible.

# The guidelines' promotion of the company's business strategy, long-term interests and sustainability

The objective is to make arfolitixorin available worldwide and in so doing improve the prognosis for patients with cancer being treated with 5-FU-based therapies. 5-FU-based chemotherapu in combination with the folate leucovorin is the core of standard treatment for several solid tumors, including colorectal cancer, and is expected to continue to form the basis of first-line treatment for the foreseeable future. The purpose of adding folate is to enhance the effect of chemotherapy, which in turn improves survival. Isofol's drug candidate arfolitixorin is a synthetic copy of the active substance in leucovorin in its pure form. It is hoped that the additional direct-acting substance arfolitixorin will further improve the efficacy of 5-FU. Improved first-line treatments offer the greatest potential to improve treatment outcomes, and Isofol's goal is for arfolitixorin to be capable of replacing leucovorin as the next-aeneration folate.

The successful implementation of the company's business strategy and safeguarding of the company's long-term interests, including its sustainability, requires the company to be able to recruit and retain skilled employees. To achieve this, Isofol needs to be able to offer competitive total remuneration. Total remuneration must be market-based and competitive and must be in line with the individual's responsibilities and powers.

Any variable cash remuneration covered by these guidelines must also aim to promote the company's business strategy and longterm interests, including its sustainability.

# **Remuneration of senior executives** *Forms of remuneration, etc.*

The company must offer total market-based remuneration that enables skilled senior executives to be recruited and retained. Remuneration within the company must be based on principles related to performance, competitiveness and fairness.

The remuneration must be market-based and consist of the following components:

fixed salary, possible variable salary pursuant to a separate agreement, pension and other benefits. In addition, the general meeting may, if it so decides, make an offer of longterm incentive programs such as share- or share price-based remuneration or incentive programs.

Such long-term incentive programs are decided by the general meeting of shareholders and are therefore not covered by these guidelines.

### Fixed salary

Fixed salary consists of a fixed cash salary, which is reviewed annually. Fixed salary reflects the demands placed on the position regarding competence, responsibility, complexity and how the position is expected to help achieve the company's objectives. Furthermore, fixed salary must be individual and differentiated and reflect predetermined and achieved performance targets.

### Variable salary

In addition to fixed salary, the CEO and other members of executive management may, under a separate agreement, receive variable salary when they meet predetermined criteria. Any variable salary consists of annual variable cash remuneration and may not exceed 50 percent of the fixed annual salary for the CEO and 33 percent for other senior executives.

The variable salary must be linked to one or more predetermined and measurable criteria and must aim to promote the company's business strategy and long-term interests, including its sustainability, for example by having a clear link to the business strategy or by furthering the long-term development of the executive. The criteria can be both financial and non-financial. The criteria can also be individualized quantitative or qualitative goals.

By linking the remuneration of senior executives to the company's earnings and sustainability, the goals promote the implementation of the companu's business strateau, its long-term interests and its competitiveness. The criteria apply for one financial year at a time. The fulfillment of criteria for the payment of variable salary is assessed annually. This assessment determines how well the criteria are met. The Remuneration Committee is responsible for the assessment of variable cash remuneration of the CEO. The CEO is responsible for the assessment of the variable cash remuneration of other senior executives. Financial targets must be assessed on the basis of the latest financial information published by the company.

The Board of Directors must be able to recover, in full or in part, variable remuneration paid for incorrect reasons in accordance with law or agreement and with the restrictions that may result therefrom.

### Pensions

For the CEO, pension benefits, including health insurance, are defined-contribution and the premiums are not to exceed 30 percent of fixed annual salary. For other members of executive management, pension benefits, including health insurance, are to be defined-contribution unless the executive is covered by a defined-benefit pension in accordance with mandatory collective agreement provisions. The premiums for defined-contribution pensions are not to exceed 30 percent of fixed annual salary. Variable cash remuneration is not to be pensionable.

# Other benefits

Other benefits, which may include a company car, travel expenses and health insurance, are market-based and constitute a limited portion of the total remuneration. Premiums and other costs arising from such benefits may amount to a maximum of ten (10) percent of fixed annual salary.

# Terms and conditions in the event of termination

In the event of termination, the CEO is subject to a mutual notice period of six months. There are no severance agreements for the CEO.

A mutual notice period of six months applies in the event of termination of other senior executives. There are no severance pay agreements with other senior executives.

## **Remuneration of Board members**

Board members are entitled to receive only such remuneration as is decided by the general meeting of shareholders. In special cases, Board members can be remunerated for services within their respective areas of expertise or competence, provided that the service performed is beyond what can be regarded as a customary assignment as a Board member. For these services (including services performed by a company wholly owned by a Board member), a market-based fee is to be paid, provided such services contribute to the implementation of the company's business strategy and the safeguarding of the company's long-term interests, including its sustainability. Such consultancy fees may not exceed the annual Board fees for each Board member and must be regulated in a consultancy agreement approved by the Board (subject to the disaualification rules in the Swedish Companies Act).

# Salary and terms of employment for employees

In preparing the Board's proposal for these remuneration guidelines, salary and terms of employment for the Company's employees have been taken into account by including information on the employees' total remuneration, the component parts of the remuneration and the increase and rates of increase in remuneration over time as part of the Remuneration Committee's and Board's basis for decision-making when evaluating the reasonableness of the guidelines and the limitations that follow from them.

### Process of preparation and decision-making

The Chairman and members of the Board of Directors are paid fees in accordance with a resolution of the Annual General Meeting. The Board of Directors has appointed a Remuneration Committee consisting of the Chairman of the Board, Jan-Eric Österlund, and the Board members Lars Lind and Alain Herrera. The Remuneration Committee is required to consider matters relating to the remuneration and other terms of employment of the executive management. Principles for the remuneration of senior executives are adopted at the Annual General Meetina. The Remuneration Committee's task is to draw up proposals in accordance with these principles. The members of the Remuneration Committee must be independent in relation to the company and executive management.

Remuneration of the CEO and other senior executives employed by the company consists of basic salary, variable remuneration, pension after variable remuneration and other benefits. Other senior executives means the two persons who, together with the CEO, make up the executive management.

The Board must draw up a proposal for new guidelines at least every four years and submit the proposal for resolution at the Annual General Meeting.

The guidelines apply until new guidelines have been adopted by the general meeting of shareholders. The Remuneration Committee monitors and evaluates programs for variable remuneration of the executive management, the application of guidelines for remuneration of senior executives, current remuneration structures and remuneration levels within the company. The remuneration of the CEO is decided within the framework of principles approved by the Board following preparation and recommendation by the Remuneration Committee. The remuneration of other senior executives is decided by the CEO within the framework of established principles and in consultation with the Remuneration Committee. The CEO and other members of executive management do not participate in the Board's processing of and decisions on remuneration-related matters insofar as they are affected bu these matters.

# Deviation from the guidelines

The Board of Directors may decide to deviate from the guidelines in full or in part if there are specific reasons to do so in individual cases and a departure is necessary to meet the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As stated above, the Remuneration Committee's tasks include preparing the Board's decisions on remuneration matters, which includes decisions on deviations from the guidelines.

# **RISKS AND UNCERTAINTIES**

Isofol conducts research and development in the field of cancer treatment, primarily for colorectal cancer. The company's business activities mainly comprise the development of the drug candidate arfolitixorin. The entire long-term operation and success of Isofol is thus dependent on the results of the arfolitixorin development program. Isofol's main risks are as follows:

• There is a risk that the planned studies will not indicate sufficient safety and efficacy to

obtain the required regulatory approvals or for the company to be able to continue to license, establish partnerships or sell any potential product.

- There is a risk that the planned studies will be delayed. Delays can occur for a variety of reasons, including difficulties in reaching agreements with clinics about participation under acceptable terms, problems in identifying patients for studies, and patients not completing a study or not returning for follow-up.
- Since Isofol is in the clinical development phase and has no revenue, its cash flow is expected to remain negative until revenue is generated. As a result, the company will require additional capital to complete the necessary studies before the drug candidate can be commercialized. The board and management continuously assess opportunities to secure funding. If the company is unable, in whole or in part, to raise sufficient capital, the development process may be delayed or discontinued.
- If Isofol does not receive the required product approvals or in the event of a future withdrawal or restriction of any approvals, this could have an adverse impact on Isofol's operations, financial position and results.
- Merck owns significant rights and patents for arfolitixorin. Isofol has been granted an exclusive worldwide license to utilize, develop and commercialize arfolitixorin for the treatment of cancer. In the event that Isofol does not meet its contractual obligations with Merck, there is a risk that Merck will terminate the agreement and the license, which would have a material negative impact on the company's operations and its ability to develop and commercialize its drug.
- Isofol is dependent on a number of key employees for the continued development of

the company's operations and preclinical and clinical projects. However, there is a risk that one or more of the company's employees could terminate their employment with Isofol or that the recruitment of new individuals and consultants with relevant knowledge and expertise could be unsuccessful, which could delay the company's development and commercialization of its drug candidate, and could have a negative impact on the company's operations, financial position and results.

- The company has not yet launched any pharmaceutical product on the market. Accordingly, no sales of products have begun, which means that Isofol's operations have so far not generated any sales revenue. Arfolitixorin is currently the company's only drug candidate.
- There is a risk that competing drugs could take market share or that competing research projects could achieve better efficacy and reach the market faster, meaning that the future value of the drug may be lower than expected.

For more information about risks and risk management, refer to Note 16.

# INSURANCE

Isofol Medical AB (publ) conducts regular reviews together with brokers and advisers, both locally and globally, ensuring that the business and area of responsibility are properly insured.

## LEGAL DISPUTES

The company was not involved in any legal disputes in 2024.

# ENVIRONMENT AND RESPONSIBILITY

Isofol's operations do not entail any specific environmental risks and do not require any specific environmental permits or decisions from authorities. Isofol believes that the company conducts its activities in accordance with applicable health and safety rules and provides its employees with a safe and healthy work environment.

The company's goal is to contribute to sustainable development and to make active efforts to improve and minimize its environmental impact to the extent that this is possible and financially reasonable. The company's studies are conducted globally, which entails travel and transportation by air. The company strives to streamline processes in dialogue with suppliers and hospitals to minimize the number of transports as far as possible.

# WORK OF THE BOARD OF DIRECTORS

At the end of 2024, the Board of Directors consisted of five ordinary members, including the Chairman, who were elected at an Extraordinary General Meeting held on January 4, 2024 and re-elected at the 2024 Annual General Meeting. The overall task of the Board is to manage the affairs of the company on behalf of the shareholders and to be responsible for the company's organization. These tasks include setting targets and strategies, devising procedures and systems to evaluate set targets, continuously assessing the companu's financial position and performance, and evaluating the operational management. In 2024, the Board held 22 meetings, of which two were statutory Board meetings and six were held per capsulam. The Board of Directors applies written rules of procedure that are revised annually and adopted by the statutory Board meeting every year. The rules of procedure regulate the distribution of work between the Board and the CEO and between the Board and the committees the Board decides to establish, as well as Board practice for the coming year. For more information,

see the Corporate Governance Report for 2024 on pages 27-35.

# INTERNAL CONTROL

For more information on internal control, refer to the Corporate Governance Report for 2024, which is included on pages 27-35 of this Annual Report.

# EXPECTATIONS REGARDING FUTURE DE-VELOPMENT

Based on the evidence and knowledge of arfolitixorin generated to date, the strong partnerships established with both clinical experts and collaborators, and the expertise and talent within the organization, Isofol is now well-positioned to continue the clinical development of arfolitixorin. The goal is clear: to improve cancer treatment for millions of patients and, in doing so, create significant value for shareholders, employees, and society as a whole.

# PROPOSED APPROPRIATION OF THE COM-PANY'S PROFIT

The following funds are at the disposal of the Annual General Meeting, amounts in SEK:

Total	72,999,631
Result for the year	-43,488,206
Retained earnings	-1,101,788,660
Share premium reserve	1,218,276,497

The Board of Directors proposes that the available profits be appropriated as follows:

Tot	al	72,999,631
То	be carried forward	72,999,631

With regard to the company's results and financial position in general, refer to the following financial statements and accompanying notes.

# **DIVIDEND POLICY**

In accordance with the Board's dividend policy, no dividend will be paid until the company's financial position permits.

# CORPORATE GOVERNANCE REPORT ISOFOL MEDICAL AB (PUBL) 2024

# INTRODUCTION

Isofol Medical AB (publ) is a Swedish public limited company with its registered office in Gothenburg, Sweden, whose shares are listed on Nasdag Stockholm and traded under the ticker ISOFOL. The Board of Directors of Isofol Medical AB (publ), corporate identitu number 556759-8064 (the "Company"), hereby submits its Corporate Governance Report for 2024, which has been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Corporate Governance Code (the "Code"; see the Swedish Corporate Governance Board's website www.bolagsstyrning.se), Nasdag Stockholm's Rule Book for Issuers, Isofol's Articles of Association, and company-specific rules and guidelines. The report has been reviewed by the company's auditors, and the auditors' opinion is included in the auditor's report on pages 54-56. In 2024, Isofol applied the Code without deviations

# ISOFOL'S CORPORATE GOVERNANCE MODEL

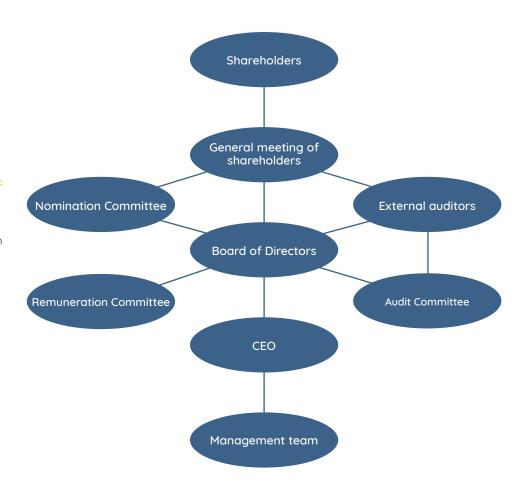
The purpose of Isofol's corporate governance is to create a clear division of roles and responsibilities between the shareholders, the Board and executive management. The governance, management and auditing of Isofol is distributed between the general meeting of shareholders, the Board and its elected committees, and the CEO. The diagram on the right illustrates Isofol's corporate governance model and who appoints the company's central bodies. The various bodies exercise their influence and control in relation to each other. The shareholders appoint the companu's Nomination Committee, Board of Directors and auditors at the general meeting of shareholders (Annual General Meeting).

# Significant external regulations and policies:

- The Swedish Companies Act
- External auditing regulations
- International Financial Reporting Standards (IFRS)
- Nasdaq Stockholm's Rule Book for Issuers
- The Swedish Corporate Governance Code
- Other applicable laws and regulations

# Significant internal regulations and policies:

- Articles of Association
- The Board's rules of procedure, including instructions for the Board's committees
- CEO's instructions, including instructions on financial reporting
- Guidelines for the remuneration of senior executives
- Financial policy
- IT policy and information security policy
- Employee handbook
- Authorization instructions
- Risk management policy
- Financial handbook, including policy for related-party transactions
- Information and insider policy



# **CORPORATE GOVERNANCE STRUCTURE** Shareholders and the share

Isofol is a CSD-registered company, which means that the company's share register is maintained by Euroclear Sweden AB. The share capital of Isofol Medical AB comprises one class of share that entitles the holder to equal voting rights and equal rights to a share of the company's assets. Isofol's shares were admitted to trading on Nasdag Stockholm on October 21, 2021. As of December 31. 2024, the total number shares and votes in the company was 161,515,440 (161,515,440), distributed between approximately 14,050 (10,200) shareholders. For further information on Isofol's ownership structure and major shareholders, refer to page 20 of the Annual Report for 2024 and www.isofolmedical.com.

There are currently no restrictions on the transferability of Isofol's shares due to legal restrictions or provisions in the Articles of Association. As far as Isofol Medical AB (publ) is aware, no agreements have been reached between any shareholders that could limit the transferability of the shares. As of December 31, 2024, no shareholder owned more than 10 percent of the company's shares.

There were no infringements of Nasdaq Stockholm's regulations or of generally acceptable practices in the stock market in accordance with a decision by the stock exchange's Disciplinary Committee or the Swedish Securities Council during the financial year.

### General meeting of shareholders

In accordance with the Swedish Companies Act, the shareholders' influence over the company is exercised at the general meeting of shareholders, which is the company's highest decision-making body. At the general meeting of shareholders, the shareholders resolve on key issues, such as amendments to the Articles of Association, adoption of income statements and balance sheets, any dividends and appropriation of the company's earnings, election of Board members and auditors, remuneration of Board members and auditors, and discharge from liability of the Board and the CEO. The general meeting also resolves on guidelines for remuneration of senior executives. The general meeting also resolves among other things on guidelines for salary and other remuneration of senior executives, any new share issues and how the Nomination Committee is to be appointed.

Annual general meetings and extraordinary general meetings are convened by publishing the convening notice in the Swedish Official Gazette (Sw. Post- och Inrikes Tidningar) and making the notice available on the company's website, www.isofolmedical. com. An announcement that notice has been served has to be published in Dagens Industri on the same date.

Shareholders who are registered in the share register maintained by Euroclear Sweden AB are entitled to attend general meetings. To attend a general meeting, shareholders must notifu the company no later than on the day specified in the notice convening the meeting. This may not be a Sunday, public holiday, Saturday, Midsummer Eve, Christmas Eve or New Year's Eve, and may not fall less than five working days prior to the meeting. At a general meeting, shareholders may be accompanied by one or two assistants, although only if the shareholder has given notification of this to the company as specified above. The annual general meeting has to be held within six months of the end of the financial uear. One share entitles the holder to one vote at general meetings. At the general meeting, each voting member may vote for

the full number of shares held or represented without restriction on voting rights.

Shareholders wishing to submit proposals to Isofol's Nomination Committee may do so by e-mail at: valberedningen@isofolmedical.com or by mail at: Isofol Medical AB, Attn: Nomination Committee, Arvid Wallgrens Backe 20, SE-413 46 Gothenburg, Sweden.

# Extraordinary General Meeting held on January 4, 2024

Isofol held an Extraordinary General Meeting on January 4, 2024 in Gothenburg. Among other resolutions, the following were adopted at the general meeting:

- The company's Board of Directors shall consist of five ordinary members without deputies.
- New election of Board members as proposed by the shareholders:
- o Jan-Eric Österlund, Chairman (newly elected)
- o Alain Herrera (newly elected)
- o Helena Taflin (newly elected)
- o Lars Lind (newly elected)
- o Sten Nilsson (newly elected)
- o That newly elected Board members shall receive remuneration for their work as Board members in accordance with the level of remuneration resolved by the 2023 AGM, in proportion to the length of their term of office.

Minutes of the Extraordinary General Meeting held on January 4, 2024 and other information are available at www.isofolmedical.com

### 2024 Annual General Meeting

The 2024 Annual General Meeting of Isofol Medical AB (publ) was held on May 8, 2024 at 14:00 at the Biotech Center, Arvid Wallgrens backe 20, 5th floor, Gothenburg. Among other resolutions, the following were passed at the Annual General Meeting:

- That the number of members of the Board of Directors shall be five ordinary members without deputies and that the number of auditors shall be one registered audit firm.
- Re-election of Jan-Eric Österlund, Alain Herrera, Helena Taflin, Lars Lind and Sten Nilsson.
- Jan-Eric Österlund was re-elected as Chairman of the Board.
- The registered audit firm KPMG AB was re-elected, and it was noted that the authorized public accountant Daniel Haglund would be the auditor in charge.
- That the remuneration of the Chairman of the Board of Directors shall be SEK 550,000, that of the other members SEK 250,000 each, that of the Chair of the Audit Committee SEK 125,000, that of the other members of the Audit Committee SEK 75,000 each, that of the Chair of the Remuneration Committee SEK 75,000 and that of the other members of the Remuneration Committee SEK 50,000 each.
- That Board members (in addition to reimbursement of travel and accommodation expenses) domiciled in Europe, but outside the Nordic region, shall receive an allowance of SEK 7,500 per in-person Board meeting. It was resolved that the same remuneration shall be paid, per trip, for travels undertaken by members of the board of directors on behalf of the company, in addition to the board work.

## 2025 Annual General Meeting

The 2025 Annual General Meeting of Isofol Medical AB (publ) will be held on May 21, 2025 at 15:00 at the Biotech Center, Arvid Wallgrens backe 20, 5th floor, Gothenburg. The company plans to hold the 2025 AGM in-person in accordance with its articles of association. Notice of the meeting is published on Isofol's website and announced in the Swedish Official Gazette (Post-och Inrikestidningar). An advertisement stating that notice has been published is placed in Dagens Industri on the same day as the announcement.

Information on the resolutions passed at the meeting will be published on the same day as the Annual General Meeting as soon as the results of the voting have been finalized. The minutes of the Annual General Meeting will be available on www.isofolmedical.com.

# **Nomination Committee**

The work of the Nomination Committee is governed by the instructions resolved upon by the Annual General Meeting. The Nomination Committee's duties are to prepare and draft proposals for the election of Board members, the Chairman of the Board, the chair of the general meeting and auditors. The Nomination Committee is also responsible for recommending the fees payable to Board members and auditors. The members of the Nomination Committee are to be announced on the company's website no later than six months prior to the Annual General Meeting.

The Nomination Committee is to consist of three members. The Chairman of the Board is not to be a member of the Nomination Committee, but is co-opted to the meetings of the Nomination Committee. The three members are to be appointed by the company's three largest shareholders in terms of voting rights at the end of September, on the basis of a share register provided by Euroclear Sweden and other reliable information. An additional member of the Nomination Committee may be appointed by a minority owner representing at least 10 percent of the votes, based on the share register provided by Euroclear Sweden AB or other reliable information. The Nomination Committee is to prepare the following proposals to the Annual General Meeting:

- Chairman of the Annual General Meeting
- Election of Board members Election of auditors
- Fees payable to Board members and the Chairman of the Board
- Fees payable to auditors
- Members of the Nomination Committee and proposed instructions for the work of the Nomination Committee

When preparing its proposal to the Board, the Nomination Committee must consider the Board's evaluation of its work and take into account the requirements regarding the Board's composition as stipulated in the Swedish Companies Act, the Swedish Corporate Governance Code and Nasdag Stockholm's Rule Book for Issuers. The Nomination Committee must also strive to ensure an even distribution of gender, age, ethnic origin and expertise, with a focus on corporate governance and experience from clinical development and commercial operations. The Nomination Committee should also take into account the requirement that the Code imposes on the size and composition of the Board, meaning that the Nomination Committee must specifically justify its proposal regarding the election of Board members,

taking into account the Code's requirement concerning the diversity and breadth of the Board.

The Nomination Committee's proposal as above and its reasoned statement are to be submitted to the company no later than one week before the notice of the Annual General Meeting is announced.

The Nomination Committee for the 2025 Annual General Meeting has been elected in accordance with the applicable principles and consists of Christian Haglund, Göran Gustafsson, Johan Möller (Chair) and Lars Lind (appointed by approximately 17% of the votes).

According to the Code, the Nomination Committee, in connection with the notice of the 2025 Annual General Meeting, has to publish a reasoned statement on the company's website concerning its proposal for the election of the Board, taking into account the Code's rules on the composition of the Board, and specifically justify the proposal taking into account the requirement that the company should seek to achieve an even gender distribution, and present a brief report on how the work of the Nomination Committee was carried out. The Nomination Committee is also required to publish relevant information on the website about the individuals proposed for election and re-election, including their main experience and education, significant appointments within and outside the company, and their shareholding in the company, as well as the shareholdinas of any related parties.

### Auditors

An external auditor is elected by the Annual General Meeting for a period of one uear at a time. The auditors audit the companu's annual accounts and accounting records as well as the management by the Board and the CEO in accordance with an auditing plan adopted together with the Board or the Audit Committee. Following the audit, the auditors are required to report their findings to management as well as the Board and the Audit Committee. At least once a year, the auditors are required to report their findings directly to the Board without the presence of executive management. The auditors also attend the Annual General Meeting, at which they report on their audit and their recommendations in the auditor's report.

The auditor has audited the annual accounts for the financial year January 1, 2024 to December 31, 2024 and reviewed the interim report for the third quarter. The auditor has also stated that this Corporate Governance Report has been prepared, and that certain disclosures in it are consistent with the annual accounts. The auditor's examination is reported primarily through the audit report, but also through specific opinions on the Corporate Governance Report, the reviewed interim report and in compliance with the guidelines for remuneration to senior executives. These are presented to the Annual General Meeting. The auditors also submit reports on reviews conducted to the Audit Committee and to the Board in its entiretu. The fees invoiced by the auditor for the past two financial years are presented in Note 4 to the annual accounts for 2024

# BOARD OF DIRECTORS

# Overall task of the Board

The overall task of the Board is to manage the affairs of the company on behalf of the shareholders and to be responsible for the company's organization. The Board's work is led by the Chairman of the Board. The Board is required to hold a statutory meeting annually after the Annual General Meeting.

In addition, the Board has to meet regularly as well as when special needs arise. At the statutory Board meeting, the company's authorized signatories have to be decided and the Board's rules of procedure, the instructions for the CEO and the instructions for financial reporting have to be reviewed and adopted. At the company's Board meetings, the company's financial situation, business development and other current issues have to be discussed. The Board exercises supervision over the CEO, regarding the execution of the Board's decisions and other matters. The Board prepares annual proposals for the guidelines on the remuneration of senior executives, which are adopted by the Annual General Meeting, monitors compliance with these guidelines and, where appropriate, submits proposals for incentive programs.

The company's auditor attends and reports to Board meetings when required. The Board is quorate if more than half its members are present. At the end of 2024, Isofol's Board of Directors comprised five members.

# Composition and independence

According to Isofol's Articles of Association, the Board of Directors is to consist of no fewer than three and no more than nine members elected by the Annual General Meeting for the period until the end of the next Annual General Meeting.

The Extraordinary General Meeting held on January 4, 2024 resolved, in accordance with the shareholders' proposal, to elect Jan-Eric Österlund (Chairman), Alain Herrera, Helena Taflin, Lars Lind and Sten Nilsson. At the same time, Mats Franzén, Jonas Pedersén and Annika Freij were relieved of their appointments to the Board. All Board members are deemed to be independent in relation to the company and its management and to the company's major shareholders.

At the Annual General Meeting held on May 8, 2024, Jan-Eric Österlund (Chairman), Alain Herrera, Helena Taflin, Lars Lind and Sten Nilsson were re-elected in accordance with the Nomination Committee's proposal until the end of the next Annual General Meeting.

Information on the Board members, including age, year of election to the Board, education, current appointments and shareholdings in the company, is presented on page 31.

## Responsibilities and work of the Board

After the general meeting of shareholders, the Board of Directors is the company's highest decision-making body and, under the Swedish Companies Act, is responsible for the company's administration and organization. The Board's responsibilities and tasks are governed by the Swedish Companies Act, the Articles of Association and the Swedish Corporate Governance Code. The work of the Board is also governed by the written rules of procedure adopted annually by the Board. These rules of procedure govern the work of the Board as well as the distribution of work and responsibility among the Board.

the committees the Chairman of the Board and the CEO. The rules of procedure also address the number of ordinary meetings to be held and the matters to be addressed at these meetings, the form of notices, meeting and resolution processes, documentation for Board meetings, the tasks of the Chairman of the Board, minutes, disgualification and conflicts of interest, mandatoru matters that the CEO is to delegate to the Board, financial reports and company signatories. The Board has also adopted instructions for the CEO and other specific policies such as a financial policy, authorization instructions and a policy on insider information. In addition to the Board meetings, the Chairman of the Board and the CEO continuously discuss matters of material importance to the company.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs, the companu's overall business plan, material organizational changes, changes in the focus of the company's operations, and the income statement and balance sheet. In addition. the Board of Directors makes decisions on investments, acquisitions and divestments of significant assets, shares or businesses, loans and credits, pledging of guarantees, and the signing of or amendments to material agreements or agreements between the company and shareholders. The Board also addresses matters that have been delegated to the Board by the CEO. The Board has overall responsibility for ensuring that the company's organization is structured so as to ensure satisfactory control of its accounting, management of funds and other financial affairs and is responsible for the ongoing evaluation of the work of the CEO. The Board is also responsible for ensuring the guality of the company's financial reporting, including systems

for monitoring and internal control of the company's financial reporting and position. In addition, the Board is responsible for ensuring that the company's external disclosure of information is characterized by openness and is correct, relevant and clear. The Board is also responsible for preparing necessary guidelines and other policy documents.

The Chairman of the Board leads and organizes the work of the Board and is specifically responsible for ensuring that the Board's work is well organized and conducted efficiently. The Chairman of the Board, in consultation with the company's CEO, is responsible for ensuring that an agenda for every meeting and any necessary documentation as the basis for decision are provided to the Board members in ample time prior to each Board meeting. The Chairman of the Board is also responsible for ensuring that each Board member regularly updates and improves their knowledge of the company and that new Board members receive the necessary induction training and other training that the Chairman and the new member deem suitable. The Chairman is further responsible for maintaining contact with the shareholders with respect to ownership issues, for conveying the views of the shareholders to the Board and ensuring that the work of the Board is evaluated annually through a systematic and structured process with the aim of developing the Board's working practices and methods. The results of the evaluation are reported to the company's Nomination Committee.

At each ordinary Board meeting, a review of the business is conducted, including advances and progress in research and development, clinical studies, business development, the company's results and position, financial reporting and forecasts.

BOARD OF DIRECTORS					
Name	<b>Jan-Eric Österlund</b> Chairman of the Board Born 1945	<b>Alain Herrera</b> Board member Born 1950	<b>Helena Taflin</b> Board member Born 1973	<b>Lars Lind</b> Board member Born 1941	<b>Sten Nilsson</b> Board member Born 1948
Elected	January 2024	January 2024	January 2024	January 2024	January 2024
Education	MSc (Engineering), MBA	MD, PhD	MD, PhD	Graduate in business and economics	MD, PhD
Current employment and background	Jan-Eric has worked for most of his professional life in private equity and management buy-outs, focus- ing on the life science industry. He has served as a director or chair- man of publicly listed companies in the United States, Canada, Switzer- land and Sweden, and in a large number of private companies in the life science, financial, pulp and paper, and engineering industries. He was previously Isofol's Chairman of the Board from 2012 to 2018 and a member of the Board for a short period in 2023.	Alain is an oncologist/hematologist and has been involved in several registration processes, including the drug oxaliplatin which, together with fluorouracil and leucovorin, today represents one of the basic treatment regimens, FOLFOX, in the treatment of colorectal cancer. Alain has been Vice President of the Department of Global Oncology Business Strategy and Develop- ment at Sanofi, where he previously held the role of Head of Global Oncology Franchise. In addition, Alain has been Chairman of Chiron Therapeutics Europe and CEO of Pierre Fabre Oncology Laborato- ries. Alain was a member of the Board of Isofol between 2018 and 2023.	Helena is a senior consultant in surgery and is active in the section for liver surgery at the Transplant Center of Sahlgrenska University Hospital. She is also the head of its clinical trials unit and was the princi- pal investigator of the investiga- tor-initiated academic study Modelle-001. Helena obtained her PhD in 2014 on folate metabolism in colorectal cancer and has contin- ued to conduct clinical studies on this topic.	Lars, representing Yield Life AB, founded Isofol together with Bengt Gustavsson and was its Chairman until 2012. He was then a member of the Board until 2018 and has been alternately chair or a member of the Nomination Committee since 2020. Lars has extensive experience in business devel- opment as a business manager, Board member and investor.	Sten is a Professor Emeritus in Oncology at Karolinska Institutet, Solna. He is a specialist in oncol- ogy and nuclear medicine. He was Head of Urological Cancer at Uppsala University Hospital, at Radiumhemmet, Karolinska University Hospital and for the Oncology Clinic. Sten leads his research program at Karolinska Comprehensive Cancer Center (CCK) and BioClinicum, Karolinska Institutet, focusing on the develop- ment of new cancer drugs. He has been Chair of the Swedish Society of Oncology, the Swedish Society of Urological Oncology and the Swedish Society of Nuclear Medi- cine. Sten is one of the founders of and main shareholders in Dextech Medical.
Other appointments	Member of the Board of Dicot AB, a life science company listed on Nasdaq First North.	Alain is a member of the Boards of, among others, IDDI, Nanobiotix, PDCline Pharma, Gustave Rous- sy-Transfert and Arcad Foundation.	Helena sits on several boards, including the Swedish Surgical Association.		Chair of the Scientific Council of Rhenman & Partners.
Shareholding*	640,000	0	250,000	407,362	3,101
Independent in relation to the company and its management	Yes	Yes	Yes	Yes	Yes
Independent in relation to the company's major shareholders	Yes erson's shareholding in the company as of M	Yes	Yes	Yes	Yes

\* Own or related natural or legal person's shareholding in the company as of March 31, 2025.

# Work of the Board and significant events in 2024

In 2024, the Board held 22 meetings, of which two were statutory Board meetings and six were held per capsulam. During the year, the Board's work mainly focused on discussing and taking strategic decisions on matters related to evaluating the way forward for arfolitixorin. The Board also discussed about the design and decisions regarding the newly approved clinical study. The Board was also involved in the budget and annual financial statements and related decisions. The attendance of the Board members at the Board meetings held during the 2024 financial year is presented in the table on the following page. During the year, no member expressed a reservation about any decision. Unresolved issues are followed up on an ongoing basis. The reporting period refers to January 1 – December 31, 2024.

## Evaluation of the Board's work

Under the Code, the Board has to evaluate its work annually through a systematic and structured process with the aim of developing its working practices and efficiency. The Board's work in 2024 was evaluated during the fourth guarter of 2024.

The evaluation was carried out by all Board members answering questions about the Board's activities. The results of the evalu-

# Board attendance in 2024

Board member	Period	Attendance at Board meetings	Attendance at Remuneration Committee meetings	Attendance at Audit Committee meetings
Jan-Eric Österlund	January 2024 –	22 out of 22	2 out of 2	4 out of 4
Alain Herrera	January 2024 –	22 out of 22	2 out of 2	-
Helena Taflin	January 2024 –	22 out of 22	-	-
Lars Lind	January 2024 –	22 out of 22	2 out of 2	4 out of 4
Sten Nilsson	January 2024 -	22 out of 22	-	-

# Board fees in 2024

Board member	Board fees (kSEK)	Audit committee fees (kSEK)	Remuneration Committee fees (kSEK)	Other remuneration* (kSEK)	Total fees (kSEK)
Jan-Eric Österlund	544	74	74	81	773
Alain Herrera	247	-	49	23	319
Helena Taflin	247	-	-	-	247
Lars Lind	247	123	51	-	421
Sten Nilsson	247	-	-	-	247
Mats Franzén**	6	-	-	-	6
Annika Freij**	3	-	-	-	3
Jonas Pedersén**	3	-	-	-	3
Total	1,544	197	174	104	2,019

\* Reimbursement for in-person meeting in Sweden in accordance with resolution of the Annual General Meeting.

\*\* Members of the Board of Directors resigned at the Extraordinary General Meeting held on January 4, 2024.

ation are collated in a report that is submitted to the Board and the members of the Nomination Committee.

# **Board committees**

The Board has established two committees from within its ranks – the Audit Committee and the Remuneration Committee – both of which operate under the instructions adopted by the Board. The Board has decided to have two committees: a Remuneration Committee and a Audit Committee.

# **Remuneration Committee**

The main tasks of the Remuneration Committee are to prepare the Board's decisions on matters relating to remuneration principles, remuneration and other terms of employment for the CEO and other senior executives. and to monitor and evaluate variable remuneration programs for executive management that are ongoing or were completed during the year. The Remuneration Committee is also responsible for monitoring and evaluating the application of the guidelines for remuneration of senior executives adopted by the Annual General Meeting, as well as the current remuneration structures and levels in the company. The committee consists of Jan-Eric Österlund (Chair), Lars Lind and Algin Herrerg, The Remuneration Committee is deemed to have met the Code's requirements for independence and the requisite knowledge and experience in matters relating to remuneration to senior executives. The Remuneration Committee met twice during the year. At these meetings, the committee discussed the existing remuneration system in the company and the proposed guidelines for remuneration of the CEO and senior executives. For information on salaries and remuneration of the CEO and senior executives, see Note 3 to the 2024 annual accounts.

# Audit Committee

The main tasks of the Audit Committee are to assist Isofol's Board in matters relating to financial reporting, auditing and risk management, to monitor the effectiveness of internal control, to inform itself about the audit of the annual accounts, and to review and monitor the impartiality and independence of the auditor. The Audit Committee is also required to assist the Nomination Committee in making proposals to the Annual General Meeting for the election of auditors. The committee maintains regular contact with Isofol's auditors. The members of the Audit Committee are Lars Lind (Chair) and Jan-Eric Österlund. The committee met the independence, accounting and auditing expertise requirements of the Swedish Companies Act. In total, the Committee met four times during the year. Isofol's auditors attended all the meetings, at which the auditor's planning of the audit, findings and examination of the Board's and management's administration of the company, as well as the company's financial statements, were discussed.

# EXECUTIVE MANAGEMENT

### CEO and executive management

The CEO is responsible for the company's day-to-day administration and the develop-

ment of Isofol in accordance with applicable legislation and rules, including Nasdag Stockholm's Rule Book for Issuers the Swedish Corporate Governance Code and the guidelines, instructions and strategies adopted by the Board. The CEO has to ensure that the Board receives the objective and relevant information required for the Board to be able to make well-founded decisions. The CEO also monitors compliance with Isofol's goals, policies and strategic plans adopted by the Board and is responsible for informing the Board about Isofol's development between Board meetings. The CEO has to take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of funds in a satisfactory manner. The CEO is therefore responsible for ensuring that the company has sound internal control and procedures to ensure that the adopted principles for financial reporting and internal control are applied. The instructions for the CEO also apply to the Deputy CEO when acting on behalf of the CEO.

The CEO leads the work of the management team, which is responsible for the overall development of the company's activities and business. At the end of 2024, the Executive Management consisted of three persons. In addition to the CEO, the management team during the year comprised:

Chief Financial Officer (CFO)Chief Medical Officer (CMO)

For more information on the senior executives in Isofol, when they took up their positions and their year of birth, education, shareholding in the company and current appointments, refer to page 34.

## **Remuneration of Board members**

The 2024 AGM resolved that, for the period until the next AGM, the remuneration of the Board of Directors for its work in 2024 is to be as follows. Fees of SEK 550,000 are to be paid to the Chairman of the Board and SEK 250,000 to each of the other members. Fees are to be paid to the Chair of the Audit Committee in the amount of SEK 125,000 and to each other member in the amount of SEK 75.000, and to the Chair of the Remuneration Committee in the amount of SEK 75,000 and to each other member in the amount of SEK 50,000. Board members (in addition to reimbursement of travel and accommodation expenses) domiciled in Europe, but outside the Nordic region, are to receive a payment of SEK 7,500 per in-person Board meeting. It was resolved that the same remuneration shall be paid, per trip, for travels undertaken by members of the board of directors on behalf of the company, in addition to the board work.

No pension premiums or similar benefits have been paid to Board members. None of the Board members are entitled to benefits after termination of their service.

### Remuneration to executive management

Remuneration matters pertaining to senior executives are normally addressed by the Board's Remuneration Committee. The Board resolves on the CEO's remuneration based on a proposal by the Remuneration Committee.

Remuneration and terms of employment for senior executives are to be based on market terms and are to comprise a weighted combination of fixed base salary, variable remuneration, pension benefits, share-based incentive programs, other benefits, and terms and conditions of termination. Guidelines for remuneration of senior executives were approved at the Annual General Meeting held on May 19, 2022, to apply until the end of the 2026 Annual General Meeting. The Board has to be entitled to deviate from the guidelines if, in individual cases, there are special reasons to warrant doing so. If deviations from the guidelines occur, the reason for the deviation is to be presented at the next Annual General Meeting. During the year, the guidelines were followed without deviations.

For a more detailed description of the terms of employment and remuneration for the Board and senior executives, refer to the Directors' Report and Notes 3 and 19 to the 2024 annual accounts respectively, and to the 2024 Remuneration Report.

MANAGEMENT			
Name	Petter Segelman Lindqvist Chief Executive Officer (CEO) Born 1981	<b>Roger Tell,</b> Chief Medical Officer, CMO Born 1965	Margareta Hagman, Chief Financial Officer (CFO) Born 1966
Employed by the com- pany	January 2024	2019 Acting Chief Executive Officer (CEO) June 2023 – January 2024	August 2024
Education	MSc, degree in business and economics from the Stockholm School of Economics and EM Lyon in France.	MD, specialist physician in oncology, Karolinska University Hospital and PhD in experimental oncology, Karolinska Institutet.	MSc, degree in business and economics from Örebro University.
Background	Experience from senior positions in the pharmaceutical industry, including GlaxoSmithKline, AbbVie and Sobi (Swedish Orphan Biovitrum). Petter has directed several product launches and taken drug candidates through clinical development and regulatory processes to market introduction.	Vice President of Clinical Development at Aprea Therapeutics AB and International Clinical Project Director at Servier in Suresnes, France. Extensive experience as an oncologist and adviser to the biopharma companies Eli Lilly, AstraZeneca and Merck Serono. Roger is also a member of the Board of Vivesto, which is listed on Nasdaq Stockholm.	Executive Vice President and Chief Financial Officer (CFO) at BioGaia AB. She has also been CFO at Xbrane Biopharma AB and Ortivus AB. In addition, Margareta is a member of the Board of Infant Bacterial Therapeutics AB, which is listed on Nasdaq Stockholm.
Holding*	65,331 shares	0 shares	40,000 shares

\* Own or related natural or legal person's shareholding in the company as of March 31, 2025.

# INTERNAL CONTROL AND RISK MANAGEMENT

The Board's responsibility for internal control is adverned by the Swedish Companies Act and the Swedish Annual Accounts Act. as well as in the Swedish Code of Corporate Governance, which contains a requirement that information about the most important aspects of Isofol's systems for internal control and risk management in connection with the company's annual financial reporting be included in the Corporate Governance Report. The Board is to ensure, among other things, that Isofol has sound internal control and formalized procedures that ensure compliance with established principles for financial reporting and internal control and that there are appropriate systems in place for monitoring and control of the company's activities and the risks associated with its operations. The internal control procedures for financial reporting have been designed to ensure reliable overall financial reporting and external reporting in accordance with IFRS, applicable laws and regulations, and other requirements to be applied by companies listed on Nasdag Stockholm. This work involves the Board, the company management and other employees. The internal control environment mainly comprises the following components: control environment, risk assessment, control activities, information and communication, and monitoring.

### **Control environment**

The control environment within Isofol is the framework for the focus and culture communicated within the organization by the company's Board of Directors and management. The Board is ultimately responsible for the internal control of the financial reporting. The Board's instructions to the CEO and established reporting instructions stipulate how the financial reporting to the Board is to be designed. The Board has also delegated to the CEO responsibility for maintaining an effective control environment, although the Board is ultimately responsible. Systems and procedures have been established to provide management with necessary reports to be able to assess risks and meet the requirements for correct financial reporting. Isofol's internal rules of procedure, instructions, policies, guidelines and manuals guide the employees and provide a clear division of roles and responsibilities to ensure effective management of the risks affecting the business. The CEO reports regularly to the Board.

Based on this effective control environment, the Board has determined that there are no special circumstances or other conditions that would warrant the introduction of an internal audit function.

# Risk assessment

Isofol's Board of Directors works continuously and systematically on risk assessments in order to identify risks and to take appropriate measures. The company conducts an annual and continuous risk review in which risks are identified from a business perspective. Isofol's most important risks are followed up by the management group during the year. Each identified risk is documented with a proposed action plan to reduce the risk as much as possible. The risk assessment is also designed to identify risks that could have a material impact on the internal control of financial reporting.

### Control activities

The primary purpose of control activities is to prevent, detect and correct errors in financial reporting. Activities and procedures are designed to manage and address significant risks related to financial reporting. The control activities include analutical follow-up and comparison of earnings performance or earnings items, authorization instructions, monthly account reconciliations, and principles of recognition and measurement. Access to IT systems is limited according to authorization, authority, responsibility and role. The control structure focuses on clear roles in the organization and division of responsibility. Continuous analysis of financial reporting is very important for ensuring that financial reporting is free from material misstatement.

### Information and communication

Isofol's information and communication channels are designed to facilitate complete and accurate financial reporting. Policies, guidelines and internal instructions concerning financial reporting are available in electronic and printed form. The employees concerned are provided with regular updates regarding changes to accounting policies, reporting reguirements or other information disclosures. The external information is intended to keep the market up to date on the company's operational development and ensure that Isofol meets the requirements for correct disclosure of information to the market. This is also governed by the company's established information policu.

## Monitoring, evaluation and reporting

The Board continuously evaluates the information provided by the executive management. The Board receives regular financial updates on Isofol's performance between Board meetings. The company's financial position, strategies and investments are discussed at each Board meeting. The effectiveness of internal control is monitored on an ongoing basis by the Board, including ensuring that action is taken to address any deficiencies, as well as following up on proposed actions identified in the context of external auditing. The company conducts an annual self-assessment of its risk management and internal control of financial reporting. The process includes a review of how established procedures and guidelines are applied.

The external auditors, the company's finance function and the Audit Committee or the Board of Directors maintain regular contact throughout the financial year in order to identify any risks at an early stage and address any issues that could impact financial reporting. The auditors also report regularly to the Board.

# Internal audit

To date, Isofol has not found a reason to establish a specific internal audit function in the financial area. The reason is that the company is relatively small in size, and the ongoing work on internal control of financial reporting has resulted in a high level of awareness of internal control within the company and the implementation of a number of control activities. Taking this into account, the Board has chosen not to establish a specific internal audit function. The Board evaluates the need for such a function on an annual basis.

# External audit

The company's auditor is appointed by the Annual General Meeting for the period up to the end of the next Annual General Meeting. The auditor audits the annual accounts and accounting records as well as the administration of the Board and the CEO. After each financial year, the auditor has to submit an audit report to the general meeting of shareholders. Each year, the company's auditor reports the findings from the audit and the assessment of the company's internal control to the Board.

# **Income statement**

kSEK	Note	2024 Jan–Dec	2023 Jan–Dec
OPERATING REVENUE			
Net revenue	2	-	721
Total operating revenue		-	721
OPERATING COSTS			
Other external costs	4, 17	-38,734	-35,136
Personnel costs	3, 19	-8,480	-7,424
Depreciation and amortization	7, 8	-3	-37
Other operating costs*		8	192
Total operating costs		-47,209	-42,405
Operating result		-47,209	-41,683
FINANCIAL ITEMS	20, 23		
Financial revenue		3,721	4,622
Financial costs		-	-10
Total financial items		3,721	4,612
Result after financial items		-43,488	-37,071
Result before tax		-43,488	-37,071
Tax on result for the period	6	-	-
Result		-43,488	-37,071
Attributable to:			
Company shareholders		-43,488	-37,071
EARNINGS PER SHARE			
Before dilution (SEK)		-0.27	-0.23
After dilution (SEK)		-0.27	-0.23

\* Relates to currency effects linked to operation.

There are no amounts to be recognized as other comprehensive income, and the result for the year consequently corresponds to comprehensive income for the year.

# **Balance sheet**

kSEK	Note	Dec 31, 2024	Dec 31, 2023
ASSETS			
FIXED ASSETS			
Intangible fixed assets			
Patents, licenses and similar rights	7	-	-
Total intangible fixed assets		-	-
Tangible fixed assets			
Equipment, tools and right-of-use assets	8	-	3
Total tangible fixed assets		-	3
Total fixed assets		-	3
CURRENT ASSETS			
Other receivables	9	1,806	2,145
Prepaid expenses and accrued income	2, 10	454	301
Cash and cash equivalents	5, 11	96,157	138,148
Total current assets		98,417	140,594
Total assets		98,417	140,597

# **Balance sheet**

kSEK	Note	Dec 31, 2024	Dec 31, 2023
EQUITY AND LIABILITIES			
EQUITY	12, 13		
Restricted equity			
Share capital		4,945	4,945
Total restricted equity		4,945	4,945
Non-restricted equity			
Share premium reserve		1,218,276	1,218,276
Accumulated losses		-1,101,789	-1,064,718
Result for the year		-43,488	-37,071
Total non-restricted equity		73,000	116,488
Total equity	_	77,945	121,433
LIABILITIES			
Long-term liabilities			
Other provisions	24	648	910
Total long-term liabilities		648	910
Current liabilities			
Accounts payable	5	2,028	1,988
Other liabilities	14	976	1,232
Accrued expenses and deferred income	5, 15	16,821	15,033
Total current liabilities		19,824	18,253
Total liabilities		20,472	19,164
Total equity and liabilities		98,417	140,597

# Statement of changes in equity

	Restricted equity	Non-restr	icted equity	
kSEK	Share capital	Share premium reserve	Accumulated losses	Total equity
Opening equity, Jan 1, 2023	4,945	1,218,276	-1,064,718	158,504
Result for the period	-	-	-37,071	-37,071
Equity Dec 31, 2023	4,945	1,218,276	-1,101,789	121,433
Opening equity, Jan 1, 2024	4,945	1,218,276	-1,101,789	121,433
Result for the period	-	-	-43,488	-43,488
Equity Dec 31, 2024	4,945	1,218,276	-1,145,277	77,945

# Cash flow statement

kSEK	Note	2024 Jan–Dec	2023 Jan–Dec
OPERATING ACTIVITIES			
Result after financial items		-43,488	-37,071
Adjustment for non-cash items	20	-255	-4,411
Income tax paid		-	-
Cash flow from operating activities before changes in working capital		-43,743	-41,482
CASH FLOW FROM CHANGES IN WORKING CAPITAL			
Increase (-)/decrease (+) in other current receivables		186	21,233
Increase (+)/decrease (-) in other current liabilities		1,571	-32,287
Change in working capital		1,757	-11,054
Cash flow from operating activities		-41,986	-52,536
INVESTING ACTIVITIES			
Divestment of tangible fixed assets	8	-	51
Divestment of financial fixed assets		-	50
Cash flow from investing activities		-	101
FINANCING ACTIVITIES			
Cash flow from financing activities		-	-
Cash flow for the period		-41,986	-52,435
Cash and cash equivalents at the beginning of the year		138,148	190,533
Exchange rate difference in cash and cash equivalents		-5	50
Cash and cash equivalents at the end of the year	11	96,157	138,148

### ADDITIONAL DISCLOSURES AND NOTES TO THE FINANCIAL STATEMENTS General information

Notes to the 2024 annual financial statements for Isofol Medical AB (publ), corporate identity number 556759-8064, with registered office in Gothenburg, Sweden, street address Arvid Wallgrens Backe 20, SE-413 46 GOTHENBURG. The company's shares have been listed on Nasdaq Stockholm since 2021.

### NOTE 1 ACCOUNTING POLICIES

### COMPLIANCE WITH STANDARDS AND LEGISLATION

The annual accounts for the company have been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities, whereby IAS 34 not having been applied. The accounting policies applied are consistent with those used by the Company in the preparation of the 2023 annual accounts, unless otherwise stated below.

New and amended standards adopted from 2024 onward are not expected to have a significant impact on the company's financial position.

In accordance with the exception permitted in RFR 2, the company does not apply IFRS 16.

MEASUREMENT PRINCIPLES APPLIED WHEN PREPARING THE FINANCIAL STATEMENTS

Assets and liabilities are recognized at historical cost, unless otherwise stated.

### AMENDED ACCOUNTING STANDARDS AS A RESULT OF NEW OR AMENDED IFRS STANDARDS

Any new or amended IFRS standards that do not come into force until coming financial years have not been applied early in preparing these financial statements. Other new or amended standards or interpretations published by the IASB are not expected to have any impact on the company's financial statements. It is uncertain what effects IFRS 18 Presentation and Disclosures in the financial statements may have for the company since RFR 2 is applied.

### CLASSIFICATION, ETC.

Fixed assets and long-term liabilities essentially consist of amounts that are expected to be recovered or paid after more than 12 months from the balance sheet date. Current assets and current liabilities principally consist of amounts that are expected to be recovered or paid within 12 months from the balance sheet date.

### FOREIGN CURRENCY TRANSLATION

### Functional currency and reporting currency

The company's functional currency is SEK, which is also the reporting currency. Accordingly, the financial statements are presented in SEK. Unless otherwise stated, all amounts are stated and rounded to the nearest thousand (kSEK).

### Transactions in foreign currency

Transactions in foreign currency are translated into the functional currency at the exchange rate on the transaction date. Monetary assets and liabilities in foreign currency are translated into the functional currency at the exchange rate on the balance sheet date. Exchange rate differences that arise during translation are recognized in profit or loss. Exchange gains and losses on operating receivables and liabilities are recognized in operating profit or loss, while exchange gains and losses on financial receivables and liabilities are recognized as financial items.

### REVENUE

Revenue is recognized at the fair value of the payment that will be received, excluding VAT, discounts and other price deductions.

The transaction price is estimated at the value that Isofol estimates will accrue to the company on commencement of the agreement, less VAT, discounts and other price deductions. The transaction price is updated on an ongoing basis if the assumptions underlying the estimate have changed.

### Licensing agreements

Revenue from licensing agreements is recognized based on the economic substance of the agreement. Revenue from licensing agreements may comprise one-off payments, licensing fees, royalties and milestone payments for the use of lsofol's intellectual property. Isofol may be entitled under its licensing agreements to receive reimbursement of costs incurred. Revenue recognition reflects the accrual of revenue based on the obligations performed under the specific contractual terms.

Isofol applies the revenue recognition criteria to each separately identified obligation to ensure that the economic substance of the transaction is reflected in the financial statements. As a result, the various transactions included in the agreements are broken down into distinct performance obligations, which are recognized separately. The agreements often include payment for the use of Isofol's intellectual property licensed to the counterparty and may include reimbursement of costs incurred in relation to a study. These obligations are analyzed to determine whether they constitute distinct performance obligations that should be recognized separately or whether they should be considered as one obligation.

The principles for revenue recognition for the performance obligations of licensing agreements are described below:

### Execution of service assignments

Fees received for research services are recognized successively over the period to which they relate. If there is no such relationship, revenue is recognized based on the degree of completion of each project/agreement. Degree of completion is determined on the basis of time spent in relation to the estimated total time for the project/agreement or based on clauses in the contract with the customer.

### **Royalties**

A counterparty may also compensate Isofol for the use of an intellectual property right by paying royalties on future sales of a drug based on the intellectual property right. Revenue for salesbased royalties promised in exchange for a license for intellectual property is recognized only when the subsequent sale takes place.

### **GOVERNMENT GRANTS**

Government grants are recognized when the company meets the conditions associated with the grants and it can be determined with certainty that the grants will be received. Paid grants are recognized in the balance sheet as deferred income and are recognized in profit or loss in the period in which the cost to which the grant relates is recognized. Government grants are recognized as other revenue when it is clear that the conditions associated with the grants have been fulfilled. The company has not received any government grants.

### FINANCIAL REVENUE AND COSTS

Financial revenue and costs consist of interest income on bank balances, receivables and interest-bearing securities, interest expenses on loans and liabilities, unrealized and realized gains and losses on financial assets, and derivative instruments used in financial activities. Exchange rate gains and losses are recognized net.

### **INCOME TAXES**

Income taxes comprise current tax and deferred tax. Income taxes are recognized in profit or loss, except when the underlying transaction is recognized in other comprehensive income or in equity, in which case the associated tax effect is recognized in other comprehensive income or in equity. Current tax is the tax to be paid or received in respect of the current year, using the tax rates that are determined, or in practice determined, on the balance sheet date. Current tax also includes adjustments of current tax attributable to earlier periods. Management periodically evaluates claims made in tax returns with respect to situations in which applicable tax regulations are subject to interpretation and, when deemed appropriate, makes provisions for amounts expected to be paid to the tax authorities. Deferred tax is calculated according to the balance sheet method, based on temporary differences between the carrying amount and tax bases of assets and liabilities. Deferred tax assets relating to deductible temporary differences and loss carryforwards are only recognized to the extent that it is probable that they can be utilized.

### FINANCIAL INSTRUMENTS

Financial instruments recognized in the balance sheet include, on the asset side, cash and bank balances, accounts receivable, other receivables and other long-term securities holdings. The liability side includes accounts payable and other liabilities. A financial asset or financial liability is recognized in the balance sheet when the company becomes a party to the instrument's contractual terms and conditions. Accounts receivable are recognized in the balance sheet when the invoice has been sent. Accounts payable are recognized when the invoice has been received. Financial assets are derecognized from the balance sheet when the rights in the contract have

been realized, expire or the company loses control of them. The same applies to parts of financial assets. Financial liabilities are derecognized from the balance sheet when the contractual obligation has been met or otherwise extinguished. The same applies to parts of financial liabilities.

### FINANCIAL ASSETS

### Initial recognition and measurement

The company classifies and recognizes financial assets in the following categories: financial assets measured at amortized cost, financial assets measured at fair value through other comprehensive income, and financial assets measured at fair value through profit or loss. Classification upon initial recognition depends on the nature of the financial asset's contractual cash flows and the company's business model for managing financial assets. The company initially measures a financial asset at fair value. For a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, the financial asset must give rise to cash flows consisting solely of payments of principal and interest on the outstanding amount.

This assessment is called the SPPI test and is conducted at the instrument level. The company' business model for managing financial assets refers to how the company manages its financial assets to generate cash flows. The business model determines whether cash flows result from the collection of contractual cash flows, the divestment of financial assets or both.

### Subsequent measurement

The subsequent measurement of investments in debt instruments depends on the company's business model for asset management and what kind of cash flows the asset gives rise to. The company classifies its investments in debt instruments in two measurement categories:

- Financial assets measured at amortized cost (debt instruments)
- Financial assets measured at fair value through profit or loss

### Financial assets measured at amortized cost (debt instruments)

This category is the most relevant for the company recognizing financial assets at amortized cost if both of the following conditions are met:

- The business model for the financial assets is to collect contractual cash flows.
- The contractual terms of the assets give rise to cash flows on specific dates consisting exclusively of payments of principal and interest on the outstanding amount.

Financial assets measured at amortized cost are then measured using the effective interest method, less any provision for value depletion. The amortized cost is equal to the amount recognized on the acquisition date, less repayment of the nominal amount, plus or minus any adjustments for effective interest. Interest income for such financial assets is recognized as financial income using the effective interest method.

The company's financial assets measured at amortized cost include accounts receivable, other current receivables and cash and bank balances. Since bank balances are payable on demand, amortized cost corresponds to the nominal amount.

A loss allowance is recognized for expected losses.

#### Cash and cash equivalents

Cash and cash equivalents in the cash flow statement include cash on hand, immediately available balances with banks and similar institutions, and short-term liquid investments with a maturity of less than three months from the acquisition date which are subject to an insignificant risk of fluctuations in value. Cash and bank balances are categorized as financial assets measured at amortized cost.

#### Fair value through profit or loss

Assets that do not meet the requirements for recognition at amortized cost or fair value through other comprehensive income are measured at fair value through profit or loss. Gains or losses on debt instruments that are recognized at fair value through profit or loss and are not included in a hedging relationship are recognized net in profit or loss in the period in which the gain or loss arises.

### Derecognition of financial assets from the statement of financial position

A financial asset (or, where applicable, part of a financial asset or a group of similar financial assets) is primarily derecognized from the company's statement of financial position report when: • the contractual rights to the cash flows from the financial asset expire, or

• the company has transferred its rights to receive the cash flows from the asset or has undertaken to pay the cash flows received in their entirety without delay to a third party.

#### FINANCIAL LIABILITIES

#### Initial recognition and measurement

The company classifies and recognizes its financial liabilities in the following categories: financial liabilities measured at fair value through profit or loss, loans and accounts payable.

All financial liabilities are initially recognized at fair value and, in the case of loans and accounts payable, minus any directly attributable transaction costs. The company's financial liabilities consist of accounts payable and other liabilities.

#### Subsequent measurement

Financial liabilities related to accounts payable and other liabilities are initially measured at fair value through profit or loss and subsequently at amortized cost using the effective interest method.

#### Loans

The company has no loans.

### Derecognition of financial liabilities from the statement of financial position

A financial liability is derecognized from the company's statement of financial assets when the obligation for the liability is canceled, terminated or expires.

### Offsetting financial assets and liabilities

Financial assets and liabilities are offset and recognized in a net amount in the balance sheet when there is a legal right to offset and when the intention is to settle the items in a net amount or to simultaneously realize the asset and settle the liability.

### ACCOUNTS PAYABLE

Accounts payable are financial instruments and represent obligations to pay for goods and services purchased from suppliers in the ordinary course of business. Accounts payable are classified as current liabilities if they fall due within one year. If not, they are recognized as long-term liabilities. Accounts payable are initially recognized at fair value and subsequently at amortized cost using the effective interest method.

### **TANGIBLE FIXED ASSETS**

Tangible fixed assets are recognized in the company's financial statements at cost, less accumulated depreciation and any impairment. Cost includes the purchase price and costs directly attributable to transporting the asset to the correct site and preparing it for use in the manner intended by the acquisition. Any additional expenditure is added to the carrying amount of the asset or recognized as a separate asset, as appropriate, only when it is probable that the future financial benefits associated with the asset will accrue to the company and the cost of the asset can be reliably measured. All other repairs and maintenance are recognized as costs in profit or loss in the period in which they occur. The carrying amount of a tangible fixed asset is derecognized from the statement of financial position when it is disposed of or divested, or when no future financial benefits are expected from the use or disposal/divestment of the asset. Gains or losses arising from the divestment or disposal of an asset consist of the difference between the selling price and the asset's carrying amount, less direct selling expenses. Gains and losses are recognized as other operating income/expenses.

### **Depreciation methods**

Depreciation takes place on a straight-line basis over the estimated useful life of the asset. The company applies component depreciation, which means that the components' estimated useful lives are used as a basis for depreciation. The estimated useful life of the company's equipment, tools, fixtures and fittings is five years. The residual values and useful lives of assets are assessed at each balance sheet date and adjusted if necessary.

### **INTANGIBLE ASSETS**

Intangible assets acquired by the company consist of patents that are recognized at cost, less accumulated amortization and any impairment. Expenses for research related to new scientific or technical knowledge are recognized as an expense when they arise. The company only has expenses for research.

#### **Depreciation methods**

Amortization is recognized in profit or loss on a straight-line basis over the estimated useful life of the intangible asset, unless the asset has an indeterminable useful life. Useful lives are reviewed at least annually. Intangible assets with determinable useful lives are amortized from the date when they become available for use. The estimated useful life of patents is ten years.

#### IMPAIRMENT

At the end of each reporting period, the company assesses whether there is any indication of a decline in value in addition to the depreciation and amortization recognized for the company's tangible and intangible assets.

### Impairment of tangible and intangible assets

If there is an indication of an impairment requirement, the asset's recoverable amount is calculated. In testing for impairment, if it is not possible to determine material independent cash flows for an individual asset and the asset's fair value less selling expenses cannot be used, the assets are grouped at the lowest level at which there are separate identifiable cash flows (cash-generating units).

The recoverable amount is the higher of fair value less selling expenses and value in use. In calculating value in use, future cash flows are discounted at a discount rate that takes into account risk-free interest and risk related to the specific asset.

### Impairment of financial assets

At the end of each reporting period, the company assesses whether there is objective evidence that a financial asset or group of financial assets needs to be impaired. Objective evidence consists of observable circumstances that have occurred and that have a negative impact on the possibility to recover the cost and of a significant or protracted decline in the fair value of a financial investment classified as a financial asset available for sale.

### **Reversal of impairment**

A previous impairment is reversed when a change has occurred in the assumptions that were used at the time of impairment to determine the asset's recoverable amount and that entails that impairment is no longer deemed to be required. Reversals of previous impairment are tested individually and recognized in profit or loss.

### **EMPLOYEE BENEFITS**

### Short-term employee benefits

Short-term employee benefits such as salaries, social security expenses, vacation pay and bonuses are expensed in the period when the employees perform their services.

### Defined-contribution pension plans

The company's pension obligations are covered only by defined-contribution pension plans. Plans in which the company's obligation is limited to the contributions the company has undertaken to pay are classified as defined-contribution. In this case, the size of the employee's pension depends on the contributions the company pays into the plan or to an insurance company and the return on capital of the contributions. Consequently, the employee bears the actuarial risk (that the remuneration may be lower than expected) and the investment risk (that the assets invested will be insufficient to yield the expected remuneration). The company's obligations pertaining to defined-contribution plans are recognized as an expense in profit or loss at the rate they are vested by the employees performing services for the company over a period of time. The company thus has no additional risk.

### PROVISIONS

A provision differs from other liabilities in that there is uncertainty about the payment date or the amount needed to settle the provision. A provision is recognized in the balance sheet when there is an existing legal or informal obligation as a result of an event that has occurred, it is probable that an outflow of financial resources will be required to settle the obligation, and the amount can be reliably estimated. The amount recognized as a provision corresponds to the best estimate of the expenditure required to settle the obligation. If the outflow of resources is expected to occur well into the future, the expected future cash flow is discounted and the provision is recognized at present value. The discount rate corresponds to the market rate before tax and the risks associated with the liability.

### EQUITY

Equity corresponds to the paid-up capital of the shareholders, adjusted for the profit or loss of previous years, less issue costs and any dividends. Transaction costs directly attributable to the issue of new shares or warrants are recognized, net of tax, in equity as a deduction from the issue proceeds. Payments received are credited to share capital (nominal value) and other contributed capital.

### DIVIDENDS

Dividends are recognized as liabilities after they have been approved by the Annual General Meeting.

### CONTINGENT LIABILITIES

A contingent liability is recognized when there is a possible commitment originating from events that have occurred and whose occurrence is confirmed only by one or more uncertain future events or when there is a commitment that is not recognized as a liability or provision because it is probable that an outflow of resources will be required.

### EARNINGS PER SHARE

The calculation of earnings per share is based on the company's result for the year attributable to the company's shareholders and on the weighted average number of shares outstanding during the year.

### CLASSIFICATION AND PRESENTATION FORMATS

The income statement and balance sheet are presented in accordance with the format prescribed in the Annual Accounts Act. The presentation format for the statement of changes in equity is consistent with the company's format, but must also include the columns stated in the Annual Accounts Act.

### NOTE 2 OPERATING SEGMENTS

### **OPERATING SEGMENTS**

Operations comprise the development of a drug candidate and are organized as coherent operations in the clinical development program that is expected to optimize the efficacy of the drug candidate. Accordingly, all of the company's operations comprise one operating segment. The operating segment is followed up in a manner that complies with the internal reporting submitted to the chief operating decision-maker, namely the CEO. Only one segment is used in the internal reporting to the CEO.

### REVENUE

Isofol's net revenue derives from licensing agreements for the licensing rights to Isofol's intellectual property. Revenue from licensing agreements may comprise one-off payments, licensing fees, royalties and milestone payments for the use of Isofol's intellectual property. Isofol may also be entitled under its licensing agreements to receive reimbursements for costs incurred for the execution of service assignments.

### Breakdown of revenue by geographic area

kSEK	2024	2023
Asia	-	721
Total	-	721

### Breakdown of revenue by type of revenue

kSEK	2024	2023
Execution of service assignments	-	721
Total	-	721

100 percent of the company's assets are in Sweden.

# **NOTE 3** EMPLOYEES, PERSONNEL COSTS, AND REMUNERATION OF SENIOR EXECUTIVES

#### Expenses for employee benefits

kSEK	2024	2023
Salaries and remuneration, etc.	5,864	5,354
Social security cost	1,444	939
Pension cost	945	1,131
Total	8,254	7,424

### Average number of em-

ployees		of whom,		
	2024	women	2023	women
Sweden	4.3	77%	4.8	72%

Gender distribution of the Board and executive manage- ment	Dec 31, 2024 Proportion of women	Dec 31, 2023 Proportion of women
Board of Directors (%)	20	33
Other senior executives (%)	33	-

Salaries and other remuneration, pension costs and pension obligations broken down into the Board of Directors, the CEO, senior executives and other employees, and social security costs in the company

ksek	2024 Board of Direc- tors and senior executives	Other em- ployees	2023 Board of Directors and senior execu- tives	Other em- ployees
Salaries and other remuneration	4,888	2,997	3,641	3,176
Other remuneration (consultancy fees)	4,338	-	1,970	-
(of which, bonuses, etc.)	(588)	(261)	(-)	(-)
Social security cost	1,279	423	695	604
(of which, bonuses, etc.)	(185)	(79)	(-)	(-)
Pension costs	501	444	253	878
Total remuneration	11,005	3,864	6,559	4,658

Senior executives means the CEO, CFO and CMO.

### **REMUNERATION OF SENIOR EXECUTIVES**

The Chairman and members of the Board of Directors are paid fees in accordance with a resolution of the Annual General Meeting. The Board of Directors has appointed a Remuneration Committee consisting of the Chairman of the Board, Jan-Eric Österlund, and the Board members Lars Lind and Alain Herrera. The Remuneration Committee is required to consider matters relating to the remuneration and other terms of employment of the executive management.

Principles for the remuneration of senior executives are adopted at the Annual General Meeting. The Remuneration Committee's task is to draw up proposals in accordance with these principles. Remuneration of the CEO and other senior executives employed by the company consists of basic salary, variable remuneration and other benefits. Other senior executives means the two persons who, together with the CEO, make up the executive management.

### CHIEF EXECUTIVE OFFICER

The Chief Executive Officer Petter Segelman Lindqvist, who took up duties on January 9, 2024, received a total salary of kSEK 2,380 during the 2024 financial year, of which a basic salary of kSEK 1,671, variable remuneration of kSEK 588 and other benefits of kSEK 121. Pension premiums for 2024 have been paid in the amount of kSEK 387.

Roger Tell served as acting CEO until January 8, 2024. His consultancy fee for that time amounted to kSEK 67.

In the event of termination, there is a mutual notice period of six months. There are no severance agreements for the CEO.

### **OTHER SENIOR EXECUTIVES**

During the financial year, salaries totaling kSEK 487 were paid to other senior executives, of which base salary was kSEK 483 and benefits were kSEK 4. Pension premiums for 2024 have been paid in the amount of kSEK 114. In addition to salary and remuneration, consultancy fees of kSEK 4,271 have been paid to other senior executives.

Consultancy fees to senior management refer to fees to the CFO Roy Jonebrant during January 2024, the CFO Magnus Hurst during the period January-August 2024 and to the CMO Roger Tell during the period January 9 to December 31, 2024.

In the event of termination, there is a mutual notice period of six months. There are no severance pay agreements with other senior executives.

### Salaries and other benefits payable to the Board 2024

kSEK	Board fees	Audit commit- tee fees	Remu- neration Commit- tee fees	Other remuner- ation	Total
Chairman of the Board (Jan–Dec) Jan-Eric Österlund	544	74	74	81	773
Board member (Jan-Dec) Alain Herrera	247	-	49	23	319
Board member (Jan-Dec) Helena Taflin	247	-	-	_	247
Board member (Jan-Dec) Lars Lind	247	123	51	_	421
Board member (Jan-Dec) Sten Nilsson	247	-	-	_	247
Chairman of the Board (Jan 1–3) Mats Franzén	6	-	-	_	6
Board member (Jan 1–3) Annika Freij	3	-	-	-	3
Board member (Jan-Dec) Jonas Pedersén	3	-	-	-	3
Remuneration of the Board of Directors	1,544	197	174	104	2,019

### Salaries and other remuneration of senior executives 2024

kSEK	Base salary	Other remunera- tion*	Variable remuner- ation	Other benefits	Pension costs	Total
<b>Chief Executive Officer</b> (Jan-Dec) Petter Segelman Lindqvist	1,671	-	588	121	387	2,767
Chief Executive Officer (Jan) Roger Tell	_	67	_	_	_	67
Other senior executives **	483	4,271	-	4	114	4,871
Total remuneration	2,154	4,338	588	125	501	7,705

\* Other remuneration relates to consultancy fees to the CMO for the full year 2024 and to the CFO during January-August. \*\* Other senior executives refers to the CMO and CFO.

### Salaries and other benefits payable to the Board 2023

kSEK	Board fees	Variable remuner- ation	Other benefits	Pension cost	Total
	lees	ution	Denents	COSI	Total
Chairman of the Board (Jan-Feb) Jan Törnell	117	-	-	-	117
Board member (Jan-Feb) Lennart Jeansson	50	-	-	-	50
Board member (Jan-Feb) Aram Mangasarian	42	-	-	-	42
Board member (Jan-Feb) Paula Boultbee	42	-	-	-	42
Board member (Jan-Feb) Alain Herrera	42	-	-	-	42
Board member (Jan-Feb) Magnus Björsne	42	-	-	-	42
Board member (Jan-Feb) Robert Marchesani	50	_	_	_	50
Board member (Jan-Feb) Anna Belfrage	63	_	-	_	63
Board member (Feb-Dec) Mats Franzén	500	_	-	_	500
Board member (Feb-Dec) Jonas Pedersén	233	_	-	_	233
Board member (Feb-Jun) Jan-Eric Österlund	117	-	-	-	117
Board member (Mar-Dec) Annika Freij	167	-	-	-	167
Remuneration of the Board of Directors	1,463	-	-	-	1,463

Salaries and other remuneration of senior executives 2023

kSEK	Base salary	Other remunera- tion*	Variable remuner- ation	Other benefits	Pension costs	Total
Chief Executive Officer (Jan-Feb) Ulf Jungnelius Bemuneration	618	_	_	26	126	770
Chief Executive Officer (Feb-Jun) Thomas Andersson Remuneration		677				677
Chief Executive Officer (Jun-Dec) Roger Tell Remuneration		1,575	-		-	1,575
Deputy CEO (Jan-Mar) Gustaf Albèrt Remuneration	499	-	-	20	127	646
Remuneration of other senior executives Total remuneration	975 <b>2,092</b>	1,181 <b>3,433</b>	-	40 <b>85</b>	179 <b>432</b>	2,375 <b>6,042</b>

\* Refers to consultancy fees for the acting CEO, CMO and CFO for 2023.

### NOTE 4 FEES AND REIMBURSEMENT OF COSTS TO AUDITORS

kSEK	2024	2023
KPMG		
Audit engagement	313	260
Total	313	260

Audit engagement refers to the statutory audit of the annual accounts and the accounting records, as well as the administration of the Board and the CEO, and to audits and reviews carried out in accordance with agreements.

This includes other duties incumbent on the auditors of the company, as well as advisory services and other assistance occasioned by observations made in the course of such examinations or such other duties.

### NOTE 5 FINANCIAL INSTRUMENTS BY CATEGORY

The company's financial assets and financial liabilities in the balance sheet are measured at amortized cost.

### Financial assets measured at amortized cost

kSEK	Dec 31, 2024	Dec 31, 2023
Accounts receivable	-	-
Cash and bank balances	96,157	138,148
Total	96,157	138,148

### Financial liabilities measured at amortized cost

kSEK	Dec 31, 2024	Dec 31, 2023
Accounts payable	2,028	1,988
Accrued expenses	15,292	14,801
Total	17,320	16,789

### Maturity structure of financial liabilities

kSEK	Dec 31, 2024		Dec 31, 2023	
Financial liabilities mature:	Within 3 months	After 3 months	Within 3 months	After 3 months
Accounts payable	2,028	-	1,988	-
Accrued expenses	8,321	6,972	7,939	6,862
Total	10,349	6,972	9,927	6,862

### Classification and fair value

kSEK	SEK Dec 31, 2024		Dec 31	, 2023
	Measured at fair value through profit or loss	Financial assets and liabilities measured at amortized cost	Measured at fair value through profit or loss	Financial assets and liabilities measured at amortized cost
Financial assets				
Cash and cash equivalents	-	96,157	-	138,148
Financial liabilities				
Accounts payable	-	2,028	-	1,988
Accrued expenses	-	15,292	-	14,801

### NOTE 6 TAXES

### Recognized in profit or loss and other comprehensive income/statement of profit and loss

kSEK	2024	2023
Current tax costs (-)/tax income (+)		
Tax costs/tax income for the year	-	-
Deferred tax costs (-)/tax income (+)		
Deferred tax attributable to temporary differences	-	-
Total recognized tax costs	-	-

### Reconciliation of effective tax

kSEK	2024		2023	3
Result before tax		-43,488		-37,071
Tax at applicable tax rate	20.60%	8,959	20.60%	7,637
Non-deductible expenses	-0.3%	-148	0.1%	46
Non-taxable revenue	0.0%	2	0.0%	-15
Increase in loss carryforwards with- out corresponding capitalization of deferred tax	-20.3%	-8,812	-20.7%	-7,668
Effective tax recognized	0.0%	-	0.0%	-

Accumulated loss carryforwards as of December 31, 2024 amounted to kSEK 1,253,531 (1,210,190). These loss carryforwards have no time limit. No taxes have been recognized directly in equity or in other comprehensive income.

### **NOTE 7** INTANGIBLE FIXED ASSETS

	Acquired intangible assets and pate		
kSEK	2024	2023	
COST			
Opening balance	993	993	
Closing balance	993	993	
ACCUMULATED AMORTIZATION			
Opening balance	-993	-993	
Amortization for the year	-	-	
Closing balance	-993	-993	
Closing balance of acquired intellectual property rights and patents	_	-	

### **NOTE 8** TANGIBLE FIXED ASSETS

	Equipment a		
kSEK	2024	2023	
COST			
Opening balance	70	535	
New acquisitions	_	-	
Divestment	-	-282	
Disposal	_	-183	
Closing balance	70	70	

	Equipment and to		
kSEK	2024	2023	
ACCUMULATED AMORTIZATION			
Opening balance	-67	-444	
Divestment	_	231	
Disposal	_	183	
Amortization for the year	-3	-37	
Closing balance	-70	-67	
Closing balance equipment and tools	0	3	

### NOTE 9 OTHER RECEIVABLES

kSEK	Dec 31, 2024	Dec 31, 2023
VAT receivable	1,514	1,167
Other receivables	292	978
Total	1,806	2,145

### NOTE 10 PREPAID EXPENSES AND ACCRUED INCOME

kSEK	Dec 31, 2024	Dec 31, 2023
Rent	30	-
Clinical studies	88	12
Other	336	289
Total	454	301

### NOTE 11 CASH AND CASH EQUIVALENTS

kSEK	Dec 31, 2024	Dec 31, 2023
The following sub-items are included in Cash and cash equiva- lents:		
Cash and bank balances	96,157	138,148
Total according to balance sheet	96,157	138,148

### NOTE 12 EQUITY

Types of shares		
Number of shares	2024	2023
ORDINARY SHARES		
Issued as of January 1	161,515,440	161,515,440
Issued as of December 31	161,515,440	161,515,440

As of December 31, 2024, the registered share capital comprised 161,515,440 ordinary shares (161,515,440) with a nominal value of SEK 0.0306 (0.0306). Holders of ordinary shares are entitled to receive dividends that are determined at a later date, and the shareholding carries entitlement to vote at general meetings with one vote per share. All shares carry the same rights to the company's remaining net assets. Non-restricted equity in the company consists of the amount available for dividends to shareholders. For Isofol, non-restricted equity in the company comprises retained earnings and the share premium reserve. The share premium reserve comprises the amounts contributed by the shareholders, in addition to the nominal value for the issued shares less any issue costs.

### NOTE 13 APPROPRIATION OF PROFIT

### PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT

The Board of Directors proposes that the non-restricted equity, SEK 72,999,631, be appropriated as follows:

To be carried forward	72,999,631
Total	72,999,631

### NOTE 14 OTHER LIABILITIES

kSEK	Dec 31, 2024	Dec 31, 2023
Personnel-related liabilities	976	1,232
Other current liabilities	-	-
Total other current liabilities	976	1,232

### NOTE 15 ACCRUED EXPENSES AND DEFERRED INCOME

kSEK	Dec 31, 2024	Dec 31, 2023
Vacation pay	425	233
Accrued salaries	1,103	-
Clinical studies	13,708	12,849
Other	1,585	1,952
Total	16,821	15,033

### NOTE 16 FINANCIAL RISKS AND RISK MANAGEMENT

The company is exposed to various forms of financial risks through its activities. Financial risks refer to fluctuations in the company's result and cash flow as a result of changes in exchange rates, interest rates and refinancing and credit risks.

The company's overall risk management focuses on safeguarding its ability to conduct its research and development and related clinical studies, and this means that the company seeks to minimize potential adverse effects on the company's financial performance and position.

The company's financial transactions and risks are managed by the CEO and CFO. The Board establishes guidelines and principles for overall risk management and for specific areas, such as liquidity risk, refinancing risk, credit risk, currency risk, interest rate risk and the use of derivative instruments as well as the investment of excess liquidity.

### CAPITAL MANAGEMENT

Since the start of its operations, Isofol has recognized a negative operating result, and its cash flow is mainly expected to remain negative until Isofol succeeds in generating revenue from a launched product or receives revenue from licensing of intellectual property. The company may also continue to require significant capital for research and development with the aim of conducting clinical studies.

### FINANCIAL POLICY

Isofol has a policy for its financial activities, the financial policy, which defines financial risks and specifies how the company is to manage these risks.

### **REFINANCING RISK**

Refinancing risk refers to the risk that cash and cash equivalents may not be available and that financing can only be obtained partially, not at all or at an increased cost. At present, the company's activities are fully financed with equity and are not, therefore, exposed to risks related to external loan financing. The primary risks thus relate to the risk of not receiving additional contributions and investments from the shareholders when needed. The issuing of equity instruments is the primary source of the company's financing and the predominant source for planned studies.

### LIQUIDITY RISK

Liquidity risk is the risk that the company will encounter difficulties in meeting its obligations related to financial liabilities. The company manages liquidity risk by continuously monitoring cash flow and establishing liquidity planning to ensure that funds are available for planned activities, thereby reducing liquidity risk and ensuring its ability to pay. The Board and management engage in long-term work with shareholders and independent investors to ensure that liquidity is available to the company when needed.

### **INTEREST RATE RISK**

Isofol's exposure to market risks from changes in interest rates relates to bank balances. The company's financial policy stipulates that any excess liquidity is to be invested in securities where the market and interest rate risk is low, and the Group's exposure to interest rate risk has thus been limited.

### CURRENCY RISK

Currency risk is the risk of fluctuations in the value of a financial instrument due to changes in exchange rates. This risk is related to changes in expected and contractual payment flows (transaction exposure), translation of liabilities in foreign currencies (translation exposure) and financial exposure in the form of currency risks in payment flows for investments. The company is affected by fluctuations in exchange rates, and the company's goal is to minimize the impact of these changes where possible with respect to practicality and cost effectiveness. Changes in EUR and USD have the most significant impact. The average exchange rate for EUR/SEK in 2024 was SEK 11.43 and for USD/SEK 10.56. A change in the average exchange rate for EUR and USD by +/-10 percent would, with all other variables held constant, have affected the company's profit before tax by +/-0.5 MSEK and +/-0.3 MSEK respectively in 2024.

### **CREDIT RISK**

Credit risk is the risk that the company's counterparty in a financial instrument cannot fulfill its obligations, thus causing the company a financial loss. The company's exposure to credit risk is limited.

### NOTE 17 LEASES

The company rents office premises in Gothenburg. The current lease for the office premises expires on March 31, 2026 with three months' notice. There are no other material rental agreements or leases

### Expensed lease payments amount to the following:

kSEK	2024	2023
Lease payments	693	978
Total lease expenses	693	978

### Future non-cancelable lease payments fall due as follows:

kSEK	Dec 31, 2024	Dec 31, 2023
Within 1 year	168	14
Between 1 and 5 years	-	-
After 5 years	-	-
Total lease expenses	168	14

### NOTE 18 PLEDGED ASSETS AND CONTINGENT LIABILITIES

kSEK	Dec 31, 2024	Dec 31, 2023
Pedged assets	none	none
Contingent liabilities	none	none

### NOTE 19 RELATED PARTIES

### Related-party relationships

Related parties are the senior executives of the company, i.e. the Board of Directors and the executive management, and their family members. Transactions with related parties are priced and conducted at arm's length. During the year, remuneration of senior executives was paid in accordance with applicable policies and guidelines. For information on the remuneration of each key individual in a management position, see Note 3. There were no other related party transactions during the period.

### NOTE 20 SPECIFICATIONS RELATED TO THE CASH FLOW STATEMENT

Cash and cash equivalents kSEK	Dec 31, 2024	Dec 31, 2023
THE FOLLOWING SUB-ITEMS ARE INCLUDED IN CASH AND BANK BALANCES:		
Cash and bank balances	96,157	138,148
Total according to balance sheet	96,157	138,148
Interest and dividends		
kSEK	2024	2023
Interest received	3,721	4,573
Interest paid	-	-
Adjustments for non-cash items		
kSEK	2024	2023
Depreciation	3	37
Exchange rate gain/loss	5	-50
Provisions	-262	65
Other	-	-4,463

### NOTE 21 EVENTS AFTER THE BALANCE SHEET DATE

Total

• In March 2025 announced that the company has received approval from the regulatory authority in German, BfArM, to initiate the new clinical study of the drug candidate arfolitixorin. The study will initially be conducted in Germany.

-255

-4.411

### NOTE 22 EARNINGS PER SHARE

Calculations have been made in accordance with IAS 33 Earnings Per Share. Earnings per share are based on the company's result for the year divided by the weighted average number of shares outstanding during the year. The weighted average number of shares during the period amounted to 161,515,440 (161,515,440).

### NOTE 23 FINANCIAL ITEMS

kSEK	2024	2023
Financial revenue		
Exchange rate gain	-	50
Other interest income	3,721	4,573
Total financial income	3,721	4,622
Financial costs		
Exchange rate losses	-	-
Other interest expenses	-	10
Total financial expenses	-	10

### NOTE 24 PROVISIONS

In 2022, Isofol entered into an agreement with a supplier to purchase packaging material for possible future sales of arfolitixorin. The use of the material is subject to approval for commercialization of arfolitixorin. The agreement includes a financial guarantee amounting to EUR 75,963, for which Isofol undertakes to bear the cost in the corresponding amount. In the first quarter of 2024, the provision was adjusted, as part of the material has been disposed of and the cost of EUR 20,527 has been settled against the provision. In view of the outcome of the study, the management considers it likely that the financial guarantee will be called. After adjustment, kSEK 648, corresponding to the present value of EUR 55,436, has been recognized as a provision in the company's balance sheet. The cost of the provision was recognized in the company's income statement in 2022. The timing of the remainder of the outflow is still uncertain, but it is estimated to be settled within a five-year period.

### NOTE 25 KEY PERFORMANCE INDICATORS AND DEFINITIONS

This report includes key performance indicators that are not defined in the Annual Accounts Act or RFR 2, but are included in the report because management believes that this information allows investors to analyze the company's earnings trend and financial position. Investors should consider these key performance indicators as a supplement to the financial information according to the Annual Accounts Act and RFR 2.

kSEK	Dec 31, 2024	Dec 31, 2023
Equity	77,945	121,433
Total assets	98,417	140,597
Equity ratio	79.2%	86.4%
Cash and cash equivalents	96,157	138,148
Working capital	78,593	122,341

### Equity ratio

Equity ratio is calculated by comparing equity with total assets and is thus a measure of the proportion of assets that are financed with equity.

### Equity

Equity consists of share capital, share premium reserve and retained earnings, including the company's result for the year.

### Cash and cash equivalents

Cash and bank balances and immediately available bank balances.

### Working capital

Working capital consists of the company's current assets less current liabilities.

### Earnings per share

The result for the period divided by the weighted average number of shares during the period, before and after dilution.

## CERTIFICATION

The Board of Directors and the CEO verify that the annual accounts have been prepared in accordance with generally accepted accounting principles in Sweden and in accordance with the international accounting standards referred to in Regulation (EC) No 1606/2002 of July 19, 2002 of the European Parliament and of the Council on the application of international accounting standards. The annual accounts give a true and fair view of the company's position and results. The Directors' Report gives a true and fair view of the development of the company's business, position and performance, and describes the material risks and uncertainties.

As stated above, the annual accounts were approved for issue by the Board and the CEO on April 10, 2025. The company's profit and loss account and balance sheet will be subject to adoption by the Annual General Meeting on May 21, 2025.

### Gothenburg, April 10, 2025

Jan-Eric Österlund Chairman

Helena Taflin Board member

Sten Nilsson Board member Alain Herrera Board member

Lars Lind Board member

Petter Segelman Lindqvist Chief Executive Officer

Our audit report has been submitted Gothenburg, April 10, 2025 KPMG AB

Daniel Haglund Authorized Public Accountant

## AUDITOR'S REPORT

To the general meeting of the shareholders of Isofol Medical AB (publ), corp. ID No 556759-8064

### REPORT ON THE ANNUAL ACCOUNTS Opinions

We have audited the annual accounts of Isofol Medical AB (publ) for the year 2024, except for the corporate governance statement on pages 27-35. The annual accounts of the company are included on pages 22-53 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of Isofol Medical AB (publ) as of 31 December 2024 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 27-35. The statutory administration report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

Our opinions in this report on the the annual accounts are consistent with the content of the additional report that has been submitted to the audit committee in accordance with the Audit Regulation (537/2014) Article 11.

### **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Isofol Medical AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts as a whole, but we do not provide a separate opinion on these matters.

### **Operating Expenses**

Refer to the accounting policies on pages 41 to 45 in the annual report for detailed information and a description of this area.

### Description of key audit matter

The company's operational expenses amounted to 47.2 million SEK during the fiscal year 2024. The majority of these costs relate to the development of the company's leading product, arfolitixorin, and primarily consist of expenses for both contracted and in-house personnel. In our audit, we have focused on these costs as they represent a significant amount and there is a risk concerning the accuracy, completeness, and timing of these expenditures.

### Response in the audit

Our review of the company's expenses has included an evaluation of the company's procedures, operational follow-up, and internal controls.

We have tested the company's controls for the accrual of incurred expenses as well as the approval and payment of supplier invoices and personnel costs. Additionally, we have reconciled and performed sample-based detailed testing against invoice documentation, agreements, and other financial statement documentation.

For personnel-related costs, we have conducted an analytical review of salaries. Our cost analysis is based both on historical data and our knowledge of the operations, as well as follow-up against internal reports. We have also assessed the content of the disclosures regarding expenses provided in the annual report.

# Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-21 och 57-59. The other information comprises also the remuneration report which we obtained prior to the date of this auditor's report. The Board of Directors and the Managing Director are responsible for this other information. Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

# Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error. In preparing the annual accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related

to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

 Identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's, use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a aoina concern.
- Evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, measures that have been taken to eliminate the threats or related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

### REPORT ON OTHER LEGAL AND REGULATO-RY REQUIREMENTS

### Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and the Managing Director of Isofol Medical AB (publ) for the year 2024 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

### **Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Isofol Medical AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

## Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the companu's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions. areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

## The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 27-35 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and are in accordance with the Annual Accounts Act. KPMG AB, Box 11908, 404 39, Göteborg, was appointed auditor of Isofol Medical AB (publ) by the general meeting of the shareholders on the 8 May 2024. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2016.

Gothenburg, April 10, 2025 KPMG AB

Daniel Haglund Authorized Public Accountant



# **Financial calendar**

Isofol intends to publish financial reports and hold meetings according to the following schedule:

Interim report January–March 2025 Annual General Meeting 2025 Interim report April–June 2025 Interim report July–September 2025 Year-end report 2025 May 21, 2025 May 21, 2025, Gothenburg July 18, 2025 November 12, 2025 February 18, 2026

The interim reports are published on the company's website, and updates about upcoming events take place continuously at www.isofolmedical.com.

# For further information

Petter Segelman Lindqvist, CEO Phone: +46 (0) 739 60 12 56 E-mail: petter.s.lindqvist@isofolmedical.com

Margareta Hagman, CFO Phone: +46 (0) 738 73 34 18 E-mail: margareta.hagman@isofolmedical.com

Isofol Medical AB (publ) Biotech Center Arvid Wallgrens Backe 20 SE-413 46 Gothenburg, Sweden

www.isofolmedical.com | info@isofolmedical.com Corporate identity number: 556759-8064 | Registered office: Gothenburg

### GLOSSARY

The following explanations are intended to help the reader understand certain specific terms and expressions in Isofol's financial reports:

### [6R]-MTHF [6R]-5,10-methylenetetrahydrofolate

BfArM The Federal Institute for Drugs and Medical Devices in Germany (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM)
CMC Chemistry, Manufacturing and Controls
CRC Colorectal cancer
EMA European Medicines Agency
FDA US Food and Drug Administration
iDSMB Independent Data Safety Monitoring Board
ORR Objective Response Rate)
OS Overall Survival
PFS Progression-Free Survival
PMDA Japanese Pharmaceuticals and Medical Devices Agency

### STUDY PHASES

### Preclinical study

Research that takes place before a drug or treatment method is sufficiently documented to be studied in humans. For example, testing of substances on tissue samples and subsequent testing on laboratory animals.

### Clinical study/trial

Investigation of a new drug or treatment method on healthy volunteers or patients where the aim is to study the efficacy and safety of an as-yet unapproved form of treatment.

### Clinical phase I

The first time when a new substance is given to humans. Phase I studies are often carried out on a small number of healthy volunteers to study safety and dosage for an as-yet unapproved form of treatment.

### Clinical phase II

Phase II refers to the first time when a drug under development is given to patients to study the safety, dosage and efficacy of an as-yet unapproved form of treatment.

### Clinical phase III

Phase III studies/trials comprise numerous patients and are often conducted over an extended period of time. They are intended to identify the efficacy and side effects of the drug under ordinary but still closely monitored conditions.

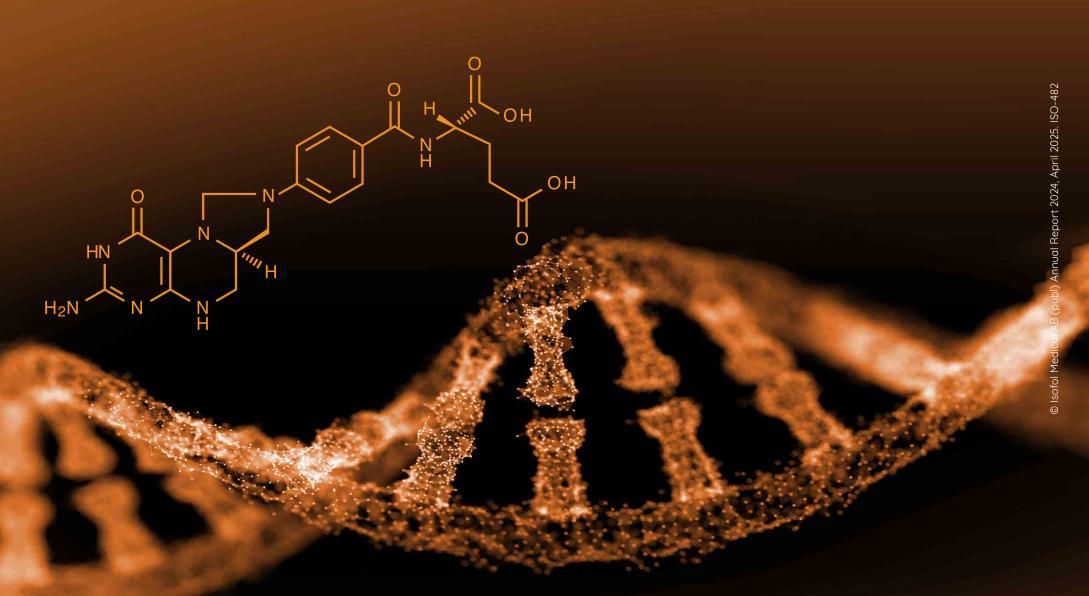
### **Pivotal study**

A clinical study designed to provide data on the efficacy and safety of the drug when applying for market approval from the FDA or EMA, for example.

### Phase IV study

A phase IV study, also referred to as a postmarketing surveillance trial or drug surveillance, is intended to ensure the drug's long-term safety and efficacy.

Production: Isofol Medical AB (publ) in collaboration with AdlerssonHeath and Carlund & Co. Photographs: page 1 IStock, page 2 Martin Fröström, page 3 iStock, page 4 Depositphoto, page 7, 8 iStock, page 12 Martin Fröström, page 18, sid 21 David Holm, page 31, 34 Martin Fröström, page 57 David Holm.



# ARFOLITIXORIN

A DRUG CANDIDATE FOR TREATMENT OF COLORECTAL CANCER

ISOFOL MEDICAL AB (publ) | Biotech Center | Arvid Wallgrens Backe 20 | SE-413 46 Gothenburg, Sweden | www.isofolmedical.com