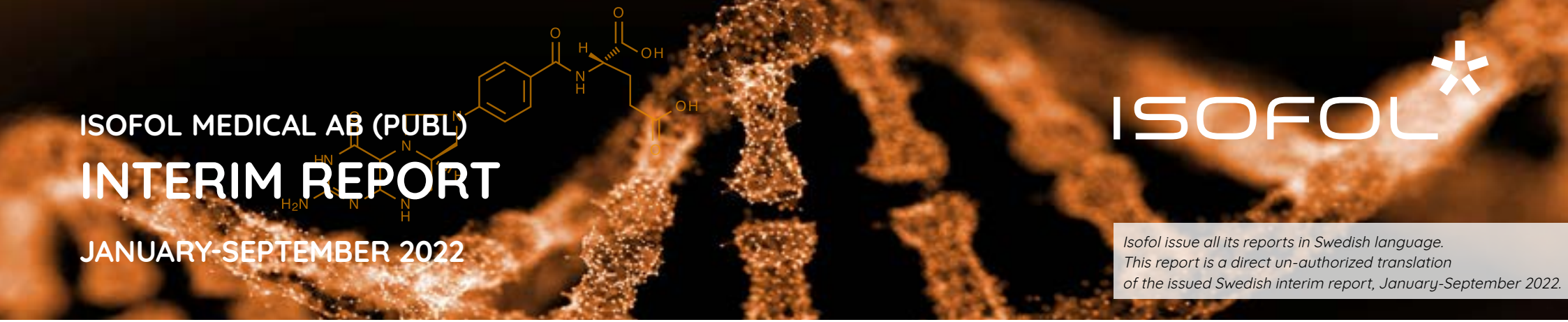

ISOFOL MEDICAL AB (PUBL)

INTERIM REPORT

JANUARY-SEPTEMBER 2022

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

Additional data from the AGENT study confirms negative top-line results

SIGNIFICANT EVENTS DURING THE THIRD QUARTER

- On July 26, Isofol received approval of a biomarker analysis patent.
- On August 3, Isofol presented the top-line results of the global pivotal phase III AGENT study. The study 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).
- On August 31, Isofol announced that based on additional study data, there was no longer reason to continue with the AGENT study. The conclusions regarding primary and secondary endpoints will not be revised. Isofol's Board resolved to assess possible alternatives for the company's future.
- On September 7, Isofol reported additional study data that laid the groundwork for the decision to terminate the study early. In parallel with this decision, Isofol's Board will continue to investigate possible alternatives to secure the largest possible value for Isofol's shareholders.

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- No significant events occurred after the end of the period.

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

Third quarter, July-September 2022

- Net revenue amounted to TSEK 2,907 (5,154) and other revenue to TSEK 0 (0)
- The result for the period amounted to TSEK -32,513 (-51,026)
- Earnings per share amounted to SEK -0.20 (-0.32)
- Cash and cash equivalents as of September 30 amounted to TSEK 234,983 (420,861)

January-September 2022

- Net revenue amounted to TSEK 10,940 (17,702) and other revenue to TSEK 1 (0)
- The result for the period amounted to TSEK -134,420 (-139,081)
- Earnings per share amounted to SEK -0.83 (-1.22)

KEY FIGURES TSEK	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Net revenue	2,907	5,154	10,940	17,702	22,407
Result for the period	-32,513	-51,026	-134,420	-139,081	-200,251
Earnings per share (SEK)	-0.20	-0.32	-0.83	-1.22	-1.59
Cash and cash equivalents	234,983	420,861	234,983	420,861	379,448

The AGENT study showed neither any clinical or commercial value

After accessing additional study data from the AGENT study, Isofol can say that there is no indication that there is any clinical or commercial value in the project. The data confirms the previously reported negative top-line results from the AGENT study, which is why the decision was made to start terminating the AGENT study ahead of schedule at the end of August. In parallel with the process to terminate the study in an ethically and scientifically appropriate manner, Isofol also implemented cutbacks and savings measures to best manage the company's resources. At the same time, Isofol's Board is assessing possible alternatives to secure the largest possible value for shareholders.

"Winding down and terminating the AGENT study will require both time and resources throughout autumn 2022 and the beginning of 2023.

Ulf Jungnelius, CEO, Isofol Medical AB (publ)

The AGENT study's top-line results were presented at the beginning of August and revealed that the study unfortunately did not achieve the primary endpoint of ORR or the key secondary endpoint of PFS. We are all dismayed and disappointed by the results. We had high hopes for improving the treatment of patients with mCRC, not least based on the results from previous studies investigating arfolitixorin.

Negative top-line results confirmed

Based on additional study data we informed in August, that it was no longer reason to continue with the AGENT study. The study data that laid the groundwork for this decision was published at the beginning of September. Although the analysis indicates that both arms performed well, for the population of all-comer mCRC patients, no statistically significant difference was shown in the results regarding ORR or PFS. Based on what we know now, this data is not going to be revised significantly in the future. Altogether, the study results show no clinical or business value for Isofol. Our ambition is to present the results from the gene expression in the near future, but we have no great hopes that the analysis will change our overall assessment of the study's results.

We are currently concluding the analysis of the study data and preparing the final study report, which we expect to be finished in the fourth quarter of 2022. A manuscript for scientific publication is also being prepared so that the scientific community can fully leverage the lessons learned from the study.

Termination of the AGENT study and savings measures in full effect

In parallel with the analysis of the study data, we began work during the quarter to terminate the AGENT study, which has to be carried out in accordance with applicable ethical aspects and regulatory requirements.

The study involved nearly 500 patients and over 90 clinics around the world. This means that each clinic needs to carry out comprehensive procedures to thoroughly document the study, and collect and quality assure the study data according to regulatory and scientific requirements, in addition to practical aspects such as destroying the drugs for the study.

Consideration also needs to be given to the patients who are being followed up, with ethical treatment and their safety in focus.
Winding down and terminating the AGENT study will therefore require both time and resources throughout autumn 2022 and the beginning of 2023. All patients were treated at the beginning of October, but extensive administrative tasks remain for the clinics before the AGENT study can be fully terminated. Our assessment is that this will be completed early in the first half of 2023.

Given the low clinical and business value of the AGENT study's results, Isofol is implementing active measures to reduce costs and secure the company's financial position. This includes terminating all ongoing pre-commercial activities and other activities not directly related to the completion of the AGENT study. As part of this work, Isofol has terminated several agreements with sub-suppliers in order to achieve cost savings. At the same time, employees have been laid off and been given notice of termination during the quarter. The cost savings we implemented during the quarter have already showed results, and costs decreased significantly during the quarter compared with earlier periods. Isofol's cash and bank balances amounted to SEK 235 million on September 30, 2022 Managing the company's financial resources has been the top priority since the beginning of August, along with finding any positive outcomes in the study data and terminating the study.

The way ahead

At the end of August, Isofol's Board decided to investigate different alternatives to secure the largest possible value for shareholders. These alternatives may include structural transactions such as clinical partnerships or a merger with another company.

I would once again like to thank Isofol's shareholders and partners, the patients who participated in the study and our employees who have supported the company during our 14-year journey. In the near future, we will focus on terminating the study and reducing the company's costs to protect the company's financial position and identify the best possible way forward for the company's shareholders.

Gothenburg, November 11, 2022

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

AGENT study terminated according to applicable ethical aspects and regulatory requirements

The top-line results from the AGENT study, which were presented in August, indicated that the study had not achieved either the primary or key secondary endpoints. After additional data was made available, Isofol determined there was no longer reason to continue with the AGENT study. The process for terminating a Phase III study involves detailed quality assurance, ethical treatment of the remaining patients and regulatory documentation. All of this requires time and resources, and the process is expected to continue throughout the fourth quarter and early into the first half of 2023.

The Phase III AGENT study was the first study in 20 years to investigate a more effective alternative to the current standard treatment for the vast majority of mCRC patients. It included over 90 clinics in the US, Canada, Europe, Australia and Japan. The randomized, controlled, multi-center Phase III study encompassed 490 patients and aimed to evaluate the efficacy and safety of arfolitixorin, [6R]-5,10-methylene-THF acid (MTHF), compared to leucovorin. Both are used in combination with 5-FU, oxaliplatin, and bevacizumab, in first-line mCRC patients.

The AGENT study did not meet its primary or key secondary endpoints,

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 tumors, safety including overall survival (OS) and patient-reported outcomes such as quality of life (QoL). Other endpoints included pharmacokinetic (PK) measurements and gene expression of folate relevant genes in tumor cells.

The top-line results, which were presented in August, revealed that the study did not achieve the primary endpoint of ORR or the key secondary endpoint of PFS. Additional data that was presented on September 7 confirmed the top-line results and reported a worse, though non statistically significant, OS. The following information laid the groundwork for Isofol's decision to terminate the AGENT study at the end of August:

- The p-value for ORR, the primary endpoint, was 0.85 and the study arms showed no difference in the results.
- PFS was 12.8 months for the arfolitixorin arm and 11.6 months for the control arm, with a p-value of 0.76.
- Analysis of OS, one of the AGENT study's safety targets, indicated that OS was worse, though with no statistical significance, for the experimental arm of the study than in the control arm.
- There was no difference between the study arms regarding the most important safety data.
- No noteworthy differences between the study arms in any of the subgroups have been identified.

The conclusion of the gene expression analysis, which was another part of the AGENT study, is not yet finished. However, the preliminary results do not indicate anything different from the rest of the study data.

This means that arfolitixorin was not deemed a new potential alternative for patients, regardless of genetic profile, in first-line treatment for mCRC. Nor are the study results pivotal for application for market approval.

Termination of the AGENT study ongoing

There are several factors to take into consideration when terminating a Phase III study, regardless of the specific results. One such factor is the patients who are still going through treatment or follow-up. They need to be treated ethically and in a medically sound manner. Given the results, patients in the experimental portion of the study were therefore given the standard treatment of leucovorin instead of arfolitixorin. At the end of September, the remaining patients receiving treatment in the framework of the AGENT study were phased out of the study.

The study involved nearly 500 patients and over 90 clinics around the world, which means the administrative work to terminate the study is extensive. After all of the patients have been treated, every clinic needs to shut down its portion of the study and provide Isofol with study data in line with regulatory and scientific requirements. These procedures and processes include thorough documentation and approval of the clinic's work within the framework of the study as well as compiling and quality assuring the study data. After this come practical measures, such as archiving study material and destroying the remaining drugs for the study.

Altogether, winding down the partnership with the clinics involved will require both time and resources throughout autumn 2022 and the beginning of the first half of 2023. Work to terminate all of our contracts will also scale up during the coming quarter in accordance with the terms of the contracts.

Final study report and scientific publication

The AGENT study's final report, including subgroup analyses, gene expression and safety data, is expected to be available in the fourth quarter of 2022. Key data will be published to enable the scientific community to fully leverage the lessons learned from the study.

Isofol is currently preparing a manuscript for scientific publication, which requires a great deal of work on the part of the study team. The intention is to submit the manuscript at the beginning of 2023.

Results of Modelle study to be presented at the end of the year

The Modelle investigator-initiated clinical study was carried out with Sahlgrenska University Hospital and included some 30 patients who were treated with arfolitixorin. The study was led by Dr. Helena Taflin and was conducted at Sahlgrenska University Hospital in a partnership with the University Hospital of Umeå. The aim of this study was to investigate in detail the effects that various folates (arfolitixorin/leucovorin) in combination with 5-FU had on patients with CRC that has metastasized to the liver. This was the first time it was possible to directly measure in both normal and tumor tissue from patients the effect that folates, including arfolitixorin, had on the enzyme targets that arfolitixorin was directed at (including the TS enzyme, which was an important target for cancer treatments insofar as it could contribute to inhibiting cell growth). The study has the potential to contribute scientific data to understanding how gene expression determines the patients' capacity to respond to various folate-based cancer treatments.

The research group plans to present the results from the study at the end of the year, but the potential commercial value for Isofol is significantly limited compared to the outcome of the AGENT study.

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

Financial information, July-September

COMPARISON BETWEEN THE THIRD QUARTER OF 2022 AND 2021

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

REVENUE

Operating revenue

Net revenue amounted to TSEK 2,907 (5,154) 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 -28,607 (-49,352), corresponding to a decrease of TSEK 20,745. As a result of the negative top-line results, all pre-commercialization activities have been terminated and measures have been taken to reduce all costs in the company. Costs for the AGENT study are generally lower, though costs for terminating the study and for preparing the study results increased compared with the previous year. During the quarter, the company initiated a savings program that has resulted in an overall cost reduction throughout the organization.

Personnel costs

Personnel costs in the Group amounted to TSEK -8,205 (-7,620), corresponding to an increase of TSEK 585. There were 15 (15) employees at the end of September 2022. Terminations of personnel began during the quarter and will continue throughout the fourth quarter.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -422 (-399).

Financial items

Financial revenue amounted to TSEK 2,676 (1,276), attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments. Financial costs amounted to TSEK -10 (-96), attributable to interest expenses.

RESULT

The operating result amounted to TSEK -35,178 (-52,205), corresponding to a reduced loss of TSEK 17,027. The result after financial items was TSEK -32,513 (-51,026), corresponding to an improvement of TSEK 18,513. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at September 30, 2022 amounted to TSEK 234,983 (420,861). No loans had been raised as of September 30, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 0 (72,638) was pledged as collateral to settle currency futures.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -44,031 (-63,069), corresponding to a change of TSEK 19,037. The negative cash flow for the period was attributable to the company's clinical activities. The year-on-year improvement in cash flow was attributable to reduced costs related to the termination of the study and pre-commercialization activities as well as general cost savings.

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 -444 (-47,098). The negative cash flow for the period was attributable to the repayment of the company's lease liabilities.

Cash flow for the period

Cash flow for the period amounted to TSEK -44,475 (-110,166), corresponding to a change of TSEK 65,691.

INVESTMENTS

Investments during July-September 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-September

COMPARISON BETWEEN JANUARY TO SEPTEMBER 2022 AND 2021

Amounts stated without parentheses refer to January-September 2022, and amounts stated in parentheses refer to January-September 2021.

REVENUE

Operating revenue

Net revenue amounted to TSEK 10,940 (17,702) for the period. 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 -127,400 (-138,545), corresponding to a decrease of TSEK 11,145. Costs for compiling and preparing study results increased while study costs for the ongoing AGENT study decreased. All pre-commercialization activities were terminated as a result of the negative study results, which entailed significantly reduced costs for pre-commercialization.

Personnel costs

Personnel costs in the Group amounted to TSEK -22,543 (-18,731), corresponding to an increase of TSEK 3,812. There were 15 (15) employees at the end of September 2022.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -1,221 (-1,198).

Financial items

Financial revenue amounted to TSEK 7,495 (2,677), attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments. Financial costs amounted to TSEK -36 (-151), attributable to interest expenses.

RESULT

The operating result amounted to TSEK -141,879 (-141,607), corresponding to an increased loss of TSEK 272. The result after financial items was TSEK -134,420 (-139,081), corresponding to an improvement of TSEK 4,661.

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

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at September 30, 2022 amounted to TSEK 234,983 (420,861). No loans had been raised as of September 30, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 0 (72,638) was pledged as collateral to settle currency futures.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -148,066 (-146,407), corresponding to a change of TSEK 1,660. The negative cash flow for the period was attributable to the company's clinical 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 -1,235 (450,844). 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 -149,301 (304,438). The negative cash flow was attributable to the company's clinical activities.

INVESTMENTS

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

Information about transactions with related parties

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

Risk management

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

The market risks considered to be of special significance in regard to Isofol's future development are linked to the availability of the financial and clinical resources to conduct the company's studies. The most significant strategic and operational risks that affect the Group and the Parent Company are described in the Annual Report for 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 third quarter was 161,515,440 (161,515,440). 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 September 30, 2022

Shareholder	Number of shares	Share capital/votes
Futur Pension (formerly Danica)	13,396,262	8.29%
Avanza Pension	8,506,408	5.27%
Swedbank Försäkring	5,195,546	3.22%
Hans Enocson	4,555,236	2.82%
Swedbank Robur Fonder	4,175,839	2.58%
Göran Gustafsson	4,110,000	2.54%
Bengt Gustafsson*	3,749,459	2.32%
Handelsbanken Fonder	3,181,967	1.97%
Sune Svedberg	2,123,331	1.31%
Bengt Halse	2,120,713	1.31%
Ten largest shareholders	**51,114,761**	**31.63%**
Other shareholders	110,400,679	68.37%
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 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.

Isofol intends to issue financial statements as follows:

Year-end report 2022	February 22, 2023
Annual Report 2022	April 2023
Interim report January-March 2023	May 3, 2023
Six-month report April-June 2023	August 22, 2023
Interim report July-September 2023	November 10, 2023
Year-end report 2023	February 20, 2024

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

Calendar

The next Annual General Meeting is scheduled to be held:

2023 Annual General Meeting	May 3, 2023

Invitation to presentation of the third quarter of 2022, November 11 at 11:00 a.m. CET.

Isofol invites investors, analysts and the media to an audiocast on November 11 at 11:00 a.m. CET in connection with the publication of the interim report for the third 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
November 11, 2022 at 11:00 a.m. CET

Link to audiocast
https://ir.financialhearings.com/isofol-medical-q3-2022

Telephone number
SE: +46 8 50 55 83 69
UK: +44 333 300 92 68
US: +1 631 913 1422 PIN: 46897527#

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

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Corporate identity number: 556759-8064 | Registered office: Gothenburg

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

Condensed consolidated income statement

TSEK	Note	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
OPERATING REVENUE						
Net revenue	2	2,907	5,154	10,940	17,702	22,407
Other revenue		–	–	1	–	–
Total operating revenue		**2,907**	**5,154**	**10,941**	**17,702**	**22,407**
OPERATING COSTS						
Other external costs		-28,607	-49,352	-127,400	-138,545	-196,712
Personnel costs		-8,205	-7,620	-22,543	-18,731	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-422	-399	-1,221	-1,198	-1,596
Other operating revenue and operating costs*		-851	12	-1,656	-835	-843
Total operating costs		**-38,085**	**-57,360**	**-152,820**	**-159,309**	**-226,872**
Operating result		**-35,178**	**-52,205**	**-141,879**	**-141,607**	**-204,465**
FINANCIAL ITEMS						
Financial revenue		2,676	1,276	7,495	2,677	4,383
Financial costs		-10	-96	-36	-151	-168
Total financial items		**2,665**	**1,180**	**7,459**	**2,526**	**4,215**
Result after financial items		**-32,513**	**-51,026**	**-134,420**	**-139,081**	**-200,251**
Tax on result for the period		–	–	–	–	–
Result		**-32,513**	**-51,026**	**-134,420**	**-139,081**	**-200,251**
Attributable to:						
Parent Company shareholders		-32,513	-51,026	-134,420	-139,081	-200,251
EARNINGS PER SHARE						
Before dilution (SEK)		-0.20	-0.32	-0.83	-1.22	-1.59
After dilution (SEK)		-0.20	-0.32	-0.83	-1.22	-1.59

* Includes currency effects associated with the business.

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

Condensed consolidated balance sheet

TSEK	Note	Sep 30, 2022	Sep 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		1,139	2,143	1,745
Total tangible fixed assets		**1,139**	**2,143**	**1,745**
Financial fixed assets				
Other long-term receivables		–	5,009	5,009
Total financial fixed assets		**–**	**5,009**	**5,009**
Total fixed assets		**1,139**	**7,152**	**6,755**
CURRENT ASSETS				
Accounts receivable	3	850	–	–
Other receivables		17,132	11,719	12,276
Prepaid expenses and accrued income		1,956	14,191	2,884
Cash and cash equivalents	3, 4, 5	234,983	420,861	379,448
Total current assets		**254,921**	**446,771**	**394,609**
Total assets		**256,059**	**453,923**	**401,363**

Condensed consolidated balance sheet

TSEK	Note	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
EQUITY AND LIABILITIES				
EQUITY	6			
Share capital		4,945	4,945	4,945
Other contributed capital		1,217,607	1,217,607	1,217,607
Retained earnings		-904,319	-704,069	-704,069
Result for the year		-134,420	-139,081	-200,251
Total equity		**183,814**	**379,403**	**318,233**
LIABILITIES				
Long-term liabilities				
Long-term lease liabilities		417	422	110
Other provisions	7	829	–	–
Total long-term liabilities		**1,246**	**422**	**110**
Current liabilities				
Accounts payable	3	16,594	13,654	17,736
Other liabilities		2,933	4,208	3,174
Accrued expenses and deferred income	3	51,474	56,236	62,110
Total current liabilities		**71,000**	**74,098**	**83,020**
Total liabilities		**72,246**	**74,520**	**83,130**
Total equity and liabilities		**256,059**	**453,923**	**401,363**

Consolidated statement of changes in equity

TSEK	Note	Share capital	Other 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		–	-48,240	–	-48,240
Over-allotment option		478	99,522	–	100,000
Result for the period		**–**	**–**	**-139,081**	**-139,081**
Equity, Sep 30, 2021		**4,945**	**1,217,607**	**-843,149**	**379,403**

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening balance, Oct 1, 2021		4,945	1,217,607	-843,149	379,403
Issue costs		–	–	–	–
Result for the period		**–**	**–**	**-61,170**	**-61,170**
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		**–**	**–**	**-134,420**	**-134,420**
Equity, Sep 30, 2022		**4,945**	**1,217,607**	**-1,038,739**	**183,814**

Consolidated cash flow statement

TSEK	Note	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
OPERATING ACTIVITIES						
Result after financial items		-32,513	-51,026	-134,420	-139,081	-200,251
Adjustments for non-cash items		-851	-881	-1,124	-1,638	-2,946
Income tax paid		–	–	–	–	–
Cash flow from operating activities before changes in working capital		**-33,364**	**-51,906**	**-135,543**	**-140,718**	**-203,196**
CASH FLOW FROM CHANGES IN WORKING CAPITAL						
Increase (-)/decrease (+) in operating receivables		-433	-3,366	-1,545	-1,588	9,860
Increase (+)/decrease (-) in operating liabilities		-10,235	-7,796	-10,978	-4,100	4,907
Change in working capital		**-10,668**	**-11,162**	**-12,523**	**-5,688**	**14,767**
Cash flow from operating activities		**-44,031**	**-63,069**	**-148,066**	**-146,407**	**-188,429**
INVESTING ACTIVITIES						
Acquisition of tangible fixed assets		–	–	–	–	–
Cash flow from investing activities		**–**	**–**	**–**	**–**	**–**
FINANCING ACTIVITIES						
Repayment of lease liabilities		-444	-388	-1,258	-1,155	-1,548
Subscription warrants, proceeds received	6	–	28	23	82	108
New share issue		–	-46,737	–	451,917	451,917
Cash flow from financing activities		**-444**	**-47,098**	**-1,235**	**450,844**	**450,477**
Cash flow for the period		-44,475	-110,166	-149,301	304,438	262,048
Cash and cash equivalents at the beginning of the period		277,727	530,682	379,448	116,393	116,393
Exchange rate difference in cash and cash equivalents		1,731	345	4,835	30	1,007
Cash and cash equivalents at the end of the period	5	**234,983**	**420,861**	**234,983**	**420,861**	**379,448**

Condensed Parent Company income statement

TSEK	Note	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
OPERATING REVENUE						
Net revenue	2	2,907	5,154	10,940	17,702	22,407
Other revenue		–	–	–	–	–
Total operating revenue		**2,907**	**5,154**	**10,940**	**17,702**	**22,407**
OPERATING COSTS						
Other external costs		-29,061	-49,761	-128,694	-139,772	-198,349
Personnel costs		-8,205	-7,620	-22,543	-18,731	-27,721
Depreciation and amortization of tangible and intangible fixed assets		-17	-19	-51	-60	-77
Other operating revenue and operating costs*		-851	12	-1,656	-835	-843
Total operating costs		**-38,134**	**-57,388**	**-152,943**	**-159,397**	**-226,990**
Operating result		**-35,228**	**-52,234**	**-142,004**	**-141,695**	**-204,583**
FINANCIAL ITEMS						
Financial revenue		2,676	1,276	7,495	2,677	4,383
Financial costs		–	-76	–	-79	-79
Total financial items		**2,676**	**1,200**	**7,495**	**2,598**	**4,304**
Result after financial items		**-32,552**	**-51,034**	**-134,509**	**-139,097**	**-200,280**
Result before tax		**-32,552**	**-51,034**	**-134,509**	**-139,097**	**-200,280**
Tax		–	–	–	–	–
Result		**-32,552**	**-51,034**	**-134,509**	**-139,097**	**-200,280**

* Includes currency effects associated with the business.

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

Condensed Parent Company balance sheet

TSEK	Note	Sep 30, 2022	Sep 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		107	175	158
Total tangible fixed assets		**107**	**175**	**158**
Financial fixed assets				
Participations in Group companies		50	50	50
Other long-term receivables		–	5,009	5,009
Total financial fixed assets		**50**	**5,059**	**5,059**
Total fixed assets		**157**	**5,235**	**5,217**
CURRENT ASSETS				
Accounts receivable		850	–	–
Other receivables		17,132	11,719	12,276
Prepaid expenses and accrued income		2,274	14,415	3,113
Cash and bank balances	4, 5	234,933	420,811	379,398
Total current assets		**255,189**	**446,945**	**394,787**
Total assets		**255,346**	**452,179**	**400,004**

Condensed Parent Company balance sheet

TSEK	Note	Sep 30, 2022	Sep 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	1,218,276	1,218,276
Retained earnings		-904,924	-704,645	-704,645
Result for the year		-134,509	-139,097	-200,280
Total non-restricted equity		**178,843**	**374,535**	**313,351**
Total equity		**183,788**	**379,480**	**318,297**
LIABILITIES				
Long-term liabilities				
Other provisions	7	829	–	–
Total provisions		**829**	**–**	**–**
Current liabilities				
Accounts payable		16,912	13,878	17,965
Other liabilities		2,343	2,586	1,632
Accrued expenses and deferred income		51,474	56,236	62,110
Total current liabilities		**70,728**	**72,699**	**81,707**
Total liabilities		**71,557**	**72,699**	**81,707**
Total equity and liabilities		**255,346**	**452,179**	**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.

New and amended standards adopted from 2022 are not expected to have any significant impact on the Group's financial position.

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 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 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Asia	2,907	5,154	10,940	17,702	22,407
Total	**2,907**	**5,154**	**10,940**	**17,702**	**22,407**

	Parent Company				
TSEK	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Asia	2,907	5,154	10,940	17,702	22,407
Total	**2,907**	**5,154**	**10,940**	**17,702**	**22,407**

Breakdown of revenue by type of revenue

	Group				
TSEK	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Execution of service assignments	2,907	5,154	10,940	17,702	22,407
Total	**2,907**	**5,154**	**10,940**	**17,702**	**22,407**

	Parent Company				
TSEK	2022 Jul-Sep	2021 Jul-Sep	2022 Jan-Sep	2021 Jan-Sep	2021 Jan-Dec
Execution of service assignments	2,907	5,154	10,940	17,702	22,407
Total	**2,907**	**5,154**	**10,940**	**17,702**	**22,407**

Contract assets

	Group		
TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Accrued income	817	1,660	1,631
Total	**817**	**1,660**	**1,631**

	Parent Company		
TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Accrued income	817	1,660	1,631
Total	**817**	**1,660**	**1,631**

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

Note 3 Financial instruments

As of September 30, 2022, the Group had financial instruments, which were measured at fair value, in the form of currency derivatives of TSEK 0 (935). 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 235,809 (421,844) and financial liabilities to TSEK 60,826 (65,589).

Note 4 Pledged assets

During the third quarter of 2022, the Group settled all outstanding currency futures and as such, pledged assets in the form of cash and cash equivalents for derivative instruments were settled. The Group has TSEK 0 (72,638) in pledged assets.

Note 5 Cash and cash equivalents

Group TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			
Cash and cash equivalents	234,983	420,861	379,448
Total	**234,983**	**420,861**	**379,448**

Parent Company TSEK	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
The following sub-items are included in cash and cash equivalents:			
Cash and bank balances	234,933	420,811	379,398
Total	**234,933**	**420,811**	**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 the Warrant Program 2018. The program consists of a maximum of 250,000 subscription warrants. The maximum of 250,000 subscription warrants entitles the holder to subscribe for a maximum of 452,849 shares (after the completion of the rights issue in June 2021).

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 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 subscription period for series 18/22 ended during the quarter 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 exercise price for series 18/23 is SEK 42.5 per share (subscription period from May 15 to July 15, 2023). Series 18/23 encompasses a maximum of 523,024 subscription warrants, which entitle the holders to subscribe for a maximum of 947,404 shares. The current recalculation factor is set at 1.81.

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 and no loans to employees remains at the end of the third quarter.

Group and Parent Company TSEK	2022 Jan-Sep	2021 Jan-Sep
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 Provisions

In the second quarter of 2022, Isofol Medical AB (publ) entered into an agreement with a supplier for purchases of packaging material for the potential future sale of arfolitixorin. Use of the material depends on an approval for the commercialization of arfolitixorin. The agreement contains a financial guarantee totaling EUR 75,963, in which Isofol commits to purchasing material for an equivalent amount. Based on the study outcome, management deemed it likely that the financial guarantee will be triggered. A total of TSEK 829, equivalent to a present value of EUR 75,963, was reported in the consolidated balance sheet and as a cost in the consolidated income sheet for the third quarter. The specific date for the outflow is still unknown and depends on the final study results, but the company's assessment is that a settlement will be made within five years.

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	Sep 30, 2022	Sep 30, 2021	Dec 31, 2021
Equity	183,814	379,403	318,233
Total assets	**256,059**	**453,923**	**401,363**
Solvency	**71.8%**	**83.6%**	**79.3%**
Cash and cash equivalents	234,983	420,861	379,448
Working capital	183,921	372,673	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 2018/2023) 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, November 11, 2022

Jan Törnell
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

AUDITOR'S REPORT

To the Board of Directors of
Isofol Medical AB (publ).
Corporate identity number 556759-8064

Introduction

We have reviewed the condensed interim financial information (interim report) of Isofol Medical AB (publ) as of September 30, 2021 and the nine-month period then ended. The Board of Directors and the CEO are responsible for the preparation and presentation of the interim financial information in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410, Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

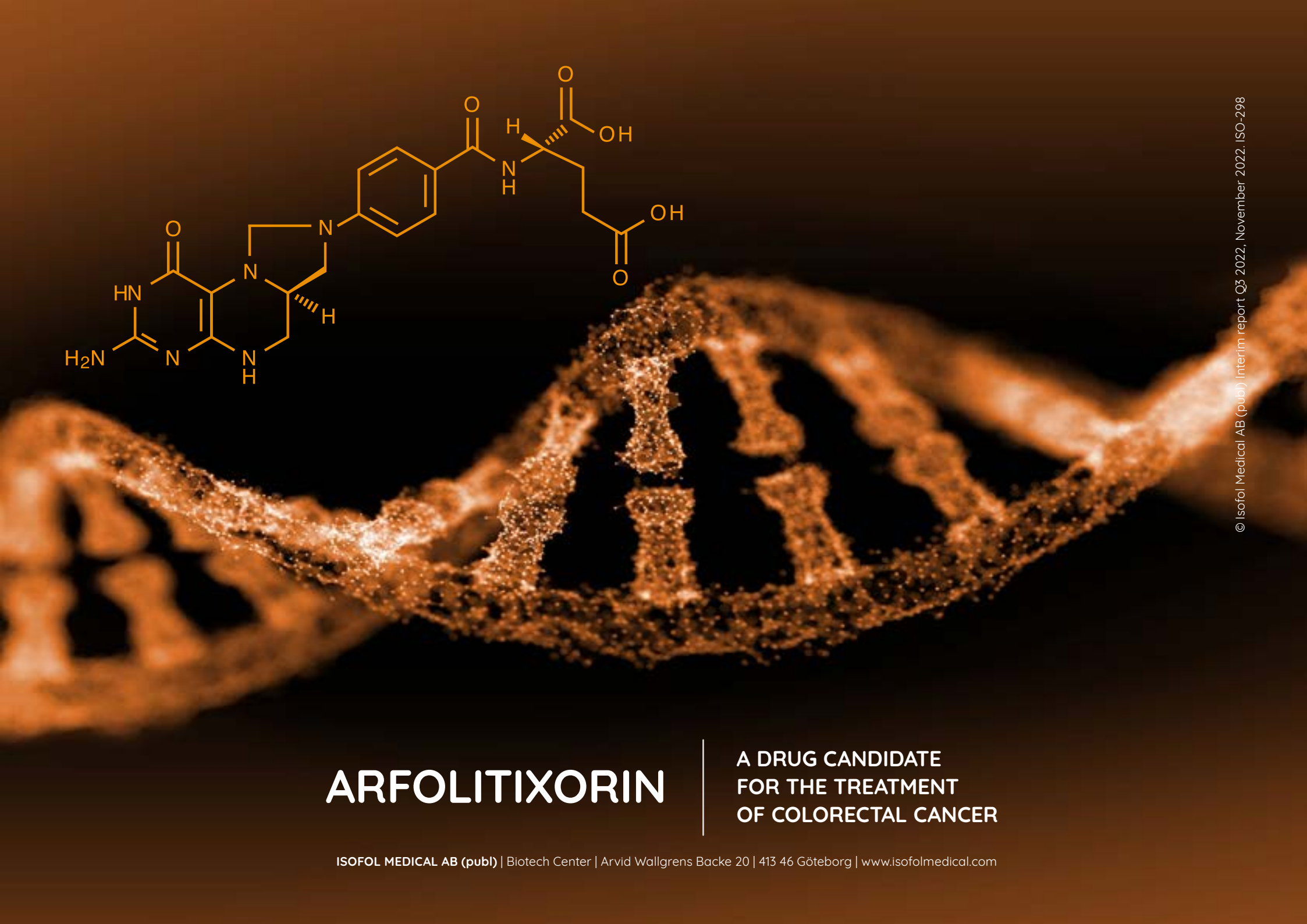
Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Gothenburg, November 11, 2022

KPMG AB

Jan Malm
Authorized Public Accountant



ARFOLITIXORIN

A DRUG CANDIDATE FOR THE TREATMENT OF COLORECTAL CANCER

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