

Negative top-line results shift focus to analysis of final data from AGENT study

SIGINIFICANT EVENTS DURING THE SECOND QUARTER

- On April 22, it was announced that the analysis process of study data from the AGENT study had begun.
- Jan Törnell was elected as new Chairman of the Board of the company in conjunction with the Annual General Meeting on May 19.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- On August 3, Isofol presented the topline results of the global pivotal AGENT study in advanced colorectal cancer. The data revealed that the study did not achieve the primary endpoint of objective response rate (ORR) or the key secondary endpoint of progression-free survival (PFS).
- In July, Isofol received approval of a biomarker analysis patent.

About Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical-stage biotechnology company that is developing and improving the current standard treatment for patients suffering from cancer by increasing treatment efficacy through the use of cytostatics. Isofol Medical is focused on developing a drug for first-line treatment of advanced colorectal cancer (mCRC) and is trying to improve the current clinical practice by realizing the full strength of 5-FU with the addition of arfolitixorin. Isofol has an exclusive global licensing agreement with Merck & Cie in Schaffhausen, Germany to develop and commercialize arfolitixorin in oncology. Isofol Medical AB (publ) is traded on Nasdaq Stockholm.

FINANCIAL INFORMATION

Second quarter, April-June 2022

- Net revenue amounted to TSEK 4,027 (7,333) and other revenue to TSEK 0 (0)
- The result for the period amounted to TSEK -54,033 (-45,394)
- Earnings per share amounted to SEK -0.33 (-0.48)
- Cash and cash equivalents at June 30 amounted to TSEK 277,727 (530,682)

First half of the year, January-June 2022

- Net revenue amounted to TSEK 8,033 (12,548) and other revenue to TSEK 1 (0)
- The result for the period amounted to TSEK -101,907 (-88,055)
- Earnings per share amounted to SEK -0.63 (-0.99)

KEY FIGURES TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Net revenue	4,027	7,333	8,033	12,548	22,407
Result for the period	-54,033	-45,394	-101,907	-88,055	-200,251
Earnings per share (SEK)	-0.33	-0.48	-0.63	-0.99	-1.59
Cash and cash equivalents	277,727	530,682	277,727	530,682	379,448

Final data to provide basis for determining potential path forward

After a few months of intensive work on quality assurance and the analysis of study data, Isofol presented its top-line results in August. Despite our high expectations, the AGENT study did not meet its primary or key secondary endpoints. Isofol's priority is to complete the data analysis and then identify and consider alternative paths forward. When the process is completed, we will be able to decide what the next step should be for Isofol's clinical program.

Disappointing top-line results given major need for new treatment alternative

It is incredibly disappointing that the results from the top-line analysis did not demonstrate the advantages we had hoped for. We were very hopeful that arfolitixorin would be able to improve the lives of patients in first-line treatment for mCRC, regardless of genetic profile. Our disappointment is compounded by the large need for new treatment alternatives for patients suffering from this severe disease.

The goal of the AGENT study was to demonstrate an improvement in ORR of at least 10 percentage points in patients treated with arfolitixorin compared with those treated with the current standard treatment. The study was also expected to demonstrate a statistically significant difference in PFS between study arms. However, the data showed that neither the primary endpoint of ORR nor the key secondary endpoint of PFS achieved statistical significance. Nor was there a meaninaful positive trend in PFS, which would have been sufficient to secure approval from the US Food and Drug Administration (FDA). We do not expect the outcome of these endpoints to change once the final data has been compiled. In light of this, it is not likely that we will be able to submit a New Drug Application (NDA) to the FDA for market approval for the intended patient population in the US. Final data and sub-group analyses will be decisive for the final assessment of our application options. Accordingly, Isofol is now facing a very challenging regulatory and commercial situation.

Decision regarding clinical program expected in first half of 2023

It is important to note that Isofol does not have access to final data yet. This data will provide the company with guidance and be decisive for determining the next step for Isofol and arfolitixorin. Our priority now is to complete the AGENT study, in accordance with regulatory requirements, obtain final data and analyze this data in detail.

The final data for the AGENT study will comprise two different "packages"; clinical data including the study's primary and secondary endpoints, and data including exploratory endpoints, such as gene expression and other biomarkers. The final data for these "packages" will be obtained at different points in the fourth quarter of 2022, and our aim is to present detailed study data at a scientific conference or in a scientific publication in 2023. This will allow the scientific community to take advantage of the lessons learned from the study.

Since presenting the top-line results, we have spoken with members of Isofol's Advisory Board and various investigators who expressed their interest in sharing their expertise when it comes time to interpreting the final data and sharing their insights with regards to future treatment alternatives. After the final data has been compiled and analyzed, we plan to engage in a dialogue with the relevant regulatory authorities to discuss potential paths forward. Isofol will not make any decisions about the next step or the future of the clinical program until this process is complete.

Continued strong financial position enables well-founded decisions

I would like to point out that Isofol has a strong financial position, which will enable us to complete the AGENT study and analyze the final data in an efficient and reliable manner. This is very important in the situation we now find ourselves in, and we therefore have no plans at the moment to make any major organizational changes. We have, however, initiated several measures in other areas to strengthen our cash position and use our financial resources in an expedient and cost-effective manner, thereby boosting our financial resilience. These measures include pausing the vast majority of the

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To determine Isofol's potential path forward, we must complete our thorough review

Ulf Jungnelius, CEO, Isofol Medical AB (publ)

ongoing pre-commercial activities and other activities not focused on the completion of the AGENT studu.

Dedicated team

I would like to take this opportunity to thank everyone involved in the AGENT study – the patients, participating clinics and, not least, the Isofol team. I would also like to thank all of the shareholders who have supported Isofol throughout our journey.

To determine Isofol's potential path forward, we must complete a thorough review of all final data. This will provide us with a good understanding of the study results and, with the input and guidance of experts and authorities, we will be able to make the right choice for Isofol's future. My colleagues and I are dedicated to, and fully focused on, completing the AGENT study. With substantiated documentation in hand, we will be able to make important strategic decisions that will allow us to leverage the potential of arfolitixorin, thereby benefiting patients.

Gothenburg, August 23, 2022

Ulf Jungnelius CEO, Isofol Medical AB (publ)

Top-line results miss AGENT study endpoints

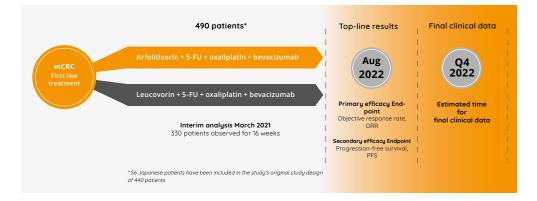
On August 3, Isofol announced that the company's global pivotal Phase III AGENT study AGENT had not achieved statistical significance between treatment arms for the primary endpoint of ORR or the secondary endpoint of PFS. This means that it will not be possible to submit an NDA to the FDA based on these results. The next step for Isofol's clinical program is to complete the data analysis to verify the top-line results and assess potential future treatment alternatives. The aim is to be able to present detailed study data at a scientific conference or in a scientific publication in 2023.

AGENT study intended as an alternative for all-comers

The Phase III AGENT study is the first study in 20 years to investigate a meaningful alternative for the current standard treatment for the vast majority of mCRC patients and includes approximately 90 clinics in the US, Canada, Europe, Australia and Japan. The randomized, controlled, multi-center Phase III study encompasses 490 patients and aims to evaluate the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin, both used in combination with 5-FU, oxaliplatin, and bevacizumab, in first-line mCRC patients.

The study was designed to demonstrate that arfolitixorin was significantly better than leucovorin. The patients were randomized on a 1:1 basis, with the primary endpoint of the study being ORR and the key secondary endpoint being PFS. Other secondary endpoints include duration of response (DOR), number of curative metastatic resections, safety and patient-reported outcomes such as quality of life (QoL). Other endpoints include pharmacokinetic (PK) measurements and gene expression of folate relevant genes in tumor cells.

The top-line results revealed that the study did not achieve the primary endpoint of ORR or



the key secondary endpoint of PFS. This means that arfolitixorin will probably not be a new potential alternative for patients, regardless of genetic profile, in first-line treatment for mCRC and that the results will not serve as the basis for market approval.

Final data analysis under way to assess potential clinical value

The AGENT study will be completed in accordance with the applicable regulations for clinical studies in order to understand how factors

such as gene expression, biomarkers, censoring and the pandemic impacted the outcome and to determine whether arfolitixorin could potentially offer clinical value for various sub-groups of mCRC patients. Isofol will obtain final data including clinical data and exploratory endpoints at two different points during the fourth quarter of 2022.

Interactions with the relevant regulatory authorities will then need to take place to discuss possible paths forward. This dialogue is preliminarily planned for H1 2023. After the data

analysis and dialogue with the regulatory authorities have been completed, a decision regarding the next step for Isofol's clinical program will be made.

Pending the results of further analyses within the framework of the AGENT study, patients remaining in the experimental arm of the study may be offered standard treatment with leucovorin, but we need to wait for the final data, including safety data, before such a decision can be made.

Key data will be presented at a scientific conference or in a scientific publication to enable the scientific community to fully leverage the lessons learned from the study. The aim is for this to take place in 2023. So as not to compromise any future conference participation or publication, no detailed data will be published before this.

Read more about the AGENT study and Isofol's operations on the company's website and in the 2021 Annual Report.

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.

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

High mortality

Despite improvements in the prognosis for patients with CRC over the past decade, the prognosis for survival is worse compared to patients with breast or prostate cancer, and CRC is the second most common cause of global 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.

Treatment of CRC

The genes of CRC cells mutate over time. This means that cytostatic treatment must be tai-

Colorectal cancer (CRC) - Large and underserved segment

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

Colorectal cancer is the third most common cancer¹ 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancers discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually are colorectal cancer September 10% of cancer discovered annually

lored if it is to be fully effective, a challenge commonly found with most forms of cancer. New drugs are continuously being introduced, usually as supplements to existing drugs rather than as replacements. These supplementary treatments are included in new combinations intended to increase the effectiveness of the treatment. The 5-FU-based combination with which arfolitixorin is being tested as a cornerstone treatment for CRC and will remain so for the foreseeable future.

As CRC develops into more advanced and metastatic stages, the use of cytostatics, biological and other targeted drugs increases. Sometimes radiation treatment is administered, particularly for patients with localized tumors.

Major need for new treatment options

One of the reasons for the pressing need for new treatments is that, compared with breast and lung cancer, mCRC patients have very few target molecules that can be attacked with new drugs, partly due to the high mutation rate of this form of cancer. New drugs such as immunotherapies are targeted to specific patient subgroups. PD-1 inhibitors, such as Keytruda, can only be used to treat approximately 4 percent of mCRC patients, while B-Raf inhibitors, such as Encorafenib+binimetinib, are effective for 8-10 percent of mCRC patients in second-line treatment.

Source:

GLOBOCAN 2020, Cancer Incidence
 and Mortality Worldwide
 GlobalData 2020

70 percent of patients treated with cytostatics

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

Financial information, April-June

COMPARISON BETWEEN THE SECOND QUARTER OF 2022 AND 2021

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

REVENUE

Operating revenue

Net revenue amounted to TSEK 4,027 (7,333) for the quarter. Revenue for the quarter was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 0 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -51,530 (-45,603), corresponding to an increase of TSEK 5,927. Compared with the year-earlier period, costs for the ongoing AGENT study were generally lower, while costs for pre-commercialization activities and costs for preparations to compile study results increased.

Personnel costs

Personnel costs in the Group amounted to TSEK -8,471 (-5,755), corresponding to an increase of TSEK 2,716. There were 14 (13) employees at the end of June.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -398 (-399).

Financial items

Financial revenue amounted to TSEK 3,134 (330), attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments. Financial costs amounted to TSEK -12 (-1,060), attributable to interest expenses.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -57,155 (-44,664), corresponding to an increased loss of TSEK 12,491. The result after financial items was TSEK -54,033 (-45,394), corresponding to an increased loss of TSEK 8,640. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at June 30, 2022 amounted to TSEK 277,727 (530,682). No loans had been raised per June 30, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 26,213 (0) was pledged as collateral to settle currency futures that will fall due for payment in the second half of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -55,143 (-44,386), corresponding to a change of TSEK -10,757. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities. The year-on-year increase in negative cash flow was due to lower revenue and higher costs for pre-commercialization activities and preparations to compile study results.

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 -398 (498,300). 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 -55,541 (453,914), corresponding to a change of TSEK -509,455. Excluding last year's share issue, cash flow for the comparative period was (-44,740). The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities.

INVESTMENTS

Investments during April-June 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.

Financial information, January-June

COMPARISON BETWEEN THE FIRST HALF OF 2022 AND 2021

Amounts stated without parentheses refer to the first half of 2022, and amounts stated in parentheses refer to the first half of 2021.

REVENUE

Operating revenue

Net revenue amounted to TSEK 8,033 (12,548) for the first half of the year. Revenue 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 -98,794 (-89,193), corresponding to an increase of TSEK 9,601. Compared with the year-earlier period, costs for pre-commercialization activities and for compiling and preparing study results increased, while study costs for the ongoing AGENT study decreased.

Personnel costs

Personnel costs in the Group amounted to TSEK -14,337 (-11,111), corresponding to an increase of TSEK 3,226. There were 14 (13) employees at the end of June.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -799 (-799).

Financial items

Financial revenue amounted to TSEK 4,819 (1,401), attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments. Financial costs amounted to TSEK -26 (-55), attributable to interest expenses.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -106,701 (-89,402), corresponding to an increased loss of TSEK 17,299. The result after financial items was TSEK -101,907 (-88,055), corresponding to a increased loss of TSEK 13,851.

The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at June 30, 2022 amounted to TSEK 277,727 (530,682). No loans had been raised per June 30, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 26,213 (0) was pledged as collateral to settle currency futures that will fall due for payment in the second half of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -104,035 (-83,338), corresponding to a change of TSEK 20,697. The higher negative cash flow was attributable to the company's clinical and pre-commercial activities.

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 -791 (497,942). 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 -104,825 (414,604). Excluding last year's share issue, cash flow for the comparative period was (-84,050). The negative cash flow was attributable to the company's clinical and pre-commercial activities.

INVESTMENTS

Investments made during the first half of 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

Emplouees

There were 14 (13) 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 (161,515,440), with a nominal value of SEK 0.0306 (0.0306). The average number of shares in the second augrter was 161.515.440 (95.325.023). From October 21, 2021, the share is listed on Nasdaq Stockholm's main list, under the commercial name "ISOFOL" and ISIN SE0009581051.

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 at June 30, 2022

Shareholder	Number of shares	Share capital/votes
Futur Pension (formerly Danica)	13,449,489	8.3 %
Avanza Pension	8,855,063	5.5 %
Handelsbanken Fonder	7,497,257	4.6 %
Swedbank Försäkring	5,333,580	3.3 %
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 %
Alfred Berg Fonder	2,350,289	1.5 %
Nordnet Pensionsförsäkring	2,346,389	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 OF MODULAR FINANCE AB. COMPILED AND PROCESSED DATA FROM SOURCES INCLUDING 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.

Audit report

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

Financial reports

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 partly related 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.

Calendar

Isofol intends to issue financial statements as follows:

Interim report July-September 2022 November 11, 2022 Year-end report 2022 February 22, 2023

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

Invitation to presentation of the first quarter of 2022, May 23 at 12.30 p.m. CEST.

Isofol invites investors, analysts and the media to an audiocast on August 23 at 12:30 p.m. CEST in connection with the publication of the interim report for the second quarter of 2022. The presentation will be held by Isofol's CEO UIf 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

August 23, 2022 at 12.30 p.m. CEST

Link to audiocast

https://tv.streamfabriken.com/isofol-medical-q2-2022

Telephone number

To participate by telephone, please call in to one of the following telephone numbers.

SE: +46 8 50 51 63 86 UK: +44 203 198 48 84

US: +1 412 317 6300, PIN 3977834#

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



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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.

Condensed consolidated income statement

TSEK	Note	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
OPERATING REVENUE						
Net revenue	2	4,027	7,333	8,033	12,548	22,407
Other revenue		-	-	1	-	-
Total operating revenue		4,027	7,333	8,034	12,548	22,407
OPERATING COSTS						
Other external costs		-51,530	-45,603	-98,794	-89,193	-196,712
Personnel costs		-8,471	-5,755	-14,337	-11,111	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-398	-399	-799	-799	-1,596
Other operating revenue and operating costs		-782	-240	-805	-847	-843
Total operating costs		-61,182	-51,997	-114,735	-101,950	-226,872
Operating result		-57,155	-44,664	-106,701	-89,402	-204,465
FINANCIAL ITEMS						
Financial revenue		3,134	330	4,819	1,401	4,383
Financial costs		-12	-1,060	-26	-55	-168
Total financial items		3,122	-729	4,794	1,346	4,215
Result after financial items		-54,033	-45,394	-101,907	-88,055	-200,251
Tax on result for the period		_	_	_		_
Result		-54,033	-45,394	-101,907	-88,055	-200,251
Attributable to:						
Parent Company shareholders		-54,033	-45,394	-101,907	-88,055	-200,251
EARNINGS PER SHARE						
Before dilution (SEK)		-0.33	-0.48	-0.63	-0.99	-1.59
After dilution (SEK)		-0.33	-0.48	-0.63	-0.99	-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	Jun 30, 2022	Jun 30, 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		1,241	2,459	1,745
Total tangible fixed assets		1,241	2,459	1,745
Financial fixed assets				
Other long-term receivables		1,910	5,009	5,009
Total financial fixed assets		1,910	5,009	5,009
Total fixed assets		3,151	7,468	6,755
CURRENT ASSETS				
Accounts receivable	3	1,626	-	_
Other receivables	3	13,598	9,405	12,276
Prepaid expenses and accrued income	3	2,460	12,231	2,884
Cash and cash equivalents	3, 4, 5	277,727	530,682	379,448
Total current assets		295,411	552,319	394,609
Total assets		298,562	559,787	401,363

Condensed consolidated balance sheet

TSEK	Note	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
EQUITY AND LIABILITIES				
EQUITY	6			
Share capital		4,945	4,945	4,945
Other contributed capital		1,217,607	1,218,007	1,217,607
Retained earnings		-904,319	-704,069	-704,069
Result for the year		-101,907	-88,055	-200,251
Total equity		216,326	430,829	318,233
LIABILITIES				
Long-term liabilities				
Long-term lease liabilities		269	769	110
Total long-term liabilities		269	769	110
Current liabilities				
Accounts payable	3	8,725	42,344	17,736
Other liabilities	3	3,279	11,127	3,174
Accrued expenses and deferred income	3	69,962	74,719	62,110
Total current liabilities		81,967	128,190	83,020
Total liabilities		82,236	128,958	83,130
Total equity and liabilities		298,562	559,787	401,363

Consolidated statement of changes in equity

		Cl	Other	B. C. C d	
TSEK	Note	Share capital	contributed capital	Retained earnings	Total
Opening balance, Jan 1, 2021		2,552	768,083	-704,068	66,567
Rights issue		1,914	398,242	-	400,157
Issue costs		-	-47,840	-	-47,840
Over-allotment option		478	99,522	-	100,000
Result for the period		-	-	-88,055	-88,055
Equity, Jun 30, 2021		4,945	1,218,007	-792,123	430,829
TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening balance, Jul 1, 2021		4,945	1,218,007	-792,123	430,829
Issue costs		-	-400	-	-400
Result for the period		-	-	-112,196	-112,196
Equity, Dec 31, 2021		4,945	1,217,607	-904,319	318,233
TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening balance, Jan 1, 2022		4,945	1,217,607	-904,319	318,233
Result for the period		-	-	-101,907	-101,907
Equity, Jun 30, 2022		4,945	1,217,607	-1,006,226	216,326

Consolidated cash flow statement

TSEK	Note	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
IJEN	Note	Apr-juii	Apr-juii	jan-jun	Jan-Jun	Jan-Dec
OPERATING ACTIVITIES						
Result after financial items		-54,033	-45,394	-101,907	-88,055	-200,251
Adjustments for non-cash items		1,013	1,108	-273	-757	-2,946
Income tax paid		-	-	-	_	-
Cash flow from operating activities before changes in working capital		-53,021	-44,285	-102,180	-88,812	-203,196
CASH FLOW FROM CHANGES IN WORKING CAPITAL						
Increase (-)/decrease (+) in operating receivables		-4,414	-1,627	-1,111	1,778	9,860
Increase (+)/decrease (-) in operating liabilities		2,292	1,527	-744	3,696	4,907
Change in working capital		-2,122	-101	-1,855	5,474	14,767
Cash flow from operating activities		-55,143	-44,386	-104,035	-83,338	-188,429
INVESTING ACTIVITIES						
Acquisition of tangible fixed assets		-	-	-	-	-
Cash flow from investing activities		-	-	-	-	-
FINANCING ACTIVITIES						
Repayment of lease liabilities		-404	-384	-814	-767	-1,548
Subscription warrants, proceeds received	6	5	30	23	55	108
New share issue		-	498,655	_	498,655	451,917
Cash flow from financing activities		-398	498,300	-791	497,942	450,477
Cash flow for the period		-55,541	453,914	-104,825	414,604	262,048
Cash and cash equivalents at the beginning of the period		332,035	77,524	379,448	116,393	116,393
Exchange rate difference in cash and cash equivalents		1,234	-756	3,104	-315	1,007
Cash and cash equivalents at the end of the period	5	277,727	530,682	277,727	530,682	379,448

Condensed parent company income statement

TSEK	Note	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
OPERATING REVENUE						
Net revenue	2	4,027	7,333	8,033	12,548	22,407
Other revenue		-	-	-	-	-
Total operating revenue		4,027	7,333	8,033	12,548	22,407
OPERATING COSTS						
Other external costs		-51,946	-46,011	-99,633	-90,011	-198,349
Personnel costs		-8,471	-5,755	-14,337	-11,111	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-17	-19	-34	-40	-77
Other operating revenue and operating costs		-782	-240	-805	-847	-843
Total operating costs		-61,216	-52,026	-114,809	-102,009	-226,990
Operating result		-57,190	-44,693	-106,776	-89,461	-204,583
FINANCIAL ITEMS						
Financial revenue		3,134	330	4,819	1,401	4,383
Financial costs		-	-1,036	-	-4	-79
Total financial items		3,134	-706	4,819	1,397	4,304
Result after financial items		-54,056	-45,398	-101,957	-88,064	-200,280
Result before tax		-54,056	-45,398	-101,957	-88,064	-200,280
Tax		-	-	-	-	-
Result		-54,056	-45,398	-101,957	-88,064	-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	Jun 30, 2022	Jun 30, 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		124	195	158
Total tangible fixed assets		124	195	158
Financial fixed assets				
Participations in Group companies		50	50	50
Other long-term receivables		1,910	5,009	5,009
Total financial fixed assets		1,960	5,059	5,059
Total fixed assets		2,083	5,254	5,217
CURRENT ASSETS				
Accounts receivable		1,626	-	_
Other receivables		13,598	9,405	12,276
Prepaid expenses and accrued income		2,689	12,455	3,113
Cash and bank balances	4, 5	277,677	530,632	379,398
Total current assets		295,590	552,492	394,787
Total assets		297,674	557,747	400,004

Condensed parent company balance sheet

TSEK	Note	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
EQUITY AND LIABILITIES				
EQUITY	6			
Restricted equity				
Share capital		4,945	4,945	4,945
Total restricted equity		4,945	4,945	4,945
Non-restricted equity				
Share premium reserve		1,218,276	1,218,676	1,218,276
Retained earnings		-904,924	-704,645	-704,645
Result for the year		-101,957	-88,064	-200,280
Total non-restricted equity		211,395	425,968	313,351
Total equity		216,340	430,914	318,297
LIABILITIES				
Current liabilities				
Accounts payable		8,954	42,568	17,965
Other liabilities		2,417	9,546	1,632
Accrued expenses and deferred income		69,962	74,719	62,110
Total current liabilities		81,333	126,833	81,707
Total liabilities		81,333	126,833	81,707
Total equity and liabilities		297,674	557,747	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 seaments

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 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 accorrantic area

		Group						
TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec			
Asia	4,027	7,333	8,033	12,548	22,407			
Total	4,027	7,333	8,033	12,548	22,407			
		Pare	nt Company					
TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec			
Asia	4,027	7,333	8,033	12,548	22,407			

Breakdown of revenue by type of revenue

			Group		
TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Execution of service assignments	4,027	7,333	8,033	12,548	22,407
Total	4,027	7,333	8,033	12,548	22,407
		Pare	nt Company		
TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec

	·				
TSEK	2022 Apr-Jun	2021 Apr-Jun	2022 Jan-Jun	2021 Jan-Jun	2021 Jan-Dec
Execution of service assignments	4,027	7,333	8,033	12,548	22,407
Total	4,027	7,333	8,033	12,548	22,407

Contract assets

	Group	
Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
912	10,716	1,631
912	10,716	1,631
Parent Company		
Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
912	10,716	1,631
		1,631
	912 912 P Jun 30, 2022	Jun 30, 2022 Jun 30, 2021 912 10,716 912 10,716 Parent Company Jun 30, 2022 Jun 30, 2021

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

Note 3 Financial instruments

As of June 30, 2022, the Group had financial instruments, which were measured at fair value, in the form of currency derivatives of TSEK -370 (0). 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 279,358 (530,758) and financial liabilities to TSEK 73,745 (114,359).

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 26,213 (0) of its cash and cash equivalents as collateral.

Note 5 Cash and cash equivalents

TSEK	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			
Cash and cash equivalents	277,727	530,682	379,448
Total	277,727	530,682	379,448
Parent Company TSEK	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			

277,677

530,682

379,398

Note 6 Equity

Total

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 the 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 pro-

gram 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 consisted of a maximum of 1,461,698 subscription warrants and is designed in such a manner that the subscription warrants were transferred at market value in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB.

At the end of each program, each subscription warrant entitles the holder to subscribe for one new share in Isofol at the applicable exercise price.

The exercise price was SEK 28.3 per share (subscription period from May 15 to July 15, 2022). As of the reporting date, this subscription warrant series passed its subscription period and no subscription warrants were exercised.

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 18/23 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 the company. 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-Jun	2021 Jan-Jun
Repayment from management and employees	5	55
Total	5	55

Upon full exercise of all warrant programs issued and outstanding for the subscription of shares, a total of 1,400,253 shares will be issued as of the reporting date, corresponding to a dilution of approximately 0.9%.

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

Note 7 Contingent liabilities

In the second guarter of 2022, Isofol Medical AB (publ) entered into an agreement with a supplier for future purchases of packaging material for the potential future sale of arfolitixorin. These future purchases are dependent on an approval for the commercialization of arfolitixorin. The agreement contains a financial guarantee in which Isofol commits to purchasing material totaling EUR 75,963 until 2027. The financial guarantee falls due for payment during 2025 until 2027. Isofol may need to pay the entire sum or the difference between the offered guarantee and to date purchased packaging material depending on the product's durability. Whether or not Isofol needs to pay an amount connected to the offered guarantee is highly uncertain. In light of this uncertainty, the company has assessed that the financial guarantee will not be recorded as a provision in the Group's statement of financial position.

Key figures and definitions

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

TSEK	2022-06-30	2021-06-30	2021-12-3
Equity	216,326	430,829	318,233
Total assets	298,562	559,787	401,363
Solvency	72.5%	77.0%	79.3%
Cash and cash equivalents	277,727	530,682	379,448
Working capital	213,445	424,129	311,589

Solvencu

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

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, August 23, 2022

Jan TörnellMagnus BjörsneChairmanBoard member

Paula BoultbeeAlain HerreraBoard memberBoard member

Anna Belfrage Robert Marchesani
Board member Board member

Aram MangasarianLennart JeanssonBoard memberBoard member

Ulf Jungnelius CEO

