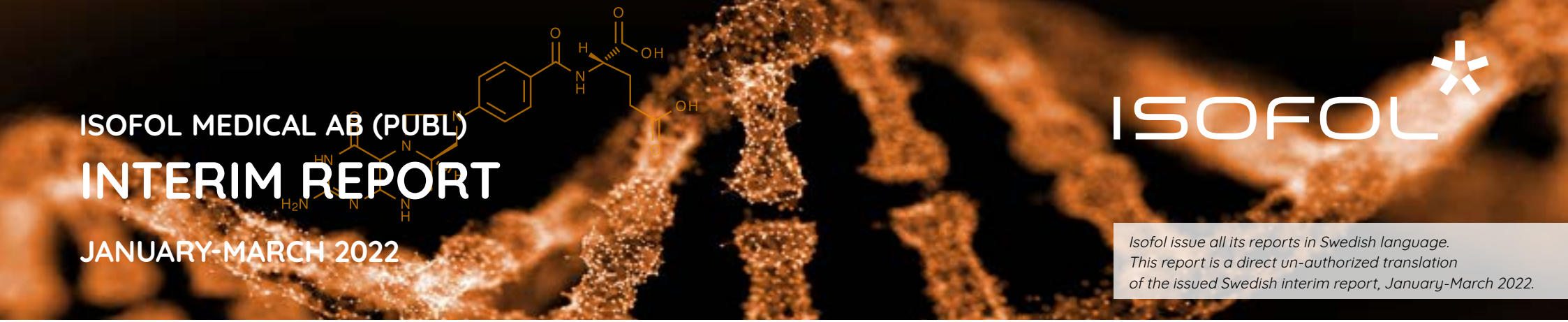


ISOFOL MEDICAL AB (PUBL)

INTERIM REPORT

JANUARY-MARCH 2022

Isofol issue all its reports in Swedish language.
This report is a direct un-authorized translation
of the issued Swedish interim report, January-March 2022.

Commercial and clinical preparations pending results of the AGENT study

SIGNIFICANT EVENTS DURING THE FIRST QUARTER

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

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- Isofol's Nomination Committee proposes the election of Jan Törnell as new Chairman of the Board at the Annual General Meeting on May 19, 2022.
- On April 22, Isofol announced that the process of analyzing study data from the AGENT study has begun.

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 primarily for the treatment of colorectal cancer (CRC), which is the third most common form of cancer worldwide and the second deadliest. 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 who are currently being treated with 5-FU-based therapies. Arfolitixorin has the potential to become the first and only direct-acting folate-based drug that enhances the cytotoxic effect in combination with 5-FU, thereby improving efficacy.

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 of the business, results and financial position in this interim report apply to both the Group and the Parent Company, unless otherwise stated.

FINANCIAL INFORMATION

First quarter, January-March 2022

- Net revenue amounted to TSEK 4,006 (5,215) and other revenue to TSEK 1 (0)
- The result for the period amounted to TSEK -47,874 (-42,662)
- Earnings per share amounted to SEK -0.30 (-0.51)
- Cash and cash equivalents at March 31 amounted to TSEK 332,035 (77,524)

KEY FIGURES TSEK	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
Net revenue	4,006	5,215	22,407
Result for the period	-47,874	-42,662	-200,251
Earnings per share (SEK)	-0.30	-0.51	-1.59
Cash and cash equivalents	332,035	77,524	379,448

The foundation has been laid for an exciting six months

The first quarter of 2022 was dominated by close and frequent dialogues with the US Food and Drug Administration (FDA) in order from them to accept the AGENT study's updated statistical analysis plan (SAP). The meetings with the FDA also included planning for a pre-New Drug Application meeting (NDA) expected to take place during the second half of 2022. In addition, extensive planning and analysis efforts, based on different outcome scenarios from the AGENT study, have been made in order to prepare potential strategies for market launch.

> *We have now passed the cut-off point, so it is possible to begun the analysis process of study data.*
>
> Ulf Jungnelius, CEO, Isofol Medical AB (publ)

In close dialogue with the FDA

We have now passed the cut-off point, so it is possible to begin the process of analyzing study data and subsequently unblind the study and thereby be able to present the study data. The initiation of data analysis was preceded by several meetings with the FDA regarding our proposed updates to the SAP. It is a major advantage that we can perform the analysis based on both the previously published censoring rules required by the FDA and on the new updated guidelines. We expect two to four months of intensive work before we can present top-line results.

The meetings with the FDA also encompassed preparations for a pre-NDA meeting planned for the second half of 2022. These dialogues with the FDA were facilitated by the Fast Track designation received by Isofol at the end of 2021.

At the beginning of 2022, our clinical team worked proactively to prepare for the data compilation and analysis of the study results. We are convinced that these efforts will lead to a more efficient process to analyze and compile the results for the New Drug Application (NDA) that will be submitted to the FDA. This work is also a valuable basis for Isofol's future Type C meetings with the FDA.

Focus on scenario analysis and pre-commercial activities in the US

We had two main priorities in our pre-commercial work during the first quarter. The first priority has been the analysis, identification and development of go-to-market strategies based on potential outcome scenarios from the AGENT study. The data and market analyses that were completed and compiled in 2021 served as an important basis in our analysis.

The second priority has been greater investments in the US market, which is Isofol's top-priority market for arfolitixorin. A US communication agency was hired, and our Medical Science Liaison (MSL) began participating in conferences and forming relationships with US physicians. We intend to add more MSLs in the long term in order to intensify efforts in this area.

Dialogues with potential partners continued, Isofol's relationships with existing players were strengthened, and conversations with new stakeholders have begun. The forthcoming top-line results and ultimately the final results are completely decisive for future potential partnership discussions.

A focus on CRC patients' difficult situation

Isofol observed World Cancer Day on February 4, and March was Colorectal Cancer Awareness Month, which we also highlighted in various ways. Even though CRC only receives this sort of attention for short periods every year, the disease and the patients who suffer from it are in our thoughts every day. My colleagues and I are driven to meet the high medical need for new drugs to treat CRC. This form of cancer is the third most common cancer diagnosis today and the second deadliest. Meanwhile, no new cancer medications have been developed for the majority of these patients in nearly 20 years. Aside from arfolitixorin, there are no other drugs under development 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. Every day, my colleagues strive to improve the quality of life for everyone who has this severe disease.

During the quarter, Isofol performed many crucial and important activities to lay the foundation for the presentation of the forthcoming study results. Isofol is now laying the foundation that will enable us to reach several important future milestones, including an application for market approval by the FDA. Approval will pave the way for arfolitixorin to be included in the US national guidelines (NCCN guidelines), thereby providing it with good opportunities to be launched as a drug on the US market.

We are in a strong position, and during the second quarter all of our energy will be devoted to data collection and analysis while ensuring data integrity, so that we will be able to present top-line results. The results will mature as more data becomes available until the final study data is ready to present. All of my colleagues are aware of the difficult situation these patients face. Being able to improve their quality of life is therefore an important factor guiding our work.

Gothenburg, May 12, 2022

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

Productive discussions with the FDA and increased investments in the US market

In the first quarter, Isofol maintained regular contact with the FDA to ensure the completion of the global pivotal AGENT study. Interactions are now ongoing within the framework of our Fast Track designation, which the FDA granted for arfolitixorin in November 2021. Moreover, Isofol's MSL is now working intensively to build relationships with the US medical community through measures including informing them about the drug candidate at US hospital clinics.

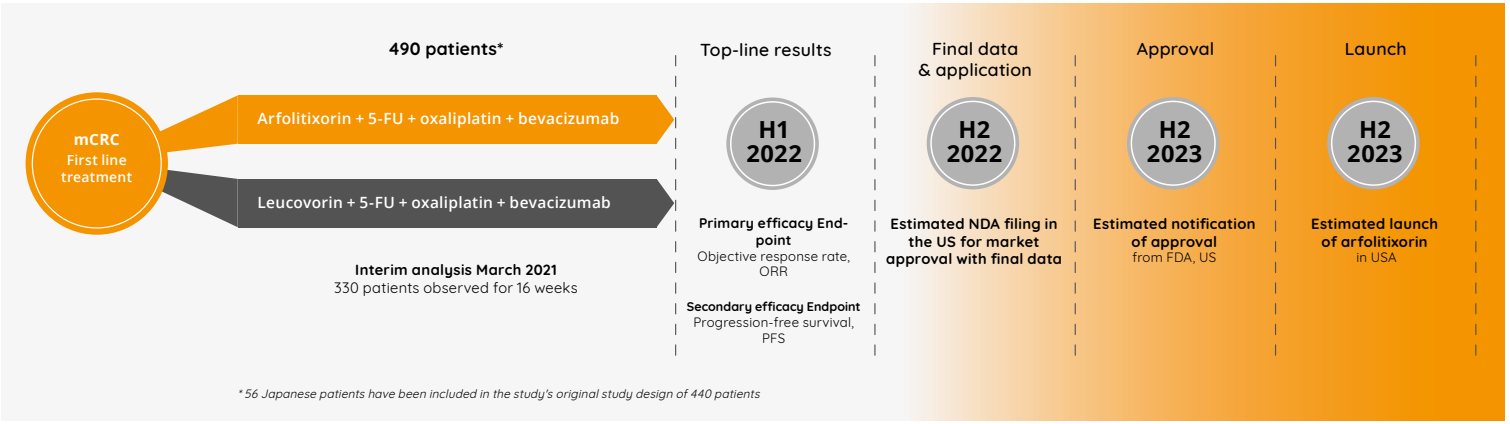
An active and close dialogue with the FDA about the AGENT study, and preparations for an NDA

The work of determining a new cut-off point to begin analysis of the data from the AGENT study began in autumn 2021. Discussions with the FDA continued in early 2022. The background of the discussions is that the FDA denied a request from the company to adjust the censoring rules for AGENT study's secondary endpoint (PFS), after more patients than expected proceeded to other treatments before the study achieved 300 PFS events. However, the study's primary endpoint, objective response rate (ORR), was not affected.

As of April 22, the FDA had not issued any opinions regarding changes, which means that Isofol could begin analysis process for study data, and the compilation, quality assurance and statistical analysis of study data was initiated.

A comprehensive and proactive effort was also made during the first quarter in order to facilitate a smooth and quality-assured read-out process. This effort is also part of Isofol's preparations for a number of Type C meetings with the FDA that are planned ahead of the submission of an NDA for arfolitixorin.

An active and close dialogue with the FDA is one of several advantages of the Fast Track designation that the FDA granted to Isofol in November 2021. This designation may result in a priority review during the next stage when the FDA processes the registration application that Isofol plans to submit, given that certain criteria have been fulfilled. In ordinary cases, NDA reviews are not performed until a drug company has submitted a complete application to the FDA, but under the Fast Track designation, the NDA is continually reviewed as material is submitted. More frequent meetings with the FDA are also held during the process.



Top-line results the next milestone in the AGENT study

The schedule for being able to present the study results (top-line results and final data) has been dependent on the FDA decision regarding the cut-off point for PFS. As a result of the discussions with the FDA about the updated SAP, the read-out process began on April 22, and the company believes that top-line results can be presented within two to four months of the beginning of the read-out process.

After the top-line data has been presented, which will provide an indication analyses will continue to be performed so that final data can be presented, which is expected to take place in the second half of 2022. This data will then form the basis of an NDA for the US market, which is Isofol's top-priority market. Given that the AGENT study is achieving its goals, Isofol's preliminary estimate is that it will be able to submit a market approval application to the FDA toward the end of 2022. With this timetable, a US launch could be possible during the second half of 2023.

The objective of the AGENT study is to be able to statistically demonstrate tumor shrinkage that is at least 10 percentage points higher (measured from the original size) in patients

treated in the arfolitixorin arm of the study compared with the control group. The secondary endpoint of the study is to demonstrate a clinically relevant extension of PFS.

The AGENT study also has an exploratory endpoint in the form of gene expression. Isofol, in collaboration with academic research groups, has previously been able to demonstrate a correlation between clinical benefit and gene expression in patients with advanced CRC who were treated with 5-FU-based cytostatic treatment. The results of the study have the potential to produce additional insights about the use of 5-FU based cytostatics in combination with arfolitixorin and a greater understanding of the role of gene expression in arfolitixorin's mechanism of action.

Medical affairs expands in the US

Despite a rising incidence of CRC, no new first-line all-comer drug treatments for advanced CRC patients, regardless of genetic profile, have been approved in almost 20 years. In an area of treatment with long-established treatment regimes, major efforts are needed to create awareness of new drug candidates to raise their profile among prevailing treatment traditions. Isofol achieves this thorough building relationships with the medical community and relevant external medical experts (key opinion leaders, KOLs) ahead of a potential launch. In order to achieve this, the first MSL was recruited for the US market at the end of 2021, and additional field-based medical personnel will be recruited during the year. The field-based medical personnel participate in scientific exchanges with KOLs and other healthcare specialists in order to inform them about arfolitixorin's properties. The field-based medical personnel also communicate and provide information about relevant trends, research, clinical practice and insights from medical conferences.

A positive reply from the FDA on the protocol for pancreatic cancer

Arfolitixorin is considered to have additional application areas aside from treating advanced CRC. Several other forms of cancer, including CRC that is not yet metastasized, are considered suitable for further studies. Cancer in the pancreas, stomach, breast, and head and neck region are forms of cancer where 5-FU is regularly used in the standard treatment and a combination with arfolitixorin it is therefore considered to be possible. What cancers including CRC and pancreatic cancer have in common is that the cancer cells have a high mutation rate, which means that the cells frequently alter their genetic makeup. This makes them difficult to treat even with the immunotherapies that are increasingly being while patients develop resistance to targeted treatments. During the quarter, the FDA provided a positive reply to the study protocol for pancreatic cancer that Isofol prepared and proposed to the authority. Isofol is now evaluating the possibility of initiating the project in the area of pancreatic cancer in collaboration with experts in the field.

Clinical development initiatives for gene expression and the Modelle study

The AGENT study analyzes patients' tumor material in a number of folate-associated genes in order to demonstrate cancer patients' ability to respond to various folate-based cancer treatments. The gene expression analysis is a partial result of the AGENT study. Isofol is convinced that biomarker analyses will be applied for all patients who are to be 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 treatment with the combination of 5-FU and arfolitixorin, thereby determining the exact genes that could lie behind a difference in clinical efficacy.

The investigator-initiated Modelle clinical study is in progress in collaboration with researchers at Sahlgrenska University Hospital. The study is led by Dr. Helena Taflin and is being conducted at Sahlgrenska University Hospital and the University Hospital of Umeå. The aim of this study is to investigate in detail the effects that various folates (arfolitixorin/leucovorin) in combination with 5-FU have on patients with CRC that has metastasized to the liver. 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 study has the potential to contribute scientific data to Isofol's ongoing clinical work in order to try to understand how gene expression determines the patients' capacity to respond to various folate-based cancer treatments.

27 of the 31 patients to be included in the study had begun their treatment at the end of March 2022. The pace of enrolment to the study is proceeding according to plan and all of the patients are expected to be included during the spring. This means that analysis of the samples collected during the study can begin in the autumn.

Strategic analysis and discussions with partners are in progress in order to optimize the commercial launch

Isofol's aim is for the market approval of arfolitixorin for the US market to be issued by the FDA at the end of 2023, provided that the outcome of the ongoing pivotal Phase III AGENT study is positive. To create the most favorable possible prospects for the commercial launch, Isofol is performing a number of preparatory activities.

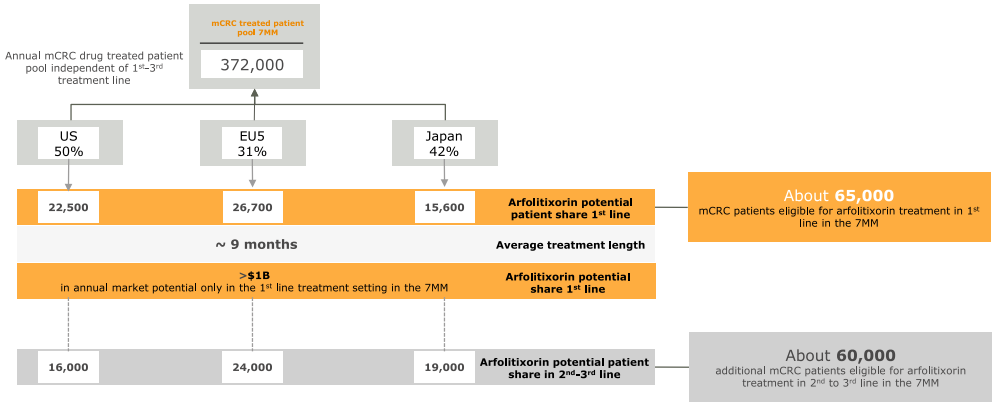
During the first quarter of 2022, Isofol continued to prepare the company for a future commercial launch of arfolitixorin. The insights and data collected in 2021 have been analyzed in order to define different go-to-market strategies. These are in themselves dependent upon various outcomes of the AGENT study. Even if the hope is always that the results of clinical studies will be crystal clear and unambiguous, some endpoints can be unclear and difficult to interpret in reality. Even if the outcome of the AGENT study does not prove to be unambiguous, most of the potential outcomes that have been identified mean a possible commercially path forward. The commercial paths will vary based on the different outcomes. Both outcomes and associated commercial scenarios have been analyzed and launch plans have been developed for each strategy during the spring. The options are also affected by the ongoing dialogues that Isofol is holding with existing and potential partners. Dialogues with potential partners intensified and became more in-depth in the first part of 2022 since we had initiated the process of analyzing and eventually presenting data on the results.

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

Commercial preparations were already being intensified in 2021 through a number of activities, such as detailed analyses of the mCRC markets in the US and Europe, including an analysis of how CRC patients are currently being treated. These analyses were performed in order to better understand and optimize arfolitixorin's future market positioning. Since the beginning of the year, commercial preparation activities have been led by Jenny Sundqvist, who was appointed as the new Chief Commercial Officer in January 2022.

In all, the data collected confirms the need for new treatments for CRC. In the updated surveys, approximately 350 physicians provided their opinions on the role of arfolitixorin in future treatment regimes. Provided the AGENT study reaches its set targets, the conclusion of the surveys is that arfolitixorin constitutes a distinct improvement compared with current treatments. In addition, payers 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 are an important component in discussions with potential partners and serve as a framework for continued commercialization planning.

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.

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

Arfolitixorin currently has patents granted for most major forms of cancer in the US, Europe, Japan, Canada, Australia, South Korea and Ukraine 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.

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 clinical advantages of using arfolitixorin may therefore be the same. These indications will require further clinical studies in order to secure regulatory approval, something which Isofol is currently 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 men and women to the same extent. However, the location of the cancer differs between the genders, with a somewhat higher proportion of men developing rectal cancer while a higher proportion of women develop cancer in the intestines. The risk of developing CRC increases with age, and the majority of patients who develop the disease do so after the age of 70. Every year about 1.9 million new patients are diagnosed with this form of cancer around the world.

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 deaths from cancer after lung cancer. The survival prognosis is very good if CRC can be diagnosed early. However, 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 advanced CRC patients are alive five years after diagnosis.

Significant market potential

The eight largest markets for CRC treatment are the US, the EU 4, the UK, Japan and China. The value of sales of drugs for the treatment of CRC totaled USD 7.6 billion in 2018, and the market is expected to grow to about USD 11 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 only be used to treat smaller target populations of colorectal patients.

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

In 2020, the UK market analysis company Global Data published a forecast for sales of drugs for the treatment of CRC in the eight largest markets up to 2028. The report describes arfolitixorin as one of the most promising drug candidates for the treatment of CRC.

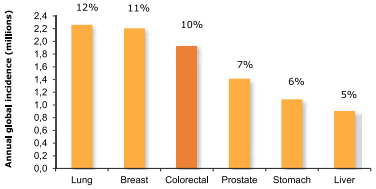
Colorectal cancer (CRC) – Large and underserved segment

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]

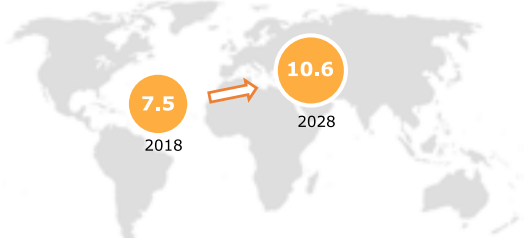
10% The 5-year survival rate for patients with stage 4 colorectal cancer (mCRC) falls to around 10%[2]

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]



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

2) GlobalData 2020

Financial information, January-March

COMPARISON BETWEEN THE FIRST QUARTERS OF 2022 AND 2021

Amounts stated without parentheses refer to the January-March 2022 period, and amounts stated in parentheses refer to January-March 2021.

REVENUE

Operating revenue

Net revenue amounted to TSEK 4,006 (5,215) for the quarter. Revenue for the quarter was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 1 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -47,263 (-43,589), corresponding to an increase of TSEK 3,674. Costs for the ongoing AGENT study are generally lower, while costs for pre-commercialization activities and costs for preparations to compile study results are increasing.

Personnel costs

Personnel costs in the Group amounted to TSEK -5,866 (-5,356), corresponding to an increase of TSEK 510. There were 14 (12) employees at the end of March 2022.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -401 (-400).

Financial items

Financial revenue amounted to TSEK 1,871 (2,107), attributable to exchange rate fluctuations in cash and cash equivalents. Financial costs amounted to TSEK -199 (-31), attributable to exchange rate fluctuations in derivative instruments and interest expenses.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -49,545 (-44,738), corresponding to an increased loss of TSEK 4,808. The result after financial items was TSEK -47,874 (-42,662), corresponding to an increased loss of TSEK 5,212. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents on March 31, 2022 amounted to TSEK 332,035 (77,524). No loans had been raised as of March 31, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 20,236 (11,269) was pledged as collateral for currency futures that will fall due for payment in the second quarter of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -48,891 (-38,952), corresponding to a change of TSEK -9,939. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities. The increased negative cash flow year-on-year was due to lower revenue and higher costs.

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 -392 (-358). The negative cash flow was primarily attributable to repayment of the company's lease liabilities.

Cash flow for the period

Cash flow for the period amounted to TSEK -49,283 (-39,310), corresponding to a change of TSEK -9,973. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities.

INVESTMENTS

Investments during January-March 2022

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. The Group has no material ongoing or planned investments.

Other information

Employees

There were 14 (12) full-time employees at the end of the reporting period, five 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 2021, 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 first 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" and ISIN SE0009581051. 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 risk. Isofol's operations are associated with risks that could have a material negative 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 2021.

Largest shareholders on March 31, 2022

Shareholder	Number of shares	Share capital/votes
Futur Pension (formerly Danica)	13,507,151	8.4%
Avanza Pension	8,696,576	5.4%
Handelsbanken Fonder	7,346,459	4.5%
Swedbank Försäkring	5,439,341	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	2,728,502	1.7%
Alfred Berg Fonder	2,366,605	1.5%
Ten largest shareholders	**57,086,425**	**35.4%**
Other shareholders	104,429,015	64.6%
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.*

SOURCE: MONITOR BY MODULAR FINANCE AB. COMPILED AND PROCESSED DATA FROM, AMONG OTHERS, EUROCLEAR, MORNINGSTAR AND THE SWEDISH FINANCIAL SUPERVISORY AUTHORITY.

Forward-looking information

Although the company's Board of Directors and management believe that the expectations stated in this report are reasonable, no guarantee can be provided that these expectations will prove to be correct. Consequently, actual future outcomes may differ significantly compared with what is stated in the forward-looking information, depending on factors including changed conditions in the economy and the market, changes in legal and regulatory requirements, as well as political measures and currency fluctuations.

The impact of Covid-19

The Covid-19 pandemic has affected how we work, but at present we do not see any negative impacts on the operations due to the pandemic.

Review report

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

Financial reports and calendar

References are to the Group unless otherwise indicated in this interim report. Major fluctuations in revenue and costs for various periods may occur due to the nature of the business. Revenue is not seasonal or regular in any other way; instead it is related above all to when milestones that generate remuneration are achieved in licensed research projects. Exactly as with revenue, costs may fluctuate between different periods. This is affected by the phases that various projects are in, since some phases generate more costs. Figures in parentheses indicate the outcome for the corresponding period in the preceding year for items related to the income statement and cash flow. Amounts are stated in TSEK unless otherwise specified. All stated amounts are rounded, which means that some totals may occasionally appear to be incorrect as a result.

Financial statements

Isofol intends to issue financial statements as follows:

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

Invitation to presentation of the first quarter of 2022, May 12 at 11:00 a.m. CEST

Isofol invites investors, analysts and the media to an audiocast on May 12 at 11:00 a.m. CEST in connection with the publication of the interim report for the first quarter of 2022. The presentation will be held by Isofol's CEO Ulf Jungnelius and CFO Gustaf Albèrt, who will present and comment on the interim report, followed by questions. The presentation will be held in English.

Date and time
May 12, 2022, 11:00 a.m. CEST

Link to webcast
https://tv.streamfabriken.com/isofol-medical-q1-2022

Telephone number
To participate by telephone, please call in to one of the following telephone numbers.
SE: +46 8 50 55 83 53
UK: +44 333 300 92 68
US: +1 631 913 1422 PIN: 80079640#

The presentation will also be available on Isofol's website afterward.

2022 Annual General Meeting

The Annual General Meeting of Isofol Medical AB (publ) will be held on Thursday May 19, 2022 at 5:00 p.m. CEST in Gothenburg. For more information, refer to the notice of the meeting published on the company's website on April 12, 2022.

The Annual Report for 2021 of Isofol Medical AB (publ) is available to download from the company's website.

For further information, contact:

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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 person above, on May 12, 2022 at 8:00 a.m. CEST

Condensed consolidated income statement

TSEK	Note	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
OPERATING REVENUE				
Net revenue	2	4,006	5,215	22,407
Other operating income		1	–	–
Total operating revenue		**4,007**	**5,215**	**22,407**
OPERATING COSTS				
Other external costs		-47,263	-43,589	-196,712
Personnel costs		-5,866	-5,356	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-401	-400	-1,596
Other operating revenue and operating costs		-22	-607	-843
Total operating costs		**-53,553**	**-49,952**	**-226,872**
Operating result		**-49,545**	**-44,738**	**-204,465**
FINANCIAL ITEMS				
Financial revenue		1,871	2,107	4,383
Financial costs		-199	-31	-168
Total financial items		**1,672**	**2,076**	**4,215**
Result after financial items		**-47,874**	**-42,662**	**-200,251**
Tax on result for the period		–	–	–
Result		**-47,874**	**-42,662**	**-200,251**
Attributable to:				
Parent Company shareholders		-47,874	-42,662	-200,251
EARNINGS PER SHARE				
Before dilution (SEK)		-0.30	-0.51	-1.59
After dilution (SEK)		-0.30	-0.51	-1.59

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	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
ASSETS				
FIXED ASSETS				
Intangible fixed assets				
Patents, licenses and similar rights		–	–	–
Total intangible fixed assets		**–**	**–**	**–**
Tangible fixed assets				
Equipment, tools and right-of-use assets		1,640	2,858	1,745
Total tangible fixed assets		**1,640**	**2,858**	**1,745**
Financial fixed assets				
Other long-term receivables		3,681	5,014	5,009
Total financial fixed assets		**3,681**	**5,014**	**5,009**
Total fixed assets		**5,321**	**7,872**	**6,755**
CURRENT ASSETS				
Accounts receivable	3	–	–	–
Other receivables	3	10,108	9,081	12,276
Prepaid expenses and accrued income	3	3,102	10,954	2,884
Cash and cash equivalents	3, 4, 5	332,035	77,524	379,448
Total current assets		**345,245**	**97,559**	**394,609**
Total assets		**350,566**	**105,431**	**401,363**

Condensed consolidated balance sheet

TSEK	Note	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
EQUITY AND LIABILITIES				
EQUITY	6			
Share capital		4,945	2,552	4,945
Other contributed capital		1,217,607	768,083	1,217,607
Retained earnings		-904,319	-704,069	-704,069
Result for the year		-47,874	-42,662	-200,251
Total equity		**270,360**	**23,905**	**318,233**
LIABILITIES				
Long-term liabilities				
Long-term lease liabilities		330	1,160	110
Total long-term liabilities		**330**	**1,160**	**110**
Current liabilities				
Accounts payable	3	16,577	15,569	17,736
Other liabilities		5,514	12,735	3,174
Accrued expenses and deferred income	3	57,784	52,062	62,110
Total current liabilities		**79,876**	**80,365**	**83,020**
Total liabilities		**80,206**	**81,526**	**83,130**
Total equity and liabilities		**350,566**	**105,431**	**401,363**

Consolidated statement of changes in equity

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2021		2,552	768,083	-704,068	66,567
Result for the period		**–**	**–**	**-42,662**	**-42,662**
Equity, Mar 31, 2021		**2,552**	**768,083**	**-746,730**	**23,905**
Opening equity, Apr 1, 2021		2,552	768,083	-746,730	23,905
Rights issue		1,914	398,242	–	400,157
Issue costs		–	-48,240	–	-48,240
Over-allotment option		478	99,522	–	100,000
Result for the period		**–**	**–**	**-157,589**	**-157,589**
Equity, Dec 31, 2021		**4,945**	**1,217,607**	**-904,319**	**318,233**

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2022		4,945	1,217,607	-904,319	318,233
Result for the period		**–**	**–**	**-47,874**	**-47,874**
Equity, Mar 31, 2022		**4,945**	**1,217,607**	**-952,193**	**270,360**

Consolidated cash flow statement

TSEK	Note	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
OPERATING ACTIVITIES				
Result after financial items		-47,874	-42,662	-200,251
Adjustments for non-cash items		-1,286	-1,865	-2,946
Income tax paid		–	–	–
Cash flow from operating activities before changes in working capital		**-49,159**	**-44,527**	**-203,196**
CASH FLOW FROM CHANGES IN WORKING CAPITAL				
Increase (-)/decrease (+) in operating receivables		3,303	3,405	9,860
Increase (+)/decrease (-) in operating liabilities		-3,036	2,170	4,907
Change in working capital		**268**	**5,575**	**14,767**
Cash flow from operating activities		**-48,891**	**-38,952**	**-188,429**
INVESTING ACTIVITIES				
Acquisition of tangible fixed assets		–	–	–
Cash flow from investing activities		**–**	**–**	**–**
FINANCING ACTIVITIES				
Repayment of lease liabilities		-411	-383	-1,548
Subscription warrants, proceeds received	6	18	25	108
New share issue		–	–	451,917
Cash flow from financing activities		**-392**	**-358**	**450,477**
Cash flow for the period		-49,283	-39,310	262,048
Cash and cash equivalents at the beginning of the period		379,448	116,393	116,393
Exchange rate difference in cash and cash equivalents		1,870	441	1,007
Cash and cash equivalents at the end of the period	5	**332,035**	**77,524**	**379,448**

Condensed Parent Company income statement

TSEK	Note	2022 Jan-Mar	2021 Jan-Mar	2021 Jan-Dec
OPERATING REVENUE				
Net revenue	2	4,006	5,215	22,407
Other operating income		–	–	–
Total operating revenue		**4,006**	**5,215**	**22,407**
OPERATING COSTS				
Other external costs		-47,687	-43,999	-198,349
Personnel costs		-5,866	-5,356	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-17	-21	-77
Other operating revenue and operating costs		-22	-607	-843
Total operating costs		**-53,593**	**-49,983**	**-226,990**
Operating result		**-49,587**	**-44,768**	**-204,583**
FINANCIAL ITEMS				
Financial revenue		1,871	2,107	4,383
Financial costs		-185	-4	-79
Total financial items		**1,685**	**2,103**	**4,304**
Result after financial items		**-47,901**	**-42,665**	**-200,280**
Result before tax		**-47,901**	**-42,665**	**-200,280**
Tax		–	–	–
Result		**-47,901**	**-42,665**	**-200,280**

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	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
ASSETS				
FIXED ASSETS				
Intangible fixed assets				
Patents, licenses and similar rights		–	–	–
Total intangible fixed assets		**–**	**–**	**–**
Tangible fixed assets				
Equipment, tools, fixtures and fittings		141	214	158
Total tangible fixed assets		**141**	**214**	**158**
Financial fixed assets				
Participations in Group companies		50	50	50
Other long-term receivables		3,681	5,014	5,009
Total financial fixed assets		**3,731**	**5,064**	**5,059**
Total fixed assets		**3,872**	**5,279**	**5,217**
CURRENT ASSETS				
Accounts receivable		–	–	–
Other receivables		10,108	9,081	12,276
Prepaid expenses and accrued income		3,102	11,178	3,113
Cash and bank balances	4, 5	331,985	77,474	379,398
Total current assets		**345,195**	**97,732**	**394,787**
Total assets		**349,067**	**103,011**	**400,004**

Condensed Parent Company balance sheet

TSEK	Note	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
EQUITY AND LIABILITIES				
EQUITY	6			
Restricted equity				
Share capital		4,945	2,552	4,945
Total restricted equity		**4,945**	**2,552**	**4,945**
Non-restricted equity				
Share premium reserve		1,218,276	768,752	1,218,276
Retained earnings		-904,924	-704,645	-704,645
Result for the year		-47,901	-42,665	-200,280
Total non-restricted equity		**265,451**	**21,443**	**313,352**
Total equity		**270,396**	**23,995**	**318,297**
LIABILITIES				
Current liabilities				
Accounts payable		16,577	15,792	17,965
Other liabilities		4,309	11,162	1,632
Accrued expenses and deferred income		57,784	52,062	62,110
Total current liabilities		**78,671**	**79,016**	**81,707**
Total liabilities		**78,671**	**79,016**	**81,707**
Total equity and liabilities		**349,067**	**103,011**	**400,004**

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 2021.

No standards, amendments or interpretations that come into force in 2022 are considered to have a material impact on the Group's financial statements.

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

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 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		
TSEK	**2022 Jan-Mar**	**2021 Jan-Mar**	**2021 Jan-Dec**
North America	–	–	–
Asia	4,006	5,215	22,407
Total	**4,006**	**5,215**	**22,407**

	Parent Company		
TSEK	**2022 Jan-Mar**	**2021 Jan-Mar**	**2021 Jan-Dec**
North America	–	–	–
Asia	4,006	5,215	22,407
Total	**4,006**	**5,215**	**22,407**

Breakdown of revenue by type of revenue

	Group		
TSEK	**2022 Jan-Mar**	**2021 Jan-Mar**	**2021 Jan-Dec**
Licensing	–	–	–
Execution of service assignments	4,006	5,215	22,407
Total	**4,006**	**5,215**	**22,407**

	Parent Company		
TSEK	**2022 Jan-Mar**	**2021 Jan-Mar**	**2021 Jan-Dec**
Licensing	–	–	–
Execution of service assignments	4,006	5,215	22,407
Total	**4,006**	**5,215**	**22,407**

Contract assets

	Group		
TSEK	**Mar 31, 2022**	**Mar 31, 2021**	**Dec 31, 2021**
Accrued income	1,401	9,570	1,631
Contract liabilities	–	–	–
Total	**1,401**	**9,570**	**1,631**

	Parent Company		
TSEK	**Mar 31, 2022**	**Mar 31, 2021**	**Mar 31, 2021**
Accrued income	1,401	9,570	1,631
Contract liabilities	–	–	–
Total	**1,401**	**9,570**	**1,631**

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

Note 3 Financial instruments

As of March 31, 2022, the Group had financial instruments, which were valued at fair value, in the form of currency derivatives of TSEK 1,478 (-47). Other financial assets and liabilities are valued 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 333,517 (77,630) and financial liabilities to TSEK 71,298 (65,540).

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 20,236 (11,269) of its cash and cash equivalents as collateral.

Note 5 Cash and cash equivalents

Group TSEK	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			
Short-term investments	–	–	–
Cash and cash equivalents	332,035	77,524	379,448
Total	**332,035**	**77,524**	**379,448**

Parent Company TSEK	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			
Short-term investments	–	–	–
Cash and bank balances	331,985	77,474	379,398
Total	**331,985**	**77,474**	**379,398**

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).

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.

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.

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.

Group and Parent Company TSEK	2022 Jan-Mar	2021 Jan-Mar
Repayment from management and employees	18	25
Total	**18**	**25**

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%.

For additional information on current incentive programs, refer to the company's website.

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	Mar 31, 2022	Mar 31, 2021	Dec 31, 2021
Equity	270,360	23,905	318,233
Total assets	**350,566**	**105,431**	**401,363**
Solvency	**77.1%**	**22.7%**	**79.3%**
Cash and cash equivalents	332,035	77,524	379,448
Working capital	265,369	17,194	311,589

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.

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, May 12, 2022

Pär-Ola Mannefred
Chairman

Magnus Björsne
Board member

Paula Boultbee
Board member

Alain Herrera
Board member

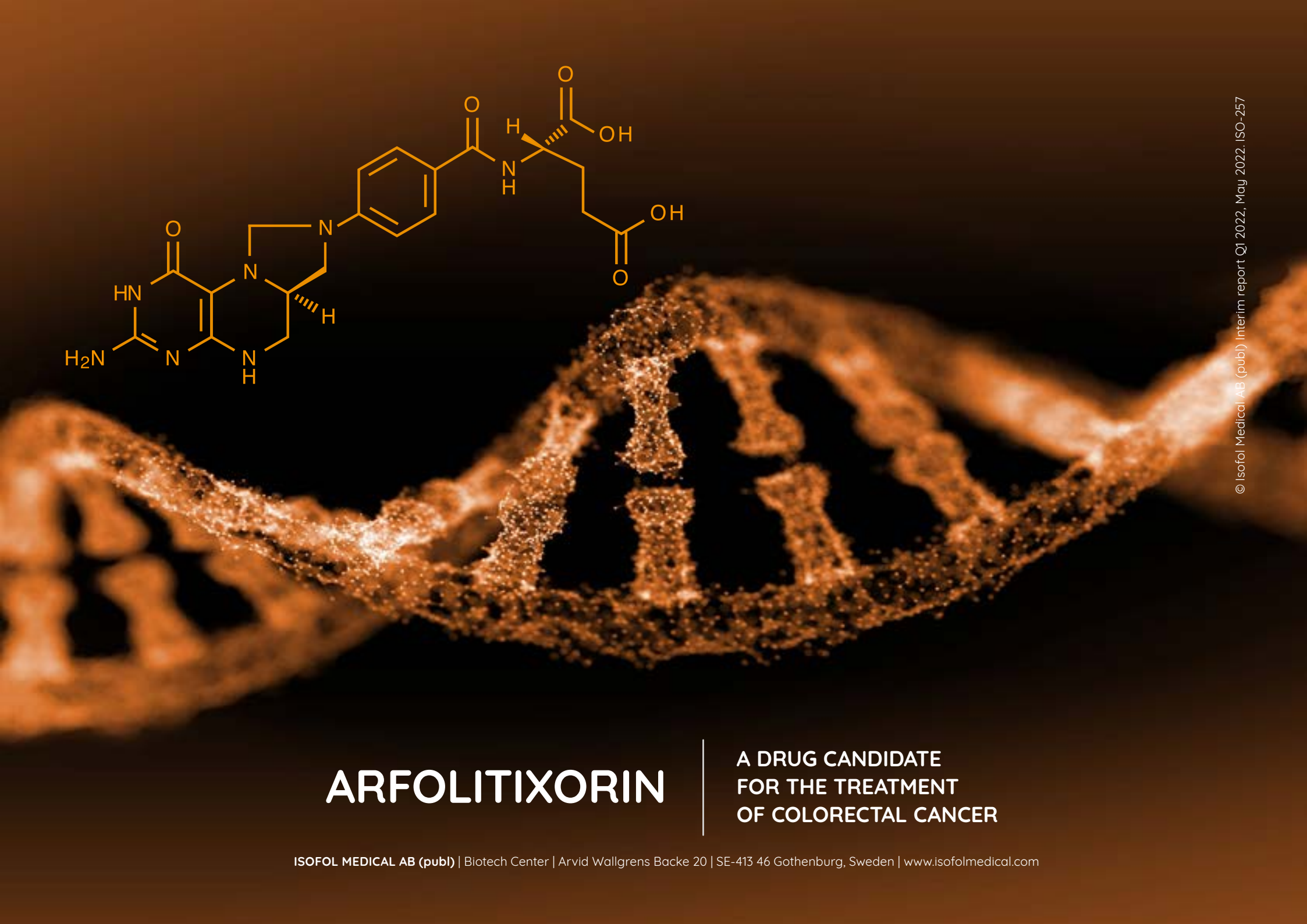
Anna Belfrage
Board member

Robert Marchesani
Board member

Aram Mangasarian
Board member

Lennart Jeansson
Board member

Ulf Jungnelius
CEO



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