
ISOFOL
ANNUAL REPORT 2021
Isofol issue all its reports in Swedish language.
This report is a direct un-authorized translation
of the issued Swedish Annual report 2021.
ARFOLITIXORIN
A DRUG CANDIDATE
FOR TREATMENT
OF COLORECTAL CANCER

CONTENTS

"In 2021, Isofol developed from a purely clinical company into a company in the pre-commercial phase."

Ulf Jungnelius, CEO

Arfolitixorin – a drug candidate for the treatment of colorectal cancer.

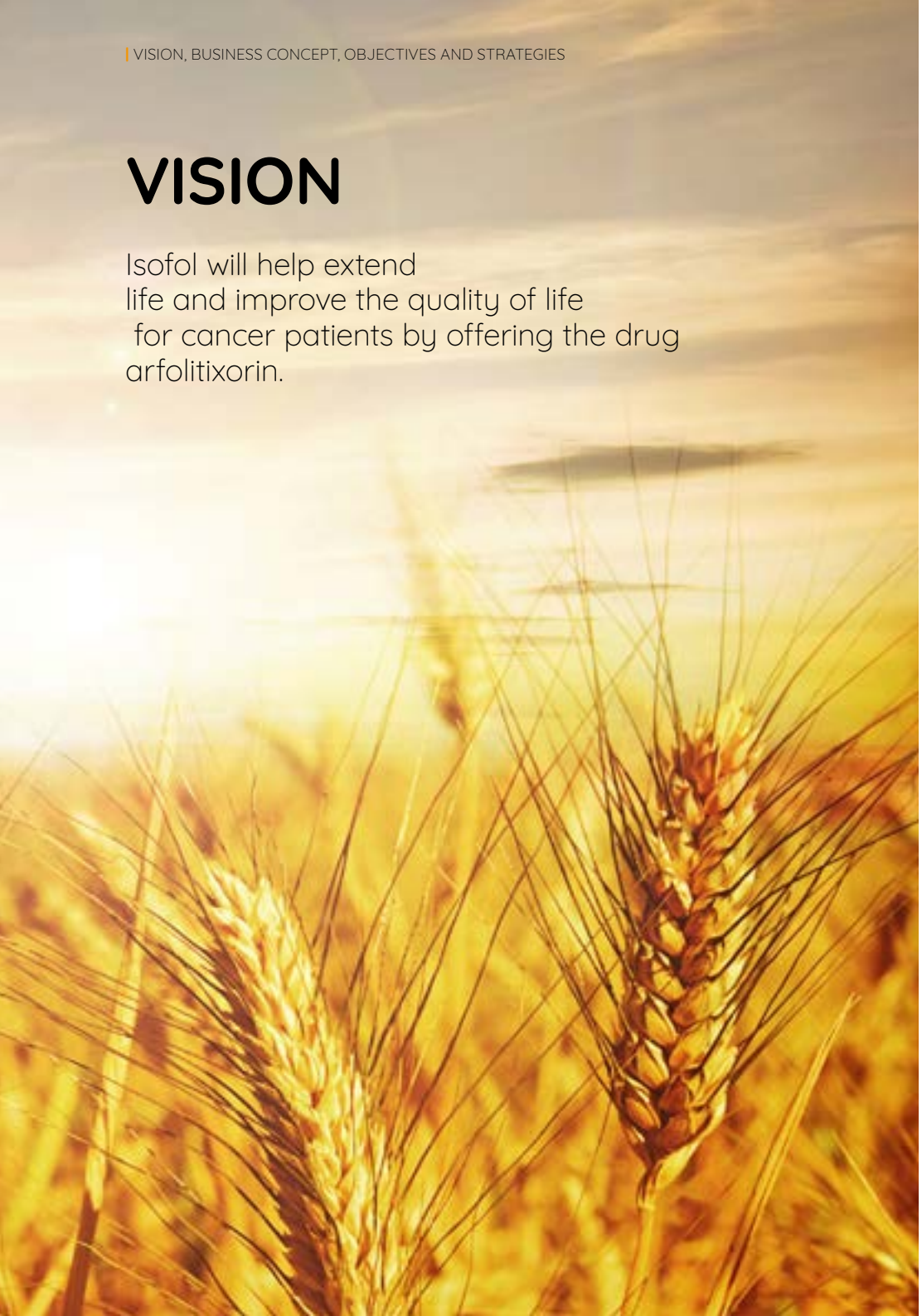
"We are a small organization and we truly support one another."

Karin Gedda
VP Clinical Operations

ISOFOL IS DEVELOPING THE CANCER DRUG ARFOLITIXORIN

Isofol Medical AB (publ) is a biotech company that is developing a drug candidate, the cancer drug arfolitixorin, which is now in the pre-commercialization phase. Arfolitixorin is being developed for the treatment of colorectal cancer (CRC), which is the third most common form of cancer worldwide. Therefore, the need for more effective drugs to treat this disease is very high. Arfolitixorin, combined with the cytostatic 5-FU, has the potential to become a new standard treatment for patients with advanced CRC for whom 5-FU-based treatment is currently the standard treatment. Arfolitixorin is the first and only direct-acting folate-based drug that enhances the cytotoxic effect in combination with 5-FU, and thereby aims to improve the efficacy of 5-FU-based treatments by potentially achieving a more powerful anti-tumor effect without diminishing safety. Isofol's primary objective is to improve treatment outcomes for approximately 370,000 advanced/metastatic CRC patients in the US, Europe and Japan.

Arfolitixorin is being developed and commercialized through a global licensing agreement with Merck & Cie in Germany. The licensing agreement also grants Isofol access to the unique patented manufacturing process for arfolitixorin. Isofol's operations are based in Gothenburg, and the company's shares traded on Nasdaq Stockholm's main market in the Mid Cap segment.



VISION

Isofol will help extend
life and improve the quality of life
for cancer patients by offering the drug
arfolitixorin.

BUSINESS CONCEPT

Isofol is focused on making arfolitixorin available worldwide and thereby improving the quality of life for patients with cancer being treated with 5-FU-based therapies.

OBJECTIVES

- Ensure the completion of the AGENT study for CRC
- Ensure that we can apply for regulatory approval for arfolitixorin as soon as possible after the end of the study
- Implement the company's commercialization plan to enable the successful launch of arfolitixorin
- Assess strategic partnerships to maximize the potential and value of arfolitixorin
- Investigate extended uses of arfolitixorin through life cycle activities

STRATEGIES

Develop arfolitixorin in oncology

Isofol is a biotech company with the goal of bringing arfolitixorin to market. The drug is intended to reduce the tumor burden, improve the quality of life and extend the lives of CRC patients. The ongoing AGENT study is focused on the treatment of metastatic CRC (mCRC), where the medical need is high. With the current treatment options, only 10 percent of mCRC patients are alive five years after diagnosis. The company will also evaluate whether arfolitixorin can be effective for other forms of cancer and thus help more patients.

Organizational strategy

Isofol has built an organization with key expertise on staff, supplemented through partnerships that ensure the best possible access to the resources not provided by the organization's own employees.

Commercial strategy and business model

To ensure that arfolitixorin can be launched immediately after receiving regulatory approval, Isofol will develop a full commercialization strategy. This strategy is to be completed before submitting an application for market approval to regulatory authorities. This approach is designed to prepare the company to commercialize arfolitixorin on its own as well as to strengthen its negotiating position with future partners. Isofol continuously evaluates various strategic partnerships, and if an agreement with a partner increases the value of arfolitixorin, we will consider it.

THE YEAR IN BRIEF

MSEK 22,4

Net revenue amounted to TSEK 22,4 (37,1) and other operating revenue to TSEK 0 (18)

MSEK -200

Result before tax amounted to SEK -200 million (-189)

SEK -1.59

Earnings per share amounted to SEK -1.59 (-3.07)

MSEK 379

Cash and cash equivalents at year-end amounted to SEK 379 million (116)

JANUARY–MARCH

- Following an interim analysis, the independent Data Safety and Monitoring Board (iDSMB) recommended that Isofol should complete the global Phase III AGENT study with 440 patients in accordance with the study protocol.
- Isofol received a Clinical Use Patent for the drug candidate arfolitixorin in Europe.
- Isofol presented a poster at the ASCO Gastrointestinal Cancer Symposium (ASCO-GI) 2021 with the gene expression results from the completed Phase I/IIa ISO-CC-005 study. The poster "confirmed" its gene expression hypothesis, with the AGENT study expected to confirm the clinical relevance of the hypothesis.

APRIL–JUNE

- Isofol carried out a successful financing round – a rights issue combined with a directed issue – that raised a total of SEK 452 million for the company after transaction costs.
- Isofol presented an abstract at the ASCO Annual Meeting in June, in which new data about the regulation of 5-FU/folate-based treatment of CRC was presented. The study shows that the activation of the cancer-contributing oncogene MYC appears to impact the efficacy of treatment with 5-FU/folate. This correlation opens the door for exploring further potential biomarker candidates as factors in 5-FU/arfolitixorin efficacy as well as combinations (including MYC inhibitors).
- Patient enrolment in the AGENT study in Japan was completed according to plan in May.

JULY–SEPTEMBER

- Intensive preparations for a change of listing to Nasdaq Stockholm, and submission of Fast Track Designation application to the US Food and Drug Administration (FDA).

OCTOBER–DECEMBER

- On October 21, Isofol's shares were listed on Nasdaq Stockholm.
- Isofol was granted Fast Track Designation by the FDA for arfolitixorin for the treatment of advanced CRC. This designation allows for a prioritized review process and can result in the expedited processing of an application, more frequent meetings with the FDA and ongoing evaluation, provided that relevant criteria are met.
- Isofol announced that the FDA denied a request from the company to adjust the censoring rules for the ongoing AGENT study's secondary endpoint after more patients than expected proceeded to other treatments before they reached progression-free survival (PFS). The study's primary endpoint, objective response rate (ORR), was not affected. An agreement for a new cut-off point for top-line results is expected in spring 2022.

EVENTS AFTER THE END OF THE YEAR

- Jenny Sundqvist assumed her role as Chief Commercial Officer on January 1, 2022.
- The company's nomination committee proposes that Jan Törnell is elected Chair of the Board of Directors of the company in connection with the 2022 AGM.
- On April 22, 2022 it was announced that data analysis of the global pivotal Phase III study AGENT had begun following a dialogue with the FDA regarding censoring rules and the requirement for progression-free survival events to begin data gathering and analysis.

COVID-19 HAD A LIMITED IMPACT ON THE COMPANY

The spread of Covid-19 during 2021 continued to have a major negative impact on society, healthcare, the economy and people's lives. The AGENT study was fully enrolled in December 2020 and the risk of delays due to patient enrolment was therefore reduced. However, there remained a risk that hospitals could close or that the collection of data could become more difficult due to future waves of Covid-19, which could delay the compilation of data ahead of the study's top-line results. Covid-19 had a relatively limited impact on Isofol and its operations in 2021. This is because Isofol continually adapted its operations and took precautionary measures in 2021 to ensure that its employees, consultants and study participants would stay safe and that the study is based on high-quality data.

“NOW WE ARE ON THE VERGE OF ONE OF THE MOST CRITICAL EVENTS IN THE COMPANY’S HISTORY”

In 2021, Isofol developed from a purely clinical company into a company in the pre-commercial phase that is preparing to ensure a successful commercial launch of arfolitixorin in the US as early as 2023. The most important milestones on the way are the presentation of study results, submission of an application for market approval, the FDA’s subsequent response to the application and ensuring inclusion in US national guidelines (NCCN guidelines). At the same time, we are continuing our commercial preparations and keeping potential licensees and partners informed to enable future licensing deals.

Sometimes it’s important to take a step back and lift one’s gaze. The fundamental reason we developed arfolitixorin is the high medical need for new drugs to treat cancer. CRC, which we have chosen to focus on for the present, is the third most common cancer diagnosis today and the second deadliest. Meanwhile, no new cancer medications have been developed for these patients in nearly 20 years. Aside from arfolitixorin, there are no new drugs in pivotal studies that we view as potential competitors for this patient group. The disease is leading to great suffering and cutting many lives short.

Critical events

Now we are on the verge of the most critical event in the company’s history, as we will be able to receive the results of the AGENT study in 2022. The outlook in terms of meeting the regulatory results appears promising based on previous study results on arfolitixorin and the fact that the regulatory authorities see a high need for new treatments. Arfolitixorin has the potential to achieve a more powerful anti-tumor effect, thereby improving treatment outcomes for a large group of CRC patients. Arfolitixorin is the first and only direct-acting folate-based drug that enhances the cytotoxic effect in combination with 5-FU. This combination therefore has the potential to become a new standard treatment for patients with advanced CRC, while being relatively straightforward to incorporate into current treatment regimes.

From a clinical perspective, we passed two important milestones in 2021 on our way to completing the study. The first milestone was the interim analysis performed by the iDSMB, after which they recommended that the AGENT study be completed according to the study plan with 440 patients. The second milestone was when the enrolment of Japanese patients was completed according to plan in May.

Fast Track Designation enhances the company’s prospects for an effective application process

In addition, in the autumn we were granted Fast Track Designation by the FDA, which entails more frequent dialogue with the agency and a more rapid application process for market approval. This is an extremely positive development and important external validation of arfolitixorin’s potential. I interpret it as confirmation of the considerable need for better treatments for CRC.

After more patients than expected were censored in autumn 2021 since they had been moved to other treatments before reaching the secondary endpoint of PFS, we were forced to adjust the cut-off point for begin-

“Thanks to the target-oriented work we did on the AGENT study and pre-commercial preparations in 2021, we are strongly positioned for 2022.

Ulf Jungnelius, CEO, Isofol

ning the analysis of top-line data, in dialogue with the FDA.

With the new cut-off point, we expect that the process of completing and analyzing the study database will take two to four months before we can communicate top-line results.

The clearance from the iDSMB, granting of Fast Track Designation and being selected to present a poster at the important ASCO-GI cancer symposium in 2021 all mean that we received multiple crucial external scientific validations of our drug candidate.

Raising awareness of arfolitixorin

However, if we are to be successful, we must not only be able to demonstrate results that lead to market approval from the authorities, we must also be able to pave the way for the drug to be prescribed in clinics afterwards. We have therefore intensified our work on pre-commercial preparations while conducting the activities that go into the study. These preparations consist of comprehensive efforts to educate the medical community in the US about arfolitixorin as well as market access initiatives in order to raise awareness about the candidate in the market. In terms of educational efforts, we have now engaged resources in the US who are tasked with attending scientific conferences and training oncologists and other important interest groups. One outcome of our market access efforts thus far is that we have been able to develop a better knowledge base for future negotiations with potential partners, which will also be used for future pricing discussions with payers, applications for inclusion in guidelines, etc. We have expanded our partnership with our commercial consultants to include communication initiatives that have the US market as their primary target group, although these initiatives will also be addressed to Europe.

Raising capital makes future milestones possible

We conducted a successful new share issue in June 2021 in order to secure the financial resources needed to perform necessary activities. These activities include completing the AGENT study and the FDA market registration application as well as initiating and accelerating global activities related to the development of medical affairs, commercial launch packages and continued partnership activities. The new share issue raised just over SEK 450 million for the company after transaction costs. The reason for the financing round was that the company's Board of Directors and management determined that we needed additional working capital after we had achieved the important established milestones for the previous financing round that took place in 2020, meaning that the study was fully enrolled, we were able to present the interim results and we had furthermore signed licensing agreements with Solasia in Japan and Endo/Paladin in Canada. Even though a great deal of the work conducted in the autumn cannot yet be seen in the form of milestones or the like, raising capital enabled the process that led up to our Fast Track Designation, a clear result of the opportunities created by this increased financial strength.

Naturally, the fact that we have been able to enter into licensing agreements for the Japanese and Canadian markets even before reporting Phase III data is a strong validation of both the scientific basis and the commercial potential of arfolitixorin. Nor do these two agreements limit our opportunities to enter into agreements for the remaining markets; the discussions with potential partners were simply constructive in this case. However, the outcome of the AGENT study is critical for our ability to enter into additional licensing agreements. Naturally, we have continued planning alternative scenarios for bringing arfolitixorin to market as fast as possible alongside our discussions with potential partners.

Listing on main market provides greater visibility

In October 2021, we took another important step in the company's evolution: the Isofol share is now traded in the Mid Cap segment on Nasdaq Stockholm's main market. Moving to a new exchange helps us raise additional awareness about Isofol through higher visibility, the inclusion of the share in a higher number of important indexes, and the share becoming suitable for investment by several institutional investors that are restricted from investing in companies on non-regulated markets. Since the change of listing, trading in the share and the number of shareholders have increased.

Patents

Given these circumstances, the intellectual property protection for our candidate is becoming increasingly important. It is therefore reassuring that the highly talented patent experts we have engaged succeeded in further strengthening our patent protection in 2021, with a clinical use patent secured in Europe for dosage regimes and combination treatment. To further strengthen our protection, additional patent applications for dosage regimes were submitted in 2021, and we intend to continue strengthening our patent protection in 2022.

Strongly positioned for the future

Thanks to the target-oriented work we did on the AGENT study and pre-commercial preparations in 2021, we are strongly positioned for 2022. In 2022, we will finally have proof of the AGENT study's results and, provided that the outcome is positive, this will enable us to bring our drug candidate across the regulatory threshold in order to make life better for the large group of patients currently suffering from advanced CRC.

I believe that we are well prepared for the important events ahead of us. With a dedicated and successful team working to complete the AGENT study, we are well equipped for the entire journey to market approval. Thus, we will hopefully realize our vision of making life better for many patients through improved treatment results for CRC.

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

ARFOLITIXORIN

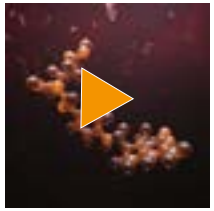
– A DRUG CANDIDATE FOR THE TREATMENT OF CRC

Arfolitixorin, in combination with 5-fluorouracil (5-FU, one of the world's most commonly used cancer drugs), is intended to meet the significant medical need within advanced/metastatic CRC.

The cytostatic 5-FU is a well-tested drug that has been used for the treatment of malignant tumors since the 1960s. It is also the foundation of the current standard treatment for patients with CRC and is administered to more than 70 percent of patients diagnosed with mCRC (read more about the disease on page 20). The currently prevailing 5-FU-based cytostatic treatment is administered in combination with both folate and other cytostatics (oxaliplatin or irinotecan, for example) as well as biological drugs such as bevacizumab and cetuximab. These combinations have been employed since 2004 and are variations on the current first-line and second-lined standard treatment.

However, current folate-based drugs require multi-stage metabolic activation. For reasons including genetic traits, this transformation and activation does not take place in all patients. Despite combination treatment with several drugs, fewer than half of patients with mCRC respond to treatment with current folate-based drugs. An academic research team with which Isofol has partnered since the beginning conducted several genetic studies in patients with mCRC who were treated at Östra Hospital in Gothenburg. The studies demonstrated that approximately three quarters of these patients have an insufficient capacity to convert and activate the ingredient, which results in significantly worse PFS compared with patients with a good capacity for conversion.

Isofol's objective in developing arfolitixorin is to address the problem for patients who are incapable of optimally assimilating current folate-based treatment, and thereby potentially create maximum benefit from combination treatment with 5-FU. Arfolitixorin is the first pure form of [6R]-MTHF and does not require any conversion to activate. Arfolitixorin is intended to improve the efficacy of 5-FU based treatments without diminishing safety. Because it is direct-acting, arfolitixorin combined with 5-FU has the potential to become a new standard treatment for patients with advanced CRC for whom 5-FU based treatment is an option.



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

SUPERIOR BIOAVAILABILITY IN CANCER TREATMENT WITH THE IMPORTANT FOLATE [6R]-MTHF

IV bolus push 1-3 min.

Given twice with a 30-60 minute interval between doses

Immediately active substance

Arfolitixorin is [6R]-MTHF ([6R]-5,10-methylene-THF)

Arfolitixorin is the first drug candidate that consists of [6R]-MTHF and requires no conversion.

In an early development phase comparative clinical study (ISO-CC-002), Isofol demonstrated statistically that CRC patients showed at least three to four times higher levels of [6R]-MTHF in the tumor when treated with arfolitixorin treatments compared with current folate-based treatments. When arfolitixorin is administered together with 5-FU in the treatment of CRC, the tumor-killing effect is enhanced and more cancer cells die. Read more about the mechanisms on the following page.

Arfolitixorin can be administered independent of gene expression

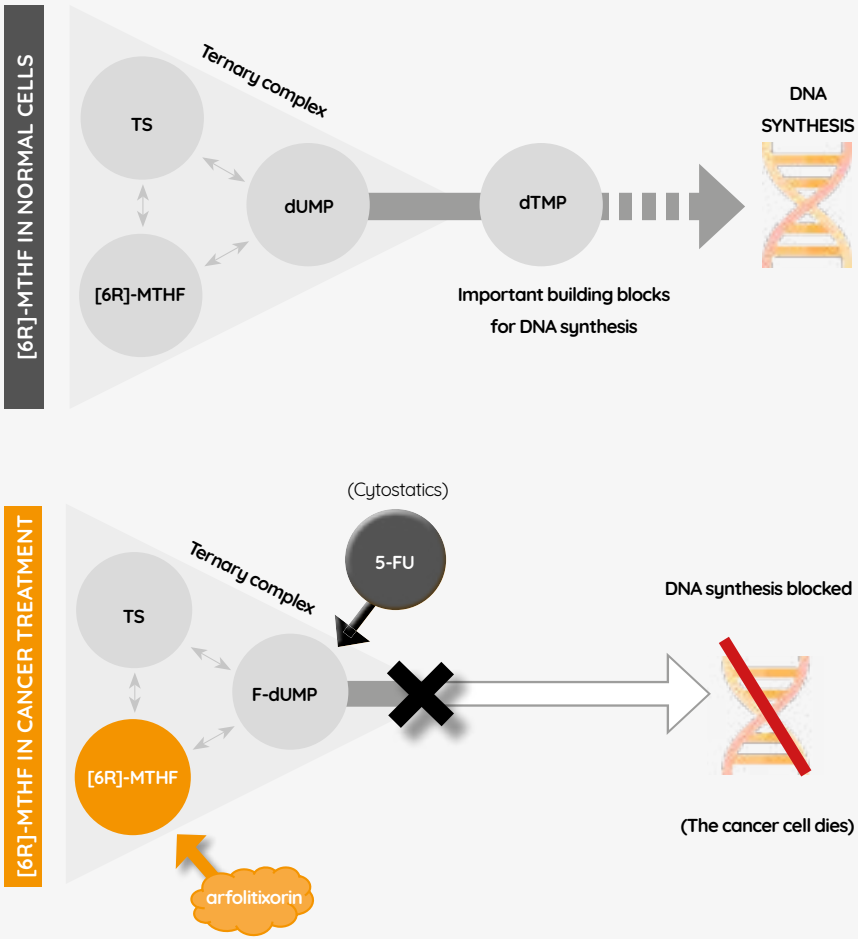
Together with academic researchers, Isofol has developed a gene test in which the expression of several folate-associated genes was examined. The objective was to demonstrate the capacity of cancer patients to respond to folate-based cancer treatment.

The analytical method has been further developed and validated by a commercial laboratory, which is required by regulatory authorities in order to receive permission to use the method in clinical settings. The clinical value of the gene expression hypothesis will be validated by the AGENT study when we have access to final data.

Potential for the treatment of multiple forms of cancer

Arfolitixorin is considered to have broad areas of application. The cytostatic combination containing 5-FU is primarily intended for the treatment of mCRC, but CRC that has not metastasized as well as other forms of cancer are considered suitable for continued development. For example, cancer in the pancreas, stomach, breast, and head and neck region are forms of tumors where 5-FU is regularly used in standard treatments and a combination with arfolitixorin may be possible. What cancers including CRC and pancreatic cancer have in common is that they are difficult to treat even with the immunotherapies that are increasingly being used, and it is common for them to become more resistant to targeted treatments.

MECHANISM OF ACTION



In normal cells:
[6R]-MTHF is a key component in cell division in healthy cells
The [6R]-MTHF molecule interacts with two other molecules in a protein complex that forms one of the building blocks of DNA (thymidine-dTMP) that is necessary for cell division (DNA synthesis) and the repair of damaged DNA.

dUMP: Deoxyuridine 5'-monophosphate
dTMP: Deoxythymidine 5'-monophosphate
TS: Thymidylate synthase
[6R]-MTHF: [6R]-5,10-methylenetetrahydrofolate

In tumor cells:
In cytostatic treatments, [6R]-MTHF (arfolitixorin) works together with 5-FU, which leads to enhanced anti-tumor efficacy
The objective is to halt cell division in the tumor, and thereby tumor growth in a cancer patient. Treatment with the cytostatic 5-FU blocks the conversion to thymidine (dTMP), one of the building blocks of DNA that is necessary for cell division. Increasing the concentration of [6R]-MTHF molecules increases the efficacy of 5-FU and the production of the building block thymidine decreases. The result is that more tumor cells die since they are starved of new building blocks for DNA. Since normal cells divide much more slowly than cancer cells, they are less affected by thymidine starvation and the side effects of 5-FU treatment are therefore relatively mild. Arfolitixorin treatment has demonstrated levels of [6R]-MTHF at least three to four times higher than with the current standard treatment. This may allow for significantly higher efficacy of 5-FU and for significantly more patients to respond to treatment.

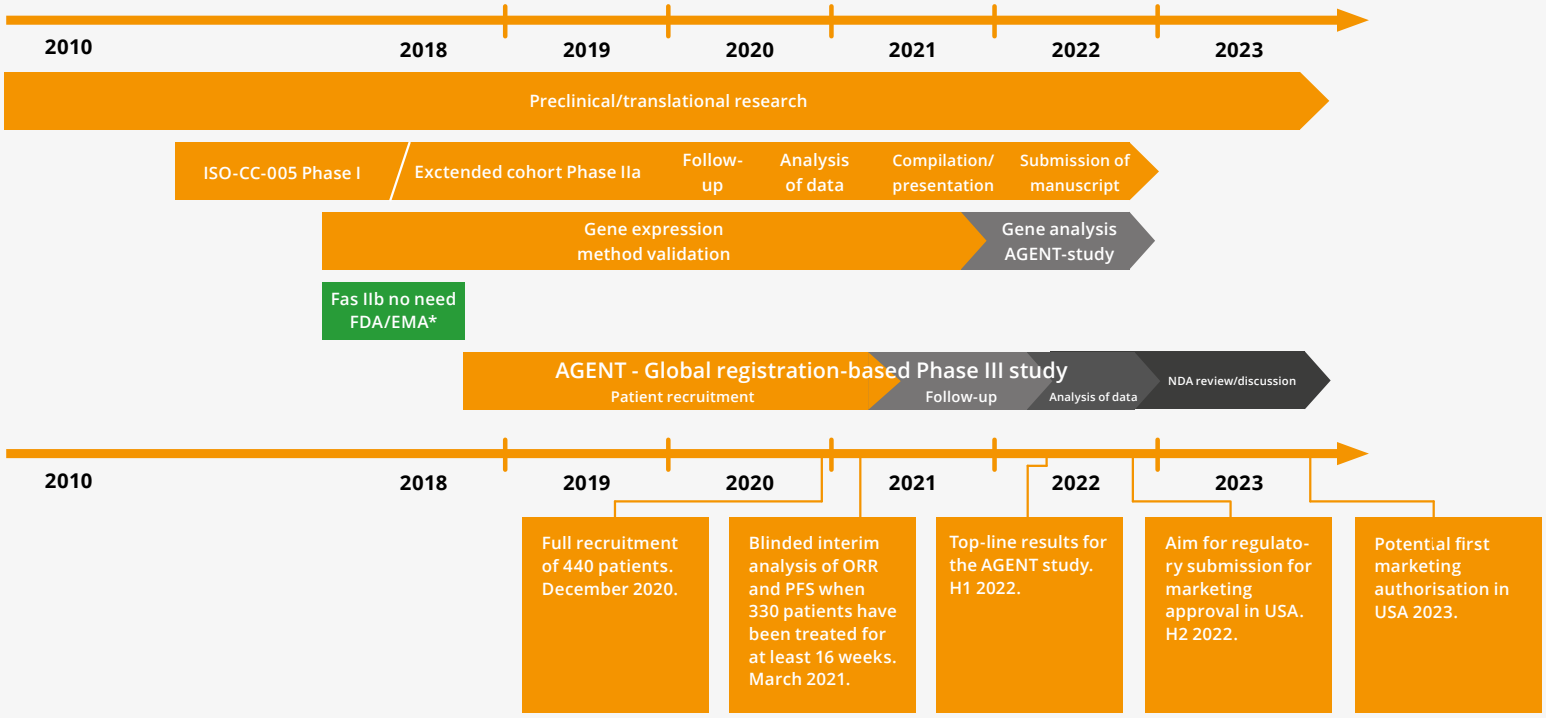
dUMP: Deoxyuridine 5'-monophosphate
dTMP: Deoxythymidine 5'-monophosphate
TS: Thymidylate synthase
[6R]-MTHF: [6R]-5,10-methylenetetrahydrofolate
5-FU: 5-fluorouracil

IND status and Fast Track Designation enable a shorter path to market

Isofol has been able to significantly shorten the development time for arfolitixorin by approximately three to four years. This has been possible because the pharmaceutical authorities (the FDA in the US and the EMA in Europe) have granted Isofol approval to move directly from a Phase I/IIa study to the ongoing global pivotal Phase III AGENT study as an investigational new drug (IND) in the US.

In addition to its IND status, Isofol was granted Fast Track Designation for arfolitixorin by the FDA in November 2021. A Fast Track Designation is granted in order to ensure that new treatments can become available faster for patients with serious diseases, thereby meeting an unmet medical need. The Fast Track Designation allows for a prioritized review process provided that relevant criteria are met, more frequent meetings with the FDA and ongoing evaluation, which means that a drug company can submit completed sections of its NDA for review by the FDA, rather than waiting for the FDA to begin the review until every section of the application is completed. The NDA review otherwise usually does not begin until the drug company has submitted the entire application to the FDA.

Timeline for the development of arfolitixorin



**** According to the FDA/EMA, no Phase IIb study is required for arfolitixorin***

The AGENT study

Isofol's global pivotal Phase III AGENT study (ISO-CC-007) in first-line treatment for mCRC was initiated in December 2018 and conducted in the in US, Canada, Europe, Australia and Japan. The study has two treatment arms: the first group is being treated with arfolitixorin and the second with leucovorin (the current folate-based treatment), both in combination with 5-FU and oxaliplatin as well as the biological drug bevacizumab.

The primary endpoint is the percentage of patients who demonstrate steady tumor shrinkage, either a partial or complete response, called the ORR. Tumor shrinkage should be demonstrated in 55–60 percent of the patients. This means an absolute improvement of ORR by at least 10 percentage points when arfolitixorin is used compared with patients treated in the control arm of the study. The secondary endpoint is PFS, which is the time until the tumor begins to grow again or the patient dies.

Both the EMA and the FDA have approved the study as the basis for an application for market registration (MAA, Marketing Authorization Application in Europe and NDA, New Drug Application in the US), provided that the study results demonstrate a statistically significant improvement in ORR and clinically relevant improvement in PFS.

Special requirements in Japan

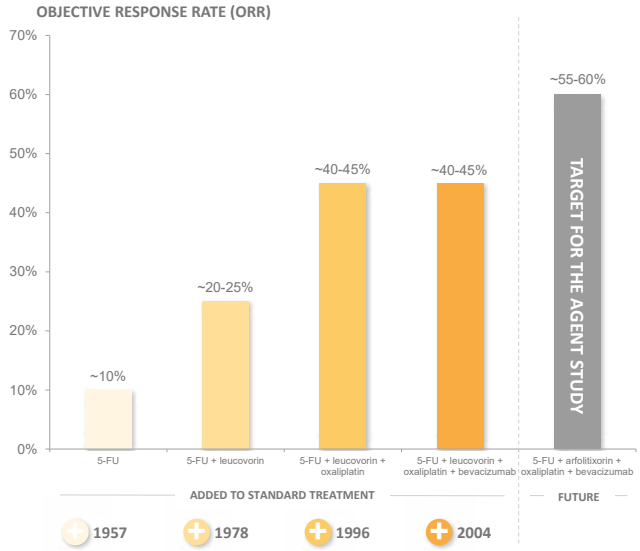
The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) has required that at least 56 patients out of the total study population be of Japanese origin for market approval in Japan. The reason is that the metabolism of Japanese patients tends to differ from patients in other countries, which is why efficacy and potential adverse effects must be evaluated separately.

No opinions on safety or protocol

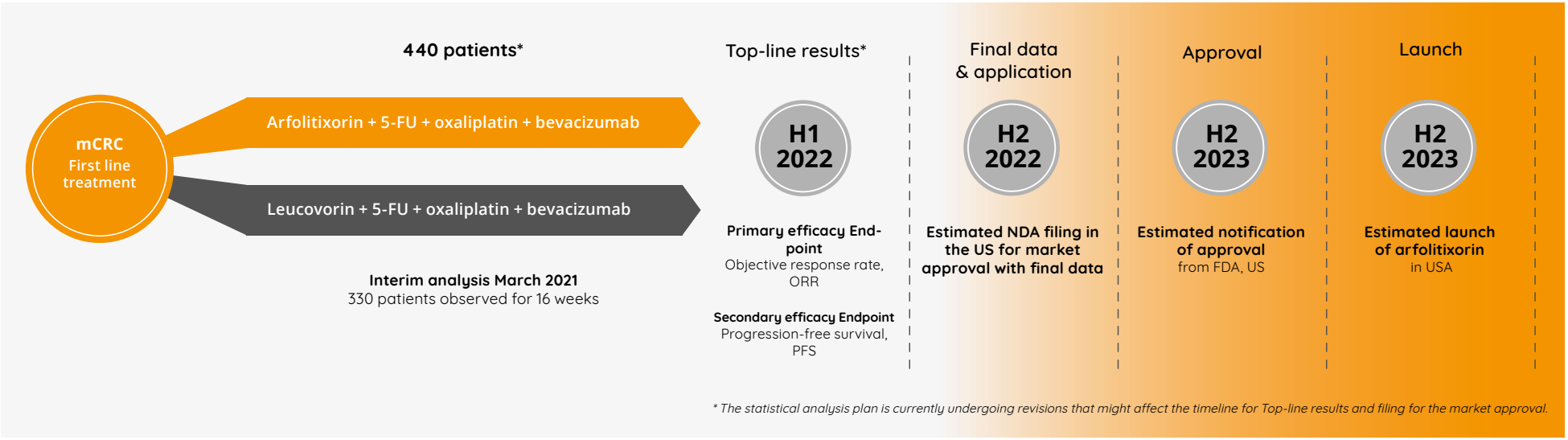
The AGENT study is a "blinded" confirmatory study for which study data is not available to Isofol while the study is in progress. The iDSMB has conducted a total of seven analyses, and none have resulted in remarks concerning safety that need to be addressed or would require the study to be suspended.

Study fully enrolled with follow-ups to come

In December 2020, 440 patients had been enrolled, and the iDSMB's recommendation in connection with the interim analysis in March 2021 was that the study could be completed



Source: 5-FU ORR: Poon MA et al. J Clin Oncol 1989; 7:1407-18; Gustavsson B et al. Clin Colorectal Cancer (2015) 14(1): 1-10.
5-FU+LV, 5-FU + LV + oxaliplatin: Average ORR based on pivotal Phase III studies from a recently completed meta-analysis/ review by Giuliani and Bonetti (2018), First-line therapies in metastatic colorectal cancer: integrating clinical benefit with the costs of drugs. International Journal of Colorectal Disease
5-FU + LV + oxaliplatin + bevacizumab: Pivotal studies N016966 and AVF2107 for bevacizumab (Saltz et al. JCO (2008) 26: 2013-2019; Loupakis F et al BJC (2018) 119:1451-1455)



according to the original study design with 440 patients, which means that the study was then fully recruited. All of the 56 Japanese patients had also been enrolled in May. The remaining patients continue to be treated, and follow-ups and multiple tumor measurements will take place in accordance with the study protocol.

Cut-off point for the read-out process adjusted

Originally, 300 PFS events, either through tumor growth or patient death, were the cut-off point for when the read-out process can begin, with subsequent compilation and statistical analysis of top-line data and final data. During autumn 2021, more patients than expected proceeded to other treatments before they reached documented tumor progression, and as a result the study was unable to achieve 300 PFS events. Isofol presented its opinions on the censoring rule that should be applied, but the FDA maintained that it was not appropriate to change the protocol during the ongoing study. Isofol has requested that the SAP to be adjusted and on April 22 consensus was reached which enabled the initiation of the completion and analysis of the study database.

Top-line data and application for market approval

Analysis of study data in the AGENT study could begin on April 22, 2022, leading to that the work of compilation, quality assurance and statistical analysis is in progress has been started. The analysis is estimated to take two to four months before when top-line results can be communicated and another three to four months before the publication of final data. If the data is determined to meet the established endpoints when the final analysis is complete (which is expected by the end of 2022), and is therefore sufficient for MAA/NDA, the AGENT study will serve as the basis for an application for market approval in the US. The objective is to submit the NDA to the FDA by the end of 2022 and notification of approval may be received in 2023, at the earliest.

Impact of genetic conditions

In parallel with the study, the gene expression test is also being optimized further in order to optimize analyses of patient data from the AGENT study. The purpose of this analysis is to study whether there are subgroups among the patients that are significantly more likely to respond to treatment with arfolitixorin compared with the control arm. The results of the gene expression analysis are expected to be presented when the final data from the AGENT study is available.

“WE ARE A SMALL ORGANIZATION AND WE TRULY SUPPORT ONE ANOTHER.”

Karin Gedda has worked at Isofol since 2018 and is responsible for the company’s operations and the implementation of the clinical studies with arfolitixorin for CRC.

What are you responsible for at Isofol?
I started at Isofol in 2018, and at that point the AGENT study was in the preparatory phase, which included selecting suppliers and finding the clinics and investigators who would be involved in the study. Today, I lead the work on the AGENT study, which includes assigning tasks to my colleagues and handling contacts with contracted sub-suppliers. I basically make sure we carry out the AGENT study as successfully as possible.

What did you do before joining Isofol?
I graduated as an analytical chemist from the University of Gothenburg and started my career at AstraZeneca in 2001. Until 2013, I worked at the analysis lab on various late-phase development projects. This initially involved lab work and preparing documentation for drug applications, etc. Then I changed track and started working on quality issues related to good manufacturing practice (GMP) and good laboratory practice (GLP). In 2013, I started working on late-phase clinical studies and was specifically responsible for the drug-related aspects. At that time, I joined a group of experts at AstraZeneca that provided support for the various clinical projects and compiled best practice that benefited the entire organization. I was also responsible for contacts with clinics and participating in investigator conferences in order to initiate studies.

What is your main focus in 2022?
Above all, carrying out the preparations for submitting our market application in the US. This work requires an enormous amount of documentation and is being performed in close collaboration with our regulatory experts. We also have a number of patients in the study who still need to be followed up, which includes ensuring that the drug is distributed to the clinics, that follow-ups required by the study protocol are carried out and that data is collected correctly in our systems. The pandemic hasn’t created any major problems for us in this regard. We have been able to conduct the study as planned.

How would you describe Isofol as a workplace?
We have a great team of colleagues who come from different backgrounds but are all solution-oriented and collaborative in their approach. Isofol has the advantage of having short decision-making paths, and everyone rolls up their sleeves to do what needs to be done. We are a small organization so everyone needs to do their part and we truly support one another. The company doesn’t have the resources and processes of a larger organization. We have to find ways to solve tasks. Isofol has also succeeded in establishing a strong sense of solidarity with our sub-suppliers, especially since we have worked with several of them for many years. Our collaborative approach has really paid off in this respect.

“Isofol has succeeded in establishing a strong sense of solidarity with our sub-suppliers.

Karin Gedda, VP Clinical Operations

A STRONG PATENT PORTFOLIO INCREASES VALUE

Isofol has an active intellectual property strategy that covers all of its important markets. The patent portfolio encompasses formulation technology, dosage regime and use.

Protecting company and business secrets is a requirement for Isofol to succeed in achieving the vision it has established. The company's intellectual property is protected primarily through patents and patent applications. Isofol works continually and proactively to protect its intellectual property rights for arfolitixorin.

The patent portfolio consists of several types of patents: ingredients, formulations and how they are to be used in treatment.

Arfolitixorin currently has patent protection in the US, Europe, Japan, Canada, Australia, South Korea and Ukraine for most major forms of cancer until 2038. The active ingredient, the arfolitixorin salt, is patent protected until 2037 in the US and until 2034 in the rest of the world (for example, Europe and China). New patents for the treatment of CRC until 2039 are also expected to be granted in the near future.

Accordingly, the company's patent protection in Europe was strengthened during the first quarter of 2021 through the approval of its clinical use patent, which includes dosage regimes and use in combination with 5-fluorouracil and other anticancer drugs, such as oxaliplatin, irinotecan and bevacizumab. New patent applications for dosage regimes were also submitted in the third quarter of 2021, and the company plans to further strengthen its patent protection in 2022.

We have a full-time employee in the patent area dedicated to supervising two important partners in the management and defense of our growing portfolio.

ISOFOL'S MAIN PATENTS

Patent no.	Patent	Type	Expiration year	Patent granted in	Application being processed in
US 10,059,710 B2 US 10,336,758 B2 US 10,570,134 B2	Arfolitixorin (6R-MTHF)	Ingredient/ Formulation/Use Pharmaceutical compositions	2037 2037 2037	US	
WO 2015/022407 EP 3033344 B2 JP 6617104 B JP 6735321 B JP 6764501 B CA 2,921,178 B	Arfolitixorin (6R-MTHF)	Ingredient Pharmaceutical compositions Use Processes	2034 2034 2034 2034 2034 2034	Europe (36 countries), Japan, China, Australia, New Zealand, Mexico, Israel, South Africa, Singapore and Hong Kong	South Korea, Brazil and India
US 9,180,128 B2	Composition with citrate	Formulation/Use	2029	US	
EP 1641460 B2 JP 4755980 B CA 2,529,531 B	Composition with citrate	Formulation/Use	2024 2024 2024	Europe (12 countries) Japan, Canada, Australia, China, India, South Korea, Mexico, Russia and South Africa	
WO 2018/065445 US 10,328,078 B2 US 10,639,311 B2 EP 3446706 B1 JP 6734308 B CA 3,073,608 B	Dosage regimes	Use	2038 2038 2038 2038 2038 2038	US, Europe (21 countries) Japan, Canada, South Korea, Russia and Hong Kong	China, Taiwan, Singapore, Australia, Israel, Mexico and Brazil
WO 2018/065446 US 11,013,744 B2 EP 3446705 B1	Dosage regimes	Use	2038 2038 2038	US, Europe (21 countries), South Korea and Russia	Japan, Canada, China, Taiwan, Singapore, Australia, Israel, Mexico and Brazil
WO 2018/150264 US 10,292,984 B2 US 10,639,311 B2 US16/866,276 (Allowed)	Enzyme inhibition, measurement of biomarkers in blood	Use	2038 2038 2038 2038	US, Australia and Ukraine	Europe, Japan, Canada, China, Taiwan, South Korea, Mexico, Singapore, New Zealand, South Africa, Israel, Hong Kong, Russia, Brazil + six other countries
WO 2019/135157	Dosage regime for ongoing clinical study	Use	2039		US, Europe, Japan, Canada, China, South Korea, Taiwan, Hong Kong, Singapore, South Africa, Israel, Mexico, Australia, Russia
WO 2015/114099 US 10,487,364 B2 EP 3099816 (Intention to Grant)	Measurement of gene expression prior to clinical treatment	Use	2035 2035 2035	US, Europe (allowed), Australia (allowed), Hong Kong	Canada
PCT/EP2021/076512	Dosage regimes	Use	2041		PCT
PCT/EP2021/076513	Dosage regimes	Use	2041		PCT
PCT/EP2021/076515	Dosage regimes	Use	2041		PCT

INITIATIVES TO MAXIMIZE ARFOLITIXORIN'S COMMERCIAL POTENTIAL

Provided that the outcome of the ongoing pivotal Phase III AGENT study is positive, Isofol's aim is for the market approval of arfolitixorin to be issued by the FDA at the end of 2023. Isofol is intensively engaged in a number of preparatory activities in order to create the most favorable possible conditions for the commercial launch. The company is thus prepared to commercialize arfolitixorin on its own, which strengthens the company's negotiating position with future partners.

In 2021, Isofol increased its focus on pre-commercial preparations, such as detailed analyses of mCRC markets in the US and Europe, including an analysis of how CRC patients are currently being treated in order to better understand and optimize arfolitixorin's future positioning in these markets. The preparations enhance the company's preparedness and position ahead of licensing negotiations with international players. A possible partner will probably value the potential for the drug more highly if they can take over a product for which the pre-commercial preparations are in progress, so that they do not need to perform comprehensive preparations in a short time. This also creates good prospects for independently commercializing arfolitixorin.

Updated market data confirms the need for new treatments for CRC.

In 2021, previously conducted market analyses were updated and strategies were prepared for market access, an analysis of the potential of the Chinese market and a needs analysis of the colorectal market were carried out, and the patient journey for CRC patients was reviewed.

An update of previously conducted market analyses was also completed, and the findings confirm the need for new treatments for CRC. In the updated surveys, approximately 350 physicians provided their opinions on the place of arfolitixorin in future treatment regimes. Provided that the AGENT study reaches its set targets, physicians conclude that arfolitixorin constitutes a distinct improvement compared with current treatments. In addition, payers questioned in the US, the EU 4 and the UK confirmed that arfolitixorin has an acceptable product profile provided that the study reaches its set targets. The findings will constitute an important component in discussions with potential partners and serve as a framework for pre-commercial preparations. In all, the analyses performed in 2021 confirmed that the previously assessed blockbuster potential is still well founded.

Work on market analyses and market access will continue in 2022, including health-economic models and compilation of the Global Value Dossier. The company's continued strategy for its pre-commercial preparations is dependent on the outcome of the AGENT study.

Strong patent protection provides the potential for the treatment of additional forms of cancer

Arfolitixorin is patent protected until 2038 in the US, Japan, Canada, Australia and Ukraine, and until 2034 in the rest of the world (for example, Europe and China), which means that there is potential for the treatment of additional forms of cancer under the patent protection. In addition to CRC, other solid tumors are also treated with the drug combination of 5-FU and folates, including tumors in the pancreas and stomach. Arfolitixorin's mechanism of action is the same for these forms of cancer as for CRC and the potential advantages of using arfolitixorin may be the same. These indications will require further clinical studies in order to secure regulatory approval, something which Isofol is evaluating.

INVESTMENT IN MEDICAL AFFAIRS INCREASE AWARENESS OF ARFOLITIXORIN

In 2021, Isofol began the process of increasing awareness of the drug candidate arfolitixorin, primarily in the US, in order to ensure awareness of arfolitixorin and the potential to add to the treatment arsenal for advanced CRC.

Despite a constantly rising incidence of CRC, no new all-comer treatments for mCRC patients, regardless of genetic profile, have been approved for first-line treatment in almost 20 years. In a market with established treatment regimes, a medical affairs organization is required to raise awareness of new drug candidates by building relationships with the medical community and relevant external medical experts (key opinion leaders, KOLs) ahead of a potential launch.

Isofol and a reputable commercial partner are conducting several activities that focus on medical affairs. The activities are being conducted in preparation for the potential commercial launch that will follow a positive outcome from the ongoing AGENT study. Like the company's other preparations to take arfolitixorin to market, efforts in this area intensified in 2021, and these activities will accelerate in the next few years. This work will primarily be conducted in and focus on the US market and be performed by medical science liaisons (MSLs), who are highly qualified medical personnel. The first MSL based in the US was recruited in 2021, and additional MSLs will be recruited in the next few years.

The MSLs' duties largely involve serving as a liaison between Isofol and external medical and scientific experts. Sharing the company's medical scientific data and obtaining information such as clinical observations are both important parts of these duties. The MSLs attend relevant scientific conferences in order to stay up to date on new clinical discoveries and maintain relationships with the medical community. They also meet with advisory boards and KOLs in order to learn from the expertise of leading CRC experts and thereby optimize Isofol's clinical program. In the future, they will train oncologists and other healthcare specialists concerning arfolitixorin's efficacy and safety. They also plan and conduct activities for important interest groups. They work closely with relevant clinics in the field.

ARFOLITIXORIN – A POTENTIAL CORNERSTONE OF STANDARD TREATMENT

There is a great need for improved treatment of mCRC. Even though medical advances have been made in the treatment of mCRC in recent years, these advances have been focused on niche patient populations. Arfolitixorin has the potential to become part of standard treatment, and it is considered a potential blockbuster in terms of market value, meaning annual sales of over USD 1 billion.

CRC – an increasingly prevalent form of cancer

The number of people who develop CRC every year is steadily increasing. In 2020, it was estimated that 1.9 million people worldwide had been diagnosed with CRC. By 2040, the number of new cases is expected to amount to 3.1 million, an increase of 60 percent.

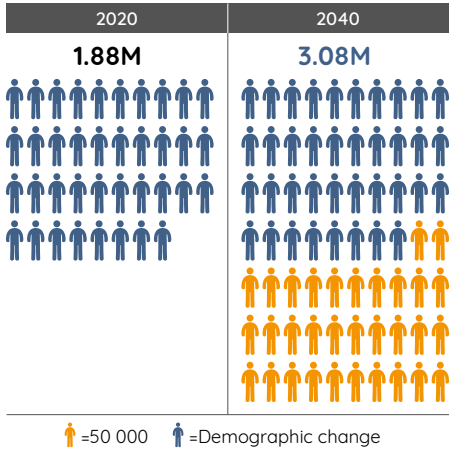
No new drug for "all-comers" since 2004

Although numerous CRC drug candidates are in clinical development, only a small number of medications are being developed for first-line treatment. Few projects have succeeded in reaching Phase III due to the complexity of the disease. No new drug candidates for the treatment of all-comers, meaning all mCRC patients regardless of genetic profile, in first-line treatment have been approved since 2004, and there are currently only a small number of projects in the late development phase.

One of the reasons for the pressing need for new treatments is that, compared with breast and lung cancer, mCRC patients have very few target molecules that can be attacked with new drugs. New drugs such as immunotherapies are targeted to specific patient subgroups. PD-1 inhibitors such as pembrolizumab are only effective for approximately 4 percent of mCRC patients. B-RAF inhibitors such as encorafenib and binimetinib are effective for approximately 8–10 percent of mCRC patients.

Great potential to be a cornerstone of standard treatment

The long-established standard regimes of 5-FU-based cytostatics, which are the standard treatment for more than 70 percent of mCRC patients, are expected to remain the standard treatment for the foreseeable future. This is because there are no drug candidates under development that are intended to replace the current standard treatment.



>60 %

A strong argument in the future marketing of arfolitixorin is that the product can be added without any major changes to the treatment strategy. Today's existing treatment options are also largely generic, which means they do not have an active sales force and are not exposed to competition from patent-protected products. As a result, the pressure from potential competitors in the market for arfolitixorin is deemed to be low.

Since arfolitixorin may be part of a cornerstone of standard treatments involving 5-FU for other forms of cancer, its commercial potential is considered to be high provided that it is approved for each disease area, also considering the long term remaining for its patent.

Significant market potential

The total drug market in the eight largest global markets for the treatment of CRC amounted to USD 7.6 billion in 2018 and is expected to grow to about USD 10.6 billion by 2028. The reason for this relatively modest market growth is that few new drugs have been launched or will be launched in the coming years. In addition, sales of drugs that have been launched recently or will be launched (not counting arfolitixorin) are expected to be relatively low since these drugs can primarily help only a smaller subgroup of CRC patients.

In the seven largest markets (the US, the EU 4, the UK and Japan), about 370,000 patients are diagnosed with mCRC each year. About 170,000 of these patients annually constitute Isofol's primary market – first-line treatment.

The estimated average treatment time is nine months for first-line treatment in clinical practice, which is a conservative assumption for estimating market potential based on the expected improvement of PFS in the AGENT study.

About another 60,000 patients (in the same geographical regions) are assessed to be able to receive second- or third-line treatment, should market approval also be received for these treatment lines. The treatment times are believed to be shorter in these cases, amounting to six months at the most in second-line treatment and about three months in third-line treatment.

One of the most promising candidates according to the market-analysis company GlobalData

In 2020, the UK market-analysis company GlobalData published a forecast for the CRC market between 2018 and 2028 for the eight largest markets: the US, the EU 4, the UK, Japan and China. The report describes arfolitixorin as one of the most promising drug candidates for CRC.

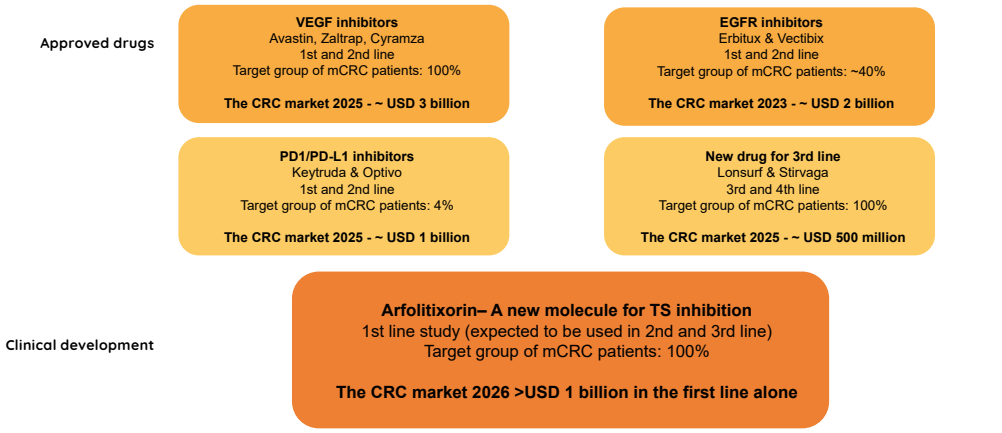
Strong interest

Isofol has conducted several market surveys that collectively demonstrate a strong interest in prescribing arfolitixorin after it receives market approval. Demand may grow rapidly when arfolitixorin is launched, and there is potential to achieve high market penetration. Through previous market and payer analyses, Isofol has determined that annual sales of arfolitixorin in the largest global markets could amount to USD 1 billion annually, corresponding to blockbuster potential.

An update to previously conducted market analyses was begun in 2021. The analysis and evaluation of the data collected confirm the need for new treatments for CRC. In the updated surveys, approximately 350 physi-

THE GLOBAL MARKET FOR CRC AROUND 2025 (7 MM)

Arfolitixorin is expected to be used in first through third-line treatment with expected maximum sales of over USD 1 billion annually

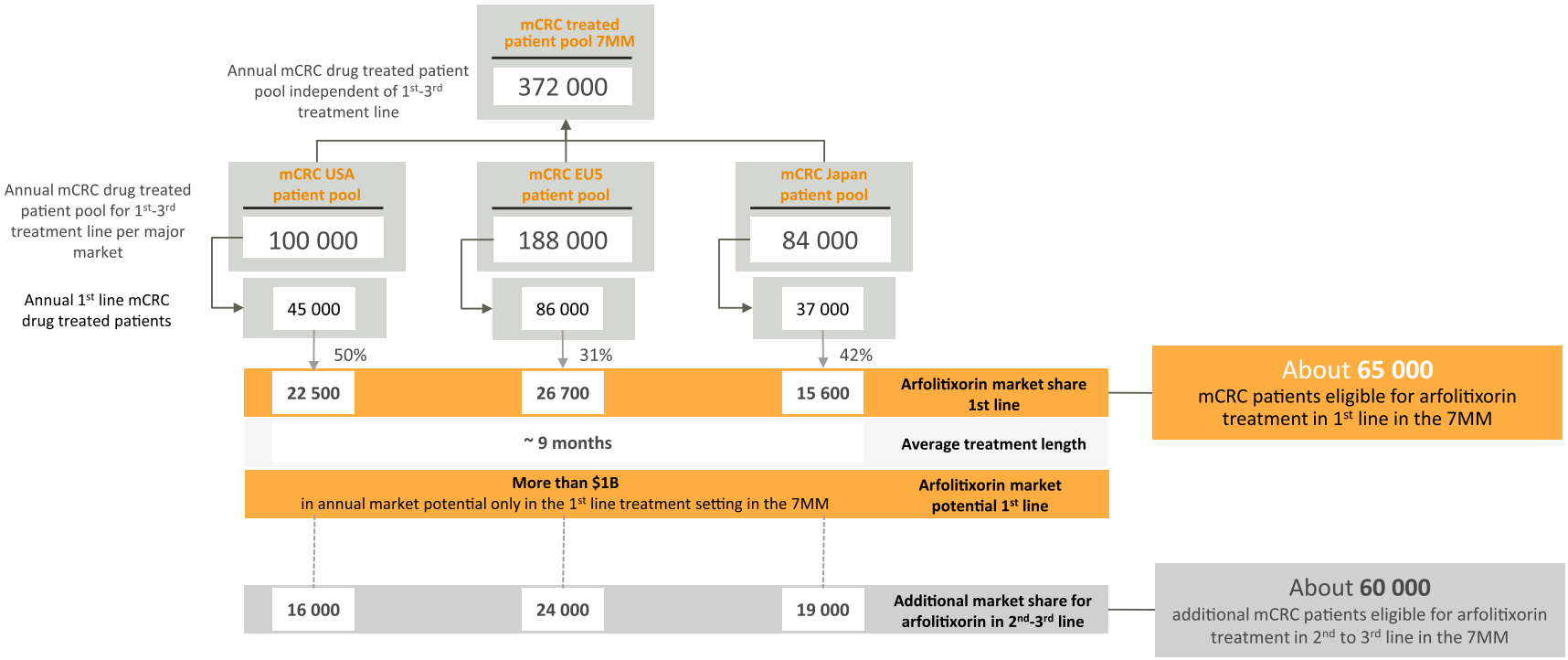


One possible comparison is Roche's drug Avastin, which has historically had annual sales of about USD 3 billion annually for CRC alone.

cians provided their opinions on the place of arfolitixorin in future treatment regimes. Provided that the AGENT study reaches its set targets, the survey shows that the physicians who participated in the survey believe that arfolitixorin constitutes a distinct improvement compared with current treatments. In addition, payers surveyed in the US, the EU 4 and the UK confirmed that arfolitixorin has an acceptable product profile provided that the study reaches its set targets. The findings will constitute an important component in discussions with potential partners and serve as a framework for the planning of commercialization efforts.

Isofol has also analyzed licensing and acquisition deals completed in the oncology area, and found that six global and 25 regional transactions that are relevant as reference points were completed in recent years. The average value of global licensing and acquisition deals is about USD 1.2 billion, while regional licensing and acquisition deals were valued at USD 22–590 million depending on the region. Even if there are several differences between the companies in the above-mentioned analysis and Isofol, the analysis could serve as an indication of how partners and investors value companies with varying clinical portfolios.

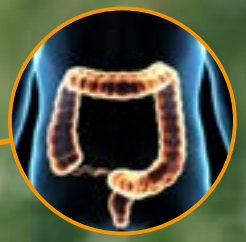
Patient target group and potential share for arfolitixorin



Source: *1.) GLOBOCAN 2018, Cancer Incidence and Mortality Worldwide. 2.) GlobalData 2017. 3.) GlobalData Colorectal Cancer: Competitive landscape to 2026. 4.) Deallus Market research and forecast model 2018.*

CRC – THE THIRD MOST COMMON FORM OF CANCER

CRC, also known as intestinal or rectal cancer, is a form of cancer that arises from uncontrolled cell growth in the large intestine, rectum or appendix. The disease often develops slowly for several years. It begins as a protruding tissue growth, called a polyp, that starts out in the mucus membrane and then grows into the intestinal cavity. Polyps can be cancerogenic, meaning they can develop into a cancer if they are not removed. Eventually, the cancer can break through the intestinal wall and spread to other organs. This is known as metastatic colorectal cancer, or mCRC.



CRC – THE THIRD MOST COMMON FORM OF CANCER

CRC, also known as intestinal or rectal cancer, is a form of cancer that arises from uncontrolled cell growth in the large intestine, rectum or appendix.

The disease often develops slowly for several years. It begins as a protruding tissue growth, called a polyp, that starts out in the mucus membrane and then grows into the intestinal cavity. Polyps can be cancerogenic, meaning they can develop into a cancer if they are not removed. Eventually, the cancer can break through the intestinal wall and spread to other organs. This is known as metastatic colorectal cancer, or mCRC.

The third most common form of cancer

CRC is the third most common cancer diagnosis globally after lung and breast cancer, and the second deadliest. It affects both men and women with an equal distribution between the genders. However, there are differences in its localization, as more men are affected by rectal cancer and more women by colon cancer. CRC mainly affects older people, with the majority becoming ill after the age of 70. The global incidence (the number of new patients who are diagnosed with this form of cancer annually) was just over 1.9 million patients a year in 2020, while about 935,000 died from the disease that year.

The causes are both environmental and hereditary

As with most other forms of cancer, there is no single known triggering factor for CRC. It is believed that the risk can be affected by diet and hereditary factors. Smoking and lifestyles leading to obesity also increase the risk.

High mortality

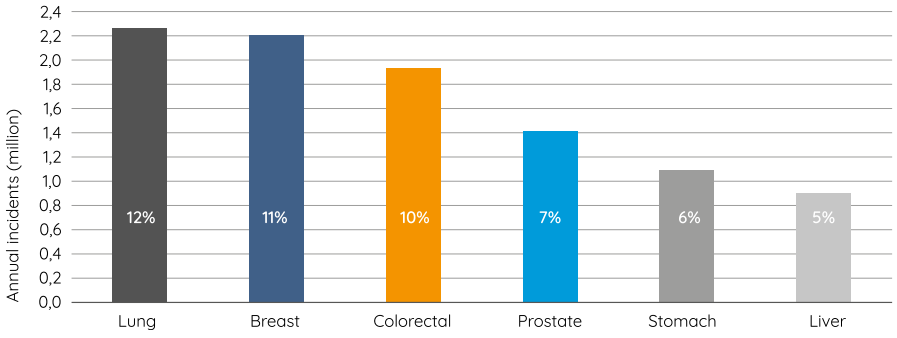
Despite improvements in the prognosis for patients with CRC over the past decade, the prognosis for survival is worse compared to patients with breast or prostate cancer, and CRC is the second most common cause of global cancer-related death after lung cancer. The prognosis for survival is better with an early diagnosis. CRC can be detected early by screening stool samples for blood, which reduces mortality. Patients in later stages, when the cancer has spread to other organs (known as metastases), have a worse prognosis and significantly higher mortality. Only 10 percent of patients with mCRC are still alive five years after diagnosis.

Treatment of CRC

The genes of CRC cells mutate over time. This means that cytostatic treatment must be tailored if it is to be fully effective, a challenge commonly found with most forms of cancer. New drugs are continuously being introduced, usually as supplements to existing drugs rather than as replacements. These supplementary treatments are included in new combinations intended to increase the effectiveness of the treatment. The 5-FU-based combination with which arfolitixorin is being tested is a basic treatment for CRC and is likely to remain so for the foreseeable future.

As CRC develops into more advanced and metastatic stages, the use of cytostatics, biological and other targeted drugs increases. Sometimes radiation treatment is administered, particularly for patients with localized tumors. Targeted therapies are less effective since the rate of mutation in CRC patients is high (microsatellite instability).

10% OF THE FORMS OF CANCER DETECTED ANNUALLY ARE CRC[1]



Source: 1) GLOBOCAN 2020, Cancer Incidence and Mortality Worldwide
2) GlobalData 2020

10% of stage IV patients survive for five years[2]

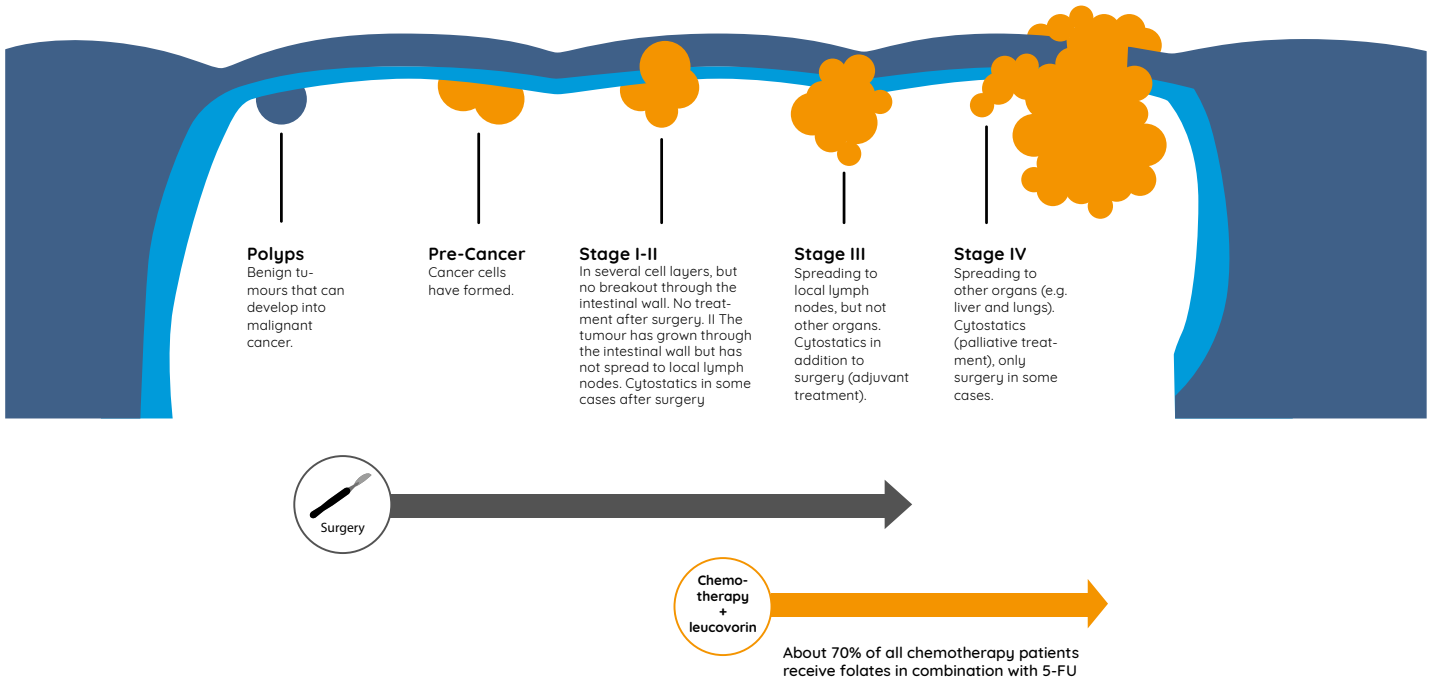
1.9 million annual global diagnoses

Stage IV – initial area of treatment for arfolitixorin

At stage IV, when the cancer has spread beyond the intestines, surgery is often avoided as it does not positively impact the prognosis. Surgery is only performed in cases where, for example, the tumor is mechanically blocking the intestinal passage. Cytostatics are the primary treatments and are intended to relieve symptoms and extend patient survival. Other forms of therapy are sometimes used as well. Even though recently developed drugs have been introduced to supplement existing combinations and to improve treatment outcomes, according to Isofol and the company's international clinical experts, the 5-FU/folate-based treatment combination is also expected to serve as the basis for the treatment of CRC in the future. Despite additional treatment alternatives being introduced, this combination has made the largest contribution to increased survival over time; see the adjacent illustration of the stages of CRC.

Radiation treatment, which plays a prominent role in the treatment of many forms of tumors, is used primarily for tumors in the rectum (rectal cancer). Immunotherapy uses the patient's own immune system to inhibit the tumor disease. Immunotherapeutic drugs, which have recently garnered considerable attention, have to date had limited clinical value for patients with CRC. At present, immunotherapy is primarily applicable within small, well-defined groups of CRC patients (only around 4 percent of patients with mCRC benefit from treatment with current immunotherapies).

STAGES AND TREATMENT OF COLORECTAL CANCER



AN ORGANIZATION THAT FOCUSES ON TWO AREAS – CLINICAL STUDY AND COMMERCIALIZATION

Isofol has in-house expertise in the company's two principal fields – the management of clinical studies and commercialization. There are established partnerships in place for other areas.

To give its ongoing drug development the best prospects for success, Isofol has functions encompassing medical expertise, management of clinical studies, quality assurance, CMC (chemistry, manufacturing and controls), business development, commercialization, finance and legal. All of these functions are needed in order to maintain a high degree of efficiency, quality and flexibility.

A dynamic organization

Skilled and dedicated employees are the foundation of our business. Isofol is a dynamic organization with a clear objective to develop new and improved treatments for patients. The company's organization is characterized by a high degree of expertise, quality, flexibility, innovation and cooperation.

At Isofol, we work in efficient interdisciplinary teams that create a dynamic corporate culture. Active knowledge exchange in our internal and external networks and partnerships with academic institutions and other partners contribute to the individual development of our employees. Isofol values diversity, equal opportunity and responsibility, and views the knowledge, creativity and commitment of all of its employees as the key to success. Its operations are based at the head office in Gothenburg, with modern and functional office premises. Two thirds of the employees work in research and development, meaning everything concerning clinical development, while the rest work in business development, accounting, IT and administration.

Executive management

The CEO leads the work of the executive management team and is responsible for the overall development of the company's activities and business. In addition to the CEO, the management team consists of three (3) people: the Chief Medical Officer (CMO) & Senior Vice President of Clinical Development (SVP); the Chief Commercial Officer (CCO); and the Chief Financial Officer (CFO) & Vice Chief Executive Officer (vCEO). At the beginning of 2022, Jenny Sundqvist took over the position of Chief Commercial Officer (CCO) and is thus a member of the company's management group and leads the company's licensing and commercialization work.

Advisory board and senior advisors

Isofol's Board Of Directors possesses solid international expertise in oncological clinical development and commercialization. We have also established an external advisory board consisting of world-leading colorectal oncologists who are at the company's disposal in its work on the clinical development and study plan. A list of these advisors can be found on Isofol's website. Isofol's founder, Bengt Gustafsson, is now a senior advisor to Isofol on folate research.

Partners

In addition to its own organization, the company has established a number of partnerships in order to bring arfolitixorin to the market.

The Surgical Oncology Laboratory – the folate research experts

The Surgical Oncology Laboratory (SOL) at Östra Hospital in Gothenburg conducts research into surgery and oncology. SOL has internationally recognized knowledge concerning research into folates, particularly with regard to folates and CRC, and cutting-edge expertise in molecular biology. Isofol's founder, Professor Bengt Gustavsson, is also the founder of SOL.

Merck & Cie – experts in ingredient processing

Merck & Cie is a subsidiary of Merck KGaA in Germany, with which Isofol has a strategic research and development partnership. The partnership, which has been formalized in a global licensing agreement, offers numerous synergies, where Isofol possesses specialist knowledge in the use of arfolitixorin for the treatment of cancer and Merck has the knowledge to synthesize a stable API (active pharmaceutical ingredient) of [6R]-MTHF and to formulate a stable drug with a long shelf life.

Recipharm – commercial manufacturer

Recipharm is the commercial manufacturer of arfolitixorin, and it is engaging in preparations together with Isofol and Merck to ensure a commercial full-scale production method for the future.

Contract research organization

A contract research organization (CRO) is a company that assists with the practical implementation of clinical studies, something that is entirely necessary for a company of Isofol's size. A CRO may, for example, provide statistical calculations and analyses, have databases for study data, work with preclinical studies, mark and distribute drugs for studies and assist companies when resources and geographic distance make it difficult to work directly with hospitals. Isofol partners with international and local CROs such as Envigo, TFS, IDDI, LINK Medical Research, Precision for Medicine, Quartz-Bio, PK-Expert, Novotech, CMIC Shiftzero K.K., Banook Group, Vigipharm and others.

Patent issues
Isofol works continually on patenting the intellectual property rights for the company's drug candidate, arfolitixorin. It takes a structured approach by working closely with internal and external experts, both national and international.

Medical affairs
Despite a rising incidence of CRC, no new all-comer treatments for mCRC patients, regardless of genetic profile, have been approved for first-line treatment in almost 20 years. In a market with established treatment regimes, initiatives are needed to raise awareness of new drug candidates by building relationships with the medical community and relevant external experts ahead of a potential launch in 2023 in the US. In order to achieve this, the first field-based medical employees (medical science liaisons or MSLs) were recruited in the US during the fourth quarter of 2021. Their job is to raise awareness of arfolitixorin in the US market. This recruitment was made possible through a partnership between Isofol and its commercial partner.

Commercialization
In 2021, Isofol moved from the clinical development phase to a pre-commercial phase. Our close partnerships with several established and recognized commercial consultants were intensified in order to support this transition. Several partners supported us with market surveys, data collection, and strategy and brand development.

We also intensified our efforts to evaluate various market launch alternatives, and thus worked even more closely with Shadow Lake Group, which supported us in the identification, evaluation and negotiations with potential partners. Shadow Lake Group has assisted Isofol in the past with the licensing deals it has already completed in Japan and Canada.

Contract and legal issues
Vinge Advokatbyrå in Gothenburg
Setterwalls Advokatbyrå AB

Pharmaceutical regulatory issues
B&H in the US and NDA Group in Europe and the US

"Companies that invest heavily in intellectual property rights must work actively with patent issues to protect their product portfolio.

Per Lindberg, Patent Strategist

Per Lindberg graduated in organic chemistry from the Faculty of Engineering at Lund University in 1977 and has been an associate professor of organic chemistry at Chalmers University of Technology since 1982. Per started his career at the Department of Pharmacology at the University of Gothenburg under Professor Arvid Carlsson, who won the Nobel Prize in Medicine in 2000. In 1982, Per began working at Hässle, which was later bought out by Astra and is now AstraZeneca R&D. At AstraZeneca, Per worked on the development of various drugs including Losec®/Prilosec® (omeprazole) and later became the main inventor of Nexium® (esomeprazole). During his time at AstraZeneca, Per was involved in in-depth analyses of both scientific and IP matters and was instrumental in driving changes and improvements to AstraZeneca's global patent filing strategy. As one of the most experienced researchers in the area of Losec/Prilosec and Nexium, he played a leading role in the development of the patent strategies for these drugs.

He has authored some 50 publications in medicinal chemistry, organic chemistry and pharmacology and owns about 35 inventorships. In 2006, he received the Swedish Academy of Pharmaceutical Sciences Prize in Medicinal Chemistry. Since 2012, he has been an independent patent and scientific consultant focusing on patent strategies.

“ESTABLISHING STRONG PATENT PROTECTION IS AN IMPORTANT PREREQUISITE FOR SUCCESS”

Isofol has worked with patent consultants Per Lindberg and Gunnel Sundén for many years in order to protect the company’s intellectual property. The aim of the collaboration is to take a proactive approach to patent-related issues and to create a link between research and legal considerations in order to establish strong protection for Isofol’s patents.

What does your assignment for Isofol involve?

My colleague Gunnel Sundén and I have worked actively with Isofol, external patent lawyers and Merck & Cie for many years to handle the company’s patent applications and their subsequent protection. We have succeeded in establishing an effective collaborative network within this group and can have discussions as peers and benefit from our individual expertise and experience. For example, the US patent lawyers have extensive experience of patent litigation in the US, and this experience is very useful in our work on new patents. Part of this work involves preparing for future patent disputes that inevitably arise when you develop a successful product. In addition to contributing to the company’s day-to-day work, such as answering questions from patent authorities, our main role is to serve as a bridge between Isofol’s scientific experts and patent lawyers.

In your opinion, what are some of the important things that a drug development company needs to think about to ensure it has strong patent protection?

Firstly, that patent work needs to be led by research and not by patent lawyers. I realized this during my time at AstraZeneca, where I was involved in the development of Losec and Nexium. Not because patent lawyers do a bad job, but because you need to understand the science and research behind the product. Unfortunately, this is too often not the case. It is also important not to apply for patents that are too broad where the company doesn’t have the time to choose the active ingredient, making it difficult to get the patent granted. Down the road, this can also impact the lifecycle management of the patent portfolio, making it difficult, for example, to apply for additional indications. Unfortunately, we have seen far too many instances in the industry where this has created problems for companies.

What is your view of Isofol’s IP situation?

I would say that because we based our work on a scientific perspective and thanks to the group of patent experts that Isofol has engaged, the company’s current IP protection is very good. A few tangible examples of how Isofol has established strong patent protection are that the dosage regime patent was already in progress when the clinical study was initiated and that Merck managed to get an ingredient patent even though the ingredient is basically an endogenous substance that itself is not patentable. Thanks to the uniqueness of the ingredient, it was nevertheless possible to get it approved. I’m a little biased when it comes to Isofol’s patent protection, but in my nearly 50 years in the industry, I’ve seen both good and less good examples.

What will be the focus of the company’s IP work in 2022?

We submitted additional applications in autumn 2021 that will need to be addressed in 2022 to enable approval. We’re also aiming to extend certain patents that have already been approved. Merck also wants to strengthen its patent protection, and we are involved in that work as well. We’ve been able to apply our work on the patent portfolio to make the regulatory processes more productive, and this work will continue in 2022. A proactive approach to patent-related issues is an important prerequisite for successfully protecting a patent portfolio. This was certainly my experience from working on Losec and Nexium, for which the patents were frequently declared invalid, particularly in the US disputes.

DRUG DEVELOPMENT IS THE FOUNDATION OF OUR SUSTAINABLE VALUE CREATION

The company's business concept is to help extend life and improve the quality of life for cancer patients by offering the drug arfolitixorin. Isofol therefore has a strong link to the UN Sustainable Development Goals (SDGs) under the 2030 Agenda, with a specific focus on Goal 3: Good health and well-being.

CRC is the third most common cancer diagnosis globally, and the second deadliest. The need for more effective drugs to treat this disease is very high. Isofol's drug candidate arfolitixorin combined with the cytostatic 5-FU has the potential to become a new standard treatment for patients with advanced CRC, thereby potentially achieving a more powerful anti-tumor effect without diminishing safety. Isofol's primary objective is to improve treatment outcomes for approximately 370,000 advanced/metastatic CRC patients in the US, Europe and Japan.

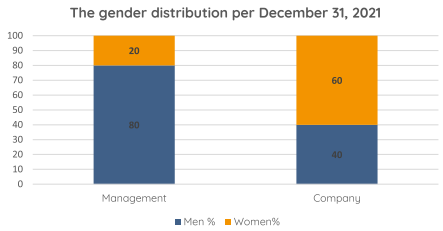
Sustainability is a given for Isofol, and the starting point for the company's sustainability efforts has been to identify the operations and areas that are material and where the company's own efforts can make the greatest difference. Three areas have been identified based on this analysis: employees, production and business ethics.

Employees

The successful implementation of the company's business strategy and the safeguarding of the company's long-term interests, including its sustainability, requires the company to be able to recruit and retain qualified employees. For this, Isofol is required to offer all of its employees a work environment that helps them thrive and develop in their professional careers. Isofol has therefore built an organization that promotes commitment, creativity and quality which also drives the company forward. At the same time, it's important for employeeship to be sustainable and long-term, based on a work environment that emphasizes physical, mental and social well-being. A good work-life balance is the basis for a healthy lifestyle in this context.

Working conditions and ensuring a healthy and sustainable work environment are the employer's responsibility, while the culture is shaped through daily interactions between employees. Employee satisfaction is measured annually through an employee survey. The global Covid-19 pandemic continued in 2021, which meant that work during the year was largely remote, so that managers' work environment responsibility was extra important in order to ensure employees' well-being in relation to their job duties.
Isofol is a knowledge-based organization and every employee has an important role to play, while at the same time it is crucial for the company to have the right expertise throughout its operations. The company supports equal opportunity and works to combat discrimination.

The gender distribution in the executive management team and the company as a whole as of December 31, 2021 is presented below.

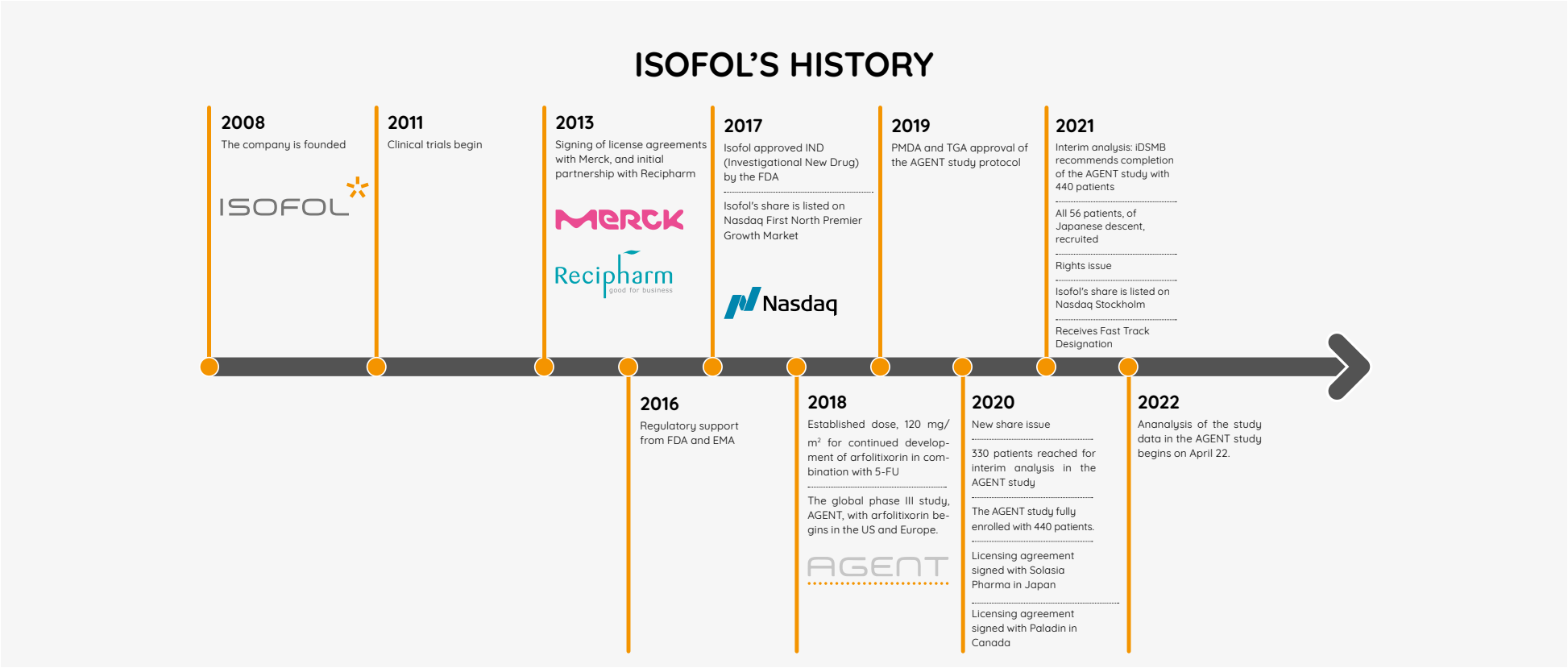


One part of the company's sustainability work involving our employees is to reduce the business's environmental impact by continually weighing the benefits of business travel against its climate impact, and considering virtual meetings instead.

Production

Isofol has high requirements for environmental responsibility. The company's resource consumption must be optimized in order to reduce its impact on the earth and the climate. A large part of our environmental impact comes from the production of the drug candidate arfolitixorin. Isofol has been cooperating with Recipharm, the commercial manufacturer of arfolitixorin, for several years. One important starting point was to begin a partnership with a contract manufacturer that meets the pharmaceutical industry's quality standards (Good Manufacturing Practice, GMP) and already had a clear emphasis on sustainability before the partnership began.

Several years ago, Recipharm established a sustainability framework that rests on Recipharm's core values and the UN Global Compact's ten principles for human rights, labor, the environment and anti-corruption. The company developed internal policies and a code of conduct for sustainability issues based on this framework. Recipharm used a materiality analysis to identify three focus areas for its sustainability efforts: reducing



greenhouse gas (GHG) emissions; assessing and monitoring suppliers; and developing its internal governance.

Recipharm is a signatory of the UN Global Compact and reports its GHG emissions to the Carbon Disclosure Project (CDP). In 2020, 22 of Recipharm's 25 manufacturing facilities were ISO 14001-certified, corresponding to 88 percent of its operations. Reducing energy consumption and GHG emissions is Recipharm's most important environmental goal. In 2020, Recipharm's direct and indirect CO2 emissions amounted to 76,506 tonnes, corresponding to a 20 percent increase compared with 2019. The increase was attributable to the acquisition of new operations. Emissions in relation to sales were lower in 2020 than in 2019, and the relative reduction in GHG emissions was primarily a result of more efficient energy use in manufacturing facilities as well as moving to energy sources with lower CO2 emissions.

Business ethics

Isofol operates in a strictly regulated industry with laws and guidelines, and compliance with established guidelines is therefore critical. Supporting a culture that encourages open discussion of ethics in the business encourages compliance with codes of conduct. Requirements for responsible conduct also apply to external suppliers and partners. They must fulfill and work towards the same guidelines that Isofol follows. Business ethics also encompasses anti-corruption efforts, especially in relation to public officials, government agency employees, healthcare professionals and patient organizations. Employees are encouraged to report suspected wrongdoing, misconduct and violations of codes of conduct.

Isofol's studies follow good clinical practice (GCP), which is an international ethical and scientific quality standard for designing, registering and reporting clinical studies that include human subjects. Acting in accordance with this standard provides assurance that the rights, safety and well-being of the patients included in the study are protected and that data from clinical studies is reliable.

ISOFOL'S SHARES HAVE GREAT POTENTIAL

Isofol is completely focused on the development and commercialization of the drug candidate arfolitixorin, and believes that the company's share has high potential for value growth, provided that the ongoing pivotal study reaches its set targets.

A billion-sized market

A launch in a billion-dollar market with the potential for second and third lines is in sight.

Read more on pages 17-19

Low barriers

Arfolitixorin is in a unique position: no new drug has been launched since 2004, and it is a replacement in a standard regime for the treatment of a growing number of patients.

Read more on pages 17-19

Long-term patent protection

Arfolitixorin has long-term patent protection, which means long-term returns.

Read more on page 14

Fast Track Designation

Isofol has received a Fast Track Designation, which entails more frequent dialogue with the FDA and a faster application process.

Read more on page 10

THE SHARE

Isofol Medical AB's (publ) share has been listed on Nasdaq Stockholm under the ticker ISOFOL since October 21, 2021. The share was previously listed on Nasdaq First North Premier Growth Market.

Share capital

As of December 31, 2021, the share capital of Isofol Medical AB (publ) amounted to SEK 4,945,252 SEK, distributed between 161,515,440 ordinary shares (83,365,966) with a nominal value of SEK 0.0306 (0.0306). All of Isofol's outstanding ordinary shares entitle the holder to one vote. The number of shareholders as of December 31, 2021 was approximately 10,100 (7,800).

Warrant Program 2020 – Series 2020/2023

At the Annual General Meeting held on June 24, 2020, the shareholders resolved to introduce an incentive program for the company CEO. The program was designed as a supplementary program exclusively for the company's CEO, who did not participate in Warrant Program 2018. The program includes a maximum of 250,000 subscription warrants, and will result in a smaller dilution for the company's shareholders since the company is canceling approximately 408,000 subscription warrants from Warrant Program 2018. The maximum of 250,000 subscription warrants entitles the holder to subscribe for a maximum of 370,000 shares (after the completion of the rights issue in June 2020). The subscription price for series 20/23 was set at SEK 37.0 per share.

After recalculation in accordance with the terms of the program due to the company's rights issue in June 2021, the current exercise price for series 20/23 is SEK 30.3 per share (subscription period from May 15 to July 15, 2023).

Warrant Program 2018 – Series 2018/2022 and Series 2018/2023.

At an extraordinary general meeting held on December 17, 2018, the shareholders resolved to introduce an incentive program for all employees in the company and future key employees. The program was designed as a long-term incentive to the company's employees and senior executives and to promote investments in and ownership of the company's shares. The program consists of a maximum of 1,461,698 subscription warrants and is designed in such a manner that the subscription warrants were transferred at market value in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB. At the end of each program, each subscription warrant entitles the holder to subscribe for one new share in Isofol at the applicable exercise price. The subscription price for series 18/22 was set at SEK 51.3 per share and the subscription price for series 18/23 at SEK 76.9 per share.

After recalculation in accordance with the terms of the program due to the company's rights issues in June 2020 and June 2021, the current exercise price for series 18/22 is SEK 28.3 per share (subscription period from May 15 to July 15, 2022) and the current exercise price for series 18/23 is SEK 42.5 per share (subscription period from May 15 to July 15, 2023).

Total dilution

The total dilutive effect for all of the outstanding incentive programs in the Company amounts to 1.5 percent of the total number of shares outstanding and votes in the Company.

Share price trend and liquidity

On December 31, 2021, the share price was SEK 9.24 per share, a decline of 67 percent compared with the closing price on December 31, 2020. The OMX Stockholm Pharmaceuticals & Biotechnology PI-index rose by 6 percent during the same period.

At year-end 2021, Isofol's market capitalization was SEK 1,492 million (2,332) based on the closing price. The highest closing price during the period was SEK 26.0 and the lowest quote during the period was SEK 7.7.

Trading volume

122.3 million (69.7) Isofol shares were traded during the period, corresponding to a turnover rate of 76 percent (83).

Dividend policy and dividend

Isofol is a biotech company and there are no plans to pay dividends in 2021 or the next few years. Dividends may be paid in the future when the Group's results and financial position so permit.

Analysts who follow Isofol

Pareto Securities, Peter Östling
Carnegie Investment Bank AB, Ulrik Trattner
Den Norske Bank, Equity Research, Patrik Ling
Redeye, Christian Binder

Investor Relations

Ulf Jungnelius, CEO
Gustaf Albèrt, Deputy CEO and CFO

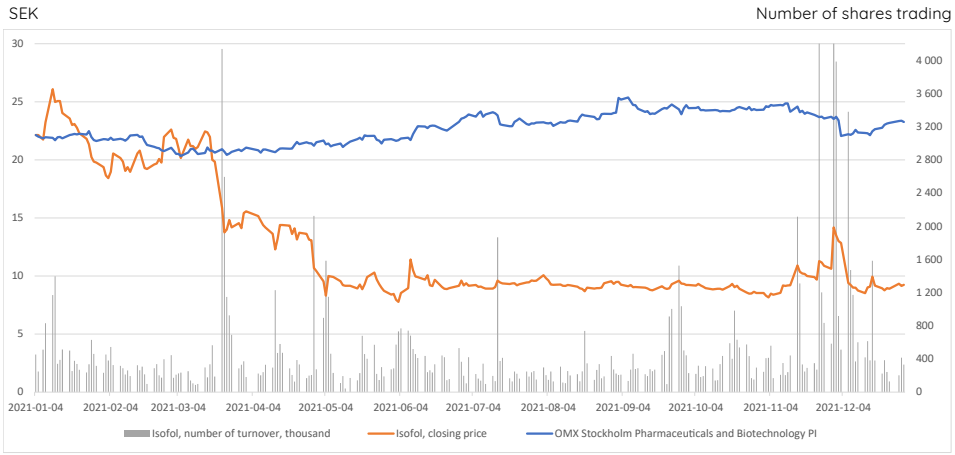
Largest shareholders

Isofol's largest shareholders based on information from Euroclear Sweden AB and Monitor as of December 31, 2021.

Shareholder	Number of shares	Share capital/votes
Futur Pension (formerly Danica)	13,486,795	8.4%
Avanza Pension	8,750,907	5.4%
Handelsbanken Fonder	7,290,946	4.5%
Swedbank Försäkring	5,511,276	3.4%
Hans Enocson	4,555,236	2.8%
AP4	4,521,257	2.8%
Swedbank Robur Fonder	4,175,839	2.6%
Bengt Gustafsson*	3,749,459	2.3%
Nordnet Pensionsförsäkring	2,826,930	1.8%
Alfred Berg Fonder	2,348,268	1.5%
Ten largest shareholders	**49,925,967**	**35.5%**
Other shareholders	111,589,473	64.5%
TOTAL	**161,515,440**	**100%**

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

Price trend 2021



The OMX Stockholm Pharmaceuticals and Biotechnology PI Index is weighted based on Isofol's share of the index based on the share price on the first day of trading in 2021.

Source: Nasdaq OMX Nordic

DIRECTORS' REPORT

The Board of Directors and CEO of Isofol Medical AB (publ), corporate identity number 556759-8064, hereby present the Annual Report and consolidated financial statements for the 2021 financial year.

OPERATIONS

The Group consists of the Parent Company, Isofol Medical AB (publ), headquartered in Gothenburg, Sweden, and the subsidiary Isofol Medical Incentive AB. The business is conducted by the Parent Company, while the subsidiary only administers the Group's incentive programs. The descriptions in the Directors' Report therefore apply to both the Group and the Parent Company, unless otherwise stated.

Isofol Medical AB (publ) is a biotech company in the final phase of the pivotal AGENT study and the pre-commercialization phase for the development of a new drug candidate: the cancer drug arfolitixorin, which is initially intended for the treatment of advanced CRC/mCRC. Arfolitixorin is a drug candidate being developed by Isofol for the treatment of CRC, the second deadliest form of cancer, with only 10 percent[1] of patients with metastatic disease surviving for more than five years and the need for more effective drugs is very high. Arfolitixorin can also be developed for the treatment of pancreatic cancer, breast cancer, gastric cancer, and head and neck cancer. In the treatment of CRC, arfolitixorin is given in combination with a cytotoxin, 5-FU (5-fluorouracil), to increase tumor shrinkage with the goal of extending the life of the cancer patient. Arfolitixorin consists of the active ingredient [6R]-MTHF ([6R]-5,10-methylenetetrahydrofolate).

Currently, the folate-based prodrugs leucovorin and levoleucovorin are used in combination with the cytostatic 5-FU in the treatment of CRC. Isofol intends to replace these prodrugs with arfolitixorin, with the objective of improving the results of treatment for approximately 370,000 CRC patients in the US, the EU 5 and Japan in first- through third-line treatment. In contrast to leucovorin and levoleucovorin, which must be converted into [6R]-MTHF in the body and tumor in order to be active in the treatment of cancer, arfolitixorin consists of the active ingredient [6R]-MTHF and no conversion is therefore required. Arfolitixorin thus has the potential to achieve a more powerful anti-tumor effect for all patients in combination with 5-FU treatment. Through a global licensing agreement with Merck & Cie, Isofol has sole rights to the development and commercialization of arfolitixorin in oncology. The licensing agreement also grants Isofol access to the unique and patented manufacturing process for arfolitixorin. Isofol is focused on making arfolitixorin accessible to patients worldwide and is currently conducting clinical studies in the US, Canada, Europe, Japan and Australia. The company routinely evaluates various strategic partnerships, and if an agreement with a global partner increases the value of arfolitixorin, the company will consider it.

Five-year summary

	2021 IFRS	2020 IFRS	2019 IFRS	2018 IFRS	2017 IFRS
Net revenue (TSEK)	22,407	37,119	107	–	227
Operating result (TSEK)	-204,465	-186,494	-167,804	-89,849	-72,587
Result after financial items (TSEK)	-200,251	-188,991	-161,583	-83,125	-72,035
Total assets, TSEK	401,363	148,130	146,470	288,552	361,276
Solvency (%)	79%	45%	72%	92%	95%
Average number of employees	13	12	14	10	10

SIGNIFICANT EVENTS DURING THE YEAR

R&D activities

Isofol held a digital poster presentation at the ASCO Gastrointestinal Cancers Symposium in January 2021. The presentation was held jointly with QuartzBio, the Sahlgrenska Academy at the University of Gothenburg and Sahlgrenska University Hospital. Together with these academic researchers, we have developed a gene analysis (gene test) in which the expression of a number of folate-associated genes was examined. The purpose was to demonstrate how the individual cancer patient's genetic conditions affect their capacity to respond to folate-based cancer treatment. The results confirm that the active ingredient in arfolitixorin is not as dependent on the individual's metabolism and that more patients respond to treatment.

The recommendation from the iDSMB, in March 2021, following the interim analysis was encouraging in many ways: firstly, we did not need to enroll any further patients, which meant we could stick to our current timeline and aim to submit our application for market approval in the end of 2022, starting with the US FDA. Secondly, it provided additional confirmation that arfolitixorin shows no signs of increased toxicity which, in combination with previous efficacy data, strengthens our belief in arfolitixorin's potential. We therefore believe we are likely to achieve a positive outcome, with potential to enter the US market as early as the end of 2022.

In the second quarter, the enrolment of Japanese patients was completed in accordance with the regulatory requirements of the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to also achieve market approval in Japan. As a result, 56 patients of Japanese origin have been enrolled in accordance with PMDA requirements. We are convinced that our completed recruitment of Japanese patients was an important step in obtaining market approval in Japan, the second largest oncology market worldwide after the US. Isofol will conduct the study in Japan in close cooperation with its licensing partner Solasia and, in accordance with the licensing agreement, Solasia will reimburse Isofol for its patient costs in Japan. We are now looking forward to continuing our partnership with Solasia concerning the development and registration of arfolitixorin and establishing a new treatment alternative for patients suffering from mCRC, which is a rapidly increasing form of cancer in Japan.

In the second quarter, financing was secured to take the AGENT study past top-line and final data and to complete chemistry, manufacturing and controls (CMC) development and validation (production of the commercial product). As such, we will also be able to complete the application for market registration and initiate and accelerate global activities related to the development of med-

1.) Epidemiology (the number of mCRC patients treated) is based on consensus from Globocan 2018–2020 and reports from GlobalData that are based on both primary and secondary analyses.

ical affairs, commercial launch packages and continued partnership activities. In addition, this enables clinical development activities concerning gene expression analysis and evaluative studies in other potential markets, such as the treatment of pancreatic cancer.

As a result of this successful financing, Isofol is shifting its focus from clinical development to pre-commercialization. The aim of the company's pre-commercial activities is to prepare for Isofol's application to the FDA for drug approval, ensure that the company is ready for license negotiations and to carry out relevant preparations for a coming market launch. Isofol has almost completed CMC development, the clinical pivotal work is in its final phase and the focus is now on creating value for arfolitixorin by intensifying our work on the pre-commercial plan. By being ready for launch as soon as we have received approval, we will be able to provide patients with quicker access to arfolitixorin, thereby increasing the value of the company in a potential global licensing deal.

In the second half of 2021, we had two main priorities. The first was to carry out commercial preparations, and the second was to take the necessary measures to be able to present the results of the AGENT study in 2022. We want to stress that commercial preparations are being carried out to ensure a successful commercial launch and to ensure that the partners we engage in discussions with evaluate our drug candidate in the right way. Interest from potential licensees and partners remains strong. We are in ongoing contact with several stakeholders, including partners, but are also fully aware that top-line data will be crucial for any continued dialogue and potential business.

As part of our efforts to achieve market approval, the FDA granted Fast Track Designation for our drug candidate arfolitixorin, which was a very positive step and serves as an important external validation of arfolitixorin's potential. We interpret this as confirmation of the large unmet need for better cancer treatments, but also as an effort from the FDA to ensure that, assuming the drug candidate arfolitixorin obtains market authorization, there will not be a supply shortage that puts patients in a difficult position. The drug candidate arfolitixorin is the first direct active folate in over 20 years. Fast Track Designation enables more frequent dialogue with the FDA, which will be significant moving forward. When we have completed our dialogue with the FDA, it will be possible to establish when the top-line results can be presented. However, we are convinced that the study will deliver high-quality results and hope that the AGENT study will have a positive outcome for patients and caregivers.

In December 2021, Isofol noted that more patients than expected had been censored without documented tumor progression and started a new therapy. We are therefore unable to deblind the study in accordance with the predetermined PFS events. Isofol has not yet had the opportunity to review the study data, and it is therefore not possible for Isofol to know whether the change is occurring in one or both treatment arms of the study, or the reason why patients proceed to other treatments.

The AGENT study's primary endpoint, overall response rate (ORR), is not affected and the study is continuing to be conducted according to plan without any major Covid-related effects or delays for the patients remaining. Since the secondary endpoint of 300 PFS events will not be reached, dialogues with the FDA about a new cut-off point to be able to initiate the analysis of the phase III data have been carried out. On April 22, 2022, the study data could begin to be analyzed and the data read-out could thus begin, including compilation, quality assurance and statistical analysis to enable top-line results to be presented. The schedule for being able to present the study results (top-line results and final data) is dependent on the FDA decision regarding the cut-off point for PFS. The company believes that top-line results can be presented two to four months after the data analysis was started.

Covid-19 has had a limited impact on the company

Covid-19 had a relatively limited impact on Isofol and its operations in 2021. The extent to which Covid-19 will impact Isofol's operations and specifically its clinical study during 2022 will largely depend on the pace at which global vaccination programs are rolled out and how quickly hospitals can return to normal operations. Isofol is carefully monitoring the development of Covid-19 and the restrictions in effect in order to assess the extent to which the operations may be impacted in the short and long term. Isofol has adapted its operations and taken continuous precautionary measures to ensure that its employees, consultants and study participants stay safe and healthy and to ensure that the study is based on high-quality data. The AGENT study was fully enrolled in December 2020 and the risk of delays due to patient recruitment has therefore been reduced. However, there remains a risk that hospitals could close or that the collection of data could become more difficult due to future waves of Covid-19, which could delay the compilation of data ahead of the study's top-line results.

Patents

During the year, Isofol received a number of new patents that provide Isofol with extensive patent protection in most key markets.

Raising of capital

During the second quarter of 2021, Isofol conducted a rights issue that was oversubscribed, which resulted in the over-allotment option being exercised and generated approximately SEK 452 million for the company after transaction costs. The current shareholders, executive management and the Board of Directors participated in the issue, as did new shareholders, which broadened the ownership base.

Listing on Nasdaq Stockholm

On October 21, an important step was taken for the company with the listing in the Mid Cap segment of Nasdaq Stockholm's main market. This allowed us to raise more awareness about Isofol and led to increased share liquidity, which is important for creating additional value for our shareholders.

SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

Organization

On January 1, 2022, Jenny Sundqvist assumed the role of Chief Commercial Officer (CCO) of the company. Jenny Sundqvist came to Isofol in August 2021 from AstraZeneca, where she served as Head of Oncology Portfolio, with responsibility for the company's annual oncology strategy. Jenny has a strong commercial and strategic background, with expertise in marketing, PR and product development of pharmaceuticals, medical devices and consumer goods.

Nomination committe

The company's nomination committee proposes that Jan Törnell is elected Chair of the Board of Directors of the company at the Annual Genereal Meeting 2022..

AGENT study

On April 22, 2022, Isofol announced that data analysis of the global pivotal Phase III study AGENT had begun following a dialogue with the FDA regarding censoring rules and the requirement for progression-free survival events to begin data gathering and analysis.

THE GROUP'S KEY FIGURES MULTI-YEAR OVERVIEW

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

THE SHARE AND OWNERSHIP STRUCTURE

The share capital in Isofol Medical AB (publ) amounts to TSEK 4,945. Isofol's shares were admitted to trading on Nasdaq Stockholm on October 21, 2021. As of December 31, 2021, the total number of shares and votes in the company amounted to 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 the Annual General Meeting. At the Annual General Meeting, 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 2021, the company had approximately 10,100 (7,800) shareholders and the ten largest shareholders owned 35.4 percent (36.1) of the outstanding shares and other shareholders owned 64.6 percent (63.9).

SALES AND RESULT

Sales in 2021 amounted to TSEK 22,407 (37,119). The company's other operating revenue in 2021 amounted to TSEK 0 (18). Other external costs during the year totaled TSEK -196,712 (-199,535). Costs for the ongoing AGENT study, which has been fully recruited since the fourth quarter of 2020, declined over the year while operating costs for commercial activities increased. The year also included costs for the listing change.

Personnel costs in the Group amounted to TSEK -27,721 (-22,740). This increase of TSEK 4,981 is mainly attributable to an increase in the number of employees.

The result after financial items amounted to TSEK -200,251 (-188,991). The Group has no tax costs since it did not report profit during the period.

LIQUIDITY AND FINANCIAL POSITION

Cash and cash equivalents at December 31, 2021 amounted to TSEK 379,448 (116,393) and working capital to TSEK 311,589 (59,717). The company has no loans.

CASH FLOW AND INVESTMENTS

Cash flow from operating activities for the year amounted to TSEK -188,429 (-160,270). The negative cash flow for the period was attributable to the company's clinical activities and the company's pre-commercialization activities as well as lower revenue compared to the preceding year. Cash flow from investing activities amounted to TSEK 0 (0). Cash flow from financing activities amounted to TSEK 450,477 (150,013), attributable to the new share issue completed during the year. Cash flow for the year amounted to TSEK 262,048 (-10,257).

EMPLOYEES

The number of employees in the Group totaled 15 (12) at year-end. The average number of employees was 13 (12). The company's employees have a very high level of education, such as doctorates or other university/college education at a master's level. At year-end, 60 percent of the company's employees were women and 40 percent were men.

GUIDELINES FOR REMUNERATION TO SENIOR EXECUTIVES

In accordance with the Swedish Companies Act, the general meeting is to decide on guidelines for remuneration to the CEO and other senior executives. Guidelines for remuneration to senior executives were adopted at the Annual General Meeting on June 24, 2020. No deviations from these guidelines have been made. The following guidelines were adopted at the Annual General Meeting on June 24, 2020.

Scope

These guidelines encompass executive management for Isofol Medical AB (publ) ("Isofol" or "the company") 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. Executive management refers to the CEO, Vice CEO and other members of executive management. Other members of executive management refer to individuals who are included in the management group and managers who report directly to the CEO, which in the company's case includes the Chief Financial Officer, Chief Medical Officer and Chief Commercial Officer.

The guidelines are forward-looking and are to be applied for agreed remuneration and changes made to already agreed remuneration, after the guidelines were adopted by the 2020 Annual General Meeting. The guidelines do not cover remuneration resolved on by the general meeting.

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

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

Isofol's business concept is to help extend life and improve the quality of life for cancer patients by offering the drug arfolitixorin globally, which will be achieved through the targets to i) ensure a successful pivotal study, ISOCC-007, in CRC, ii) ensure market approval for the drug candidate arfolitixorin, initially in the US, Europe and Japan, and iii) establish a solid commercialization plan for the successful launch of arfolitixorin.

The successful implementation of the company's business strategy and the safeguarding of the company's long-term interests, including its sustainability, requires the company to be able to recruit and retain qualified employees. For this, Isofol is required 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 long-term interests, including its sustainability.

Remuneration to senior executives

Forms of remuneration, etc.

Isofol must offer total market-based remuneration that ensures that senior executives can be recruited and retained. Remuneration within Isofol 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, any 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 long-term incentive programs such as share- or share-price-based remuneration or incentive programs. Such long-term incentive programs are decided by the general meeting 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, in accordance with 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 to senior executives to the company's earnings and sustainability, the goals promote the implementation of the company's business strategy, its long-term interests and its competitiveness. The criteria must 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 to the CEO. The CEO is responsible for the assessment of the variable cash remuneration to other executives. Financial targets must be assessed on the basis of the latest financial information published by the company. When the measurement period for fulfilling the criteria for the payment of variable remuneration is completed, the extent to which the criteria are met must be determined. The Remuneration Committee is responsible for this assessment. As far as financial targets are concerned, the assessment is based on 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 the law or an agreement and with the restrictions that may result therefrom.

Pensions

For the CEO, pension benefits, including health insurance, are defined-contribution and the premiums must not exceed 20 percent of the 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 must not exceed 30 base amounts annually. Variable cash remuneration must not 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 10 percent of the fixed annual salary.

Terms and conditions of termination

The CEO is subject to a notice period of six months in the event of resignation. In the event of termination by the company, a notice period of a maximum of six months applies. In the event of termination by the company, severance pay may be paid up to an amount corresponding to a maximum of 12 months' fixed salary and without deductions should the CEO receive remuneration from a new employment or assignment. The notice periods for other senior executives are normally three to six months. In the event of termination by the company, a notice period of a maximum of six months applies. No severance pay has been agreed with other senior executives.

Remuneration to Board members

Board members are entitled to receive only such remuneration as is decided by the general meeting. 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 Isofol'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 Swedish Companies Act's disqualification rules).

Salary and terms of employment for employees

When preparing the Board's proposal for these remuneration guidelines, the salaries and terms of employment for the company's employees have been taken into account, meaning information on employees' total remuneration, the components of the remuneration and the increase and rate of increase in the remuneration over time. These have also been part of the Remuneration Committee's and the Board's decision documentation when assessing the fairness of the guidelines and the limitations that arise from them.

Preparation and decision-making process

The Board of Directors has established a Remuneration Committee consisting of the Chairman of the Board and two Board members. The members of the Remuneration Committee must be independent in relation to the company and executive management. The committee's tasks include preparing the Board's decision on proposals for guidelines on remuneration to senior executives. 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. The Remuneration Committee monitors and evaluates programs for variable remuneration to executive management, the application of guidelines for remuneration to senior executives, current remuneration structures and remuneration levels within the company. The remuneration to the CEO is decided within the framework of principles approved by the Board after preparation and recommendation by the Remuneration Committee. The remuneration to 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 by the matters.

Deviating 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, part of the Remuneration Committee's tasks involves 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 (CRC). The company's business activities mainly comprise the development of the drug candidate arfolitixorin. All of Isofol's long-term business and success is therefore dependent on the results of the ongoing development program for arfolitixorin, which comprises, for example, research, preclinical and clinical studies, preparation and manufacturing of the drug candidate arfolitixorin, internally generated intellectual property rights and licensing agreements, and preparatory commercial activities. It is not possible to predict the outcome of the development program. If the ongoing development program for arfolitixorin is negatively impacted to any extent, for example, by the ongoing pivotal AGENT study being delayed or suspended for any reason, or if the results of the trial do not achieve an acceptable safety profile, display undesirable side effects or do not support the intended treatment efficacy and the drug candidate is therefore not approved, Isofol may be forced to cease all or parts of its operations. Isofol's operations are associated with risks that could have a material negative impact on the Group's operations, financial position and result.

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 Group 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 conditions, problems in identifying patients for the studies, and patients not completing a study or not returning for follow-ups.
- If Isofol does not receive the required product approvals or in the event of a future withdrawal or restriction of any approvals, this could lead to significant adverse effects on Isofol's activities, financial position and results.
- Merck owns significant rights and patents to 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 Group'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 Group's operations and preclinical and clinical projects. However, there is a risk that one or more of the Group's employees could terminate their employment with the Group or that the recruitment of new individuals and consultants with relevant knowledge and expertise could be unsuccessful, which could delay the Group's development and commercialization of its drug candidate, and could have a negative impact on the Group's activities, financial position and results.
- The Group has not yet launched any pharmaceutical product in the market. Accordingly, no sales of products have begun, which means that Isofol's activities have so far not generated any sales revenue. Arfolitixorin is currently the Group's only drug candidate.
- The Group has revenue from licensing agreements from licensees. This revenue may consist of milestone payments and sales-based royalties. All such revenue is dependent on the successful development of the company's product candidate and the achievement of agreed development and regulatory milestones as well as on the subsequent product launch and market sales. The amount of future sales of Isofol's and its licensees' products, if any, is uncertain and ultimately depends on a variety of factors, such as clinical results and marketing success. Should a licensee decide to discontinue or terminate sales of a product, and the decision is expected to be beyond Isofol's control, Isofol's revenue and financial position could be adversely affected.
- Competing drugs could take market share or competing research projects could achieve better efficacy and reach the market faster, meaning the future value of the drug may be lower than expected.
- The phase II pivotal study is conducted in currencies other than SEK, with USD and EUR being the most important currencies, which means that the operations are exposed to a currency risk. Some of the company's cash and cash equivalents are held in USD and EUR for the upcoming pivotal study. The finance policy is updated at least once a year.
- Since the outbreak of the Covid-19 virus, the company has carefully monitored developments and their impact. Accordingly, there is a risk that the continued spread of Covid-19 could, by itself or in combination with other circumstances, have a negative impact on the company's possibility to conduct clinical studies and compile results, particularly with respect to delays.

For more information about risks and risk management, refer to Note 17.

INSURANCE

Isofol Medical AB (publ) conducts regular reviews with brokers and advisers, both locally

and globally, which ensure that the business and area of responsibility are properly insured.

LEGAL DISPUTES

The company was not involved in any legal disputes in 2021.

ENVIRONMENT AND RESPONSIBILITY

Isofol's activities 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 actively strive to improve and minimize its environmental impact to the extent that this is possible and financially reasonable. Our studies are conducted globally, and this entails travel and transport by air. The company believes that the business is conducted in accordance with current and applicable health and safety rules, and provides its employees with a safe and healthy working environment.

WORK OF THE BOARD OF DIRECTORS

The company's Board of Directors consists of eight (8) ordinary members, including the Chairman, all of whom were elected by the 2021 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 company's financial position and performance, and evaluating the operational management. In 2021, the Board met 19 times. 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, and the Board's practices for the coming year.

INTERNAL CONTROL

For more information on internal control, refer to the Corporate Governance Report for 2021, which is included on pages 37–46 of this Annual Report.

PARENT COMPANY

The Group's Parent Company is Isofol Medical AB (publ). The Parent Company's activities are essentially in line with the Group's, as all activities are conducted in the Parent Company, except for the administration of incentive programs. The result for the year and the financial position of the Parent Company are essentially in line with the corresponding items for the Group, which means that comments regarding the Group also largely apply to the Parent Company.

EXPECTATIONS REGARDING FUTURE PERFORMANCE

Isofol is working intensively on the pivotal Phase III AGENT study for arfolitixorin (ISO-CC-007) and on preparations for a future commercial launch. The study will include 440 patients undergoing first-line treatment for CRC. Patient enrollment is being conducted at approximately 90 clinics across the US, Canada, Europe, Australia and Japan, and the primary results of the study are expected to be available two to four months after the data analysis was initiated on April 22, 2022. Isofol's goal with the study is to show that arfolitixorin significantly increases the clinical benefit for patients with mCRC, with a retained safety profile. The prerequisites for completing the pivotal AGENT study and applying for market approval are favorable, and the project is currently expected to command a significant market value. The company has revenue from licensing agreements but no revenue from the sale of pharmaceuticals. Until arfolitixorin starts generating revenue, Isofol is dependent on external funding to ensure its continued operation. Isofol future prospects are positive.

PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT

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

Share premium reserve	1,218,276,497
Retained earnings	-704,644,513
Result for the year	-200,279,963
Total	**313,352,021**

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

To be carried forward	313,352,021
Total	**313,352,021**

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) 2021

INTRODUCTION

Isofol Medical AB (publ) is a Swedish public limited company based in Gothenburg, Sweden, with its shares listed on Nasdaq Stockholm and traded under the ticker ISOFOL. The Board of Directors of Isofol Medical AB (publ), corporate identity number 556759-8064 (the "Company"), hereby submits its Corporate Governance Report for 2021, 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), Nasdaq Stockholm's Rule Book for Issuers, Isofol's Articles of Association, and company-specific rules and guidelines. The report has been audited by the company's auditors and the auditors' opinion is included in the audit report on pages 74–77. In 2021, 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 company management. The governance, management and auditing of Isofol is distributed between the general meeting, the Board and its elected committees, and the CEO. The diagram to 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 company's Nomination Committee, Board of Directors and auditors at the 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 and information rules 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
- Finance policy
- IT policy and information security policy
- Employee handbook
- Authorization instructions
- Risk management policy
- Finance 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 in 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 Nasdaq Stockholm Mid Cap on October 21, 2021. As of December 31, 2021, the total number shares and votes in the company was 161,515,440 (83,365,966), distributed between approximately 10,100 (7,800) shareholders. For further information on Isofol's ownership structure and major shareholders, refer to pages 29–30 of the Annual Report for 2021 and 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, 2021, no shareholder owned more than 10 percent of the company's shares.

There were no violations 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

In accordance with the Swedish Companies Act, the shareholders' influence over the company is exercised at the general meeting, which is the company's highest decision-making body. At the general meeting, the shareholders resolve on central 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 to Board members and auditors, and discharge from liability of Board members and the CEO. The meeting also resolves on guidelines for remuneration to senior executives and on guidelines for salary and other remuneration to senior executives, any new share issues and how the Nomination Committee is to be appointed.

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 is 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 participate in general meetings. To participate in a general meeting, shareholders must notify the company not 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 is to be held within six months from the end of the financial year. 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 who wish 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.

2021 Annual General Meeting

Isofol's 2021 Annual General Meeting was held on June 23 in Gothenburg. Among other resolutions, the following resolutions were passed at the Annual General Meeting:

- The number of Board members and auditors.
- Remuneration to the Chairman of the Board, the Board members elected by the Annual General Meeting and auditors.
- In accordance with the proposal in the notice of the meeting, that the Board members until the next Annual General Meeting would comprise:
  - o Pär-Ola Mannefred, Chairman (re-elected)
  - o Alain Herrera (re-elected)
  - o Paula Boultbee (re-elected)
  - o Magnus Björsne (re-elected)
  - o Robert Marchesani (re-elected)
  - o Anna Belfrage (re-elected)
  - o Aram Mangasarian (re-elected)
  - o Lennart Jeansson (re-elected)
- Re-election of KPMG AB as auditor, with Jan Malm as Auditor in Charge.
- Adoption of the income statement and balance sheet for the Parent Company and the Group.
- Appropriation of the company's earnings so that the available funds according to the adopted balance sheet are carried forward.
- Discharge of the Board members and CEO from liability for the 2020 financial year.
- Determination that no dividend is to be paid for 2020 in accordance with the Board's proposal.
- Adoption of instructions for the Nomination Committee in accordance with the Nomination Committee's proposal.
- The remuneration report for the financial year 2020 was approved in accordance with the Board's proposal.

The minutes from the 2021 Annual General Meeting, the instructions for the Nomination Committee's work and other information are available on the company's website, www.isofolmedical.com.

2022 Annual General Meeting

The 2022 Annual General Meeting of Isofol Medical AB (publ) will be held at 5:00 p.m. on May 19, 2022 at At Park Conference Center, Kungsportsavenyn 36, Gothenburg. The company plans to conduct the 2022 Annual

General Meeting as a hybrid meeting, which means that shareholders may attend the meeting in person or choose to vote in advance (postal voting) with the support of temporary legislation.

The notice of the meeting was published on Isofol's website on April 12 and announced in the Swedish Official Gazette and on Isofol's website on April 14. An advertisement stating that the notice had been published was inserted 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. A speech by the CEO will be made available on the company's website ahead of the Annual General Meeting. The minutes from 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 on 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 Chairman 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 at least four members, one of whom is to be the Chairman of the Board. The other 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 to Board members and the Chairman of the Board
- Fees 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 Nasdaq 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 activities. 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 in accordance with the 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 Annual General Meeting on June 23, 2021 adopted instructions for the Nomination Committee.

The Nomination Committee for the 2022 Annual General Meeting was appointed in accordance with these principles and comprises Malin Björkmo (Chairman), Lars Lind, Ulrik Grönvall, and Mats Ola Palm (appointed by approximately 12 percent of the votes) as well as Chairman of the Board Pär-Ola Mannefred. Updated principles for the composition of the Nomination Committee and instructions to the Nomination Committee will be resolved on by the Annual General Meeting on May 19, 2022.

According to the Code, the Nomination Committee, in connection with the notice of the 2022 Annual General Meeting, is 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 to publish relevant information on the website about the individuals proposed for election and re-election, including their main experience and education, significant assignments within and outside the company, and their shareholding in the company as well as the shareholdings of any related parties.

Auditors

An external auditor is elected by the Annual General Meeting for a period of one year at a time. The auditors audit the company's Annual Report and accounting records as well as the management by the Board and the CEO in accordance with an auditing plan established together with the Board or the Audit Committee. In connection with the audit, the auditors must report their observations to Group management as well as the Board and the Audit Committee. At least once a year, the auditors must report their observations directly to the Board without the presence of executive management. The auditors also participate in the Annual General Meeting, at which they report on their audit and their recommendations in the audit report.

The auditor has audited the Annual Report and consolidated financial statements for the January 1, 2021–December 31, 2021 financial year 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 information herein is consistent with the Annual Report and the consolidated financial statements. 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 at the Annual General Meeting. The auditors also submit reports on audits conducted to the Audit Committee and to the Board in its entirety. The fees invoiced by the auditor for the past two financial years are presented in Note 5 on page 61.

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 to hold a statutory meeting annually after the Annual General Meeting.

In addition, the Board is to meet regularly as well as when special circumstances arise. At the statutory Board meeting, the company's authorized signatories are to be decided and the Board's rules of procedure, the instructions for the CEO and the instructions for financial reporting are to be reviewed and established. At the company's Board meetings, the company's financial situation, business development and other current issues are 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 for remuneration to 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. There is a quorum if more than half the Board members are present. Isofol's Board of Directors currently comprises eight members.

BOARD OF DIRECTORS

	Pär-Ola Mannefred Chairman of the Board Born 1961	**Magnus Björsne** Board member Born 1964	**Paula Boultbee** Board member Born 1958
Name			
Elected to the Board	2019	2018	2018
Education	MBA	PhD, MBA	RN
Background	Entrepreneur and operates own investment business. Co-Owner of Residenset Partners AB.	Chairman of Termino C 2915 AB. Board member of Beactica Therapeutics AB and Termino C 2915 AB. Various executive positions, including responsibility for business development at AstraZeneca AB.	Paula's expertise spans global commercialization planning, pre-launch preparations, major drug launch initiatives and patient advocacy. She has been involved in introducing and supporting brands such as Imbruvica (ibrutinib), Glivec / Gleevec (imatinib), Aranesp (darbopoetin), Camptosar (irinotecan) and Vectibix (panitumumab). Paula has also held executive positions with and advised large companies such as Pharmacia (Pfizer), Novartis, Amgen, Proteolix (Onyx), Dendreon, Incyte and Pharmacyclics. Paula most recently worked at Oncopeptides AB as Chief Commercial Officer.
Current employment and other appointments	Board assignments with Residenset Partners AB (and subsidiaries), Aktiebolaget Äpplet (own holding company), Johanneberg Science Park AB and BRF Geijersgatan.	Board member of SwedenBIO Service AB. Deputy Board member of Anivator AB. CEO of AstraZeneca BioVentureHub AB.	Board chair at the Max Foundation.
Shareholding*	194,448	0	0
Independent in relation to the company and its management	Yes	Yes	Yes
Independent in relation to the company's major shareholders	Yes	Yes	Yes

* Own or related natural or legal person's shareholding in the company as of December 31, 2021

BOARD OF DIRECTORS

					
Name	**Alain Herrera** Board member Born 1950	**Robert Marchesani** Board member Born 1962	**Anna Belfrage** Board member Born 1962	**Aram Mangasarian** Board member Born 1969	**Lennart Jeansson** Board member Born 1941
Elected to the Board	2018	2019	2019	2020	2021
Education	MD, PhD	MBA	MBA	PhD, MBA	MBA
Background	Alain has been directly involved in a number of registration processes, including for the drug oxaliplatin. Prior to working as an expert adviser in oncology, Dr. Herrera was Vice President of the Department of Global Oncology Business Strategy and Development at Sanofi, where he previously held the role of Head of the Global Oncology Franchise. Dr. Herrera was also Chairman of Chiron Therapeutics Europe and CEO of Pierre Fabre Oncology Laboratories.	Robert worked for more than 25 years at Eli Lilly & Company, where he led global brand strategy and marketing, and launched a number of cancer treatments, including ALIMTA® (pemetrexed), Gemzar® (gemcitabine) and Verzenio™ (abemaciclib).	Until May 2019, Anna was Chief Financial Officer (CFO) of Södra Skogsägarna with responsibility for purchasing and IT. Prior to that, she served as acting CEO of Beijer Electronics and CFO of ABS Group in the Cardo Group and held various roles in industrial companies such as Dresser Wayne Fueling Systems, Obducat, Lund Eastern Energy and Åkerlund & Rausing and Price Waterhouse.	Aram has over 20 years of experience in the biotechnology industry. He has held senior positions in biotechnology companies such as C10 Pharma in Norway, Novexel in France and Exonhit Therapeutics in France and has worked on raising capital in public companies and negotiating licensing and sales agreements with leading pharmaceutical companies such as Roche, Merck & Co and AstraZeneca. Aram holds a PhD in biology from UC San Diego in the US and an MBA from INSEAD in France.	Lennart has negotiation experience from several of Swedish industry's largest corporate deals, including Volvo's sale of Volvo Cars, the acquisition of Renault and Mack Trucks, and Stena Sessan's sale of the shares in the pharmaceutical company Meda. Former Deputy CEO of the Volvo Group, CEO of Volvo Cars, and Chairman of Skandia, 6 AP Fonden and Stena AB. Lennart has also been a Board member of Atlas Copco and Bilia.
Current employment and other appointments	Board member of IDDI, Nanobiotix and PDC Line Pharma. Various management positions at Alain Oncologie Consulting, AD Bio Consulting and Pharma Engine Europe.	Robert Marchesani is president of Proventus Consulting LLC and an adjunct faculty member and executive mentor at Butler University, Lacy School of Business in Indianapolis, Indiana.	Board member of Note AB, Mycronic AB, Ellevio AB, CINT AB and Elopak AS.	CEO and Board member of Noxxon Pharma, Berlin.	Board member of Stena Sessan AB and Clean Motion AB.
Shareholding*	0	5,000	5,250	0	953,750
Independent in relation to the company and its management	Yes	Yes	Yes	Yes	Yes
Independent in relation to the company's major shareholders	Yes	Yes	Yes	Yes	Yes

* Own or related natural or legal person's shareholding in the company as of December 31, 2021

Composition and independence

According to Isofol's Articles of Association, the Board of Directors is to consist of no fewer than three (3) and no more than nine (9) members elected by the Annual General Meeting for the period until the end of the next Annual General Meeting. At the Annual General Meeting on June 23, 2021, eight (8) ordinary members were elected: Pär-Ola Mannefred (Chairman of the Board), Alain Herrera, Paula Boultbee, Bob Marchesani, Anna Belfrage, Magnus Björsne, Aram Mangasarian and Lennart Jeansson, all of whom were appointed until the end of the next Annual General Meeting. All Board members are deemed to be independent in relation to the company and its management and to the company's major shareholders.

Information on the Board members including age, year of election to the Board, education, current assignments and shareholdings in the company is presented on pages 40–41.

Responsibilities and work of the Board

After the general meeting, the Board of Directors is the company's highest decision-making body and, according to the Swedish Companies Act, is responsible for the company's management 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 established annually by the Board. These rules of procedure govern the work of the Board as well as the division 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, disqualification and conflicts of interest, mandatory 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 finance policy, authorization instructions and an information and insider policy. 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 company's overall business plan, material organizational changes, changes in the focus of the company's operations, and the income statement and balance sheet. The Board of Directors also 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 quality 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 decision documentation 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 introductory training and other training that the Chairman and the new member find suitable. The Chairman is also 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 work formats 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 Group's results and position, financial reporting and forecasts.

Work of the Board and significant events in 2021

In 2021, the Board held nineteen (19) meetings, of which one (1) was the statutory Board meeting and six (6) were held per capsulam. The work of the Board during the year mainly revolved discussing and making strategic decisions on matters regarding the company's completion of the pivotal study for the drug candidate arfolitixorin, strategic planning of pre-commercialization activities, the company's financing and organizational development.

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 2021 financial year is presented in the table on the next page. The figures in parentheses indicate the maximum number of meetings each member could have attended. During the year, no member expressed reservations about any decision. Open questions are followed up on an ongoing basis. The reporting period refers to January 1– December 31, 2021.

Evaluation of the Board's work

According to the Code, the Board is to evaluate its work annually through a systematic and structured process with the aim of developing its work formats and efficiency. The Board's work in 2021 was evaluated during the first quarter of 2022.

The evaluation was carried out through all Board members answering a questionnaire about the Board's activities. The results of the evaluation are compiled 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 established by the Board.

Board member	Elected	Attendance at Board meetings	Attendance at Remuneration Committee meetings	Attendance at Audit Committee meetings	Independent in relation to the company and its management	Independent in relation to the company's major shareholders
Pär-Ola Mannefred	2019	19 (19)	4 (4)	7 (7)	Yes	Yes
Magnus Björsne	2018	17 (19)			Yes	Yes
Paula Boultbee	2018	19 (19)			Yes	Yes
Alain Herrera	2018	18 (19)			Yes	Yes
Robert Marchesani	2019	19 (19)	4 (4)		Yes	Yes
Anna Belfrage	2019	19 (19)	1 (1)	7 (7)	Yes	Yes
Aram Mangasarian	2020	19 (19)			Yes	Yes
Lennart Jeansson	2021	8 (8)	3 (3)		Yes	Yes

As of the date of the Annual Report, the Board has held a total of four (4) meetings in 2022.

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 to senior executives adopted by the Annual General Meeting as well as the current remuneration structures and levels in the company. The Remuneration Committee comprises Per-Ola Mannefred (Chairman), Lennart Jeansson and Robert Marchesani. The Remuneration Committee is deemed to meet the Code's requirements for independence and the requisite knowledge and experience in matters relating to remuneration to senior executives. The Remuneration Committee met four (4) times during the year. At these meetings, the committee discussed the existing remuneration system of the company, the proposed guidelines for the remuneration to the CEO and senior executives, and ongoing incentive programs. For information on salaries and remuneration to the CEO and senior executives, see Note 4 on pages 59–61 of Isofol's 2021 Annual Report.

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 Report and consolidated financial statements, and to review and monitor the impartiality and independence of the auditor. The Audit Committee is also 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 Audit Committee comprises Anna Belfrage (Chairman) and Pär-Ola Mannefred. The committee meets the independence, accounting and auditing competence requirements of the Swedish Companies Act. The committee met seven (7) times during the year. Isofol's auditors attended three (3) of the meetings at which the auditor's planning of the audit, observations and examination of the Board's and management's management of the company and the company's financial statements were discussed.

EXECUTIVE MANAGEMENT

CEO and company management

The CEO is responsible for the company's day-to-day management and the development of Isofol in accordance with applicable legislation and rules, including Nasdaq Stockholm's Rule Book for Issuers, the Swedish Corporate Governance Code and the guidelines, instructions and strategies established by the Board. The CEO is 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 established by the Board and is responsible for informing the Board about Isofol's development between Board meetings. The CEO is 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 established principles for financial reporting and internal control are applied. The instructions to the CEO also apply to the Vice CEO when acting on behalf of the CEO.

The CEO leads the work of the management group, which is responsible for the overall development of the company's activities and business. In addition to the CEO, the management group during the year comprised:

- Chief Medical Officer (CMO) & Senior Vice President of Clinical Development (SVP)
- Chief Commercial Officer (CCO)
- Chief Financial Officer (CFO) & Vice Chief Executive Officer (vCEO)

Company management comprises four (4) individuals.

For more information on the senior executives in Isofol, when they assumed their positions and their year of birth, education, shareholding in the company and current assignments, refer to page 45.

Remuneration to Board members

The 2021 Annual General Meeting resolved that, for the period up to the next Annual General Meeting, the following fees would be paid to the Board for its work in 2021: a fee of SEK 550,000 is to be paid to the Chairman of the Board and SEK 250,000 to each of the other Board members; a fee of SEK 75,000 is to be paid to the Chairman of the Audit Committee and SEK 40,000 to each of the other members. A fee of SEK 50,000 is to be paid to the Chairman of the Remuneration Committee and SEK 25,000 to each of the other members. Board members domiciled in Europe, but outside the Nordic region, are to receive remuneration of SEK 7,500 per physical Board meeting and Board members domiciled in North America are to receive remuneration of SEK 15,000 per physical Board meeting. Remuneration in addition to the aforementioned fees comprises consultancy fees to Board members.

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 addressed by the Board's Remuneration Committee. The Board decides on the CEO's remuneration based on a proposal by the Remuneration Committee. Remuneration and employment terms for senior executives are to be based on market terms and are to comprise a weighted combination of fixed salary, variable remuneration, pension benefits, other benefits, and terms and conditions of termination.

Remuneration and employment terms 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 to senior executives were approved by the 2020 Annual General Meeting. The Board has the right 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.

The CEO and other senior executives were paid salary and other remuneration for the 2021 financial year in accordance with the table below. All amounts are presented in SEK.

For a more detailed description of the employment terms and remuneration for the Board and senior executives, refer to the Directors' Report and Notes 4 and 20 of the 2021 Annual Report and to the 2021 Remuneration Report.

MANAGEMENT

Name	**Ulf Jungnelius,** Chief Executive Officer (CEO) Born 1951	**Jenny Sundqvist** Chief Commercial Officer (CCO) Born 1971	**Roger Tell,** Chief Scientific Office (CSO) Chief Medical Officer (CMO) Senior Vice President of Clinical Development, SVP Born 1965	**Gustaf Albèrt,** Chief Financial Officer (CFO) Vice Chief Executive Officer (vCEO) Born 1968
Employed by the company	2019	2021	2019	2017
Education	MD, Karolinska Institutet.	Bachelor of Science in International Trade & Finance from Louisiana State University and MBA from McCombs School of Business.	MD, specialist physician in oncology, Karolinska University Hospital and PhD in experimental oncology, Karolinska Institutet.	Master of Science in International Accounting and Auditing, School of Business, Economics and Law at the University of Gothenburg.
Background	Ulf has been CEO of Isofol since November 2019 and prior to that was a Board member of Isofol from 2010 to 2019, serving as the company's clinical and regulatory expert. He has held senior positions at US companies such as Celgene, Takeda, Pfizer and Eli Lilly.	Jenny most recently worked at AstraZeneca where she was responsible for the oncology portfolio. Jenny has an impressive commercial career in consumer goods and medical devices and over 16 years in the pharmaceutical industry.	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 a number of biopharma companies, including Eli Lilly, AstraZeneca and Merck Serono.	Broad financial and operational experience. Most recently served as CEO of Elanders Sverige AB and prior to that as CFO of the same company. Previously worked as an accountant for 17 years, 11 of which as an Authorized Public Accountant at Deloitte and Arthur Andersen.
Holding	408,338 shares*, 250,000 warrants	0 shares*, 49,134 warrants	5,000 shares*, 176,300 warrants	35,359 shares*, 176,300 warrants

Reporting period refers to January 1–December 31, 2021	Base salary	Benefits	Bonus	Pension costs	Total
Ulf Jungnelius, CEO	3,537,738	144,210	1,509,549	711,748	5,903,245
Gustaf Albèrt, Vice CEO	2,017,620	84,181	675,296	482,432	3,259,529
Other senior executives (2)	3,800,851	125,649	659,204	890,669	5,476,373
Total	**9,356,208**	**354,040**	**2,844,049**	**2,084,849**	**14,639,146**

* Own or related natural or legal person's holding of shares and other financial instruments in the company. Largest shareholders at December 31, 2021

** Isofol Medical AB (publ) Warrant Program 2018 series 2018/2022 and series 2018/2023.

*** Isofol Medical AB (publ) Warrant Program 2020.

INTERNAL CONTROL AND RISK MANAGEMENT

The Board's responsibility for internal control is governed by the Swedish Companies Act and the Swedish Annual Accounts Act, which contain requirements that information about the most important aspects of Isofol's systems for internal control and risk management is to be included in the Corporate Governance Report in connection with the company's annual financial reporting. The Board's responsibility for internal control is also governed by the Code. 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 Nasdaq Stockholm. This work involves the Board, Group 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 the financial reporting.

Control activities

The primary purpose of the control activities is to prevent, detect and correct errors in the financial reporting. Activities and procedures are designed to manage and address significant risks related to financial reporting. The control activities include analytical follow-up and comparison of earnings performance or earnings items, authorization instructions, monthly account reconciliations, and accounting and valuation principles. Access to IT systems is limited according to authorization, authority, responsibility and role. The control structure focuses on clear roles in the organization and a division of responsibility. Continuous analysis of the financial reporting is very important for ensuring that the 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 format. The employees concerned are provided with regular updates regarding changes to accounting principles, reporting requirements or other information disclosures.

The company's 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 information disclosure to the market. This is also governed by the company's established information policy.

Monitoring, evaluation and reporting

The Board continuously evaluates the information provided by Group management. The Board receives regular financial updates on Isofol's performance between Board meetings. The Group'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 the external audit. 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 maintain regular contact throughout the financial year in order to identify any risks at an early stage and address any issues that could impact the financial reporting. The auditors also report regularly to the Board, mainly through meetings with the Audit Committee.

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 Group 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 in the Group 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 Report and accounting records as well as the administration of the Board and the CEO. After each financial year, the auditor must submit an audit report to the general meeting. Each year, the company's auditor reports its observations from the audit and its assessment of the company's internal control to the Board.

CONSOLIDATED INCOME STATEMENT

January 1–December 31 TSEK	Note	2021	2020
OPERATING REVENUE			
Net revenue	3	22,407	37,119
Other operating revenue		–	18
Total operating revenue		**22,407**	**37,137**
OPERATING COSTS			
Other external costs	5	-196,712	-199,535
Personnel costs	4, 20	-27,721	-22,740
Depreciation and amortization of tangible and intangible fixed assets	8, 9, 18	-1,596	-1,770
Other operating revenue and operating costs		-843	413
Total operating costs		**-226,872**	**-223,631**
Operating result		**-204,465**	**-186,494**
FINANCIAL ITEMS	22, 25		
Financial revenue		4,383	4
Financial costs		-168	-2,501
Total financial items		**4,215**	**-2,497**
Result after financial items		**-200,251**	**-188,991**
Tax on result for the period	7	–	–1
Result for the year		**-200,251**	**-188,992**
Attributable to:			
Parent Company shareholders		-200,251	-188,992
EARNINGS PER SHARE	24		
before dilution (SEK)		-1.59	-3.07
after dilution (SEK)		-1.59	-3.07

There are no amounts to be recognized as other comprehensive income, which is why the result for the year corresponds to comprehensive income for the year.

CONSOLIDATED BALANCE SHEET

TSEK	Note	Dec 31, 2021	Dec 31, 2020
ASSETS			
Intangible fixed assets			
Patents	8	–	–
Tangible fixed assets			
Equipment, tools and right-of-use assets	9	1,745	3,258
Financial fixed assets			
Other long-term receivables	26	5,009	5,031
Total fixed assets		**6,755**	**8,289**
Current assets			
Accounts receivable	6	–	2,318
Other receivables	6, 10	12,276	8,740
Prepaid expenses and accrued income	6, 11	2,884	12,390
Cash and cash equivalents	6, 12, 19	379,448	116,393
Total current assets		**394,609**	**139,841**
Total assets		**401,363**	**148,130**
EQUITY	13		
Share capital		4,945	2,552
Other contributed capital		1,217,607	768,083
Retained earnings		-704,069	-515,077
Result for the year		-200,251	-188,992
Total equity		**318,233**	**66,567**
LONG-TERM LIABILITIES			
Long-term lease liabilities	18	110	1,439
Total long-term liabilities		**110**	**1,439**
CURRENT LIABILITIES			
Accounts payable	6	17,736	20,889
Other liabilities	6, 15, 18	3,174	5,724
Accrued expenses and deferred income	6, 16	62,110	53,511
Total current liabilities		**83,020**	**80,124**
Total liabilities		**83,130**	**81,563**
Total equity and liabilities		**401,363**	**148,130**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

TSEK	Share capital	Other contributed capital	Retained earnings including result for the year	Total
Opening equity, Jan 1, 2020	981	619,003	-515,076	104,908
COMPREHENSIVE INCOME FOR THE YEAR				
Result for the year			-188,992	-188,992
Other comprehensive income for the year				
Comprehensive income for the year			**-188,992**	**-188,992**
TRANSACTIONS WITH GROUP SHAREHOLDERS				
Contributions from and distributions to shareholders				
Subscription warrants, repurchases		-57		-57
New share issue, issued subscription warrants		60		60
Rights issue	1,309	148,280		149,589
Issue costs		-28,941		-28,941
Over-allotment option	262	29,738		30,000
Total contributions from and distributions to shareholders	**1,571**	**149,080**		**150,651**
Closing equity, Dec 31, 2020	**2,552**	**768,083**	**-704,068**	**66,567**

TSEK	Share capital	Other contributed capital	Retained earnings including result for the year	Total
Opening equity, Jan 1, 2021	2,552	768,083	-704,068	66,567
COMPREHENSIVE INCOME FOR THE YEAR				
Result for the year			-200,251	-200,251
Other comprehensive income for the year				
Comprehensive income for the year			**-200,251**	**-200,251**
TRANSACTIONS WITH GROUP SHAREHOLDERS				
Contributions from and distributions to shareholders				
Rights issue	1,914	398,242		400,157
Issue costs		-48,240		-48,240
Over-allotment option	478	99,522		100,000
Total contributions from and distributions to shareholders	**2,392**	**449,524**		**451,917**
Closing equity, Dec 31, 2021	**4,945**	**1,217,607**	**-904,319**	**318,233**

CONSOLIDATED CASH FLOW STATEMENT

January 1–December 31 TSEK	Note	2021	2020
OPERATING ACTIVITIES			
Result after financial items		-200,251	-188,991
Adjustments for non-cash items	22	-2,946	3,958
Income tax paid		–	-1
Cash flow from operating activities before changes in working capital		**-203,196**	**-185,033**
Cash flow from changes in working capital			
Increase (-)/decrease (+) in operating receivables		9,860	-14,050
Increase (+)/decrease (-) in operating liabilities		4,907	38,813
Change in working capital		**14,767**	**24,763**
Cash flow from operating activities		**-188,429**	**-160,270**
INVESTING ACTIVITIES			
Acquisition of tangible fixed assets	9	–	–
Cash flow from investing activities		**–**	**–**
FINANCING ACTIVITIES			
Repayment of lease liability	18	-1,548	-1,553
Subscription warrants, proceeds received	13	108	308
New share issue		451,917	151,258
Cash flow from financing activities		**450,477**	**150,013**
Cash flow for the year		262,048	-10,257
Cash and cash equivalents at the beginning of the year		116,393	126,983
Exchange rate difference in cash and cash equivalents		1,007	-334
Cash and cash equivalents at the end of the year	**12**	**379,448**	**116,393**

PARENT COMPANY INCOME STATEMENT

January 1–December 31 TSEK	Note	2021	2020
OPERATING REVENUE			
Net revenue	3	22,407	37,119
Other operating revenue		–	–
Total operating revenue		**22,407**	**37,119**
OPERATING COSTS			
Other external costs	5, 18	-198,349	-201,231
Personnel costs	4, 20	-27,721	-22,740
Depreciation and amortization of tangible and intangible fixed assets	8, 9	-77	-197
Other operating revenue and operating costs		-843	413
Total operating costs		**-226,990**	**-223,754**
Operating result		**-204,583**	**-186,635**
FINANCIAL ITEMS	22, 25		
Financial revenue		4,383	4
Financial costs		-79	-2,358
Total financial items		**4,304**	**-2,354**
Result after financial items		**-200,280**	**-188,989**
APPROPRIATIONS			
Group contributions paid		–	-293
Result before tax		**-200,280**	**-189,282**
Tax on result for the year	7	–	–
Result for the year		**-200,280**	**-189,282**

There are no amounts to be recognized as other comprehensive income, which is why the result for the year corresponds to comprehensive income for the year.

PARENT COMPANY BALANCE SHEET

January 1–December 31 TSEK	Note	Dec 31, 2021	Dec 31, 2020
ASSETS			
Intangible fixed assets			
Patents, licenses and similar rights	8	–	–
Tangible fixed assets			
Equipment, tools, fixtures and fittings	9	158	235
Financial fixed assets			
Participations in Group companies	21	50	50
Other long-term receivables	13, 26	5,009	6,631
Total fixed assets		**5,217**	**6,916**
Current assets			
Accounts receivable	6	–	2,318
Other receivables	6, 10, 13	12,276	8,740
Prepaid expenses and accrued income	6, 11	3,113	12,614
Cash and bank balances	6, 12, 19	379,398	114,862
Total current assets		**394,787**	**138,534**
Total assets		**400,004**	**145,450**

January 1–December 31 TSEK	Note	Dec 31, 2021	Dec 31, 2020
EQUITY AND LIABILITIES			
Equity	13, 14		
Restricted equity			
Share capital		4,945	2,552
Non-restricted equity			
Share premium reserve		1,218,276	768,753
Retained earnings		-704,645	-515,363
Result for the year		-200,280	–189,282
Total equity		**318,297**	**66,660**
Current liabilities			
Accounts payable	6	17,965	21,113
Other liabilities	6, 15	1,632	4,166
Accrued expenses and deferred income	6, 16	62,110	53,511
Total current liabilities		**81,707**	**78,790**
Total liabilities		**81,707**	**78,790**
Total equity and liabilities		**400,004**	**145,450**

PARENT COMPANY STATEMENT OF CHANGES IN EQUITY

	Restricted equity	Non-restricted equity			
TSEK	**Share capital**	**Share premium reserve**	**Retained earnings**	**Result for the year**	**Total equity**
Opening equity, Jan 1, 2020	981	619,616	-353,871	-161,492	105,234
COMPREHENSIVE INCOME FOR THE YEAR					
Result for the year	–	–	–	-189,282	-189,282
Other comprehensive income for the year	–	–	–	–	–
Comprehensive income for the year	**–**	**–**	**–**	**-189,282**	**-189,282**
Appropriation of profit	–	–	-161,492	161,492	–
New share issue, issued subscription warrants	–	60	–	–	60
Rights issue	1,309	148,280	–	–	149,589
Over-allotment option	262	29,738	–	–	30,000
Issue costs	–	-28,941	–	–	-28,941
Closing equity, Dec 31, 2020	**2,552**	**768,753**	**-515,363**	**-189,282**	**66,660**

TSEK	**Share capital**	**Share premium reserve**	**Retained earnings**	**Result for the year**	**Total equity**
Opening equity, Jan 1, 2021	2,552	768,753	-515,363	-189,282	66,660
COMPREHENSIVE INCOME FOR THE YEAR					
Result for the year	–	–	–	-200,280	-200,280
Other comprehensive income for the year	–	–	–	–	–
Comprehensive income for the year	**–**	**–**	**–**	**-200,280**	**-200,280**
Appropriation of profit	–	–	-189,282	189,282	–
New share issue, issued subscription warrants	–	–	–	–	–
Rights issue	1,914	398,242	–	–	400,157
Over-allotment option	478	99,522	–	–	100,000
Issue costs	–	-48,240	–	–	-48,240
Closing equity, Dec 31, 2021	**4,945**	**1,218,277**	**-704,645**	**-200,280**	**318,297**

PARENT COMPANY CASH FLOW STATEMENT

January 1–December 31 TSEK	Note	2021	2020
OPERATING ACTIVITIES			
Result after financial items		-200,280	-188,989
Adjustments for non-cash items	22	-4,465	2,110
Income tax paid		–	–
Cash flow from operating activities before changes in working capital		**-204,745**	**-186,879**
Cash flow from changes in working capital			
Increase (-)/decrease (+) in operating receivables		9,860	-14,050
Increase (+)/decrease (-) in operating liabilities		4,789	38,871
Change in working capital		**14,649**	**24,821**
Cash flow from operating activities		**-190,095**	**-162,058**
INVESTING ACTIVITIES			
Acquisition of tangible fixed assets	9	–	–
Cash flow from investing activities		**–**	**–**
FINANCING ACTIVITIES			
Loans for employee stock options	13	1,707	543
New share issue		451,917	151,258
Cash flow from financing activities		**453,624**	**151,801**
Cash flow for the year		263,529	-10,256
Cash and cash equivalents at the beginning of the year		114,862	125,452
Exchange rate difference in cash and cash equivalents		1,007	-334
Cash and cash equivalents at the end of the year	**12**	**379,398**	**114,862**

SUPPLEMENTARY DISCLOSURES AND NOTES ON THE FINANCIAL STATEMENTS

General information

Notes on the 2021 Annual Report for the Isofol Medical Group and its Parent Company, Isofol Medical AB (publ), corporate identity number 556759–8064, headquartered in Gothenburg, Sweden, street address Arvid Wallgrens Backe 20, SE-413 46 Gothenburg. The Parent Company's shares have been listed on Nasdaq Stockholm since October 21, 2021.

This annual report was subject to approval by the Board on April 27, 2022

NOTE 1 ACCOUNTING PRINCIPLES

COMPLIANCE WITH STANDARDS AND LEGISLATION

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. The Swedish Financial Reporting Board's recommendation RFR 1 Supplementary Accounting Rules for Groups has also been applied.

The Parent Company's Annual Report has been prepared in accordance with the Swedish Annual Accounts Act (1995:1554) and the application of Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. This entails that IFRS measurement and disclosure rules are applied, with the exception of deviations presented in the section "Parent Company accounting principles." The changes that have been implemented and are to be implemented in connection with RFR 2 Accounting for Legal Entities are not expected to have any impact on Isofol's financial statements.

The accounting principles stated below have been applied consistently to all periods presented in the consolidated financial statements. The Group's accounting principles have also been consistently applied by the Group companies.

MEASUREMENT PRINCIPLES APPLIED WHEN PREPARING THE FINANCIAL STATEMENTS

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

ASSESSMENTS AND ESTIMATES IN THE FINANCIAL STATEMENTS

Preparing the financial statements in accordance with IFRS standards requires that company management assess the application of the Group's accounting principles and estimates for accounting purposes. The actual outcome may deviate from these estimates. Estimates and assumptions are evaluated on an ongoing basis. Changes to estimates are recognized in the period in which the change is made if the change only affects that period, or in the period in which the change is made and in future periods if the change affects both the current period and future periods. The areas covered by a higher degree of assessment or complexity, or areas where assumptions and estimates have a material impact on the consolidated financial statements, are disclosed in Note 2.

AMENDED ACCOUNTING STANDARDS AS A RESULT OF NEW OR AMENDED IFRS

Any new or amended IFRS that do not come into force until coming financial years have not been applied in advance when preparing these financial statements. Other new or amended standards or interpretations published by the IASB are not expected to have any impact on the Group's or the Parent Company's financial statements.

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.

CONSOLIDATION PRINCIPLES

Subsidiaries

The consolidated financial statements cover the Parent Company Isofol Medical AB (publ) and the wholly owned Swedish subsidiary Isofol Medical (Incentive) AB.

Consolidation principles

Subsidiaries are companies under the controlling influence of Isofol Medical AB (publ). A controlling influence exists if Isofol Medical AB (publ) has influence over the investment object, is exposed to or entitled to a variable return from its involvement, and can use its influence over the investment to influence the return. When assessing whether a controlling influence exists, potential voting shares are taken into account along with whether de facto control exists. Business combinations are recognized in accordance with the acquisition method.

This method entails that the acquisition of a subsidiary is regarded as a transaction through which the Group indirectly acquires the assets of the subsidiary and assumes its liabilities. In the acquisition analysis, assets and liabilities are recognized at fair value according to the established acquisition analysis. The difference between the cost of the subsidiary's shares and the fair value of the acquired assets, assumed liabilities and contingent liabilities constitutes the Group's goodwill. The purchase consideration also includes the fair value of all assets and liabilities resulting from a contingent consideration agreement. Acquisition-related costs are expensed as incurred. The financial statements of subsidiaries are recognized in the consolidated financial statements from the acquisition date until the date on which the controlling influence ceases.

Transactions eliminated on consolidation

Intra-group receivables and liabilities, revenue or expenses, and unrealized gains or losses arising from intra-Group transactions between Group companies are eliminated in their entirety when preparing the consolidated financial statements. Unrealized losses are eliminated in the same manner, but only to the extent that there is no impairment requirement.

Note 1, cont.

FOREIGN CURRENCY TRANSLATION

Functional currency and reporting currency

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

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 Isofol's intellectual property. Isofol may be entitled under its licensing agreements to receive compensation for costs incurred. Revenue recognition reflects the accrual of revenue based on the commitments 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 compensation for the use of Isofol's intellectual property licensed to the counterparty and may include compensation for costs incurred in relation to a study. These commitments are analyzed to determine whether they constitute distinct performance obligations that should be recognized separately or whether they should be considered one obligation.

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

Licensing and milestone payments

Revenue from technology licenses is recognized as revenue over the license period. Signing fees and other payments received in connection with contract offerings are recognized as revenue when the conditions for receiving them are met. Milestone payments are recognized as revenue when the related milestones are met.

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 sales-based 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 Group 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 regula-

Note 1, cont.

tions 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 they can be utilized. The value of deferred tax assets is reduced when it is no longer deemed probable that they can be utilized.

FINANCIAL INSTRUMENTS

Financial instruments recognized in the balance sheet include, on the asset side, cash and cash equivalents, 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 Group 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 Group's business model for managing financial assets. The Group 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 Group's business model for managing financial assets refers to how the Group 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 Group's business model for asset management and what kind of cash flows the asset gives rise to. The Group 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 Group. The Group recognizes 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 for the assets give rise to cash flows on specific days 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 Group's financial assets measured at amortized cost include accounts receivable, other current receivables and cash and cash equivalents. 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. Short-term liquid investments in fixed income funds are measured at fair value and categorized as financial assets measured at fair value, with changes in value recognized in profit or loss.

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.

The Group's financial assets measured at fair value through profit or loss include fixed income funds that are classified as cash and cash equivalents. Fixed income funds can easily be converted into cash and are subject to an insignificant risk of changes in value.

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 Group's statement of financial position report when:

- the contractual rights to the cash flows from the financial asset expire,

or

Note 1, cont.

- the Group has transferred its rights to obtain 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 Group 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 Group'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 Group has no loans.

Derecognition of financial liabilities from the statement of financial position

A financial liability is derecognized from the consolidated statement of financial assets when the obligation for the liability is cancelled, 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.

CURRENCY DERIVATIVES

Currency derivatives are measured at fair value in the balance sheet. Any gains or losses are recognized in net financial items in profit or loss. The derivatives are recognized under the heading "Current receivables and current liabilities" and are categorized as Level 2 instruments in the fair value hierarchy in accordance with IFRS 13. There are no official market listings for the currency derivatives and the market value obtained by the bank is used to determine the fair value of the derivatives. This market valuation is based on the difference between the forward rate and the current forward rate. The bank uses available market information and calculates an indicative market value.

TANGIBLE FIXED ASSETS

Tangible fixed assets are recognized in the consolidated 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 Group 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 principles

Depreciation takes place straight-line over the estimated useful life of the asset. The Group applies component depreciation, which means that the components' estimated useful lives are used as a basis for depreciation. The estimated useful life of the Group'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 Group consist of patents that are recognized at cost, less accumulated amortization and any impairment.

Amortization principles

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 indefinite 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 Group'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 calcu-

Note 1, cont.

lated. 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 contributions and vacation pay are expensed in the period when the employees perform their services.

Defined-contribution pension plans

The Group's pension obligations are encompassed 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 Group 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. When subscription warrants are exercised, the company issues new shares. Payments received are credited to share capital (nominal value) and other contributed capital.

WARRANT PROGRAMS

Share-based incentive programs are recognized in accordance with IFRS 2. There are two outstanding incentive programs based on subscription warrants aimed at the CEO and employees. Those individuals who subscribed for subscription warrants have paid a premium corresponding to the market value of the subscription warrants calculated using the Black & Scholes model. Since the market value has been paid, there is no impact on the company's result for the period or on its financial position. A description of the subscription warrants can be found in Note 13.

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 several 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 Group's result for the year attributable to the shareholders of the Parent Company and on the weighted average number of shares outstanding during the year.

PARENT COMPANY ACCOUNTING PRINCIPLES

The Parent Company has prepared its Annual Report in accordance with the Swedish Annual Accounts Act (1995:1554) and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities. The statements issued by the Swedish Financial Reporting Board applying to listed companies is also applied. RFR 2 requires that the Parent Company, in the An-

Note 1, cont.

nual Report for the legal entity, applies all IFRS and statements adopted by the EU to the extent that this is possible within the framework of the Annual Accounts Act and the Pension Obligations Vesting Act and taking into consideration the relationship between accounting and taxation. The recommendation specifies the exceptions and amendments to IFRS that must be applied.

DIFFERENCES BETWEEN THE GROUP AND PARENT COMPANY ACCOUNTING PRINCIPLES

The differences between Group and Parent Company accounting principles are presented below. The accounting principles stated below for the Parent Company have been consistently applied in all periods presented in the Parent Company's financial statements. The principles are unchanged compared with the previous year.

CLASSIFICATION AND PRESENTATION FORMATS

The income statement and balance sheet are presented in accordance with the form of presentation prescribed in the Annual Accounts Act. The presentation format for the statement of changes in equity is also consistent with the Group's format, but must also include the columns stated in the Annual Accounts Act. The differences between the Group's reports and the Parent Company's income statement and balance sheet mainly pertain to equity.

SUBSIDIARIES

Participations in subsidiaries are recognized at cost less any impairment. The recoverable amount is calculated if there is an indication of impairment of participations in subsidiaries. Impairment is recognized if the recoverable amount is less than the carrying amount. Impairment is recognized in the items "Result from participations in Group companies."

GROUP CONTRIBUTIONS

Group contributions are recognized as appropriations.

LEASES

In accordance with the exception permitted in RFR 2, the Parent Company does not apply IFRS 16. Expenses related to leases are determined each year and recognized straight-line over the lease term. Rewards received in connection with the signing of a lease are to be recognized in profit or loss as a reduction of the lease payments on a straight-line basis over the lease term. Variable payments are expensed in the periods in which they arise.

NOTE 2 SIGNIFICANT ESTIMATES AND ASSESSMENTS

When the Board of Directors and company management prepare financial statements in accordance with applied accounting principles, certain estimates must be made that may affect the carrying amounts of assets, liabilities, revenue and expenses.

These estimates and assessments are reviewed continuously and are based on historical experience and other factors, including expectations of future events considered reasonable under the prevailing circumstances. Changes in estimates are recognized in the period when the change is made if the change affects that period only, or in the period when the change is made and in future periods if the change affects the period in question and future periods.

Uncertainty in estimates gives rise to a significant risk that the value of assets or liabilities may need to be significantly adjusted during the coming financial year.

Revenue

Isofol has complex licensing agreements and management must make assessments and estimates in applying the principles for revenue recognition. The section on accounting principles relating to revenue sets out the areas where assessments and estimates need to be made. Areas that are important in the assessment are the breakdown and identification of the different commitments in contracts, how the price of these commitments should be allocated, when in time and how the commitments should be recognized (at a point in time or over time). Isofol must also determine whether an agreement containing a license to use Isofol's intellectual property constitutes a right of use, which is recognized at a point in time, or a right to access, which is recognized over time.

Expenditure for product development

Development costs for research aimed at obtaining new scientific knowledge, and where the research results are applied to produce a new product, are expensed in the period in which they arise. The Group's development project is a Phase II/III project. Accordingly, company management has assessed that no development costs have been or will be capitalized for the ongoing development project.

Input goods

Input goods are expensed when purchased in cases where they are not intended for sale, or when providing services. According to company management, input goods such as proprietary drug candidates or input goods that are part of the ongoing development project are to be expensed as incurred.

Deferred tax assets

As of December 31, 2021, tax loss carryforwards in the Group amounted to TSEK 1,013,590 (763,572). Until such time as the Group reports positive results for the ongoing Phase III study and taking into account the fact that there are no temporary tax differences against which the loss carryforward can be offset, the assessment is that no deferred tax assets will be recognized.

Impact of Covid-19 on the Group's risks

To date, Covid-19 has had a relatively limited impact on Isofol and its operations. The extent to which Covid-19 will impact Isofol's operations and specifically its clinical study during 2022 will largely depend on the pace at which global vaccination programs are rolled out and how quickly hospitals can return to normal operations. Isofol is carefully monitoring the development of Covid-19 and assessing the extent to which the operations may be impacted in the short and long term and which restrictions apply in each country. Isofol has adapted its operations and taken continuous precautionary measures to ensure that its employees, consultants and study

Note 3, cont.

participants stay safe and healthy and to ensure that the study is based on high-quality data. The AGENT study was fully enrolled in December 2020 and the risk of delays due to patient recruitment has therefore been reduced. However, there remains a risk that hospitals could close or that the collection of data could become more difficult due to future waves of Covid-19, which could delay the compilation of data ahead of the study's top-line results.

NOTE 3 OPERATING SEGMENTS

OPERATING SEGMENTS

The Group's operations comprise the development of the drug candidate arfolitixorin and are organized as a cohesive business within the framework of the ongoing Phase III AGENT study. Accordingly, all of the Group'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

	Group		Parent Company	
TSEK	**2021**	**2020**	**2021**	**2020**
North America	–	11,089	–	11,089
Asia	22,407	26,030	22,407	26,030
Total	**22,407**	**37,119**	**22,407**	**37,119**

Breakdown of revenue by type of revenue

	Group		Parent Company	
TSEK	**2021**	**2020**	**2021**	**2020**
Licensing	–	27,431	–	27,431
Execution of service assignments	22,407	9,688	22,407	9,688
Total	**22,407**	**37,119**	**22,407**	**37,119**

Contract assets

	Group		Parent Company	
TSEK	**2021**	**2020**	**2021**	**2020**
Accrued income	1,631	11,065	1,631	11,065
Contract liabilities	–	–	–	–
Total	**1,631**	**11,065**	**1,631**	**11,065**

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

NOTE 4 EMPLOYEES, PERSONNEL COSTS AND REMUNERATION TO SENIOR EXECUTIVES

Expenses for employee benefits

TSEK	**2021**	**2020**
GROUP		
Salaries and remuneration, etc.	20,712	17,268
Social security contributions	3,407	2,394
Pension cost	3,602	3,078
Total	**27,721**	**22,740**

TSEK	**2021**	**2020**
PARENT COMPANY		
Salaries and remuneration, etc.	20,712	17,268
Social security contributions	3,407	2,394
Pension cost	3,602	3,078
Total	**27,721**	**22,740**

Average number of employees

	2021	**of whom, women**	**2020**	**of whom, women**
PARENT COMPANY				
Sweden	13	55%	12	49%
Total Parent Company	**13**	**55%**	**12**	**49%**
Group total	**13**	**55%**	**12**	**49%**

Note 4, cont.

Gender distribution of the Board and company management	2021 Proportion of women	2020 Proportion of women
PARENT COMPANY		
Board of Directors	27%	31%
Other senior executives	0%	0%

	2021	2020
GROUP		
Boards of Directors	23%	27%
Other senior executives	0%	0%

Salaries, other remuneration and social security contributions

TSEK	2021	2020
PARENT COMPANY		
Salaries and remuneration	20,712	17,268
Social security contributions	7,009	5,471
(of which, pension cost)	(3,602)	(3,078)

Salaries and other remuneration distributed between senior executives and other employees as well as social security contributions in the Parent Company

TSEK	2021 Senior executives (4 individuals)	Other employees	2020 Senior executives (4 individuals)	Other employees
PARENT COMPANY				
Salaries and other remuneration	12,554	8,158	11,419	5,849
(of which, bonuses, etc.)	(2,844)	(1,089)	(1,981)	(626)
Social security contributions	2,843	4,166	2,655	2,816
(of which, bonuses, etc.)	(573)	(321)	(413)	(197)

Senior executives refer to the CEO, CMO, CCO and CFO.

CEO

During the 2021 financial year, CEO Ulf Jungnelius received a total salary of TSEK 5,047, of which TSEK 3,538 relates to base salary including vacation allowance and TSEK 1,510 relating to variable remuneration. The company car benefit amounted to TSEK 144. The pension premium amounted to 20 percent of salary, of which TSEK 711 pertained to 2021. The company has a notice period of six months as regards the CEO, and the CEO is also subject to a notice period of six months. In the event that the company terminates employment (except for serious breaches of contract), severance pay of 12 months' salary is payable. Employment is regulated in a CEO agreement.

During the 2021 financial year, Vice CEO Gustaf Albért received a total salary of TSEK 2,693, of which TSEK 2,018 relates to base salary including vacation allowance and TSEK 675 relates to variable remuneration.Isofol paid TSEK 482 in pension premiums in 2021.

OTHER SENIOR EXECUTIVES

During the 2021 financial year, other senior executives received salary and benefits amounting to TSEK 4,460 (4,435) including vacation allowance, of which TSEK 3,801 (3,870) relates to base salary and TSEK 659 (565) to variable remuneration. Benefits amounting to TSEK 126 (159) were paid, including TSEK 126 (159) in company car benefits and TSEK 0 (0) in other benefits. Premiums for customary occupational pension were paid. The retirement age is 65. Other senior executives have a notice period of three to six months if employment is terminated by the company and three to six months if they resign. No
senior executives are entitled to severance pay. As of December 31, there is an outstanding loan to senior executives of TSEK 10 (70) for subscription warrants.

Salaries and other remuneration, pension costs and other pension obligations for the CEO, Vice CEO and Board TSEK	2021 Senior executives	2020 Senior executives
GROUP		
Salaries and other remuneration	10,455	8,830
(of which, bonuses, etc.)	(2,185)	(1,416)
Pension costs	1,194	1,107
Pension obligations	–	–
Total remuneration	11,649	9,937

Note 4, cont.

Salaries and other benefits to the Board Parent Company 2021

TSEK	Base salary Board fees	Variable remuner-ation	Other benefits	Pension cost	Total
Chairman of the Board Pär-Ola Mannefred, private					
Remuneration from the Parent Company	653	–	–	–	653
Board member					
Lennart Jeansson, private					
Remuneration from the Parent Company	143	–	–	–	143
Board member					
Aram Mangasarian, private					
Remuneration from the Parent Company	263	–	–	–	263
Board member Paula Boultbee, private					
Remuneration from the Parent Company	263	–	–	–	263
Board member Alain Herrera, private					
Remuneration from the Parent Company	263	–	–	–	263
Board member Magnus Björsne, private					
Remuneration from the Parent Company	263	–	–	–	263
Board member Robert Marches-ani , private					
Remuneration from the Parent Company	288	–	–	–	288
Board member Anna Belfrage, private					
Remuneration from the Parent Company	350	–	–	–	350
Remuneration to the Board from the Parent Company	**2,486**	**–**	**–**	**–**	**2,486**

TSEK	Base salary	Variable remuner-ation	Other benefits	Pension cost	Total
CEO (Ulf Jungnelius) Remuneration from the Parent Company	3,538	1,510	144	712	5,903
Vice CEO (Gustaf Albèrt) Remuneration from the Parent Company	2,018	675	84	482	3,260
Remuneration to the CEO and Vice CEO from the Parent Company	**5,555**	**2,185**	**228**	**1,194**	**9,163**
Total remuneration from the Parent Company	**8,042**	**2,185**	**228**	**1,194**	**11,649**

Salaries and other benefits to the Board Parent Company 2020

TSEK	Base salary Board fees	Variable remuner-ation	Other benefits	Pension cost	Total
Chairman of the Board Pär-Ola Mannefred, private					
Remuneration from the Parent Company	615	–	–	–	615
Board member Aram Mangasarian, private					
Remuneration from the Parent Company	117	–	–	–	117
Board member Paula Boultbee, private					
Remuneration from the Parent Company	225	–	–	–	225
Board member Alain Herrera, private					
Remuneration from the Parent Company	233	–	–	–	233
Board member Magnus Björsne, private					
Remuneration from the Parent Company	225	–	–	–	225

Note 4, cont.

TSEK	Base salary Board fees	Variable remuner-ation	Other benefits	Pension cost	Total
Board member Robert Marchesani, private					
Remuneration from the Parent Company	265	–	–	–	265
Board member Anna Belfrage, private					
Remuneration from the Parent Company	325	–	–	–	325
Remuneration to the Board from the Parent Company	**2,004**	**–**	**–**	**–**	**2,004**

TSEK	Base salary	Variable remuner-ation	Other benefits	Pension cost	Total
CEO (Ulf Jungnelius) Remuneration from the Parent Company	3,284	990	123	671	5,068
Vice CEO (Gustaf Albèrt) Remuneration from the Parent Company	1,921	426	81	436	2,864
Remuneration to the CEO and Vice CEO from the Parent Company	**5,205**	**1,416**	**204**	**1,107**	**7,932**
Total remuneration from the Parent Company	**7,209**	**1,416**	**204**	**1,107**	**9,937**

NOTE 5 FEES AND REMUNERATION TO AUDITORS

TSEK	2021	2020
GROUP		
KPMG		
Audit engagement	240	220
Audit services in addition to audit engagement	–	–
Tax advisory services	–	–
Other assignments*	337	367
Total	**577**	**587**

TSEK	2021	2020
PARENT COMPANY		
KPMG		
Audit engagement	240	220
Audit services in addition to audit engagement	–	–
Tax advisory services	–	–
Other assignments	337	367
Total	**577**	**587**

* For 2021, pertains mainly to quality assurance services related to the rights issue in June 2021.

Audit engagement refers to the statutory audit of the Annual Report, the consolidated financial statements 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 6 FINANCIAL INSTRUMENTS BY CATEGORY

Financial assets measured at amortized cost

TSEK	2021	2020
GROUP		
Accounts receivable	–	2,318
Receivables from employees	23	131
Cash and cash equivalents	379,448	116,393
Total	**379,472**	**118,842**

TSEK	2021	2020
PARENT COMPANY		
Accounts receivable	–	2,318
Receivables from employees	23	131
Receivables from subsidiaries	–	1,600
Cash and bank balances	379,398	114,862
Total	**374,422**	**118,911**

Note 6, cont.

Financial liabilities measured at amortized cost

TSEK	2021	2020
GROUP		
Accounts payable	17,736	20,889
Accrued expenses	54,820	48,788
Total	**72,556**	**69,677**

TSEK	2021	2020
PARENT COMPANY		
Accounts payable	17,965	21,113
Accrued expenses	54,820	48,788
Total	**72,784**	**69,901**

Maturity structure of financial liabilities

TSEK	2021		2020	
Financial liabilities as of December 31, 2021 mature:	**Within 3 months**	**After 3 months**	**Within 3 months**	**After 3 months**
GROUP				
Accounts payable	17,736	–	20,889	–
Accrued expenses	54,820	–	48,788	–
Total	**72,556**	**–**	**69,677**	**–**

TSEK	2021		2020	
PARENT COMPANY				
Accounts payable	17,965	–	21,113	–
Accrued expenses	54,820	–	48,788	–
Total	**72,784**	**–**	**69,901**	**–**

The Group's financial assets and financial liabilities in the balance sheet are measured at amortized cost, with the exception of financial instruments in the form of currency derivatives, which are measured at fair value.

Classification and fair value

TSEK	2021		2020	
	Measured at fair value through profit or loss	**Financial assets measured at amortized cost**	**Measured at fair value through profit or loss**	**Financial assets measured at amortized cost**
GROUP				
Financial assets				
Currency futures	1,663	–	–	–
Accounts receivable	–	–	–	2,318
Receivables from employees	–	23	–	131
Cash and cash equivalents	–	379,448	–	116,393
Financial liabilities				
Currency futures	–	–	1,872	–
Accounts payable	–	17,736	–	20,889
Accrued expenses	–	54,820	–	48,788

Classification and fair value

TSEK	2021		2020	
	Measured at fair value through profit or loss	**Financial assets measured at amortized cost**	**Measured at fair value through profit or loss**	**Financial assets measured at amortized cost**
PARENT COMPANY				
Financial assets				
Currency futures	1,663	–	–	–
Accounts receivable	–	–	–	2,318
Receivables from employees	–	23	–	131
Receivables from subsidiaries	–	–	–	1,600
Cash and cash equivalents	–	379,398	–	114,862
Financial liabilities				
Currency futures	–	–	1,872	–
Accounts payable	–	17,965	–	21,113
Accrued expenses	–	54,820	–	48,788

NOTE 7 TAXES

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

TSEK	2021	2020
GROUP		
Current tax costs (-)/tax income (+)		
Tax costs/tax income for the year*	–	-1
Deferred tax costs (-)/tax income (+)		
Deferred tax attributable to temporary differences	–	–
Total recognized tax costs in the Group	**–**	**-1**

* Refers to previous years' tax costs in the subsidiary

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

TSEK	2021	2020
PARENT COMPANY		
Current tax costs (-)/tax income (+)		
Tax costs for the year	–	–
Deferred tax costs (-)/tax income (+)		
Deferred tax attributable to temporary differences	–	–
Total recognized tax costs in the Parent Company	**–**	**–**

Reconciliation of effective tax

TSEK	2021		2020	
GROUP				
Result before tax		-200,251		-188,991
Tax at applicable tax rate for the Parent Company	20.60%	41,252	21.40%	40,444
Non-deductible expenses	0.1%	165	1.1%	2,097
Non-taxable revenue	-0.8%	-1,663	0.0%	–
Other unrecognized expenses	-24.1%	-48,240	-15.3%	-28,941
Increase in loss carryforwards without corresponding capitalization of deferred tax	4.2%	8,486	-7.2%	-13,600
Effective tax recognized	**0.0%**	**–**	**0.0%**	**–**

Reconciliation of effective tax

TSEK	2021		2020	
PARENT COMPANY				
Result before tax		-200,280		-189,282
Tax at applicable tax rate for the Parent Company	20.60%	41,258	21.40%	40,506
Non-deductible expenses	0.1%	165	1.1%	2,097
Non-taxable revenue	-0.8%	-1,663	0.0%	0
Other unrecognized expenses	-24.1%	-48,240	-15.3%	-28,941
Increase in loss carryforwards without corresponding capitalization of deferred tax	4.2%	8,480	-7.2%	-13,662
Effective tax recognized	**0.0%**	**–**	**0.0%**	**–**

Accumulated loss carryforwards as of December 31, 2021 amounted to TSEK 1,013,590 (763,572). These loss carryforwards have no time limit. No taxes have been recognized directly in equity or in other comprehensive income.

NOTE 8 INTANGIBLE FIXED ASSETS

	Acquired intangible assets Patents	
TSEK	Group	Parent Company
COST		
Opening balance, Jan 1, 2021	994	994
Closing balance, Dec 31, 2021	**994**	**994**
ACCUMULATED AMORTIZATION		
Opening balance, Jan 1, 2021	-994	-994
Amortization for the year	–	–
Closing balance, Dec 31, 2021	**-994**	**-994**
Closing balance, Dec 31, 2021	**–**	**–**

	Acquired intangible assets Patents	
TSEK	Group	Parent Company
COST		
Opening balance, Jan 1, 2020	994	994
Closing balance, Dec 31, 2020	**994**	**994**

Note 9, cont.

	Acquired intangible assets Patents	
TSEK	**Group**	**Parent Company**
ACCUMULATED AMORTIZATION		
Opening balance, Jan 1, 2020	-900	-900
Amortization for the year	-94	-94
Closing balance, Dec 31, 2020	**-994**	**-994**
Closing balance, Dec 31, 2020	**-**	**-**

NOTE 9 TANGIBLE FIXED ASSETS

	Equipment and tools	
TSEK	**Group**	**Parent Company**
COST		
Opening balance, Jan 1, 2021	535	535
New acquisitions	-	-
Closing balance, Dec 31, 2021	**535**	**535**

	Equipment and tools	
TSEK	**Group**	**Parent Company**
ACCUMULATED DEPRECIATION		
Opening balance, Jan 1, 2021	-300	-300
Depreciation for the year	-77	-77
Closing balance, Dec 31, 2021	**-377**	**-377**
Closing balance, Dec 31, 2021	**158**	**158**

	Equipment and tools	
TSEK	**Group**	**Parent Company**
COST		
Opening balance, Jan 1, 2020	535	535
New acquisitions	-	-
Closing balance, Dec 31, 2020	**535**	**535**
ACCUMULATED DEPRECIATION		
Opening balance, Jan 1, 2020	-197	-197
Depreciation for the year	-103	-103
Closing balance, Dec 31, 2020	**-300**	**-300**
Closing balance, Dec 31, 2020	**235**	**235**

	Right-of-use assets	
TSEK	**Group**	**Parent Company**
COST		
Opening balance, Jan 1, 2021	5,745	-
New acquisitions	83	-
Divestments	-155	-
Closing balance, Dec 31, 2021	**5,673**	**-**
ACCUMULATED DEPRECIATION		
Opening balance, Jan 1, 2021	-2,722	-
Depreciation for the year	-1,518	-
Divestments	155	-
Closing balance, Dec 31, 2021	**-4,085**	**-**
Closing balance, Dec 31, 2021	**1,587**	**-**

	Right-of-use assets	
TSEK	**Group**	**Parent Company**
COST		
Opening balance, Jan 1, 2020	5,480	-
New acquisitions	640	-
Divestments	- 375	-
Closing balance, Dec 31, 2020	**5,745**	**-**
ACCUMULATED DEPRECIATION		
Opening balance, Jan 1, 2020	-1,382	-
Depreciation for the year	-1,573	-
Divestments	233	-
Closing balance, Dec 31, 2020	**-2,722**	**-**
Closing balance, Dec 31, 2020	**3,023**	**-**

NOT 10 OTHER RECEIVABLES

TSEK	**Dec 31, 2021**	**Dec 31, 2020**
GROUP		
Other receivables	4,817	4,122
Advance payments to suppliers	5,796	4,618
Currency derivatives	1,663	-
Total	**12,276**	**8,740**

Note 10, cont.

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
Other receivables	4,817	4,122
Advance payments to suppliers	5,796	4,618
Currency derivatives	1,663	–
Total	**12,276**	**8,740**

NOTE 11 PREPAID EXPENSES AND ACCRUED INCOME

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Accrued income	1,631	11,065
Rent	114	120
Clinical studies	129	331
Pre-commercial activities	262	–
Other	748	874
Total	**2,884**	**12,390**

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
Accrued income	1,631	11,065
Rent	343	343
Clinical studies	129	331
Pre-commercial activities	262	–
Other	748	874
Total	**3,113**	**12,614**

NOTE 12 CASH AND CASH EQUIVALENTS

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
The following sub-items are included in cash and cash equivalents:		
Cash and cash equivalents	379,448	116,393
Short-term investments, equal to cash and cash equivalents	–	–
Total according to statement of financial position	**379,448**	**116,393**

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
The following sub-items are included in cash and cash equivalents:		
Cash and bank balances	379,398	114,862
Short-term investments, equal to cash and cash equivalents	–	–
Total according to balance sheet	**379,398**	**114,862**

NOTE 13 EQUITY

Types of shares Number of shares	2021	2020
ORDINARY SHARES		
Issue on Jan 1	83,365,966	32,054,802
New share issue	78,149,474	51,311,164
Issued as of 31 December – paid	**161,515,440**	**83,365,966**

As of December 31, 2021, the registered share capital comprised 161,515,440 ordinary shares (83,365,966) 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 have the same rights to the Group's remaining net assets. Non-restricted equity in the Parent Company consists of the amount available for dividends to shareholders. For Isofol, non-restricted equity in the Parent Company comprises retained earnings and the share premium reserve. The share premium reserve and other contributed capital comprise the amounts contributed by the shareholders in addition to the nominal value for the issued shares less any issue costs.

WARRANT PROGRAM 2020

The Annual General Meeting on June 24, 2020 resolved to establish a long-term incentive program ("Warrant Program 2020") aimed at the CEO of the company. Warrant Program 2020 should be seen as a supplementary program aimed exclusively at the company's CEO, who did not participate in Warrant Program 2018. The program, which includes a maximum of 250,000 subscription warrants, will result in a smaller dilution for the company's shareholders since the company canceled approximately 408,000 subscription warrants from Warrant Program 2018 in conjunction with the 2020 Annual General Meeting. The maximum of 250,000 subscription warrants entitles the holder to subscribe for a maximum of 370,000 shares (after the completion of the rights issue in June 2020). In August 2020, the CEO subscribed for all 250,000 subscription warrants at a price corresponding to SEK 0.24 per subscription warrant, generating SEK 60,000 in warrant premiums. The subscription warrants were transferred at market value. The subscription price for series 20/23 was set at SEK 37.0 per share.

Note 13, cont.

After recalculation in accordance with the terms of the program due to the company's rights issue in June 2021, the current exercise price for series 20/23 is SEK 30.3 per share (subscription period from May 15 to July 15, 2023). The current recalculation factor is set at 1.81.

WARRANT PROGRAMS 2018/22 AND 2018/23

At an extraordinary general meeting held on December 17, 2018, the shareholders resolved to introduce an incentive program for all employees in the company and future key employees. The program was designed as a long-term incentive to the company's employees and senior executives and to promote investments in and ownership of the company's shares. The program consists of a maximum of 1,461,698 subscription warrants and is designed in such a manner that the subscription warrants were transferred at market value in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB. At the end of each program, each subscription warrant entitles the holder to subscribe for one new share in Isofol at the applicable exercise price. The subscription price for series 18/22 was set at SEK 51.3 per share and the subscription price for series 18/23 at SEK 76.9 per share.

After recalculation in accordance with the terms of the program due to the company's rights issues in June 2020 and June 2021, the current exercise price for series 18/22 is SEK 28.3 per share (subscription period from May 15 to July 15, 2022) and the current exercise price for series 18/23 is SEK 42.5 per share (subscription period from May 15 to July 15, 2023). The current recalculation factor is set at 1.81.

In early February 2020 and in May 2020, 207,287 subscription warrants were repurchased by Isofol. These subscription warrants were attributable to individuals who had terminated their employment with Isofol. The repurchase took place at market value, calculated according to the Black & Scholes model. The market valuation was performed by an external valuation consultant. The repurchase pertained to Warrant Programs 2018/2022 and 2018/2023 issued in January 2019. Of the total number of warrants, approximately 408,000 subscription warrants remained that had not been transferred or repurchased by participants whose employment with the company had ended. In conjunction with the 2020 Annual General Meeting, all outstanding subscription warrants in Warrant Program 2018 were canceled. The company's management and employees paid the warrant proceeds in 2019, pertaining to Warrant Program 2018, through a cash payment and a loan from the company. The loan will be paid off over three years.

In November 2020, subscription warrants were repurchased from a senior executive who had terminated his employment with Isofol Medical AB (publ). The repurchase was based on a market valuation in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB. The repurchase comprised a total of 117,534 warrants at a total cost of SEK 73,460 and pertained to Warrant Program 2018. In conjunction with the repurchase, all repurchased subscription warrants were transferred at market value to the newly appointed Chief Commercial Officer (CCO), Tony Gustavsson.

In December 2021, subscription warrants were repurchased from a senior executive who had terminated his employment with Isofol Medical AB (publ). The repurchase was based on a market valuation in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB. The repurchase comprised a total of 117,534 warrants at a total cost of SEK 1,011 and pertained to Warrant Program 2018. In conjunction with the repurchase, 49,134 repurchased subscription warrants were transferred at market value to the newly appointed Chief Commercial Officer (CCO), Jenny Sundqvist, and the remaining 68,400 subscription warrants to members of the clinical team.

Upon full exercise of all warrant programs issued for the subscription of shares, a total of 2,359,980 shares will be issued, corresponding to a dilution of approximately 1.5%.

TSEK	2021	2020
GROUP		
Subscription warrants, proceeds	–	–
Loans to management and employees	–	–
Repayment from management and employees	82	305
Repurchase of subscription warrants	0	-57
Issued subscription warrants, CEO	–	60
Issued as of 31 December – paid	**82**	**308**

NOTE 14 APPROPRIATION OF PROFIT

PROPOSED APPROPRIATION OF THE COMPANY'S PROFIT

The Board of Directors proposes that the non-restricted equity, SEK 313,352,021, be appropriated as follows:

To be carried forward	313,352,021
Total	**313,352,021**

NOTE 15 OTHER LIABILITIES

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Other current liabilities		
Personnel-related liabilities	1,632	2,175
Current lease liabilities	1,542	1,677
Currency derivatives	–	1,872
Other current liabilities	–	–
Total other current liabilities	**3,174**	**5,724**

Note 15, cont.

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
Personnel-related liabilities	1,632	2,175
Currency derivatives	–	1,872
Other current liabilities	–	119
Total other current liabilities	**1,632**	**4,166**

NOTE 16 ACCRUED EXPENSES AND DEFERRED INCOME

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Vacation pay	2,463	1,506
Accrued salaries	4,828	3,216
Clinical studies	45,587	46,353
Other	9,233	2,435
Total	**62,110**	**53,511**

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
Vacation pay	2,463	1,506
Accrued salaries	4,828	3,216
Clinical studies	45,587	46,353
Other	9,233	2,435
Total	**62,110**	**53,511**

NOTE 17 FINANCIAL RISKS AND RISK MANAGEMENT

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

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

The Group's financial transactions and risks are managed by the Parent Company through 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. Isofol may also continue to require significant capital for research and development with the aim of completing the ongoing clinical study of arfolitixorin.

FINANCE POLICY

Isofol has a Group-wide policy for its financial activities – the finance 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 Group's activities are fully financed with equity and are not, therefore, exposed to risks related to external loan financing. The primary risks therefore 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 Group's financing and the dominant 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 Group 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. Given that the company currently has limited self-financing capacity, it is essential that financing can be secured from owners and independent investors in order for the company to operate as planned. 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 Group's finance 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 currency risks. 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.

Note 17, cont.

The Group is affected by fluctuations in exchange rates, and the Group'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. To date, this impact has been limited, but most of the costs for Isofol's clinical studies and pre-commercial activities will be in these currencies.

CREDIT RISK

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

NOTE 18 LEASES

The Group rents office premises in Gothenburg. The current lease for the office premises expires on December 31, 2022. The Group has also signed leases for company cars and some office equipment.

Rental fees are linked to the CPI and vary with the market as a whole. Variable payments are invoiced on a 1:1 basis and an annual reconciliation is carried out. There are no restrictions as a result of signed leases. In cases where refurbishment and extensions have been financed by the Group, an individual assessment is made as to whether the costs are approved for capitalization or whether they are to be expensed in their entirety.

Cost disclosures, leases

TSEK	2021	2020
GROUP		
Depreciation of right-of-use assets	1,518	1,573
(- Of which, office premises)	(1,118)	(1,118)
(- Of which, vehicles)	(372)	(427)
(- Of which, other equipment)	(28)	(28)
Interest expense, lease liability	89	143
Lease expense for short-term leases	103	103
Lease expense for assets of low value	–	–
Variable lease payments	–	–
Total	**1,710**	**1,819**

Cash flow disclosures, leases

TSEK	2021	2020
GROUP		
Repayment of lease liability	1569	1553
Interest expense, lease liability	89	143
Lease expense for short-term leases	103	103
Lease expense for assets of low value	–	–
Variable lease payments	–	–
Total	**1,761**	**1,799**

Additional right-of-use assets

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Vehicles	–	640
Other equipment	83	–
Total	**83**	**640**

Carrying amount of right-of-use assets

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Office premises	1,118	2,236
Vehicles	401	773
Other equipment	69	14
Total	**1,588**	**3,023**

Carrying amount of lease liabilities

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Long-term lease liabilities	110	1,439
Current lease liabilities	1,542	1,677
Total	**1,653**	**3,117**

Expensed lease payments amount to the following:

TSEK	2021	2020
PARENT COMPANY		
Minimum lease payments	1,740	1,799
Total lease expenses	**1,740**	**1,799**

Note 18, cont.

Future non-cancellable lease payments fall due as follows:

	Group		Parent Company	
TSEK	**2021**	**2020**	**2021**	**2020**
Within 1 year	1,641	1,654	1,693	1,758
Between 1 and 5 years	99	1,651	99	1,703
After 5 years	–	–	–	–
Total lease expenses	**1,739**	**3,305**	**1,791**	**3,461**

NOTE 19 PLEDGED ASSETS, CONTINGENT LIABILITIES AND CONTINGENT ASSETS

Group

TSEK	**Dec 31, 2021**	**Dec 31, 2020**
PLEDGED ASSETS		
In the form of pledged assets for own liabilities and provisions	–	–
Restricted bank balances	50	50
Total pledged assets	**50**	**50**
Contingent liabilities	none	none

Parent Company

TSEK	**Dec 31, 2021**	**Dec 31, 2020**
PLEDGED ASSETS		
In the form of pledged assets for own liabilities and provisions	–	–
Restricted bank balances	50	50
Total pledged assets	**50**	**50**
Contingent liabilities	none	none

Pledged assets also refer to collateral in the form of cash and cash equivalents for derivative instruments. The company has pledged TSEK 42,124 (40,898) of its cash and cash equivalents as collateral for currency futures.

NOTE 20 RELATED PARTIES

Related parties

The Parent Company has a related-party relationship with its subsidiary, Isofol Medical (Incentive) AB. Other related comprise senior executives in the company, meaning the Board and company management and their family members. Transactions with related parties are priced and take place on market terms. Remuneration to senior executives was paid according to applicable policies and guidelines during the year. For information on remuneration to each key employee in senior management, refer to Note 4. No other related-party transactions took place during the period.

NOTE 21 GROUP COMPANIES

Specification of the Parent Company's direct holdings of participations in subsidiaries

Subsidiary/ Corp. ID no. / Registered office	**No. of participations**	**Participations in %**	**Carrying amount**	
			Dec 31, 2021	**Dec 31, 2020**
Isofol Medical (Incentive) AB,				
556894-0133/Gothenburg	500	100	50	50

NOTE 22 SPECIFICATIONS RELATED TO THE CASH FLOW STATEMENT

Cash and cash equivalents – Group

TSEK	**Dec 31, 2021**	**Dec 31, 2020**
THE FOLLOWING SUB-ITEMS ARE INCLUDED IN CASH AND CASH EQUIVALENTS:		
Cash and cash equivalents	379,448	116,393
Short-term investments, equal to cash and cash equivalents	–	–
Total according to balance sheet	**379,448**	**116,393**

Cash and cash equivalents – Parent Company

TSEK	**Dec 31, 2021**	**Dec 31, 2020**
THE FOLLOWING SUB-ITEMS ARE INCLUDED IN CASH AND CASH EQUIVALENTS:		
Cash and bank balances	379,398	114,862
Short-term investments, equal to cash and cash equivalents	–	–
Total according to balance sheet	**379,398**	**114,862**

Interest and dividends

TSEK	2021	2020
GROUP		
Interest received	1,503	4
Interest paid	-168	-1,740

TSEK	2021	2020
PARENT COMPANY		
Interest received	1,503	4
Interest paid	-79	-1,597

Adjustments for non-cash items

TSEK	2021	2020
GROUP		
Depreciation and amortization	1,596	1,770
Exchange rate gain/loss	-1,007	334
Financial instruments	-3,535	1,872
Long-term lending	–	–
Other	1	-17
Total	**-2,946**	**3,958**

TSEK	2021	2020
PARENT COMPANY		
Depreciation and amortization	77	197
Exchange rate gain/loss	-1,007	334
Financial instruments	-3,535	1,872
Long-term lending	–	–
Group contributions paid	–	-293
Other	1	–
Total	**-4,464**	**2,110**

NOTE 23 EVENTS AFTER THE BALANCE SHEET DATE

- Jenny Sundqvist assumed her role as Chief Commercial Officer on January 1, 2022.
- The company's nomination committee proposes that Jan Törnell is elected chair of the board at the Annual General Meeting 2022..
- On April 22, 2022, it was announced that data analysis of the global pivotal Phase III study AGENT had begun following a dialogue with the FDA regarding censoring rules and the requirement for progression-free survival events to begin data gathering and analysis.

NOTE 24 EARNINGS PER SHARE

Calculations have been made in accordance with IAS 33 Earnings Per Share. Earnings per share are based on the Group's result for the year attributable to the shareholders of the Parent Company divided by the weighted average number of shares outstanding during the year. To calculate earnings per share after dilution, the weighted average number of outstanding ordinary shares is adjusted for the dilution effect of all potential ordinary shares. These potential ordinary shares are attributable to the warrants allotted to the Board of Directors and the CEO as well as the employees who have vested stock options. See Notes 4 and 13. If the result for the year is negative, the warrants are not considered dilutive. For information on changes in the number of shares outstanding, see Note 13 Equity. The weighted average number of shares during the period amounted to 125,645,164 (61,468,785).

NOTE 25 FINANCIAL ITEMS

TSEK	2021	2020
GROUP		
Financial revenue		
Exchange rate gain	843	–
Gain, financial instruments	3,535	–
Other interest income	5	4
Total financial income	**4,383**	**4**
Financial costs		
Exchange rate losses	–	-334
Loss, financial instruments	–	-2,014
Other interest expenses	-168	-153
Total financial expenses	**-168**	**-2,501**

TSEK	2021	2020
PARENT COMPANY		
Financial revenue		
Exchange rate gain	843	–
Gain, financial instruments	3,535	–
Other interest income	5	4
Total financial income	**4,383**	**4**

Note 25, cont.

TSEK	2021	2020
Financial costs		
Exchange rate losses	–	-334
Loss, financial instruments	–	-2,014
Other interest expenses	-79	-10
Total financial expenses	**-79**	**-2,358**

NOTE 26 LONG-TERM RECEIVABLES

As part of the AGENT study, Isofol signed an agreement with a CRO in the US to manage and coordinate the AGENT study in the US. In accordance with the agreement, Isofol paid an advance in 2018 through 2020 of 15 percent of the order value, corresponding to TUSD 980 (TSEK 8,761), which in 2020 was offset down to 7.5 percent of the total order value. The remaining 7.5 percent is contractually due to be settled in early 2023 and is therefore classified as a financial fixed asset corresponding to TSEK 5,009. The receivable is denominated in USD but Isofol has SEK as its reporting and functional currency.

In addition, the Group and the Parent Company had a long-term receivable from employees relating to loans to employees in respect of the Warrant Programs 2018 series 2018/2022 and series 2018/2023. This receivable was settled during the financial year.

Specification of other long-term receivables

TSEK	Dec 31, 2021	Dec 31, 2020
GROUP		
Clinical studies	5,009	5,009
Receivables from employees	–	22
Total	**5,009**	**5,031**

TSEK	Dec 31, 2021	Dec 31, 2020
PARENT COMPANY		
Clinical studies	5,009	5,009
Receivables from employees	–	22
Receivables from subsidiaries	–	1,600
Total	**5,009**	**6,631**

NOTE 27 INFORMATION REGARDING THE PARENT COMPANY

Isofol Medical AB (publ) is a Swedish-registered limited liability company with its registered office in Gothenburg. The Parent Company's shares are listed on Nasdaq Stockholm. The address of the head office is Arvid Wallgrens Backe 20, SE-413 46 Gothenburg. The consolidated financial statements for 2021 comprise the Parent Company and its subsidiaries, which are jointly referred to as the Group.

NOTE 28 KEY FIGURES AND DEFINITIONS

This report includes key figures that are not defined in IFRS, but are included in the report because management believes that this information allows investors to analyze the Group's earnings trend and financial position. Investors should consider these key figures as a supplement to the IFRS financial information.

TSEK	Dec 31, 2021	Dec 31, 2020
Equity	318,233	66,567
Total assets	**401,363**	**148,130**
Solvency	**79.3%**	**44.9%**
Cash and cash equivalents	379,448	116,393
Working capital	311,589	59,717

SOLVENCY
Solvency 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, other contributed capital and retained earnings, including the Group's result for the year.

CASH AND CASH EQUIVALENTS
Cash and cash equivalents comprise cash and bank balances, immediately available bank balances and other money market instruments with original maturities of less than three months.

WORKING CAPITAL
Working capital consists of the Group'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.

To calculate earnings per share after dilution, the weighted average number of outstanding ordinary shares is adjusted for the dilution effect of all potential ordinary shares. These potential ordinary shares are attributable to the warrants included in Warrant Program 2018 (series 2018/2022 and series 2018/2023) and Warrant Program 2020. If the result for the period is negative, the warrants are not considered dilutive.

CERTIFICATION

The Board of Directors and the CEO verify that the Annual Report has been prepared in accordance with generally accepted accounting principles in Sweden, and that the consolidated financial statements have been prepared in accordance with the international accounting standards referred to in the European Parliament and Council's Regulation (EC) no. 1606/2002 of July 19, 2002 on the application of international accounting standards. The Annual Report and consolidated financial statements provide a true and fair view of the Parent Company's and the Group's position and result. The Directors' Report for the Parent Company and the Group provides a fair overview of the Parent Company's and the Group's performance and the Group's activities, position and result, and describe significant risks and uncertainties facing the Parent Company and the companies included in the Group.

As stated above, the Annual Report and consolidated financial statements have been approved for issuance by the Board and the CEO on April 27, 2022. The consolidated income statement and statement of financial position and the Parent Company's income statement and balance sheet are subject to adoption by the Annual General Meeting on May 19, 2022.

Gothenburg, April 27, 2022

Pär-Ola Mannefred
Chairman

Magnus Björsne
Board member

Paula Boultbee
Board member

Alain Herrera
Board member

Robert Marchesani
Board member

Anna Belfrage
Board member

Aram Mangasarian
Board member

Lennart Jeansson
Board member

Ulf Jungnelius
CEO

Our audit report has been submitted
Gothenburg, April 27, 2022
KPMG AB

Jan Malm
Authorized Public Accountant

AUDITOR´S REPORT

To the general meeting of the shareholders of Isofol Medical AB (publ), corp. id 556759-8064

REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

Opinions

We have audited the annual accounts and consolidated accounts of Isofol Medical AB (publ) for the year 2021, except for the corporate governance statement on pages 37-46. The annual accounts and consolidated accounts of the company are included on pages 31-73 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 the parent company as of 31 December 2021 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2021 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 37-46. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the statement of comprehensive income and statement of financial position for the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's 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 the parent company and the group 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 and consolidated 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 and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

The company´s costs

See principles on pages 53-58 in the annual account and consolidated accounts for information and description of the matter.

Description of key audit matter

The costs for the company's operations amounted to SEK 226,9 million during the financial year 2021. Most of the costs relate to the development of the company's leading product Arfolitixorin and consist mainly of expenses for hired and own staff.

In our audit, we have focused on these costs as they together amount to a significant amount and that there is a risk regarding the accuracy, completeness and accrual of these expenses.

Response in the audit

Our review of the costs has included an evaluation of the company's routines, business follow-up and internal control.

We have tested the company's controls for provision for accrued expenses and approval and payment of supplier invoices and personnel costs. We have also reconciled and performed detailed testing against invoice documentation, agreements and other year-end documentation.

For personnel-related costs we performed an analytical review of salaries. Our analyze of costs is based on both historical and even on our knowledge of the business and follow-up on internal reports.

We have also assessed the content of the information on costs provided in the annual report and consolidated accounts.

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 1-30 and 78-80. The other information comprises also of 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 consolidated accounts and that they give a fair presentation

in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. 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 and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group'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 and consolidated 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 and consolidated 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 and consolidated 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 and consolidated 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 and the group'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 and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated 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 a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

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 REGULATORY REQUIREMENTS

Auditor's audit of the administration and the proposed appropriations of profit or loss

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Isofol Medical AB (publ) for the year 2021 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 the parent company and the group 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 and the group's type of operations, size and risks place on the size of the parent company's and the group'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 and the group'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 company'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 ESEF REPORT

Opinion

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Managing Director have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Isofol Medical AB (publ) for year 2021.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report #[CT22sc75WX0FVMc=] has been prepared in a format that, in all material respects, enables uniform electronic reporting.

Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility 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 evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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 Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Managing Director determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error..

Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 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 aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 *Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements* and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Managing Director, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of the assumptions made by the Board of Directors and the Managing Director.

The procedures mainly include a technical validation of the Esef report, i.e. if the file containing the Esef report meets the technical specification set out in the Commission's Delegated Regulation (EU) 2019/815 and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the Esef report has been marked with iXBRL which enables a fair and complete machine-readable version of the consolidated statement of financial performance, financial position, changes in equity and cash flow.

The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 37-46 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR´s auditing 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 consolidated 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 June 23, 2021. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2016.

Gothenburg, April 27, 2022

KPMG AB

Jan Malm
Authorized Public Accountant

GLOSSARY

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

Censoring in the AGENT study PFS data for all patient in the study cannot be included in the analysis due to that they have started another treatment prior to reaching progress. The exclusion is done according to FDA and EMA guidelines, which were in force at the start of the study.
CMC Chemistry, manufacturing and controls
CRC Colorectal cancer
iDSMB Independent Data Safety Monitoring Board
EMA European Medicines Agency
FDA US Food and Drug Administration
Final study result More detailed information from the study is planned for presentation at medical congresses and/or in peer-reviewed journals.
IND Investigational New Drug (for the FDA)
Interim analysis The AGENT study included an interim analysis, the primary objective of which was
to finalize the size of the study, meaning how many patients are to be enrolled
[6R]-MTHF [6R]-5,10-methylenetetrahydrofolate
MTX Methotrexate
ORR Objective response rate
OS Overall survival
TGA Australian Therapeutic Goods Administration

PMDA Japanese Pharmaceuticals and Medical Devices Agency
Top-line results A summary from a clinical study of demographic data, data for the primary endpoint and a summary of safety data, which is based on a deblinded, locked database.
PFS Progression-free survival

STUDY PHASES

Preclinical study
Research that takes place before a drug or treatment method is sufficiently documented to be studied in humans. Includes 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 map 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 Paues Åberg Communication and Carlund & Co.
Photos: page 1 iStock, page 3 Depositphoto (Ukraine), page 4 Depositphoto, Nasdaq Stockholm, page 5 Björn Eklund, page 13 Cecilia Hedström, page 20 Depositphoto (Ukraine), page 40, 41, 45, Magnus Sundberg, Cecilia Hedström, Falkuggla AB and Martin Fröström, page 79 David Holm and private photos.

Financial reports

The following reports are scheduled for publication:

Interim report January-March 2022	May 12, 2022
Interim report April-June 2022	August 23, 2022
Interim report July-September 2022	November 10, 2022
Year-end report 2022	February 23, 2023

Interim reports are published on the company's website www.isofolmedical.com

Calendar

2022 Annual General Meeting	May 19, 2022

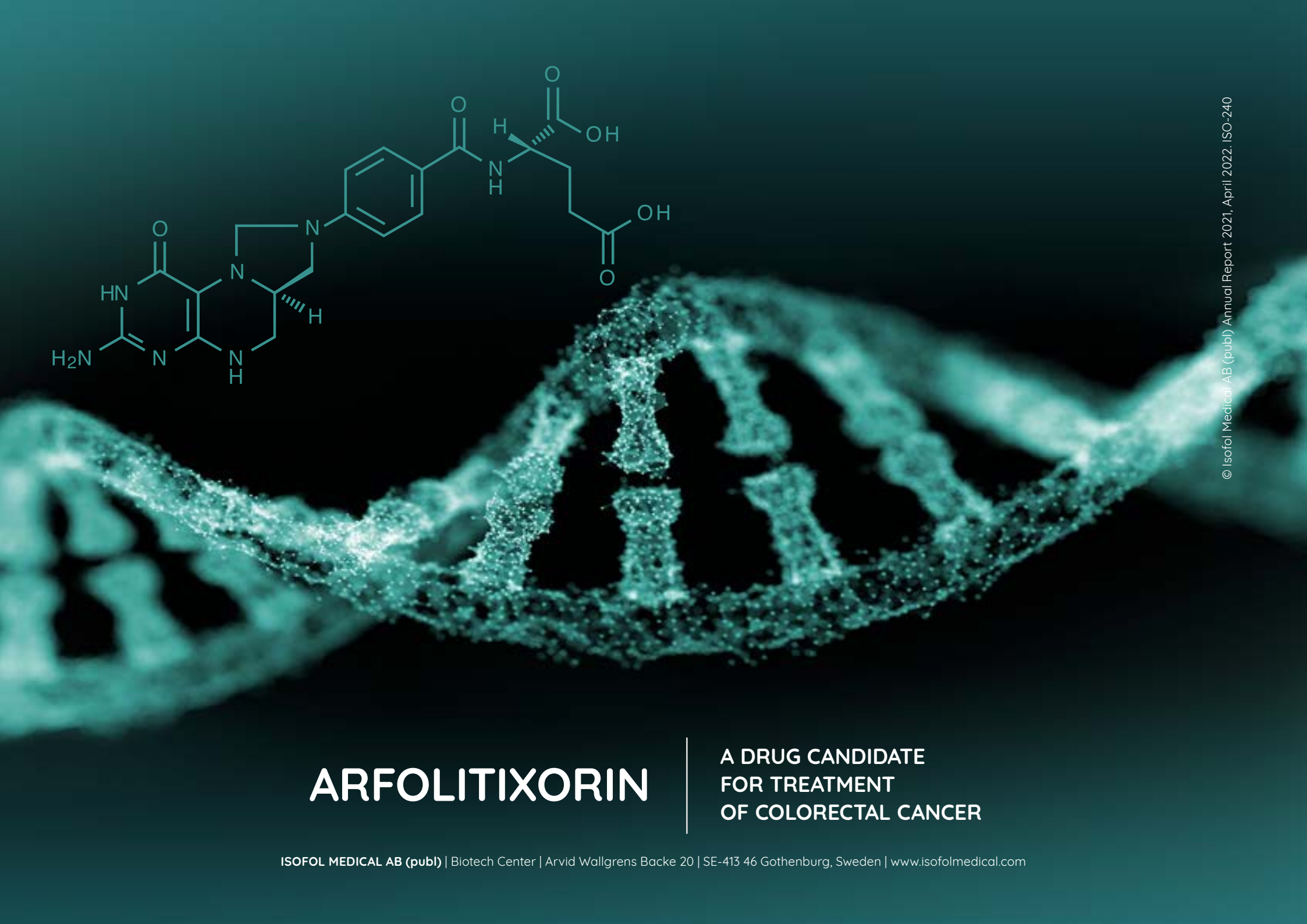
For further information, contact:

Ulf Jungnelius, CEO
Telephone: +46 709 16 89 55
Email: jungnelius@isofolmedical.com

Gustaf Albèrt, CFO
Telephone: +46 709 16 83 02
Email: gustaf.albert@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



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