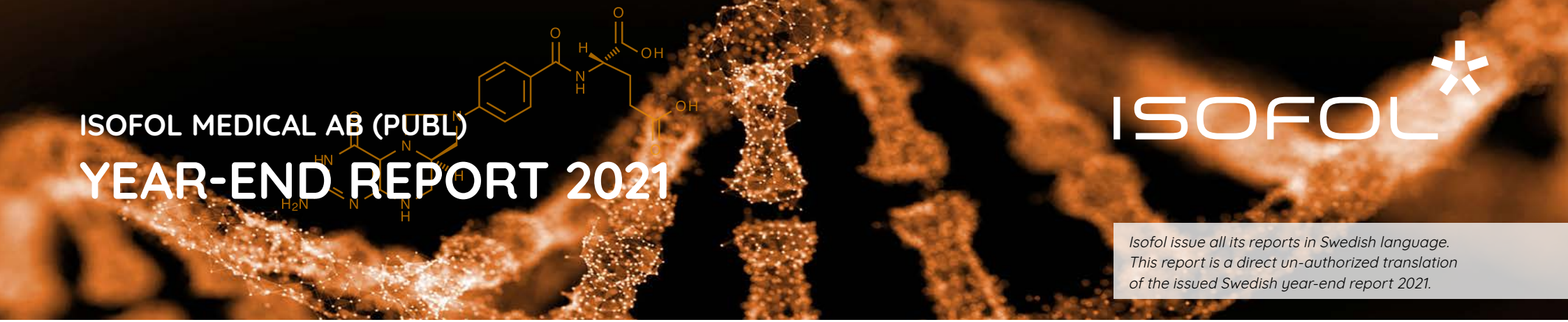


ISOFOL MEDICAL AB (PUBL)

YEAR-END REPORT 2021

Isofol issue all its reports in Swedish language. This report is a direct un-authorized translation of the issued Swedish year-end report 2021.

High level of activity to complete the AGENT study and prepare for commercialization

SIGNIFICANT EVENTS DURING THE FOURTH QUARTER

- On October 21, Isofol's shares were listed on Nasdaq Stockholm.
- Isofol was granted Fast Track Designation by the US Food and Drug Administration (FDA) for arfolitixorin for the treatment of advanced colorectal cancer (CRC).
- 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 tumor progression (PFS). However, the study's primary endpoint, objective response rate (ORR), was not affected and an agreement for a new cut-off point for top-line results is expected in spring 2022.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- Jenny Sundqvist assumed her role as Chief Commercial Officer on January 1, 2022.

FINANCIAL INFORMATION

Fourth quarter, October–December 2021

- Net revenue amounted to TSEK 4,704 (18,680) and other revenue to TSEK 0 (18)
- The result for the period amounted to TSEK -61,170 (-54,659)
- Earnings per share amounted to SEK -0.38 (-0.66)
- Cash and cash equivalents on December 31 amounted to TSEK 379,448 (116,393)

January–December 2021

- Net revenue amounted to TSEK 22,407 (37,119) and other revenue to TSEK 0 (18)
- The result for the period amounted to TSEK -200,251 (-188,992)
- Earnings per share amounted to SEK -1.59 (-3.07)
- The Board of Directors proposes that no dividend will be paid for the 2021 financial year

Isofol is developing the cancer drug arfolitixorin

Isofol is developing the drug candidate arfolitixorin to improve the efficacy of standard 5-FU-based chemotherapy for advanced colorectal cancer (CRC). Arfolitixorin is currently being evaluated in the global pivotal Phase III AGENT study in patients with advanced CRC.

The Group consists of the Parent Company, Isofol Medical AB (publ), 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 of the business, results and financial position in this interim report apply to both the Group and the Parent Company, unless otherwise stated.

KEY FIGURES TSEK	2021 Oct–Dec	2020 Oct–Dec	2021 Jan–Dec	2020 Jan–Dec
Net revenue	4,704	18,680	22,407	37,119
Result for the period	-61,170	-54,659	-200,251	-188,992
Earnings per share (SEK)	-0.38	-0.66	-1.59	-3.07
Cash and cash equivalents	379,448	116,393	379,448	116,393

Focus on completing the AGENT study and market launch

In the fourth quarter of 2021, efforts to establish the best possible conditions ahead of a future commercial launch continued. An important step in accomplishing this is to complete our ongoing study and enabling us to apply for market approval. Our Fast Track Designation will be valuable to us in this regard as we complete the final stage of our pivotal Phase III AGENT study. We have also continued commercial preparations.

Preparation for a successful commercial launch

In the second half of 2021, we have 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. I 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 evaluates 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. Pending top-line data, the updated market analysis has acted as an important framework for these discussions. Our efforts to prepare for the planned market launch include increasing knowledge of arfolitixorin in the US market, where we took a number of important steps during the quarter that are described in more detail later in this report.

Fast Track Designation an important step

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. I interpret this as a confirmation of the large unmet need of better cancer treatments, but also as an effort from the FDA to ensure that, assuming market authorization of the drug candidate arfolitixorin, we secure a supply shortage of folates for 5-FU treatment that puts patients in a difficult position. The drug candidate arfolitixorin is the first direct active folate for over 20 years.

Fast Track Designation enables more frequent dialog 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, caregivers and our shareholders.

A new chapter in Isofol's history

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

Successful 2021

2021 can be summed up with a number of positive events that signaled important external validations of arfolitixorin's potential to benefit CRC patients. The Independent Data and Safety Monitoring Board's (iDSMB) positive recommendation following its interim analysis enabled us to continue with the study as planned without expansion (including more patients). We held a digital poster presentation at ASCO-GI that demonstrated that the active ingredient in arfolitixorin is not dependent on the individual's metabolism. The new share issue carried out in June secured the financial resources required to complete the AGENT study and later on submit a completed application for market registration to the FDA and initiate and accelerate global activities in the development of Medical Affairs, the commercial launch package and continued partnership activities.

Prospects for an invigorating 2022

Year 2022 will be the most exciting year in Isofol's history as we expect the results of the AGENT study. Our focus will thus be fully focused on implementing the activities and actions necessary to be able to present the results and complete the application for a market approval in the United States. In parallel, we will continue our efforts to prepare for commercial launch.

I want to express my thanks to the Isofol team for their hard work in moving the company closer to market launch. We are well prepared for 2022, both to handle the upcoming study results and the continued work for a possible market launch at the end of 2023. I would also like to express my thanks to our shareholders for their ongoing confidence. I look forward to continuing to lead Isofol to the market and thereby contribute to improving the quality of life for everyone suffering from metastasized colorectal cancer (mCRC).

Gothenburg, February 24, 2022

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

> "The approval of Fast Track Designation was a very positive development.
>
> Ulf Jungnelius, CEO, Isofol Medical AB (publ)

The AGENT study continuing as planned and Medical Affairs activities intensifying

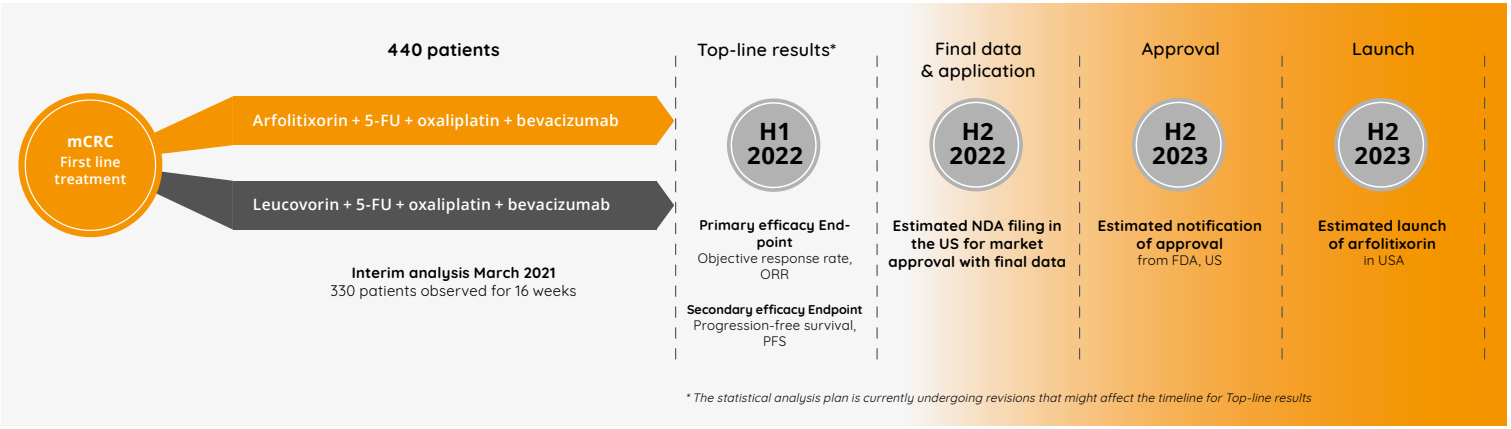
In the fourth quarter, Isofol maintained regular contact with the FDA to ensure the completion of the global pivotal AGENT study. Interactions are currently ongoing within the framework of our Fast Track Designation, which was granted for arfolitixorin in November. Activities in Medical Affairs – the function responsible for managing our relationships with the medical community – have also intensified with the recruitment of the first field-based medical employee (Medical Science Liaison) in the US. This individual will be tasked with spreading awareness of arfolitixorin by informing clinics in the US market about the drug candidate.

Update concerning the AGENT study

During the quarter we identified that more than expected patients were censored without a documented progression event for starting a new treatment. Thus, we are unable to unblind 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 for patients proceeding to other treatments. However, the iDSMB has repeatedly reviewed the safety data of the study with no resulting changes, indicating that the reason is not due to a safety issue with the study.

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, Isofol has requested from the FDA that the censoring rules be adjusted in accordance with the new ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) guidelines adopted by the FDA in May 2021. However, the FDA denied the request this quarter during a Type C meeting and will analyze the study results based on the original censoring rules for PFS. This may mean that the cut-off point for when the analysis of the study results can begin will need to be adjusted from 300 PFS events.



Top-line results the next milestone in the AGENT study

Discussions with the FDA concerning a new cut-off point to begin the analysis of the Phase III data are ongoing and Isofol hopes to reach an agreement with the FDA regarding the new cut-off point in spring 2022. When the new cut-off point has passed, the read-out process can 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 PFS cut-off point. The company believes that top-line results will likely be able to be presented at the end of the second quarter of 2022.

Ongoing analysis of the final data will then form the basis for a New Drug Application (NDA) in the US, which is the highest priority market for Isofol. The submission of the application for market approval to the FDA is preliminarily expected to take place in the fourth quarter of 2022, with a potential launch in the US during the second half of 2023, provided that the AGENT study reaches its target.

The statistical goal of the AGENT study is to be able to improve tumor shrinkage, measured

from the baseline, by at least 10 percentage points in patients treated with arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab compared with those treated with a leucovorin combination and to achieve a clinically relevant extension of PFS.

The AGENT study also has an exploratory endpoint in the form of gene expression, as Isofol's previous collaborations with academic research groups demonstrated a correlation between clinical benefit and gene expression in patients suffering from mCRC who were treated with 5-FU based chemotherapy. The results of the study have the potential to produce additional guidance about the use of 5-FU based chemotherapy in combination with arfolitixorin and a greater understanding of the role of gene expression in the mechanism of action of arfolitixorin.

Fast Track Designation granted by the FDA

Ahead of the submission of drug applications to the pharmaceutical authorities in the US, additional preparatory activities were carried out in the fourth quarter. The FDA granted approval of Fast Track Designation for arfolitixorin in the fourth quarter. The FDA's decision is based on the potential for arfolitixorin to address a large unmet medical need for new and more effective treatments of mCRC, the second deadliest and third most common form of cancer. Fast Track Designation is a process designed by the FDA to facilitate the development and expedite the review of new drugs to treat serious conditions, thereby meeting an unmet medical need. Fast Track 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. This means that a drug company can submit completed sections of its NDA for review by the FDA, rather than waiting until all parts of the application have been completed. The NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

First Medical Science Liaison recruited in the US

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 regimens, investments are required to raise awareness of new drug candidates by building relationships with the medical community and relevant external experts (Key Opinion Leaders) ahead of a potential launch. To accomplish this, the first of a number of field-based medical personnel has been recruited in the US. This has been accomplished through a collaboration between Isofol and Syneos Health. The duties of the field-based medical personnel include taking part in scientific exchanges with KOLs and other healthcare specialists concerning the efficacy and safety of arfolitixorin. These personnel will also be tasked with communicating and informing about related market trends, research, clinical practice and insights from relevant medical conferences.

Clinical development initiatives for gene expression and the Modelle study

In the AGENT study, we will analyze patient tumor material in relatationship to folate-associated genes. Isofol is convinced that biomarker analyses designed to demonstrate the capacity of cancer patients to respond to different folate-based cancer treatments will be applied to all patients treated with 5-FU treatment regimes in the future, provided that a gene-dependent effect can be confirmed in the AGENT study. However, further clinical studies are required to establish a better picture of the gene expressions that are relevant for 5-FU and thereby determine the exact genes that could lead to a difference in clinical efficacy.

An investigator-initiated clinical study (Modelle study) is currently being carried out in collaboration with researchers at Sahlgrenska University Hospital. It intends to investigate, more in detail, the effects that various folates (arfolitixorin/leucovorin) together with 5-FU have on mCRC patients with liver metastases. This is a groundbreaking study as it is the first time it will be possible to directly measure the effect that folates have on the enzyme targets that arfolitixorin is directed at (including the TS enzyme, which is an important target for cancer treatments insofar as it can contribute to inhibiting cell growth). As such, the analysis has the potential to contribute scientific data to Isofol's ongoing clinical work to trying to understand how gene expression determines the patients' capacity to respond to various folate-based cancer treatments.

Currently, about half of the expected patients have been recruited to the study, which will be conducted by Helena Taflin at Sahlgrenska University Hospital. During the fourth quarter, Norrland University Hospital in Umeå also participated in the study and their first patient was included within the framework of the study. The fact that the study now involves an additional hospital will hopefully speed up the pace of recruitment.

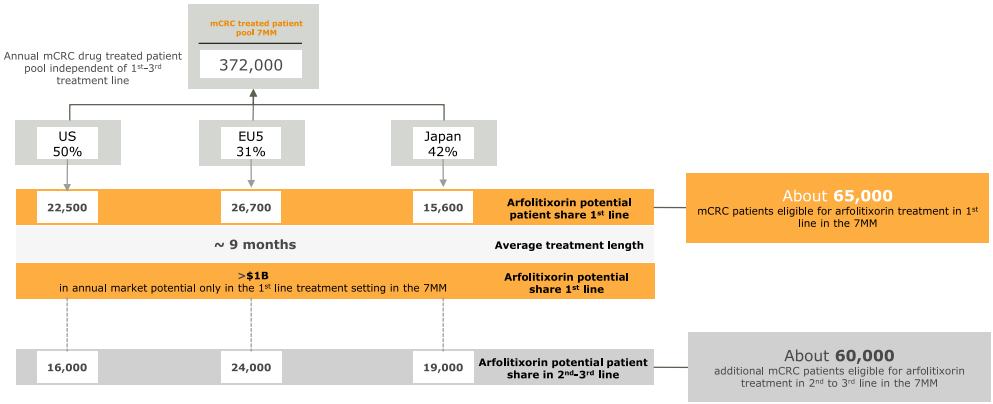
Intense work ongoing to create favorable conditions for commercial launch

Isofol´s ambition is to obtain a market approval for arfolitixorin from the FDA in US, at the end of 2023, provided that the outcome of the ongoing pivotal Phase III AGENT study is positive. To create the most favorable prerequisites possible for the commercial launch, Isofol has initiated a number of preparatory activities.

> I look forward to shouldering the role of CCO and it is an honor to assume responsibility for the commercial preparations for arfolitixorin. We have made significant advances in our commercial preparations and strengthened our collaborations with external partners to create the best conditions possible.
>
> Jenny Sundqvist, CCO, Isofol Medical AB (publ)

Commercial preparations intensified in 2021 with the initiation of additional activities, 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 understand and optimize arfolitixorin's future positioning in the markets. Since January 1, 2022, commercial preparation activities have been led by Jenny Sundqvist, who was appointed Isofol's new Chief Commercial Officer.

Arfolitixorin target patient populations and potential patient share



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 modell 2018.*

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

Isofol has initiated a number of activities to prepare the company for a future commercial launch of arfolitixorin. During the year, an update of previously conducted market analyses commenced, as did the preparation of strategies for market access. The fourth quarter was dominated by compilations and analyses of the findings received in the last half of the year.

The findings confirm the need for new treatments for CRC. In the updated surveys, approximately 350 physicians expressed their views on the roll of arfolitixorin in future treatment regimes. Provided that the AGENT study reaches its set targets, physicians conclude that arfolitixorin constitutes an improvement compared with current treatments. In addition, payers who have been interviewed in the US, the EU4 and the UK, confirmed that arfolitixorin has an acceptable product profile provided that the study reaches its set targets. The findings will now constitute an important component in discussions with potential partners and serve as a framework for the planning of commercialization efforts.

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

Arfolitixorin is patent protected until 2038 in the US and Japan 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 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.

CRC – the third most common form of cancer

CRC, also known as intestinal or rectal cancer, is a form of cancer that arises from mutations in the mucus membranes of the intestine and is the third most common form of cancer after lung and breast cancer and the second deadliest.

CRC 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) is approximately 1.9 million patients a year.

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. Patients in later stages, when the cancer has spread to other organs (known as metastases/mCRC), have a worse prognosis and significantly higher mortality. Only 10 percent of patients with mCRC are still alive five years after diagnosis.

Significant market potential

The total drug market for the eight largest 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 EU4, the UK and Japan), about 370,000 patients are diagnosed with mCRC each year. About 170,000 of these patients annually comprise Isofol's primary market – first-line treatment.

Given that Isofol's primary market consists of the first-line treatment of mCRC patients, the company estimates that its annual sales of arfolitixorin in the seven largest markets could amount to USD 1 billion given market approval.

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

In 2020, the UK market-analysis company GlobalData published a forecast for the CRC market between 2020 and 2028 for the eight largest markets: the US, the EU4, the UK, Japan and China. The report describes arfolitixorin as one of the most promising drug candidates for CRC together with Array BioPharma's/Pfizer's BRAF inhibitor encorafenib (Braftovi).

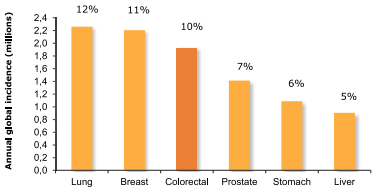
Colorectal cancer (CRC) – Large and underserved segment

3rd most common and 2nd deadliest cancer with an urgent large unmet need

COLORECTAL CANCER FACTSHEET

Colorectal cancer is the third most common cancer[1]

10% of cancers discovered annually are colorectal cancer



1.9M 1.9M people are diagnosed with CRC each year globally[1]

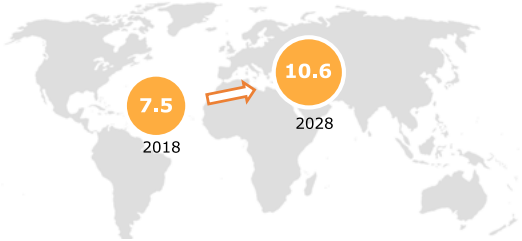
10% The 5-year survival rate for patients with stage 4 colorectal cancer (mCRC) falls to around 10%[2]

GROWING INCIDENCE

>60% The global burden of CRC is expected to increase by over 60% from 1.9M 2020 cases to 3.1M in 2040[1]

GLOBAL CRC MARKET $10.6B IN 2028

Total market size will grow ~$3B from 2018 to 2028[2]



Financial information, October-December

COMPARISON BETWEEN THE FOURTH QUARTER OF 2021 AND 2020

Amounts stated without parentheses refer to October-December 2021, and amounts stated in parentheses refer to October-December 2020.

REVENUE

Operating revenue

Net revenue amounted to TSEK 4,704 (18,680) for the quarter. Revenue for the quarter was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 0 (18).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -58,168 (-59,866), corresponding to a decrease of TSEK 1,698. Costs for the ongoing AGENT study were lower compared with the year-earlier period, mainly due to the study having been fully recruited since the fourth quarter of 2020 and at the same time, pre-commercialization costs have increased and the fourth quarter also included costs for the listing change.

Personnel costs

Personnel costs in the Group amounted to TSEK -8,990 (-8,376), corresponding to an increase of TSEK 614. There were 15 (12) employees at the end of December 2021.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -397 (-438).

Net financial items

Net financial items amounted to TSEK 1,689 (-4,932), of which TSEK 1,705 (-4,898) was attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments and TSEK -16 (-34) to interest.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -62,858 (-49,727), corresponding to an increased loss of TSEK 13,131. The result after financial items was TSEK -61,170 (-54,659), corresponding to an increased loss of TSEK 6,511. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at December 31, 2021 amounted to TSEK 379,448 (116,393). No loans had been raised at December 31, 2021 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 42,124 (40,898) was pledged as collateral for currency futures that will fall due for payment in the first half of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -42,022 (-35,103), corresponding to a change of TSEK -6,919. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities and lower revenues compared to the same period last year.

Cash flow from investing activities

Cash flow from investing activities during the period amounted to TSEK 0 (0).

Cash flow from financing activities

Cash flow from financing activities during the period amounted to TSEK -368 (-325). The negative cash flow was attributable to the repayment of the company's lease liability.

Cash flow for the period

Cash flow for the period amounted to TSEK -42,390 (-35,427), corresponding to a change of TSEK -6,963. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities.

INVESTMENTS

Investments during October-December 2021

The Group's investments during the period amounted to TSEK 0 (0). Most of the Group's costs are related to research and development. These costs are expensed on an ongoing basis and are thus not classified as investments. Besides its planned studies, the Group has no material ongoing or planned investments.

Financial information, January-December

COMPARISON BETWEEN JANUARY-DECEMBER 2021 AND 2020

Amounts stated without parentheses refer to January-December 2021, and amounts stated in parentheses refer to January-December 2020.

REVENUE

Operating revenue

Net revenue amounted to TSEK 22,407 (37,119) for the period. Revenue was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 0 (18).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -196,712 (-199,535), corresponding to a decrease of TSEK 2,823. Costs for the ongoing AGENT study, which has been fully recruited since the fourth quarter of 2020, have declined over the year. and at the same time, costs for pre-commercialization activities have increased and the fourth quarter included costs for the listing change.

Personnel costs

Personnel costs in the Group amounted to TSEK -27,721 (-22,740), corresponding to an increase of TSEK 4,981. There were 15 (12) employees at the end of December 2021.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -1,596 (-1,770).

Net financial items

Net financial items amounted to TSEK 4,215 (-2,497), of which TSEK 4,378 (-2,350) was attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments and TSEK -163 (-147) to interest.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -204,465 (-186,494), corresponding to an increased loss of TSEK 17,971. The result after financial items was TSEK -200,251 (-188,991), corresponding to an increased loss of TSEK 11,260. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at December 31, 2021 amounted to TSEK 379,448 (116,393). No loans had been raised at December 31, 2021 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 42,124 (40,898) was pledged as collateral for currency futures that will fall due for payment in the first half of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -188,429 (-160,270), corresponding to a change of TSEK -28,159. The negative cash flow for the period was attributable to the company's clinical activities and the company's pre-commercialization activities and lower revenues compared to the same period last year.

Cash flow from investing activities

Cash flow from investing activities during the period amounted to TSEK 0 (0).

Cash flow from financing activities

Cash flow from financing activities during the period amounted to TSEK 450,477 (150,013). The positive cash flow for the period was attributable to the new share issue completed during the second quarter.

Cash flow for the period

Cash flow for the period amounted to TSEK 262,048 (-10,257). The positive cash flow for the period was attributable to the new share issue completed during the second quarter. Excluding the share issue, cash flow for the period amounted to TSEK -189,869 (-161,515).

INVESTMENTS

Investments during January-December 2021

The Group's investments during the period amounted to TSEK 0 (0). Most of the Group's costs are related to research and development. These costs are expensed on an ongoing basis and are thus not classified as investments. Besides its planned studies, the Group has no material ongoing or planned investments.

Other information

Organization and personnel

There were 15 full-time employees at the end of the reporting period, six of whom were men and nine of whom were women, and all of whom were employed at the company's head office in Gothenburg, Sweden. The company also has approximately ten consultants, most of whom are considered to work full time or almost full time for Isofol.

Information about transactions with related parties

Remuneration to the Group's senior executives was paid according to applicable policies during the period. No other related-party transactions took place during the period.

Risk management

Isofol works continuously to identify, evaluate and manage risks in various systems and processes. Risk analyses are conducted on an ongoing basis for the business, but also for activities that lie outside Isofol's normal quality system.

The market risks considered to be of special significance in regard to Isofol's future development are linked to the availability of the financial and clinical resources to conduct the company's studies. The most significant strategic and operational risks that affect the Group and the Parent Company are described in the Annual Report for 2020, and are unchanged since then.

The company is mainly affected by currency risks due to the fact that the pivotal study is essentially paid in USD and EUR. In accordance with the company's financial risk policy, the company exchanges USD and EUR to manage and reduce currency exposure.

Number of shares

The number of shares at the end of the period was 161,515,440 (83,365,966), with a nominal value of SEK 0.0306 (0.0306). The average number of shares in the fourth quarter was 161,515,440 (83,365,966). From October 21, 2021, the share is listed on Nasdaq Stockholm's main list, under the commercial name "ISOFOL". The share was previously listed on First North Premier Growth Market.

Events after the end of the reporting period

No significant events other than those stated on page 1 have occurred since the end of the reporting period.

Significant risks and uncertainty factors

Isofol's main business is the research and development of one drug, arfolitixorin. This business is capital-intensive and associated with risks that could have a significant adverse impact on the Group's operations, financial position and result. A more detailed description of Isofol's main risks and the uncertainty factors faced by the Group and the Parent Company is presented in the Annual Report for 2020.

Largest shareholders at 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 holding shares (direct and indirect) and other financial instruments in the company.*

ISOFOL'S LARGEST SHAREHOLDERS BASED ON INFORMATION FROM EUROCLEAR SWEDEN AB AND MONITOR AT DECEMBER 31, 2021.

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 and as well as the restrictions that apply in each country. 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. 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 recruited 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.

THE NOMINATION COMMITTEE FOR THE 2022 ANNUAL GENERAL MEETING

The Nomination Committee for the 2022 Annual General Meeting consists of Chairman Malin Björkmo, Lars Lind, Ulrik Grönvall, Mats-Ola Palm and Pär-Ola Mannefred. Shareholders who wish to submit proposals to Isofol's Nomination Committee for 2022 can contact Isofol Medical AB (publ), Attn: The Nomination Committee, Arvid Wallgrens Backe 20, 413 46 Gothenburg, Sweden or by email to valberedningen@isofolmedical.com.

Annual General Meeting

The Annual General Meeting of Isofol Medical AB (publ) will be held in Gothenburg on May 19, 2022.

Given the considerable uncertainty regarding developments with the prevailing pandemic, decisions will be taken at a later stage to enable implementation of the necessary precautions to ensure that the Annual General Meeting can be conducted with minimal risk to shareholders, employees and other participants.

Shareholders who wish to have matters addressed at the Meeting may submit a written request to the Board of Directors. Such requests are to be submitted by post to Isofol Medical AB (publ), Attn: Chairman of the Board, Arvid Wallgrens Backe 20, 413 46 Gothenburg, Sweden or by email to arsstamma@isofolmedical.com and must be received by the Board of Directors no later than five weeks prior to the Meeting, or in ample time to allow the matter to be added to the agenda for the Meeting, if required.

Annual Report

Isofol's Annual Report for 2021 is expected to be available for download on Isofol's website during the week of May 25, 2022.

FINANCIAL REPORTS

The following reports are scheduled for publication:

Annual Report 2021	April 2022
Interim report January-March 2022	May 12, 2022
Six-month 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

Review report

This report has not been reviewed by the Group's auditors.

For further information, contact:

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

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

This report has been prepared in a Swedish original and has been translated into English. In the event of differences between the two, the Swedish version shall apply.

The information was submitted for publication, through the agency of the contact people above, at 8:00 a.m. (CET) on February 24, 2022.

Condensed consolidated income statement

TSEK*	Note	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
OPERATING REVENUE					
Net revenue	2	4,704	18,680	22,407	37,119
Other revenue		–	18	–	18
Total operating revenue		**4,704**	**18,698**	**22,407**	**37,137**
OPERATING COSTS					
Other external costs		-58,168	-59,866	-196,712	-199,535
Personnel costs		-8,990	-8,376	-27,721	-22,740
Depreciation and amortization of tangible and intangible fixed assets		-397	-438	-1,596	-1,770
Other operating revenue and operating costs**		-7	255	-843	413
Total operating costs		**-67,563**	**-68,425**	**-226,872**	**-223,631**
Operating result		**-62,858**	**-49,727**	**-204,465**	**-186,494**
FINANCIAL ITEMS					
Net financial items		1,689	-4,932	4,215	-2,497
Total financial items		**1,689**	**-4,932**	**4,215**	**-2,497**
Result after financial items		**-61,170**	**-54,659**	**-200,251**	**-188,991**
Tax charged to result for the year		–	–	–	-1
Result		**-61,170**	**-54,659**	**-200,251**	**-188,992**
Of which attributable to Parent Company shareholders		-61,170	-54,659	-200,251	-188,992
Earnings per share before and after dilution, SEK		-0.38	-0.66	-1.59	-3.07

** Certain figures may not tally due to rounding.*

*** Includes currency effects associated with the business.*

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

Condensed consolidated balance sheet

TSEK*	Note	Dec 31, 2021	Dec 31, 2020
ASSETS			
FIXED ASSETS			
Intangible fixed assets			
Patents		–	–
Total intangible fixed assets		**–**	**–**
Tangible fixed assets			
Equipment, tools, fixtures and fittings		1,745	3,258
Total tangible fixed assets		**1,745**	**3,258**
Financial fixed assets			
Other long-term receivables		5,009	5,031
Total financial fixed assets		**5,009**	**5,031**
Total fixed assets		**6,755**	**8,289**
CURRENT ASSETS			
Current receivables	3	15,160	23,448
Cash and cash equivalents	3, 4, 5	379,448	116,393
Total current assets		**394,609**	**139,841**
Total assets		**401,363**	**148,130**

** Certain figures may not tally due to rounding.*

Condensed consolidated balance sheet

TSEK*	Note	Dec 31, 2021	Dec 31, 2020
EQUITY AND LIABILITIES			
EQUITY			
Equity	6	318,233	66,567
Total equity		**318,233**	**66,567**
LIABILITIES			
Long-term liabilities			
Long-term lease liability		110	1,439
Total long-term liabilities		**110**	**1,439**
Current liabilities			
Current lease liability		1,542	1,677
Other current liabilities	3	81,478	78,447
Total current liabilities		**83,020**	**80,124**
Total liabilities		**83,130**	**81,563**
Total equity and liabilities		**401,363**	**148,130**

** Certain figures may not tally due to rounding.*

Consolidated statement of changes in equity

TSEK*	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2020		981	619,003	-515,076	104,908
Subscription warrants, repurchases	6	–	-57	–	-57
New share issue, issued subscription warrants	6	–	60	–	60
Rights issue		1,309	148,280	–	149,589
Over-allotment option		262	29,738	–	30,000
Issue costs		–	-28,941	–	-28,941
Result for the period		**–**	**–**	**-188,992**	**-188,992**
Equity, Dec 31, 2020		**2,552**	**768,083**	**-704,068**	**66,567**

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2021		2,552	768,083	-704,068	66,567
Rights issue		1,914	398,242	–	400,157
Over-allotment option		478	99,522	–	100,000
Issue costs		–	-48,240	–	-48,240
Result for the period		**–**	**–**	**-200,251**	**-200,251**
Equity, Dec 31, 2021		**4,945**	**1,217,607**	**-904,319**	**318,233**

** Certain figures may not tally due to rounding.*

Consolidated cash flow statement

TSEK*	Note	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
OPERATING ACTIVITIES					
Result after financial items		-61,170	-54,659	-200,251	-188,991
Adjustments for non-cash items		-1,308	5,417	-2,946	3,958
Income tax paid**		–	–	–	-1
Cash flow from operating activities before changes in working capital		**-62,478**	**-49,242**	**-203,196**	**-185,033**
CASH FLOW FROM CHANGES IN WORKING CAPITAL					
Increase (-)/decrease (+) in operating receivables		11,448	325	9,860	-14,050
Increase (+)/decrease (-) in operating liabilities		9,007	13,815	4,907	38,813
Change in working capital		**20,456**	**14,139**	**14,766**	**24,763**
Cash flow from operating activities		**-42,022**	**-35,103**	**-188,429**	**-160,270**
INVESTING ACTIVITIES					
Acquisition of tangible fixed assets		–	–	–	–
Cash flow from investing activities		**–**	**–**	**–**	**–**
FINANCING ACTIVITIES					
Repayment of lease liability		-393	-394	-1,548	-1,553
Subscription warrants, proceeds received	6	25	70	108	308
New share issue		–	–	451,917	151,258
Cash flow from financing activities		**-368**	**-325**	**450,477**	**150,013**
Cash flow for the period		-42,390	-35,427	262,048	-10,257
Cash and cash equivalents at the beginning of the period		420,861	153,612	116,393	126,983
Exchange rate difference in cash and cash equivalents		977	-1,791	1,007	-334
Cash and cash equivalents at the end of the period	5	**379,448**	**116,393**	**379,448**	**116,393**

** Certain figures may not tally due to rounding.*

*** Includes currency effects associated with the business..*

Condensed Parent Company income statement

TSEK*	Note	2021 Oct-Dec	2020 Oct-Dec	2021 Jan-Dec	2020 Jan-Dec
OPERATING REVENUE					
Net revenue	2	4,704	18,680	22,407	37,119
Other revenue		–	–	–	–
Total operating revenue		**4,704**	**18,680**	**22,407**	**37,119**
OPERATING COSTS					
Other external costs		-58,577	-60,292	-198,349	-201,231
Personnel costs		-8,990	-8,376	-27,721	-22,740
Depreciation and amortization		-18	-40	-77	-197
Other operating revenue and operating costs**		-7	255	-843	413
Total operating costs		**-67,593**	**-68,453**	**-226,990**	**-223,754**
Operating result		**-62,888**	**-49,772**	**-204,583**	**-186,635**
FINANCIAL ITEMS					
Net financial items		1,706	-4,900	4,304	-2,354
Total financial items		**1,706**	**-4,900**	**4,304**	**-2,354**
Result after financial items		**-61,183**	**-54,673**	**-200,280**	**-188,989**
Result before tax		**-61,183**	**-54,673**	**-200,280**	**-188,989**
Group contributions paid		–	-293	–	-293
Tax		–	–	–	–
Result		**-61,183**	**-54,965**	**-200,280**	**-189,282**

** Certain figures may not tally due to rounding.*

*** Includes currency effects associated with the business.*

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

Condensed Parent Company balance sheet

TSEK*	Note	Dec 31, 2021	Dec 31, 2020
ASSETS			
FIXED ASSETS			
Intangible fixed assets			
Patents		–	–
Total intangible fixed assets		**–**	**–**
Tangible fixed assets			
Equipment, tools, fixtures and fittings		158	235
Total tangible fixed assets		**158**	**235**
Financial fixed assets			
Participations in Group companies		50	50
Other long-term receivables		5,009	6,631
Total financial fixed assets		**5,059**	**6,681**
Total fixed assets		**5,217**	**6,916**
CURRENT ASSETS			
Current receivables	3	15,389	23,672
Cash and bank balances	3, 4, 5	379,398	114,862
Total current assets		**394,787**	**138,534**
Total assets		**400,004**	**145,450**

TSEK*	Note	Dec 31, 2021	Dec 31, 2020
EQUITY AND LIABILITIES			
Equity		318,297	66,660
Total equity		**318,297**	**66,660**
Current liabilities	3	81,707	78,790
Total liabilities		**81,707**	**78,790**
Total equity and liabilities		**400,004**	**145,450**

** Certain figures may not tally due to rounding.*

Notes

Note 1 Accounting principles

This interim report has been prepared in accordance with the Swedish Annual Accounts Act and IAS 34 Interim Financial Reporting for the Group and in accordance with the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities for the Parent Company. Unless otherwise stated below, the accounting principles applied for the Group and the Parent Company are consistent with the accounting principles used for the preparation of the Annual Report for 2020.

New and amended standards adopted from 2021 are not expected to have any significant impact on the Group's financial position.

The Parent Company does not apply IFRS 16 in accordance with the exception in RFR 2.

Note 2 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 corresponding 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 is attributable to revenue 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			
TSEK	**2021 Oct-Dec**	**2020 Oct-Dec**	**2021 Jan-Dec**	**2020 Jan-Dec**
North America	–	11,089	–	11,089
Asia	4,704	7,591	22,407	26,030
Total	**4,704**	**18,680**	**22,407**	**37,119**

	Parent Company			
TSEK	**2021 Oct-Dec**	**2020 Oct-Dec**	**2021 Jan-Dec**	**2020 Jan-Dec**
North America	–	11,089	–	11,089
Asia	4,704	7,591	22,407	26,030
Total	**4,704**	**18,680**	**22,407**	**37,119**

Breakdown of revenue by type of revenue

	Group			
TSEK	**2021 Oct-Dec**	**2020 Oct-Dec**	**2021 Jan-Dec**	**2020 Jan-Dec**
Licensing	–	11,089	–	27,431
Execution of service assignments	4,704	7,591	22,407	9,688
Total	**4,704**	**18,680**	**22,407**	**37,119**

	Parent Company			
TSEK	**2021 Oct-Dec**	**2020 Oct-Dec**	**2021 Jan-Dec**	**2020 Jan-Dec**
Licensing	–	11,089	–	27,431
Execution of service assignments	4,704	7,591	22,407	9,688
Total	**4,704**	**18,680**	**22,407**	**37,119**

Contract assets

	Group	
TSEK	**Dec 31, 2021**	**Dec 31, 2020**
Accrued income	1,631	11,065
Contract liabilities	–	–
Total	**1,631**	**11,065**

	Parent Company	
TSEK	**Dec 31, 2021**	**Dec 31, 2020**
Accrued income	1,631	11,065
Contract liabilities	–	–
Total	**1,631**	**11,065**

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

Note 3 Financial instruments

As of December 31, 2021, the Group had financial instruments, which were measured at fair value, in the form of currency derivatives of TSEK 1,663 (-1,872). Other financial assets and liabilities are measured at amortized cost. There are no significant differences between fair value and carrying amount in respect of financial assets and liabilities. As of the balance sheet date, the carrying amount of the Group's financial assets amounted to TSEK 381,135 (118,849) and the carrying amount of the Group's financial liabilities to TSEK 72,556 (71,549).

Note 4 Pledged assets

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

Note 5 Cash and cash equivalents

Group TSEK	Dec 31, 2021	Dec 31, 2020
The following sub-items are included in cash and cash equivalents:		
Short-term investments	–	–
Cash and cash equivalents	379,448	116,393
Total	**379,448**	**116,393**

Parent Company TSEK	Dec 31, 2021	Dec 31, 2020
The following sub-items are included in cash and cash equivalents:		
Short-term investments	–	–
Cash and bank balances	379,398	114,862
Total	**379,398**	**114,862**

Note 6 Equity

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). The subscription period will extend from May 15, 2023 to July 15, 2023. The subscription price for shares subscribed for with the support of the subscription warrants was set at SEK 30.3 per share.

In August, 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.

WARRANT PROGRAM 2018

At the end of each program, each subscription warrant entitles the holder to subscribe for one new share in Isofol at a fixed exercise price. The exercise price for series 18/22 is SEK 28.3 per share (subscription period from May 15 to July 15, 2022), and the exercise price for series 18/23 is SEK 42.5 per share (redemption period from May 15 to July 15, 2023).

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 of the remaining 408,000 warrants regarding the 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.

Group and Parent Company TSEK	2021	2020
Subscription warrants, proceeds	–	–
Loan to management and employees	–	–
Repayment from management and employees	82	305
Repurchase of subscription warrants	0	-57
Issued subscription warrants, CEO	–	60
Total	**82**	**308**

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 of the repurchased subscrip-

tion 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%.

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 in relation to 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.

The Board's certification

The Board of Directors and the CEO hereby affirm that the interim report provides a fair overview of the operations, financial position and result of the Group and the Parent Company and describes the material risks and uncertainties facing the Parent Company and the companies included in the Group.

Gothenburg, February 24, 2022

Pär-Ola Mannefred
Chairman

Magnus Björsne
Board member

Paula Boultbee
Board member

Alain Herrera
Board member

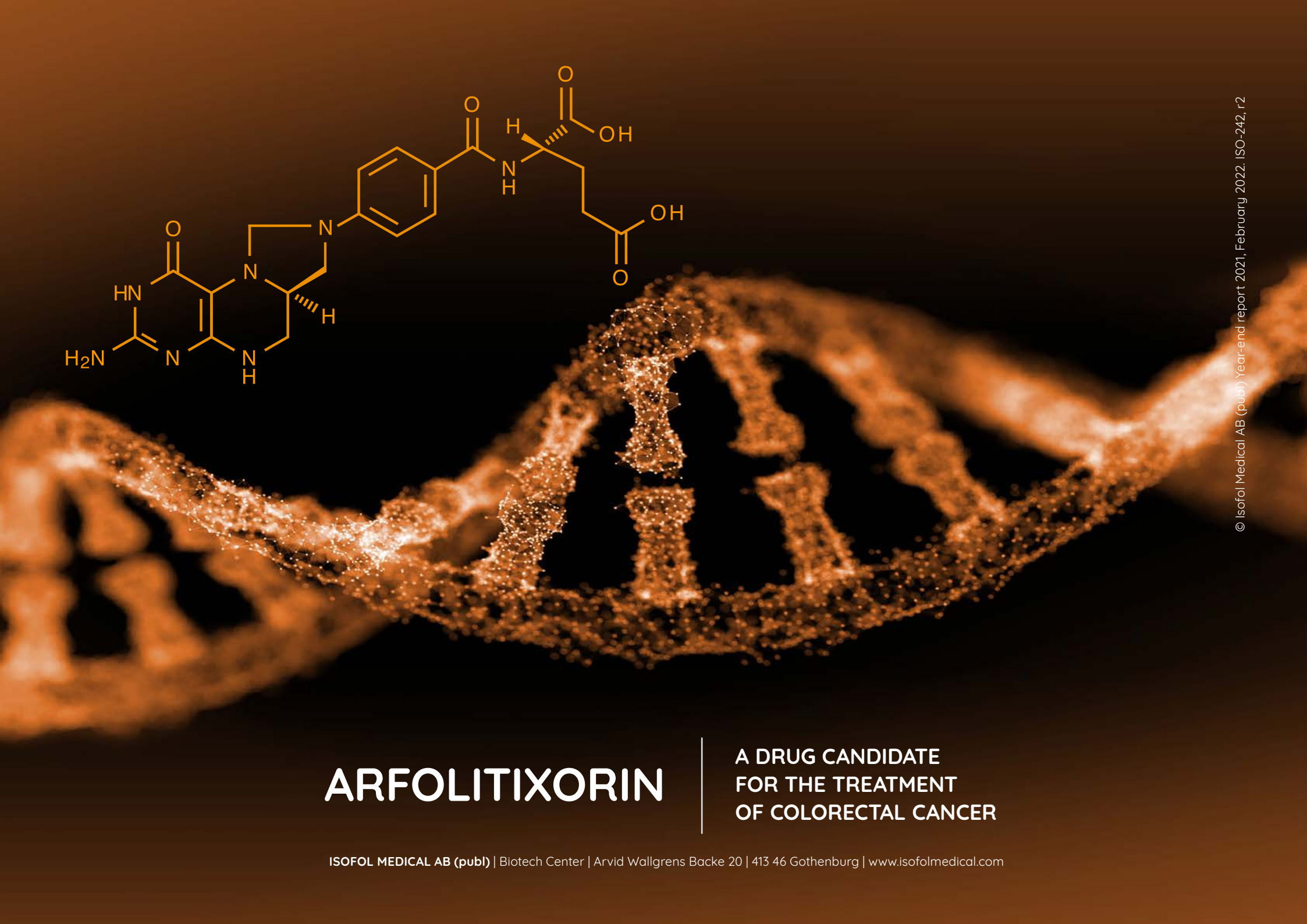
Anna Belfrage
Board member

Robert Marchesani
Board member

Aram Mangasarian
Board member

Lennart Jeansson
Board member

Ulf Jungnelius
CEO



ARFOLITIXORIN

A DRUG CANDIDATE FOR THE TREATMENT OF COLORECTAL CANCER

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