

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

Final data from the AGENT study confirms negative topline results

SIGNIFICANT EVENTS DURING THE FOURTH QUARTER

- On November 3 Isofol appointed its nomination committee ahead of the Annual General Meeting 2023 in accordance with the principles adopted at the Annual General Meeting on May 19, 2022.
- On November 25 Isofol announced that the analysis of the AGENT study's final data confirmed the negative topline results that were presented in August 2022. In addition, no predictive biomarkers for gene expression were identified for clinical response.
- On November 28 Isofol announced that CEO Dr. Ulf Jungnelius MD would step down on June 1, 2023.
- On December 21 Isofol announced that CFO and deputy CEO Gustaf Albèrt would leave the company during 2023.

SIGNIFICANT EVENTS AFTER THE END OF QUARTER

- An extraordinary general meeting was held on February 13, 2023 to, in accordance with the board's proposal, decide on an extra dividend and voluntary liquidation. However, the board's proposal failed to reach the required voting majority and the resolution was therefore not adopted. As a consequence of the decision all members of the board of directors made their positions available and will not stand for re-election.
- A written request for convening an extraordinary general meeting was received in January 2023 from shareholders with a total shareholding corresponding to more than 10 percent of the shares in the company to elect a new board. Notice of the extraordinary general meeting was sent out on February 3, 2023, and will be held on February 28, 2023.

Om Isofol Medical AB (publ)

Isofol Medical AB (publ) is a clinical-stage biotechnology company that has focused its operations on developing and improving the current standard treatment for patients suffering from cancer by increasing treatment efficacy through the use of cytostatics. Isofol's ambition was to develop a drug for first-line treatment of advanced colorectal cancer (mCRC), thereby seeking 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, Switzerland, to develop and commercialize arfolitixorin in oncology. Isofol Medical AB (publ) is traded on Nasdaq Stockholm..

FINANCIAL INFORMATION

Fourth quarter, October-December 2022

- Net revenue amounted to TSEK 1,857 TSEK (4,704) and other revenue to TSEK 57 (0)
- The result for the period amounted to TSEK -25,335 (-61,170)
- Earnings per share amounted to SEK -0.16 (-0.38)
- Cash and cash equivalents as of December 31 amounted to TSEK 190,583 (379,448)

January-December 2022

- Net revenue amounted to TSEK 12,797 TSEK (22,407) and other revenue to TSEK 59 (0)
- The result for the period amounted to TSEK -159,755 (-200,251)
- Earnings per share amounted to SEK -0.99 (-1.59)
- The Board of Directors proposes that no dividend will be paid for the 2022 financial year

| KEY FIGURES TSEK | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Net revenue | 1,857 | 4,704 | 12,797 | 22,407 |
| Result for the period | -25,335 | -61,170 | -159,755 | -200,251 |
| Earnings per share (SEK) | -0.16 | -0.38 | -0.99 | -1.59 |
| Cash and cash equivalents | 190,583 | 379,448 | 190,583 | 379,448 |

Continued focus on closing down the AGENT study and cost-cutting measures

Following final analysis of the AGENT study's data in the fourth quarter, we were able to conclude in November that, unfortunately, the negative topline results announced in August were confirmed. During the fourth quarter, closure of the AGENT study progressed according to plan and at the time of this report's publication, all clinics in the study have completed their work, destruction of study medicine is underway, and archiving is being completed. The work evaluating possible courses of action regarding Isofol's future was assessed, and in light of this investigation, Isofol's board of directors proposed that an extraordinary general meeting in February should decide to distribute as much of the company's capital as possible and to liquidate the company. However, the board's proposal did not achieve the required voting majority on this extraordinary meeting and was therefore not adopted.

Final data confirms study results

Isofol's final analysis of data from the AGENT study was conducted during the fourth quarter and the final data confirmed the previously reported negative conclusions about the topline results, that is the study met neither its primary nor key secondary endpoints. In addition, a clear trend towards lower survival levels fulfilling the US FDA's definition of "detrimental overall survival" was observed in the arfolitixorin arm. Analysis of patient subgroups did not display any differences in arfolitixorin's favor, nor did gene expression analyses confirm the hypothesis that patients with high levels of gene expression treated with leucovorin would have a better antitumoral effect than those with low levels of gene expression. No difference in tumor response was observed between patients with high and low levels of gene expression among the 245 patients included in the leucovorin arm. This means that the AGENT study did not meet the targets previously agreed upon with pharmaceutical authorities for the submission of a new drug application.

As the AGENT study was so crucial to the company's future, the Board of Directors commissioned two external expert groups to review both the study data and the company's conclusions. Both groups concluded that the company's interpretation of the study results was correct and that no difference between arfolitixorin and leucovorin in a 5-FU-based treatment regimen could be detected.

Furthermore, external statistics consultants assessed that the AGENT-study could not demonstrate that arfolitixorin was "non-inferior" to leucovorin because the study was not designed to show this. The company therefore believes that arfolitixorin would not have a good chance of competing with generic leucovorin in combination with 5-FU. An additional argument against using arfolitixorin as a generic drug is that the synthesis of arfolitixorin is more complicated than the synthesis of leucovorin and would therefore be more expensive to produce. Furthermore, arfolitixorin's clear tendency towards lower long-term survival compared with leucovorin in the AGENT study is a red flag

for pharmaceutical regulators and ethics committees when patients are exposed to the combination of arfolitixorin and 5-FU. Finally, the AGENT study's results risk negatively affecting physicians' choice of arfolitixorin over leucovorin.

Continued prioritizing of the AGENT study's closure

The scale of the AGENT study required significant efforts to terminate it. Certain administrative tasks remain before the study can be formally and fully concluded in line with current regulatory requirements. The extensive work to shut down the study has proceeded during the quarter in a planned and efficient manner. By the end of the year, all 90 clinics participating in the AGENT study had completed the work that was required of them. All related activities, such as destruction of study medicine, documentation, and necessary archiving, are expected to be completed during the first quarter of 2023.

Efforts to prepare a manuscript for publication in a scientific journal within oncology also



” Although the results of the AGENT study were negative for Isofol, this work is a component of the conclusion and the findings will hopefully benefit the scientific community.

Ulf Jungnelius, vd, Isofol Medical AB (publ)

continued during the fourth quarter. Although the results of the study were negative for Isofol, this work is a component of the AGENT study's conclusion and the findings will hopefully benefit the scientific community. Our ambition is to submit the article in the spring of 2023.

Cost-cutting measures in focus

In parallel with the termination of the study and external experts' assessment of the results, Isofol has continued to implement previously communicated downsizing and cost-cutting measures. Minimizing costs as much as possible and safeguarding the company's financial position, alongside identifying ways forward for arfolitixorin, has been the focus of Isofol's management ever since topline results were obtained in early August.

Virtually all employees and consultants have been given notice during the quarter and as such will leave the company during the coming periods as their notice periods expire. Several of these measures have made an impact during the fourth quarter. Compared with the

same period last year costs were reduced by approx. 40 MSEK during the fourth quarter of 2021 and by approx. 46 MSEK compared with the third quarter of 2022. As of December 31, 2022, Isofol's capital amounted to 190 MSEK and working capital amounted to 158 MSEK.

Courses of action assessed

The year began with high expectations and intensive work to prepare for commercialization. The optimistic view of the future ended abruptly in August when the AGENT study did not achieve the pharmaceutical authorities' requirements for market approval. The results are of course very disappointing for everyone involved. The company's top priority since topline results became available has been to complete the analysis of the study data and investigate all possible clinical and commercially viable paths forward to bring arfolitixorin to market. Given the results of the study, the company evaluated opportunities to conduct additional studies or to pursue a structured transaction, including a reverse acquisition. Powerful measures were taken as early as August to preserve the company's financial standing and optimize its prospects, regardless of the way forward.

As more data became available, it became increasingly clear that it would not be possible

to bring arfolitixorin to market in combination with 5-FU-based treatment regimens without new clinical studies being conducted. In light of the external expert panels' conclusions, the company believes that arfolitixorin lacks clinical value for the treatment of metastatic colorectal cancer in combination with 5-FU, as a new development plan must take into account the 11% risk of early death in the arfolitixorin arm. Our current assessment is that a new safe dosing regimen must be developed in a Phase I study and shown to be effective in a Phase II study in order to obtain ethics committee and regulatory approval to initiate new pivotal Phase III studies on patients. This would lead to a development plan lasting at least 6-8 years and costing at least another 500 MSEK, all while the patent's lifespan is decreasing, thereby impairing its commercial value.

Given the results of the AGENT study, arfolitixorin is judged to have a low clinical and commercial value. The prospects of whether a structured deal could be implemented to potentially obtain a premium on Isofol's capital and to determine whether any value can be extracted from the stock exchange listing, organization and possible loss deduction were investigated. The company and the board were in contact with more than 30 companies and had

in-depth discussions with six of them. The companies were assessed on the basis of, among other things, value, risk associated with development, proximity to positive cash flow, maturity/marketability, proposed premium on Isofol's assets, development plans and ownership structure. The depth of analysis differed between companies. After careful evaluation and analysis, the board assessed that there were no conditions for carrying out a deal that would be of more value to shareholders than an extra dividend and liquidation.

In conclusion, the board and management were in consensus that the likelihood of commercial success for arfolitixorin in combination with 5-FU based regimens was low, even if clinical development could be financed, which in turn was considered to be very challenging. In order to ensure that as much of the company's remaining assets as possible would benefit its shareholders, the board proposed that the shareholders, at the extraordinary general meeting on February 13, decide to distribute as much of the capital as possible and initiate the liquidation process.

However, the board's proposal for an extra dividend to the shareholders and voluntary liquidation of the company did not achieve the required voting majority at the meeting and

was therefore not adopted. As a consequence of the rejection of its proposals, all members of the board of directors made their positions available.

An additional extraordinary general meeting will be held on February 28 to elect a new board of directors. This due to a request from shareholders with a total holding corresponding to more than 10 percent of the shares in the company.

Given the conditions that have prevailed since we reported topline results, I am impressed by collegial attitude of all employees who, despite the circumstances, have maintained a high level of efficiency and attention to detail in their work. I am personally very grateful for the staff's professionalism and fine efforts throughout the year. Given the outcome of the extraordinary general meeting held on February 13, the future of Isofol is now in the hands of the board of directors who have been proposed for election on 28 February.

Gothenburg, February 22, 2023

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

Termination of the AGENT study nearly completed

The final data from the AGENT study which became available to the company during the fourth quarter confirmed the topline results initially presented in August. In addition to the final review of the AGENT study, the company also analyzed gene expression data during the fourth quarter but concluded that no predictive biomarkers could be identified. The primary focus, alongside identification of how the company's assets can best benefit the shareholders, was to effectively close down the AGENT study in accordance with all regulatory requirements. Work to prepare a manuscript for publication in a scientific oncology journal is also progressing according to plan.

Results and conclusions

The AGENT study concluded that neither the primary endpoint of objective tumor response (ORR) nor the key secondary endpoint of progression-free survival (PFS) were met. With regards to safety data, there were no differences between the study arms with the exception of a non-statistically significant detriment in overall survival (OS) in the arfolitixorin arm. The risk of mortality was 11% greater in the experimental arm of the study compared to the control arm. No significant differences between the study arms in any subgroup were identified. Gene expression was included in the study as an exploratory endpoint, but it too did not demonstrate any predictive value for arfolitixorin-treated patients. Overall, the study results do not indicate any clinical or commercial value for Isofol.

Since the AGENT study was so crucial for the company's future, the board appointed two external expert groups to review the data and the company's conclusions. Both groups concluded that the company's interpretation of the study's outcome was correct and that no difference between arfolitixorin and leucovorin in a 5-FU-based treatment regimen could be identified. The external groups differed in their as-

essment of whether there is a way forward for arfolitixorin. One group concluded that there was no way forward for arfolitixorin in 5-FU-based combination cancer treatment while the other group saw a need to further investigate a potential way forward for arfolitixorin but did not specify what this would entail in terms of time and resources as well as capital requirements.

Furthermore, external statistical consultants assessed whether the AGENT study could show that arfolitixorin is at least as good as leucovorin which could possibly allow arfolitixorin to compete with generic leucovorin. Their conclusion was that the AGENT study could not show whether arfolitixorin is equivalent to leucovorin as the study was not designed to show this. Additional arguments that reduce the likelihood of generic use of arfolitixorin are that the synthesis of arfolitixorin is more complicated than the synthesis of leucovorin, making it more expensive to produce, as well as arfolitixorin's clear tendency towards poorer long-term survival compared with leucovorin in the AGENT-study. The latter risks negatively impacting regulators, ethics committees and physicians' choice of arfolitixorin over leucovorin.

Termination of the AGENT study is intensified

The company worked at a rapid pace throughout the quarter to shut down the AGENT study at its 90 participating clinics. This work included the destruction of all study medicine and compilation of necessary documentation. As clinics concluded their work, the subsequent administrative work at Isofol intensified. Given that the AGENT study was a large global Phase III study with nearly 500 patients in various locations around the world, closing the clinics entails an extensive process that consumes time and resources. In addition to regulatory and ethical components, various contacts with authorities and clinics involved, partners, as well as careful administration of information and data need to be managed and secured in various ways. For the most part, the work that remains involves documentation and archiving, which is expected to be completed in the first quarter of 2023.

The company is also working on preparing a manuscript for a scientific publication. The aim is to make key insights and lessons learned from the study available so that they can benefit the global scientific community - not least when it comes to gene expression. The aim is to

submit the paper to a publication in the spring of 2023. Certain efforts have also been made to secure the assets of the company's IP and patent portfolio.

The Modelle study compiles data

In collaboration with Sahlgrenska University Hospital, an investigator-initiated clinical study (Modelle) is conducted and involves about 30 patients. The study is led by Dr Helena Taflin and is conducted at Sahlgrenska University Hospital in collaboration with Norrland University Hospital. The aim of the study is to investigate in detail the effect of different folates (arfolitixorin/leucovorin) in combination with 5-FU on patients with colorectal cancer that has metastasized to the liver. This is the first time it is possible to directly measure TS-inhibition in both normal and tumor patient tissue. The TS enzyme is an important target for this type of cancer treatment through inhibition of cell growth. Patients receive only one treatment of folate + 5-FU in conjunction with surgery, so no clinical conclusions can be drawn.

The research team plans to report results from the study in 2023. Our assessment is that despite the scientific value of the study, the insights from the study have no commercial value for Isofol given the negative outcomes of the AGENT study.

Read more about the AGENT study on the company's website and in the annual report 2021.

Financial information, October-December

COMPARISON BETWEEN THE FOURTH QUARTER OF 2022 AND 2021

Amounts stated without parentheses refer to October-December 2022, and amounts stated in parentheses refer to October-December 2021.

REVENUE

Operating revenue

Net revenue amounted to TSEK 1,857 (4,704) for the period. Revenue was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 57 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -14,714 (-58,168), corresponding to a decrease of TSEK 43,453. Costs for the AGENT study are lower as the study is being terminated. On the other hand, costs for compiling and analyzing the study results and terminating the study according to ethical and regulatory requirements increased compared with the previous year. All pre-commercialization activities were ended during the third quarter, which meant that costs declined significantly compared with the previous year. The company's savings program continued during the quarter, resulting in a general reduction in the cost base.

Personnel costs

Personnel costs in the Group amounted to TSEK -12,205 (-8,990), corresponding to an increase of TSEK 3,215. Severance pay to the CEO was recognized during the quarter, contributing to the high-

er personnel costs. There were 13 (15) employees at the end of December 2022. Layoffs of employees continued during the quarter.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -421 (-397).

Financial items

Financial revenue amounted to TSEK 255 (1,706), attributable to exchange rate fluctuations in cash and cash equivalents as well as other interest income. Financial costs amounted to TSEK -8 (-17), attributable to interest expenses.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -25,581 (-62,858), corresponding to an improvement of TSEK 37,277. The result after financial items was TSEK -25,335 (-61,170), corresponding to an improvement of TSEK 35,835. The Group has no tax costs since there was no profit in the comparative period.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at December 31, 2022 amounted to TSEK 190,583 (379,448). No loans had been raised at December 31, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 0 (42,124) 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 -42,909 (-42,022), corresponding to a change of TSEK

887. The cash flow is attributable to reduced costs as a result of general cost savings, as well as an increased rate of regulation of working capital attributable to the study.

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 -446 (-368). 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 -43,355 (-42,390), corresponding to a change of TSEK 965.

INVESTMENTS

Investments during October-December 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-December

COMPARISON BETWEEN JANUARY-DECEMBER 2022 AND 2021

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

REVENUE

Operating revenue

Net revenue amounted to TSEK 12,797 (22,407) for the period. Revenue was attributable to reimbursements for the AGENT study in Japan. Other revenue amounted to TSEK 59 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -142,114 (-196,712), corresponding to a decrease of TSEK 54,598. Costs for preparing, compiling and analyzing study results increased while costs for the 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. There was a general decrease in company costs as a result of the company's savings program initiated during the third quarter.

Personnel costs

Personnel costs in the Group amounted to TSEK -34,748 (-27,721), corresponding to an increase of TSEK 7,027. The increase was attributable to the CEO's severance pay and stay-on agreements to key employees to stay on. There were 13 (15) employees at the end of December 2022.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -1,642 (-1,596).

Financial items

Financial revenue amounted to TSEK 7,750 (4,383), attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments. Financial costs amounted to TSEK -44 (-168), attributable to interest expenses.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -167,460 (-204,465), corresponding to an improvement of TSEK 37,005. The result after financial items was TSEK -159,755 (-200,251), corresponding to an improvement of TSEK 40,496.

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

CASH AND CASH EQUIVALENTS

Cash and cash equivalents at December 31, 2022 amounted to TSEK 190,583 (379,448). No loans had been raised at December 31, 2022 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 0 (42,124) 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 -190,975 (-188,429), corresponding to a change of TSEK 2,546. The negative cash flow for the period was attributable to the company's clinical activities. Cash flow from operating activities decreased significantly as a result of general cost savings,

while at the same time the rate of regulation of working capital attributable to the study increased.

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 -1,681 (450,477). 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 -192,656 (262,048). The negative cash flow was attributable to the company's clinical activities.

INVESTMENTS

Investments during

January-December 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

Organization and employees

There were 13 (15) full-time employees at the end of the reporting period, four 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 and conclude the company's study. 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 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, arfoltixorin. 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 December 31, 2022

| Shareholder | Number of shares | Share capital/votes |
|---------------------------------|--------------------|---------------------|
| Futur Pension | 13,221,262 | 8.19% |
| Avanza Pension | 11,383,878 | 7.05% |
| Göran Gustafsson | 5,294,991 | 3.28% |
| Swedbank Försäkring | 5,195,845 | 3.22% |
| Hans Enocson | 4,555,236 | 2.82% |
| Bengt Gustafsson* | 3,749,459 | 2.32% |
| Linc AB | 2,972,419 | 1.84% |
| Nordnet Pensionsförsäkring | 2,211,703 | 1.37% |
| Mats Franzén | 2,125,652 | 1.32% |
| Sune Svedberg | 2,123,331 | 1.31% |
| Ten largest shareholders | 52,833,776 | 32.71% |
| Other shareholders | 108,681,664 | 67.29% |
| TOTAL | 161,515,440 | 100.00% |

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

SOURCE: MONITOR BY MODULAR FINANCE AB. COMPILED AND PROCESSED DATA FROM 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.

Review report

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

THE NOMINATION COMMITTEE FOR THE 2023 ANNUAL GENERAL MEETING

The Nomination Committee for the 2023 Annual General Meeting consists of Chairman Lars Lind, Malin Björkmo, Johan Möller and Mats-Ola Palm. Proposals must be received by the Nomination Committee by March 12, 2023 to be included in the notice and agenda of the 2023 Annual General Meeting. Shareholders who wish to submit proposals to Isofol's Nomination Committee for 2023 can contact Isofol Medical AB (publ), Attn: The Nomination Committee, Arvid Wallgrens Backe 20, 413 46 Gothenburg, Sweden or by email to valberedningen@isofolmedical.com.

Annual General Meeting

The Annual General Meeting of Isofol Medical AB (publ) will be held in Gothenburg on May 3, 2023.

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

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:

| | |
|------------------------------------|-------------------|
| 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 fourth quarter of 2022, February 22 at 11:00 a.m. CET.

Isofol invites investors, analysts and the media to an audiocast on February 22 at 11:00 a.m. CET in connection with the publication of the interim report for the fourth 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

February 22, 2023 at 11:00 a.m. CET

Link to audiocast

Use the following link to participate online, where questions may be submitted in writing:

<https://ir.financialhearings.com/isofol-medical-q4-2022>

Conference call

Use the link below to register to participate via conference call. Upon registering, you will receive the telephone number and a meeting ID to log into the conference call. There will be an opportunity to ask questions verbally during the call.

<https://conference.financialhearings.com/teleconference/?id=5002218>

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



For further information, contact:

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Isofol Medical AB (PUBL)

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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 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|---|------|-----------------|-----------------|-----------------|-----------------|
| OPERATING REVENUE | | | | | |
| Net revenue | 2 | 1,857 | 4,704 | 12,797 | 22,407 |
| Other revenue | | 57 | - | 59 | - |
| Total operating revenue | | 1,915 | 4,704 | 12,856 | 22,407 |
| OPERATING COSTS | | | | | |
| Other external costs | | -14,714 | -58,168 | -142,114 | -196,712 |
| Personnel costs | | -12,205 | -8,990 | -34,748 | -27,721 |
| Depreciation and amortization of tangible and intangible fixed assets | | -421 | -397 | -1,642 | -1,596 |
| Other operating revenue and operating costs* | | -156 | -7 | -1,812 | -843 |
| Total operating costs | | -27,496 | -67,563 | -180,316 | -226,872 |
| Operating result | | -25,581 | -62,858 | -167,460 | -204,465 |
| FINANCIAL ITEMS | | | | | |
| Financial revenue | | 255 | 1,706 | 7,750 | 4,383 |
| Financial costs | | -8 | -17 | -44 | -168 |
| Total financial items | | 246 | 1,689 | 7,706 | 4,215 |
| Result after financial items | | -25,335 | -61,170 | -159,755 | -200,251 |
| Tax on result for the period | | - | - | - | - |
| Result | | -25,335 | -61,170 | -159,755 | -200,251 |
| Attributable to: | | | | | |
| Parent Company shareholders | | -25,335 | -61,170 | -159,755 | -200,251 |
| EARNINGS PER SHARE | | | | | |
| Before dilution (SEK) | | -0.16 | -0.38 | -0.99 | -1.59 |
| After dilution (SEK) | | -0.16 | -0.38 | -0.99 | -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 | 2022-12-31 | 2021-12-31 |
|--|---------|----------------|----------------|
| 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 | | 4,013 | 1,745 |
| Total tangible fixed assets | | 4,013 | 1,745 |
| Financial fixed assets | | | |
| Other long-term receivables | | - | 5,009 |
| Total financial fixed assets | | - | 5,009 |
| Total fixed assets | | 4,013 | 6,755 |
| CURRENT ASSETS | | | |
| Accounts receivable | | - | - |
| Other receivables | | 17,652 | 12,276 |
| Prepaid expenses and accrued income | | 1,215 | 2,884 |
| Cash and cash equivalents | 3, 4, 5 | 190,583 | 379,448 |
| Total current assets | | 209,451 | 394,609 |
| Total assets | | 213,464 | 401,363 |

Condensed consolidated balance sheet

| TSEK | Note | 2022-12-31 | 2021-12-31 |
|--------------------------------------|------|----------------|----------------|
| EQUITY AND LIABILITIES | | | |
| EQUITY | | | |
| | 6 | | |
| Share capital | | 4,945 | 4,945 |
| Other contributed capital | | 1,217,607 | 1,217,607 |
| Retained earnings | | -904,319 | -704,069 |
| Result for the year | | -159,755 | -200,251 |
| Total equity | | 158,479 | 318,233 |
| LIABILITIES | | | |
| Long-term liabilities | | | |
| Long-term lease liabilities | | 2,405 | 110 |
| Other provisions | 7 | 845 | - |
| Total long-term liabilities | | 3,250 | 110 |
| Current liabilities | | | |
| Accounts payable | 3 | 7,520 | 17,736 |
| Other liabilities | | 3,334 | 3,174 |
| Accrued expenses and deferred income | 3 | 40,881 | 62,110 |
| Total current liabilities | | 51,735 | 83,020 |
| Total liabilities | | 54,985 | 83,130 |
| Total equity and liabilities | | 213,464 | 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 |
| Over-allotment option | | 478 | 99,522 | - | 100,000 |
| Issue costs | | - | -48,240 | - | -48,240 |
| Result for the period | | - | - | -200,251 | -200,251 |
| Equity, Dec 31, 2021 | | 4,945 | 1,217,607 | -904,319 | 318,233 |

| 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 | | - | - | -159,755 | -159,755 |
| Equity, Dec 31, 2022 | | 4,945 | 1,217,607 | -1,064,074 | 158,479 |

Consolidated cash flow statement

| TSEK | Note | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|--|------|-----------------|-----------------|-----------------|-----------------|
| OPERATING ACTIVITIES | | | | | |
| Result after financial items | | -25,335 | -61,170 | -159,755 | -200,251 |
| Adjustments for non-cash items | | 1,573 | -1,308 | 450 | -2,946 |
| Income tax paid | | - | - | - | - |
| Cash flow from operating activities before changes in working capital | | -23,762 | -62,478 | -159,305 | -203,196 |
| CASH FLOW FROM CHANGES IN WORKING CAPITAL | | | | | |
| Increase/decrease in other current receivables | | 1,040 | 11,448 | -504 | 9,860 |
| Increase/decrease in other current liabilities | | -20,187 | 9,007 | -31,166 | 4,907 |
| Change in working capital | | -19,147 | 20,456 | -31,670 | 14,767 |
| Cash flow from operating activities | | -42,909 | -42,022 | -190,975 | -188,429 |
| INVESTING ACTIVITIES | | | | | |
| Acquisition of tangible fixed assets | | - | - | - | - |
| Cash flow from investing activities | | - | - | - | - |
| FINANCING ACTIVITIES | | | | | |
| Repayment of lease liability | | -446 | -393 | -1,704 | -1,548 |
| Subscription warrants, proceeds received | 6 | - | 25 | 23 | 108 |
| New share issue | | - | - | - | 451,917 |
| Cash flow from financing activities | | -446 | -368 | -1,681 | 450,477 |
| Cash flow for the period | | -43,355 | -42,390 | -192,656 | 262,048 |
| Cash and cash equivalents at the beginning of the period | | 234,983 | 420,861 | 379,448 | 116,393 |
| Exchange rate difference in cash and cash equivalents | | -1,044 | 977 | 3,791 | 1,007 |
| Cash and cash equivalents at the end of the period | 5 | 190,583 | 379,448 | 190,583 | 379,448 |

Condensed Parent Company income statement

| TSEK | Note | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|--|------|-----------------|-----------------|-----------------|-----------------|
| OPERATING REVENUE | | | | | |
| Net revenue | 2 | 1,857 | 4,704 | 12,797 | 22,407 |
| Other revenue | | - | - | - | - |
| Total operating revenue | | 1,857 | 4,704 | 12,797 | 22,407 |
| OPERATING COSTS | | | | | |
| Other external costs | | -15,019 | -58,577 | -143,713 | -198,349 |
| Personnel costs | | -12,205 | -8,990 | -34,748 | -27,721 |
| Depreciation and amortization | | -16 | -18 | -67 | -77 |
| Other operating revenue and operating costs* | | -156 | -7 | -1,812 | -843 |
| Total operating costs | | -27,396 | -67,593 | -180,340 | -226,990 |
| Operating result | | -25,539 | -62,888 | -167,543 | -204,583 |
| FINANCIAL ITEMS | | | | | |
| Financial revenue | | 255 | 1,706 | 7,750 | 4,383 |
| Financial costs | | - | - | - | -79 |
| Total financial items | | 255 | 1,706 | 7,750 | 4,304 |
| Result after financial items | | -25,284 | -61,183 | -159,793 | -200,280 |
| Result before tax | | -25,284 | -61,183 | -159,793 | -200,280 |
| Tax | | - | - | - | - |
| Result | | -25,284 | -61,183 | -159,793 | -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 | 2022-12-31 | 2021-12-31 |
|--|------|----------------|----------------|
| 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 | | 91 | 158 |
| Total tangible fixed assets | | 91 | 158 |
| Financial fixed assets | | | |
| Participations in Group companies | | 50 | 50 |
| Other long-term receivables | | - | 5,009 |
| Total financial fixed assets | | 50 | 5,059 |
| Total fixed assets | | 141 | 5,217 |
| CURRENT ASSETS | | | |
| Accounts receivable | | - | - |
| Other receivables | | 17,652 | 12,276 |
| Prepaid expenses and accrued income | | 1,564 | 3,113 |
| Cash and cash equivalents | 4, 5 | 190,533 | 379,398 |
| Total current assets | | 209,749 | 394,787 |
| Total assets | | 209,890 | 400,004 |

Condensed Parent Company balance sheet

| TSEK | Note | 2022-12-31 | 2021-12-31 |
|--------------------------------------|------|----------------|----------------|
| EQUITY AND LIABILITIES | | | |
| EQUITY | 6 | | |
| Restricted equity | | | |
| Share capital | | 4,945 | 4,945 |
| Total restricted equity | | 4,945 | 4,945 |
| Non-restricted equity | | | |
| Share premium reserve | | 1,218,276 | 1,218,276 |
| Retained earnings | | -904,924 | -704,645 |
| Result for the year | | -159,793 | -200,280 |
| Total non-restricted equity | | 153,559 | 313,352 |
| Total equity | | 158,504 | 318,297 |
| LIABILITIES | | | |
| Long-term liabilities | | | |
| Other provisions | 7 | 845 | - |
| Total long-term liabilities | | 845 | - |
| Current liabilities | | | |
| Accounts payable | | 7,869 | 17,965 |
| Other liabilities | | 1,791 | 1,632 |
| Accrued expenses and deferred income | | 40,881 | 62,110 |
| Total current liabilities | | 50,541 | 81,707 |
| Total liabilities | | 51,386 | 81,707 |
| Total equity and liabilities | | 209,890 | 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 arfolitoxin and are organized as a cohesive business within the framework of the AGENT study. Accordingly, all of the Group's operations comprise one operating segment. The operating segment is followed up in a manner that complies with the internal reporting submitted to the chief operating decision maker, namely the CEO. Only one segment is used in the internal reporting to the CEO.

REVENUE

Isofol's net revenue derives from licensing agreements for the licensing rights to Isofol's intellectual property. Revenue from licensing agreements may comprise one-off payments, licensing fees, royalties and milestone payments for the use of Isofol's intellectual property. Isofol may also be entitled under its licensing agreements to receive reimbursements for costs incurred for the execution of service assignments.

Breakdown of revenue by geographic area

| TSEK | Group | | | |
|---------------|-----------------|-----------------|-----------------|-----------------|
| | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
| North America | - | - | - | - |
| Asia | 1,857 | 4,704 | 12,797 | 22,407 |
| Total | 1,857 | 4,704 | 12,797 | 22,407 |

| TSEK | Parent Company | | | |
|---------------|-----------------|-----------------|-----------------|-----------------|
| | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
| North America | - | - | - | - |
| Asia | 1,857 | 4,704 | 12,797 | 22,407 |
| Total | 1,857 | 4,704 | 12,797 | 22,407 |

Breakdown of revenue by type of revenue

| TSEK | Group | | | |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|
| | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
| Licensing | - | - | - | - |
| Execution of service assignments | 1,857 | 4,704 | 12,797 | 22,407 |
| Total | 1,857 | 4,704 | 12,797 | 22,407 |

| TSEK | Parent Company | | | |
|----------------------------------|-----------------|-----------------|-----------------|-----------------|
| | 2022 Oct-Dec | 2021 Oct-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
| Licensing | - | - | - | - |
| Execution of service assignments | 1,857 | 4,704 | 12,797 | 22,407 |
| Total | 1,857 | 4,704 | 12,797 | 22,407 |

Contract assets

| TSEK | Group | |
|----------------------|------------|--------------|
| | 2022-12-31 | 2021-12-31 |
| Accrued income | 559 | 1,631 |
| Contract liabilities | - | - |
| Total | 559 | 1,631 |

| TSEK | Parent Company | |
|----------------------|----------------|--------------|
| | 2022-12-31 | 2021-12-31 |
| Accrued income | 559 | 1,631 |
| Contract liabilities | - | - |
| Total | 559 | 1,631 |

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

Note 3 Financial instruments

As of December 31, 2022, the Group had no financial instruments measured at fair value, which was recognized in the form of currency derivatives of TSEK 0 (1,663). 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 190,583 (381,135) and financial liabilities to TSEK 37,542 (72,556).

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 (42,124) in pledged assets.

Note 5 Cash and cash equivalents

| Group TSEK | 2022-12-31 | 2021-12-31 |
|--|-------------------|-------------------|
| The following sub-items are included in cash and cash equivalents: | | |
| Cash and cash equivalents | 190,583 | 379,448 |
| Total | 190,583 | 379,448 |
| Parent Company TSEK | 2022-12-31 | 2021-12-31 |
| The following sub-items are included in cash and cash equivalents: | | |
| Cash and bank balances | 190,533 | 379,398 |
| Total | 190,533 | 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 third quarter of 2022 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 was paid off over three years and no loans to employees remain at the end of the fourth quarter.

| Group TSEK | 2022 | 2021 |
|---|-----------|-----------|
| Repayment from management and employees | 23 | 82 |
| Total | 23 | 82 |

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 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 2022, Isofol Medical AB (publ) entered into an agreement with a supplier for purchases of packaging material for the potential future sale of arfollitoxin. Use of the material depends on an approval for the commercialization of arfollitoxin. The agreement contains a financial guarantee totaling EUR 75,963, in which Isofol commits to purchasing material for an equivalent amount. Based on the outcome of the AGENT study, management deems it likely that the financial guarantee will be triggered. A total of TSEK 845, 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 of 2022. The specific date for the outflow is still unknown, but it is expected 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 | 2022-12-31 | 2021-12-31 |
|---------------------------|----------------|----------------|
| Equity | 158,479 | 318,233 |
| Total assets | 213,464 | 401,363 |
| Solvency | 74.2% | 79.3% |
| Cash and cash equivalents | 190,583 | 379,448 |
| Working capital | 157,716 | 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.

The Board's certification

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

Gothenburg, February 22, 2023

Jan Törnell
Chairman

Magnus Björsne
Board member

Paula Boulton
Board member

Alain Herrera
Board member

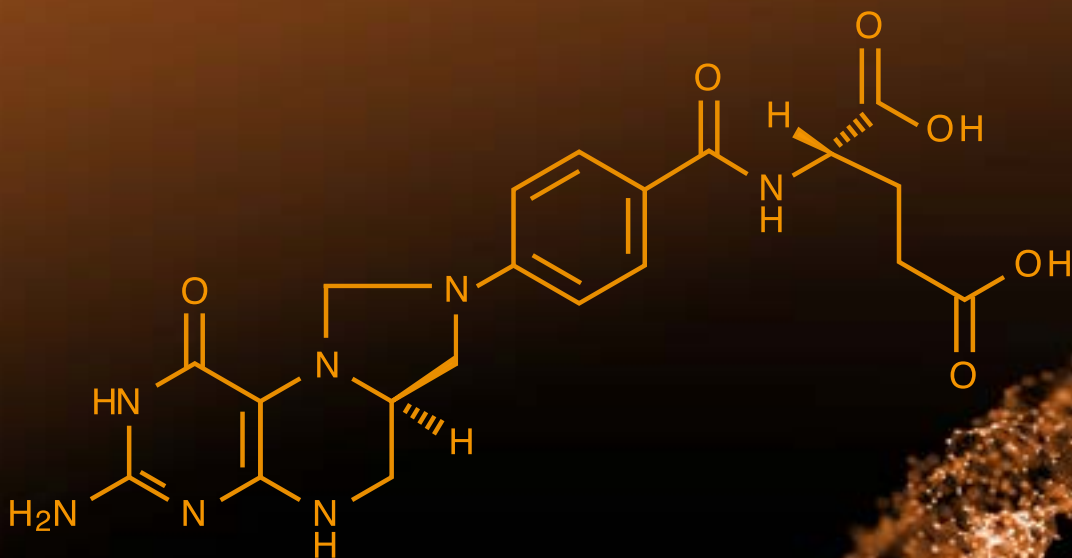
Anna Belfrage
Board member

Robert Marchesani
Board member

Aram Mangasarian
Board member

Lennart Jeansson
Board member

Ulf Jungnelius
CEO



ARFOLITIXORIN

A DRUG CANDIDATE
FOR THE TREATMENT
OF COLORECTAL CANCER

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