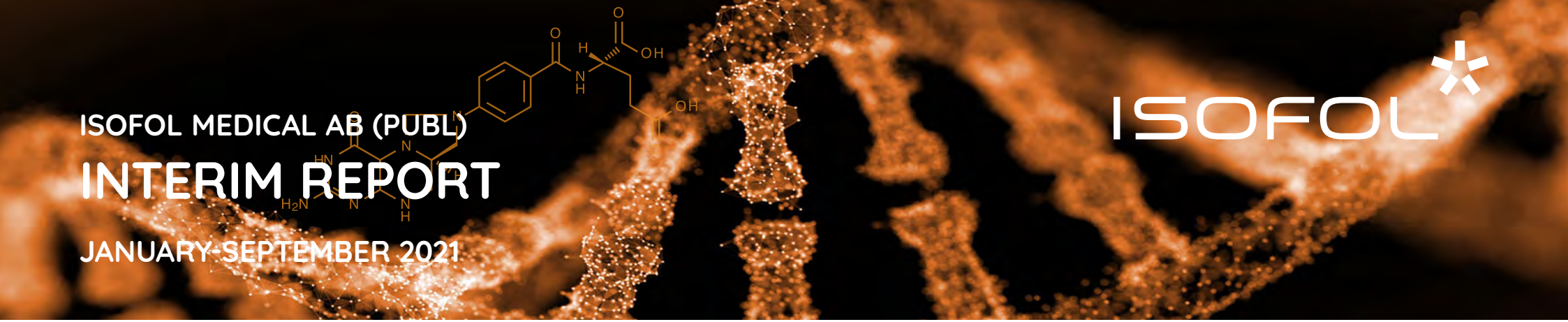


ISOFOL MEDICAL AB (PUBL)

INTERIM REPORT

JANUARY-SEPTEMBER 2021

ISOFOL

Intense work to move the company closer to market launch

SIGINIFICANT EVENTS DURING THE THIRD QUARTER

- No significant events to report during the quarter

SIGNIFICANT EVENTS AFTER THE END OF THE PERIOD

- On October 21, Isofol was listed on Nasdaq Stockholm

FINANCIAL INFORMATION

Third quarter, July-September 2021

- Net revenue amounted to TSEK 5,154 (18,439) and other revenue to TSEK 0 (0)
- The result for the period amounted to TSEK -51,026 (-30,100)
- Earnings per share amounted to SEK -0.32 (-0.36)
- Cash and cash equivalents at September 30 amounted to TSEK 420,861 (153,612)

January-September 2021

- Net revenue amounted to TSEK 17,702 (18,439) and other revenue to TSEK 0 (0)
- The result for the period amounted to TSEK -139,081 (-134,333)
- Earnings per share amounted to SEK -1.22 (-2.48)

Isofol is developing the cancer drug arfolitixorin

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

The Group consists of the Parent Company, Isofol Medical AB (publ), and the subsidiary, Isofol Medical Incentive AB. The business is conducted by the Parent Company, while the subsidiary only administers the Group's incentive programs. The descriptions of the business, results and financial position in this interim report apply to both the Group and the Parent Company, unless otherwise stated.

KEY FIGURES TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Net revenue	5,154	18,439	17,702	18,439	37,119
Result for the period	-51,026	-30,100	-139,081	-134,333	-188,992
Earnings per share (SEK)	-0.32	-0.36	-1.22	-2.48	-3.07
Cash and cash equivalents	420,861	153,612	420,861	153,612	116,393

Intense work to move the company closer to market launch

During the third quarter, we focused on ensuring that our global pivotal Phase III study, AGENT, will be completed in an effective and safe manner in parallel with securing the regulatory process through status meetings with various pharmaceutical authorities. We are also accelerating the pace of our commercial preparations ahead of the upcoming market launch of arfolitixorin, which is expected to take place within two years. Through these initiatives, we are establishing the prerequisites to create maximum value for Isofol's shareholders.

"The listing on Nasdaq Stockholm will strengthen our profile and our brand in the market.

Ulf Jungnelius, CEO, Isofol Medical AB (publ)

Thanks to the new share issue carried out in June, we secured the financial resources required to complete the AGENT study and to submit an application for approval to the US Food and Drug Administration (FDA). The financial resources obtained by the company in conjunction with the share issue will provide Isofol with greater stability in its work and better prerequisites to complete the ongoing AGENT study. Since financing was secured, we have been working intensely to carry out the plans promised in conjunction with the announcement of the new share issue. As we move closer to achieving top-line results, we are also increasing our activities with potential partners.

For the AGENT study, we are awaiting the next milestone, which will occur when 300 patients have either suffered from tumor growth or have died (PFS events), after which the analysis process for top-line results can begin with the compilation and statistical analysis of data. The latest forecast suggests that 300 PFS events will occur by the end of this year or the beginning of 2022. As part of the efforts to prepare the application of the drug application to the FDA, additional authority contacts were established during the quarter that will facilitate the upcoming New Drug Approval (NDA) application.

Additional pre-commercial activities commenced

The initiatives that commenced earlier this year in the form of an analysis of the potential of the Chinese market, an update of previously completed market and payer analyses and the preparation of strategies for market access have been completed. Perhaps the most interesting revelation is that we have confirmed that the previously assessed blockbuster potential is still well founded. Market analyses have also revealed that almost all of the interviewed prescribers believe that arfolitixorin is an improvement compared with existing treatment alternatives. These developments will be presented in more detail at a later time.

During the quarter, work on our pre-commercial plan continued and more activities commenced, the most important of which is the ongoing recruitment of a number of Medical Science Liaisons (MSL). MSLs are field-based medical personnel who will provide information about arfolitixorin in US clinics.

Clinical development initiatives for gene expression

We are convinced that biomarker analyses designed to demonstrate the capacity of cancer patients to respond to different folate-based cancer treatments will be applied to all patients treated with 5-FU treatment regimes in the future. Additional analyses of gene expression can be carried out thanks to the financing the company received in the summer, the results of which are expected to be presented in conjunction with the report on the final data from the AGENT study in the second half of 2022.

Listing on Nasdaq Stockholm

On October 21, we were able to begin a new chapter in the history of the company through a listing on the main list at Nasdaq Stockholm. This is an important and natural step in the development of the company and creates favorable prerequisites to further increase knowledge among investors about Isofol as a company in the late development phase with blockbuster potential. The listing on Nasdaq Stockholm will strengthen our profile and our brand in the market and improve our opportunities to gain access to Swedish and international capital markets. Having been admitted to the main list is an affirmation of quality for our organization and business. The listing change is expected to result in increased liquidity in the share, which will create greater value for our shareholders.

An exciting future awaits

As we look to the future, we have many important milestones ahead that we can look forward to in the form of top-line results and final data leading to the submission of the application for market approval. It is gratifying to see the entire Isofol team united in the task of bringing arfolitixorin to the market. This will enable Isofol to contribute to an improved quality of life for those suffering from metastasized colorectal cancer (mCRC) by offering a new, comprehensive drug that meets the acute, significant medical need of these patients.

Gothenburg, November 11, 2021

Ulf Jungnelius
CEO, Isofol Medical AB (publ)

Preparations continue ahead of the upcoming top-line results

The AGENT study is fully recruited and patients are being followed up with respect to the efficacy endpoints that are defined in the study. The next milestone will be when 300 PFS events have occurred, which will impact the subsequent analysis process.

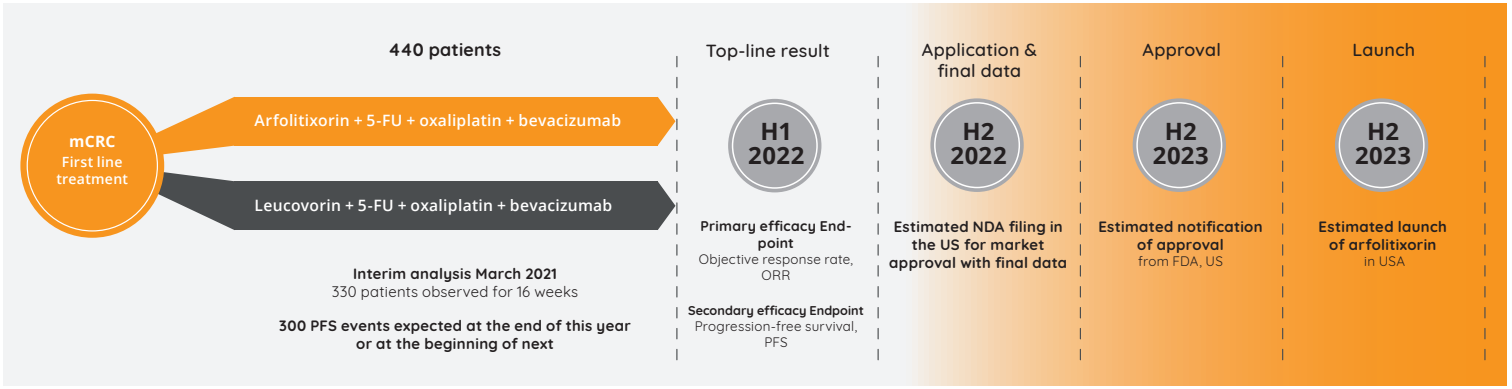
The AGENT study is a randomized Phase III study for which top-line results are expected to be reported in the first half of 2022.

Top-line results expected during first half of 2022

When the 300 PFS events have occurred, an analysis process involving the compilation and statistical analysis of top-line results will commence. Once the outcome is clear, it will need to be evaluated ahead of an NDA (New Drug Application) in the US and a Marketing Authorisation Application (MAA) in Europe.

The schedule for presenting the results of the study depends on when the 300 PFS events take place, either through tumor growth or the death of a patient. The timing will be impacted by how the patients' diseases develop, with the current assessment suggesting that this will occur at the end of 2021 or the beginning of 2022.

After the 300 PFS events have occurred, the read-out process can begin, including compilation, quality assurance and statistical analysis to enable top-line results to be presented. The presentation of top-line results is expected to take place in the first half of 2022. Final data will then form the basis for an application for market approval from the FDA in the US. This application is amning to be submitted in the second half of 2022 and a notification of approval is expected to be received in the second half of 2023.



The primary efficacy endpoint in the study is objective response rate (ORR), and the secondary efficacy endpoints are progression-free survival (PFS) and duration of response (DOR). These efficacy endpoints were determined in consultation with the pharmaceutical authorities to be able to evaluate the efficacy of arfolitixorin in the best possible way ahead of a possible market approval. ORR has become an increasingly common way of evaluating drug candidates in first-line treatment given that overall survival rate (OS) is a less suitable efficacy endpoint due in part to heterogeneity in subsequent therapies. These efficacy endpoints tend to be used for similar studies, and while ORR has been selected to evaluate a direct tumor effect, PFS is an event-driven endpoint that is often used for studies of metastasized cancer and includes the time that the patient remains alive after treatment has commenced without the tumors continuing to grow. In other words, PFS measures how long the patient remains alive without the disease worsening.

The statistical goal of the AGENT study is to be able to improve tumor shrinkage by at least 10 percentage points in patients treated with arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab compared with those treated with a leucovorin combination and in addition to achieve an extension of PFS.

The AGENT study also has an exploratory endpoints including gene expression, which in collaboration with an academic reaserach group, showed a correlation between clinical benefit and gene expression in patients suffering from mCRC treated with 5-FU based chemotherapy in combination with arfolitixorin. The results of the study have the potential to produce additional guidelines about the use of 5-FU based chemotherapy in combination with arfolitixorin and a greater understanding of the role of gene expression in the mechanism of action of arfolitixorin.

Preparations for application in the second half of 2022

Ahead of the submission of drug applications to the pharmaceutical authorities in the US and Europe, additional preparatory activities were carried out in the third quarter of 2021. During the quarter we had a constructive discussion with the FDA, in a Type C meeting, about CMC related issue, which we expect will facilitate the upcoming NDA application.

More than half of patients recruited in an investigator-initiated study

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

Currently, over half of the approximately 30 patients required have been recruited. To date, the study has only been conducted at Sahlgrenska University Hospital, but one patient from the University Hospital of Umeå was recruited during the quarter, with plans to operate in the fourth quarter. Expanding the study to include more clinics will hopefully accelerate the pace of recruitment.

CRC – the third most common form of cancer

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

CRC affects both men and women with an equal distribution between the genders. However, there are differences in its localization, as more men are affected by rectal cancer and more women by colon cancer. CRC mainly affects older people, with the majority becoming ill after the age of 70. The global incidence (the number of new patients who are diagnosed with this form of cancer annually) is approximately 1.9 million patients a year.

High mortality

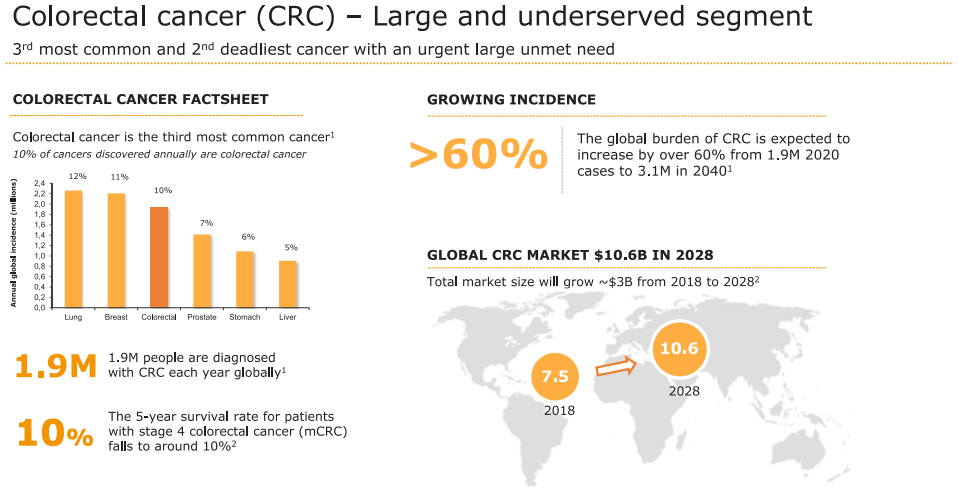
Despite improvements to the prognosis for patients with CRC over the past decade, the prognosis for survival is worse compared to patients with breast or prostate cancer, and CRC is the second most common cause of global cancer-related death after lung cancer. The prognosis for survival is better with an early diagnosis. Patients in later stages, when the cancer has spread to other organs (known as metastases), have a worse prognosis and significantly higher mortality. Only 10 percent of patients with mCRC are still alive five years after diagnosis.

Significant market potential

The total drug market in the eight largest global markets for the treatment of CRC amounted to USD 7.6 billion in 2018 and is expected to grow to about USD 10.6 billion by 2028. The reason for this relatively modest market growth is that few new drugs have been launched or will be launched in the coming years.

In addition, sales of drugs that have been launched recently or will be launched (not counting arfolitixorin) are expected to be relatively low since these drugs can primarily help only a smaller subgroup of CRC patients.

In the seven largest markets (the US, Japan and the EU 5), about 370,000 patients are diagnosed with mCRC each year. About 170,000 of these patients annually comprise Isofol's primary market – first-line treatment. About another 60,000 patients (in the same geographical regions) are assessed to be able to receive second- or third-line treatment, should market approval also be received for these treatment lines.

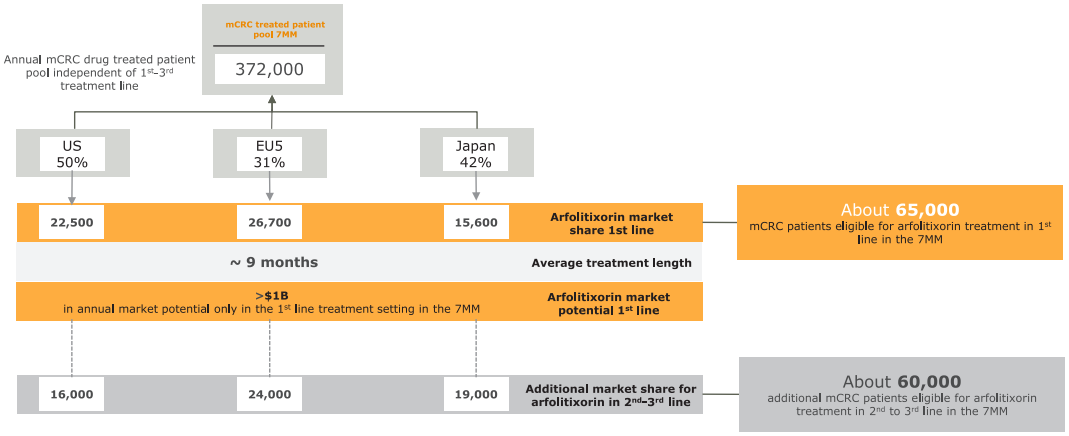


One of the most promising candidates according to the market-analysis company Global Data

In 2018, the UK market-analysis company Global Data published a forecast for the CRC market between 2018 and 2028 for the eight largest markets (8MM) – the US, the EU 5, Japan and China. The report describes arfolitixorin as one of the most promising drug candidates for CRC together with Array BioPharma's/Pfizer's BRAF inhibitor encorafenib (Braftovi).

Commercial preparations are intensified

Isofol's aim is for the market approval of arfolitixorin to be issued by the US FDA in the second half of 2023, provided that the outcome of the ongoing pivotal Phase III study is positive. To create the most favorable prerequisites possible for the commercial launch, Isofol has already initiated a number of activities within the framework of its global preparation program. For commercial and medical preparations, Isofol collaborates with the consultancy firm Syneos Health, which offers qualified and integrated clinical and commercial solutions and has a major global organization with over 24,000 employees. Over the years, Syneos has built up an understanding of arfolitixorin and its unique possibilities. In 2021, the partnership has intensified, not least through starting to recruit field-based medical personnel to provide scientific information about arfolitixorin at US clinics.



Source: GlobalData 2020

Isofol have initiated a number of activities to prepare for a future commercial launch of arfolitixorin. Earlier in the year, an analysis of the potential of the Chinese market and an update of previously completed market and payer analyses were initiated. The company also began preparing strategies for market access. All of these initiatives were completed in the third quarter. The pre-commercial work continued through the initiation of further activities, including an analysis of the prerequisites for market access in the US, positioning analyses for the mCRC market and an analysis of the current treatment of CRC patients.

Building knowledge

Despite a rising incidence of CRC, no new broad treatments for mCRC patients, regardless of genetic profile, have been approved for first-line treatment in almost 20 years. In a market with established treatment regimens, increased knowledge of arfolitixorin will therefore be fundamental ahead of a launch. Isofol has engaged Syneos health to support with increasing the scientific knowledge of arfolitixorin among oncologists at cancer clinics. To this end, Syneos are recruting MSLs, which are field based medical personnel, to provide scientific information about arfolitixorin and its potential use in the US market.

Updated market and payer survey confirms blockbuster potential

Through previous market and payer analyses, Isofol has determined that annual sales of arfolitixorin in the largest global markets could amount to USD 1 billion, corresponding to blockbuster potential. A more detailed market and payer survey completed during the quarter, in which about 350 physicians expressed their views on the place of arfolitixorin in future treatment regimes, confirmed this commercial potential. If the study reaches its established targets, the prescribers that took part in the study view arfolitixorin as an improvement compared with current treatments. About 25–30 percent of prescribers view the product as a significant or very significant improvement and an additional 50 percent view arfolitixorin as a moderate improvement. The survey also demonstrated that the likelihood of physicians prescribing arfolitixorin will be high given these circumstances. For first-line treatment, 51 percent of the physicians questioned responded that they are very likely to certain that they will prescribe arfolitixorin if the product is approved. If the drug candidate was also approved for second- and third-line treatment, 44 percent and 39 percent of the physicians questioned, respectively, stated they are very likely to certain that they would prescribe arfolitixorin.

Assessing market potential in the Chinese market

Work to develop a strategy for the Chinese market's commercial potential proceeded during the quarter. Once an analysis is complete, Isofol will determine how arfolitixorin could best benefit Chinese patients. For a potential approval, the Chinese National Medical Products Administration (NMPA) imposed a requirement that additional clinical studies be conducted on Chinese patients.

Imminent launch opportunity

Provided the study results are favorable, an application for market approval is expected to be filed with the US FDA during the second half of 2022, with a potential launch in the US in the second half of 2023.

Financial information, July-September

COMPARISON BETWEEN THE THIRD QUARTER OF 2021 AND 2020

Amounts stated without parentheses refer to July-September 2021, and amounts stated in parentheses refer to July-September 2020.

REVENUE

Operating revenue

Net revenue amounted to TSEK 5,154 (18,439) for the quarter. Revenue for the quarter was attributable to reimbursements for the AGENT study in Japan. Other revenue was unchanged compared with the year-earlier period at TSEK 0 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -49,352 (-45,887), corresponding to an increase of TSEK 3,465. Costs were higher compared with the year-earlier period, mainly due to costs for initiated pre-commercial activities. Costs for the ongoing AGENT study were generally somewhat lower compared with the year-earlier period, mainly due to the study having been fully recruited since the fourth quarter of 2020 and patients in later study phases.

Personnel costs

Personnel costs in the Group amounted to TSEK -7,620 (-4,486), corresponding to an increase of TSEK 3,134. There were 15 (12) employees at the end of September 2021.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -399 (-451).

Net financial items

Net financial items amounted to TSEK 1,180 (1,400), of which TSEK 1,275 (1,190) was attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments and TSEK -95 (210) to interest.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -52,205 (-31,500), corresponding to an increased loss of TSEK 20,705. The result after financial items was TSEK -51,026 (-30,100), corresponding to an increased loss of TSEK 20,926.

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, 2021 amounted to TSEK 420,861 (153,612). No loans had been raised at September 30, 2021 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 72,638 (67,302) was pledged as collateral to settle currency futures which are due until the second quarter of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -63,069 (-29,617), corresponding to a change of TSEK -33,452. The increased negative cash flow was mainly due to the company's clinical activities and increased pre-commercial activities and related advance payments.

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 -47,098 (-2,338). The negative cash flow for the period was attributable to the payment of transaction costs related to the new share issue completed during the second quarter.

Cash flow for the period

Cash flow for the period amounted to TSEK -110,166 (-31,955), corresponding to a change of TSEK -78,211. The increased negative cash flow was mainly attributable to the payment of transaction costs related to the new share issue completed during the quarter.

Excluding payments related to the share issue, cash flow for the period amounted to TSEK -63,429 (-29,905), corresponding to a change of TSEK -33,524. The negative cash flow for the period was attributable to the company's clinical and pre-commercial activities.

INVESTMENTS

Investments during July-September 2021

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

Financial information, January-September

COMPARISON BETWEEN JANUARY-SEPTEMBER 2021 AND 2020

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

REVENUE

Operating revenue

Net revenue amounted to TSEK 17,702 (18,439) for the period. Revenue was attributable to reimbursements for the AGENT study in Japan. Other revenue was unchanged compared with the year-earlier period at TSEK 0 (0).

OPERATING COSTS

Other external costs

Other external costs amounted to TSEK -138,545 (-139,668), corresponding to a decrease of TSEK 1,123. Despite costs for pre-commercial activities initiated in the third quarter, costs were lower compared with the year-earlier period. The lower costs were mainly attributable to fewer patient visits to sites for the AGENT study. The ongoing AGENT study with 440 patients was fully recruited in the fourth quarter of 2020.

Personnel costs

Personnel costs in the Group amounted to TSEK -18,731 (-14,363), corresponding to an increase of TSEK 4,368. There were 15 (12) employees at the end of September 2021.

Depreciation and amortization

Depreciation, amortization and impairment of tangible and intangible fixed assets during the period amounted to TSEK -1,198 (-1,332).

Net financial items

Net financial items amounted to TSEK 2,526 (2,435), of which TSEK 2,673 (2,788) was attributable to exchange rate fluctuations in cash and cash equivalents and derivative instruments and TSEK -147 (-353) to interest.

RESULT

Operating result (EBIT)

The operating result amounted to TSEK -141,607 (-136,768), corresponding to an increased loss of TSEK 4,839. The result after financial items was TSEK -139,081 (-134,333), corresponding to an increased loss of TSEK 4,748.

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, 2021 amounted to TSEK 420,861 (153,612). No loans had been raised at September 30, 2021 and no loans have been raised since then. Of the Group's cash and cash equivalents, TSEK 72,638 (67,302) was pledged as collateral to settle currency futures that which are due until the second quarter of 2022.

CASH FLOW

Cash flow from operating activities

Cash flow from operating activities during the period amounted to TSEK -146,407 (-125,165), corresponding to a change of TSEK -21,242. The negative cash flow for the period was attributable to the company's clinical activities and the company's pre-commercialization 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 450,844 (150,337). The positive cash flow for the period was attributable to the new share issue completed during the second quarter.

Cash flow for the period

Cash flow for the period amounted to TSEK 304,438 (25,172). The positive cash flow for the period was attributable to the new share issue completed during the second quarter.

Excluding the share issue, cash flow for the period amounted to TSEK -147,479 (-126,086). The change of TSEK -21,393 was attributable to the company's ongoing clinical activities and pre-commercialization activities.

INVESTMENTS

Investments during January-September 2021

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

Other information

Organization and personnel

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

Information about transactions with related parties

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

Risk management

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

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

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

Number of shares

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

Events after the end of the reporting period

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

Significant risks and uncertainty factors

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

Largest shareholders at September 30, 2021

Shareholder	Number of shares	Share capital/votes
Futur Pension (formerly Danica)	13,335,256	8.26%
Avanza Pension	7,927,068	4.91%
Handelsbanken Fonder	5,938,471	3.68%
Nordnet Pensionsförsäkring	5,433,172	3.36%
Swedbank Försäkring	5,268,567	3.26%
Hans Enocson	4,555,236	2.82%
AP4	4,521,257	2.80%
Swedbank Robur Fonder	4,175,839	2.59%
Bengt Gustafsson*	3,749,459	2.32%
Peak Asset Management	3,381,964	2.09%
Ten largest shareholders	**58,286,289**	**36.09%**
Other shareholders	103,229,111	63.91%
TOTAL	**161,515,440**	**100%**

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

SOURCE: ISOFOL'S LARGEST SHAREHOLDERS BASED ON INFORMATION FROM EUROCLEAR SWEDEN AB AT SEPTEMBER 30, 2021.

Impact of Covid-19 on the Group's risks

To date, Covid-19 has had a relatively limited impact on Isofol and its operations. The extent to which Covid-19 will impact Isofol's operations and specifically its clinical study during the rest of 2021 will largely depend on the pace at which global vaccination programs are rolled out and how quickly hospitals can return to normal operations. Isofol is carefully monitoring the development of Covid-19 and assessing the extent to which the operations may be impacted in the short and long term. Isofol has adapted its operations and taken continuous precautionary measures to ensure that its employees, consultants and study participants stay safe and healthy and to ensure that the study is based on high-quality data. The AGENT study was fully recruited in December 2020 and the risk of delays due to patient recruitment has therefore been reduced. However, there remains a risk that hospitals could close or that the collection of data could become more difficult due to future waves of Covid-19, which could delay the compilation of data ahead of the study's top-line results.

Financial reports and calendar

For information about the Group's financial reports and calendar, refer to page 20.

Review report

This report has been reviewed by the Group's auditors.

Condensed consolidated income statement

TSEK	Note	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
OPERATING REVENUE						
Net revenue	2	5,154	18,439	17,702	18,439	37,119
Other revenue		-	-	-	-	18
Total operating revenue		**5,154**	**18,439**	**17,702**	**18,439**	**37,137**
OPERATING COSTS						
Other external costs		-49,352	-45,887	-138,545	-139,668	-199,535
Personnel costs		-7,620	-4,486	-18,731	-14,363	-22,740
Depreciation and amortization of tangible and intangible fixed assets		-399	-451	-1,198	-1,332	-1,770
Other operating revenue and operating costs*		12	885	-835	157	413
Total operating costs		**-57,360**	**-49,939**	**-159,309**	**-155,207**	**-223,631**
Operating result		**-52,205**	**-31,500**	**-141,607**	**-136,768**	**-186,494**
FINANCIAL ITEMS						
Net financial items		1,180	1,400	2,526	2,435	-2,497
Total financial items		**1,180**	**1,400**	**2,526**	**2,435**	**-2,497**
Result after financial items		**-51,026**	**-30,100**	**-139,081**	**-134,333**	**-188,991**
Tax charged to result for the year		-	-	-	-	-1
Result		**-51,026**	**-30,100**	**-139,081**	**-134,333**	**-188,992**
Of which attributable to Parent Company shareholders		-51,026	-30,100	-139,081	-134,333	-188,992
Earnings per share before and after dilution, SEK		-0.32	-0.36	-1.22	-2.48	-3.07

* 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, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS				
FIXED ASSETS				
Intangible fixed assets				
Patents		-	19	-
Total intangible fixed assets		**-**	**19**	**-**
Tangible fixed assets				
Equipment, tools, fixtures and fittings		2,143	3,771	3,258
Total tangible fixed assets		**2,143**	**3,771**	**3,258**
Financial fixed assets				
Other long-term receivables		5,009	5,063	5,031
Total financial fixed assets		**5,009**	**5,063**	**5,031**
Total fixed assets		**7,152**	**8,853**	**8,289**
CURRENT ASSETS				
Current receivables	3	25,910	25,136	23,448
Cash and cash equivalents	3, 4, 5	420,861	153,612	116,393
Total current assets		**446,771**	**178,747**	**139,841**
Total assets		**453,923**	**187,600**	**148,130**

Condensed consolidated balance sheet

TSEK	Note	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES				
EQUITY				
Equity	6	379,403	121,226	66,567
Total equity		**379,403**	**121,226**	**66,567**
LIABILITIES				
Long-term liabilities				
Long-term lease liability		422	2,025	1,439
Total long-term liabilities		**422**	**2,025**	**1,439**
Current liabilities				
Current lease liability		1,623	1,597	1,677
Other current liabilities	3	72,475	62,753	78,447
Total current liabilities		**74,098**	**64,350**	**80,124**
Total liabilities		**74,520**	**66,375**	**81,563**
Total equity and liabilities		**453,923**	**187,600**	**148,130**

Consolidated statement of changes in equity

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2020		981	619,003	-515,076	104,908
Subscription warrants, repurchases	6	-	-57	-	-57
Rights issue		1,309	148,280	-	149,589
Over-allotment option		262	29,738	-	30,000
Issue costs		-	-28,941	-	-28,941
Result for the period		**-**	**-**	**-104,234**	**-104,234**
Equity, Sep 30, 2020		**2,552**	**768,023**	**-619,310**	**151,265**

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Oct 1, 2020		2,552	768,023	-619,310	151,265
New share issue, issued subscription warrants	6	-	60	-	60
Result for the period		**-**	**-**	**-84,758**	**-84,758**
Equity, Dec 31, 2020		**2,552**	**768,083**	**-704,068**	**66,567**

TSEK	Note	Share capital	Other contributed capital	Retained earnings	Total
Opening equity, Jan 1, 2021		2,552	768,083	-704,068	66,567
Rights issue		1,914	398,242	-	400,157
Over-allotment option		478	99,522	-	100,000
Issue costs		-	-48,240	-	-48,240
Result for the period		**-**	**-**	**-139,081**	**-139,081**
Equity, Sep 30, 2021		**4,945**	**1,217,607**	**-843,149**	**379,403**

Consolidated cash flow statement

TSEK	Note	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
OPERATING ACTIVITIES						
Result after financial items		-51,026	-30,100	-139,081	-134,333	-188,991
Adjustments for non-cash items		-881	-740	-1,638	-1,456	3,958
Income tax paid*		-	-	-	-	-1
Cash flow from operating activities before changes in working capital		**-51,906**	**-30,839**	**-140,718**	**-135,789**	**-185,033**
CASH FLOW FROM CHANGES IN WORKING CAPITAL						
Increase (-)/decrease (+) in operating receivables		-3,366	-8,918	-1,588	-14,375	-14,050
Increase (+)/decrease (-) in operating liabilities		-7,796	10,140	-4,100	24,999	38,813
Change in working capital		**-11,162**	**1,222**	**-5,688**	**10,624**	**24,763**
Cash flow from operating activities		**-63,069**	**-29,617**	**-146,407**	**-125,165**	**-160,270**
INVESTING ACTIVITIES						
Acquisition of tangible fixed assets		-	-	-	-	-
Cash flow from investing activities		**-**	**-**	**-**	**-**	**-**
FINANCING ACTIVITIES						
Repayment of lease liability		-388	-390	-1,155	-1,159	-1,553
Subscription warrants, proceeds received	6	28	102	82	238	308
New share issue**		-46,737	-2,050	451,917	151,258	151,258
Cash flow from financing activities		**-47,098**	**-2,338**	**450,844**	**150,337**	**150,013**
Cash flow for the period		-110,166	-31,955	304,438	25,172	-10,257
Cash and cash equivalents at the beginning of the period		530,682	185,709	116,393	126,983	126,983
Exchange rate difference in cash and cash equivalents		345	-142	30	1,457	-334
Cash and cash equivalents at the end of the period	5	**420,861**	**153,612**	**420,861**	**153,612**	**116,393**

* Refers to previous years' tax costs in the subsidiary

** Comment on Q3 2021: Refers to the payment of transaction costs related to the new share issue completed during the second quarter of 2021.

Condensed Parent Company income statement

TSEK	Note	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
OPERATING REVENUE						
Net revenue	2	5,154	18,439	17,702	18,439	37,119
Other operating revenue		-	-	-	-	-
Total operating revenue		**5,154**	**18,439**	**17,702**	**18,439**	**37,119**
OPERATING COSTS						
Other external costs		-49,761	-46,313	-139,772	-140,939	-201,231
Personnel costs		-7,620	-4,486	-18,731	-14,363	-22,740
Depreciation and amortization		-19	-52	-60	-157	-197
*Other operating revenue and operating costs**		12	885	-835	158	413
Total operating costs		**-57,388**	**-49,966**	**-159,397**	**-155,301**	**-223,754**
Operating result		**-52,234**	**-31,527**	**-141,695**	**-136,862**	**-186,635**
FINANCIAL ITEMS						
Net financial items		1,200	1,435	2,598	2,546	-2,354
Total financial items		**1,200**	**1,435**	**2,598**	**2,546**	**-2,354**
Result after financial items		**-51,034**	**-30,092**	**-139,097**	**-134,316**	**-188,989**
Result before tax		**-51,034**	**-30,092**	**-139,097**	**-134,316**	**-188,989**
Group contributions paid		-	-	-	-	-293
Tax		-	-	-	-	-
Result		**-51,034**	**-30,092**	**-139,097**	**-134,316**	**-189,282**

* 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, 2021	Sep 30, 2020	Dec 31, 2020
ASSETS				
FIXED ASSETS				
Intangible fixed assets				
Patents		-	19	-
Total intangible fixed assets		**-**	**19**	**-**
Tangible fixed assets				
Equipment, tools, fixtures and fittings		175	256	235
Total tangible fixed assets		**175**	**256**	**235**
Financial fixed assets				
Participations in Group companies		50	50	50
Other long-term receivables		5,009	6,663	6,631
Total financial fixed assets		**5,059**	**6,713**	**6,681**
Total fixed assets		**5,235**	**6,988**	**6,916**
CURRENT ASSETS				
Current receivables	3	26,134	25,367	23,672
Cash and bank balances	3, 4, 5	420,811	152,081	114,862
Total current assets		**446,945**	**177,448**	**138,534**
Total assets		**452,179**	**184,436**	**145,450**

TSEK	Note	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
EQUITY AND LIABILITIES				
Equity		379,480	121,391	66,660
Total equity		**379,480**	**121,391**	**66,660**
Current liabilities	3	72,699	63,045	78,790
Total liabilities		**72,699**	**63,045**	**78,790**
Total equity and liabilities		**452,179**	**184,436**	**145,450**

Notes

Note 1 Accounting principles

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

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

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

Note 2 Operating segments

OPERATING SEGMENTS

The Group's operations comprise the development of the drug candidate arfolitixorin and are organized as a cohesive business within the framework of the ongoing Phase III AGENT study. Accordingly, all of the Group's operations comprise one operating segment. The operating segment is followed up in a manner corresponding with the internal reporting submitted to the chief operating decision maker, namely the CEO. Only one segment is used in the internal reporting to the CEO.

REVENUE

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

Breakdown of revenue by geographic area

	Group				
TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
North America	-	-	-	-	11,089
Asia	5,154	18,439	17,702	18,439	26,030
Total	**5,154**	**18,439**	**17,702**	**18,439**	**37,119**

	Parent Company				
TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
North America	-	-	-	-	11,089
Asia	5,154	18,439	17,702	18,439	26,030
Total	**5,154**	**18,439**	**17,702**	**18,439**	**37,119**

Breakdown of revenue by type of revenue

	Group				
TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Licensing	-	16,342	-	16,342	27,431
Execution of service assignments	5,154	2,097	17,702	2,097	9,688
Total	**5,154**	**18,439**	**17,702**	**18,439**	**37,119**

	Parent Company				
TSEK	2021 Jul-Sep	2020 Jul-Sep	2021 Jan-Sep	2020 Jan-Sep	2020 Jan-Dec
Licensing	-	16,342	-	16,342	27,431
Execution of service assignments	5,154	2,097	17,702	2,097	9,688
Total	**5,154**	**18,439**	**17,702**	**18,439**	**37,119**

Contract assets

	Group		
TSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
Accrued income	1,660	10,606	11,065
Contract liabilities	-	-	-
Total	**1,660**	**10,606**	**11,065**

	Parent Company		
TSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
Accrued income	1,660	10,606	11,065
Contract liabilities	-	-	-
Total	**1,660**	**10,606**	**11,065**

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

Note 3 Financial instruments

As of September 30, 2021, the Group had financial instruments, which were measured at fair value, in the form of currency derivatives of TSEK 935 (1,333) and holdings in a short-term fixed income fund of TSEK 0 (6,728). 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 421,844 (155,145) and the carrying amount of the Group's financial liabilities to TSEK 65,589 (54,240).

Note 4 Pledged assets

Pledged assets refers to collateral in the form of cash and cash equivalents for derivative instruments, specifically currency futures. The company has pledged TSEK 72,638 (67,302) of its cash and cash equivalents as collateral.

Note 5 Cash and cash equivalents

Group TSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
The following sub-items are included in cash and cash equivalents:			
Short-term investments	-	6,783	-
Cash and cash equivalents	420,861	146,829	116,393
Total	**420,861**	**153,612**	**116,393**

Parent Company TSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
The following sub-items are included in cash and cash equivalents:			
Short-term investments	-	6,783	-
Cash and bank balances	420,811	145,299	114,862
Total	**420,811**	**152,081**	**114,862**

Note 6 Equity

WARRANT PROGRAM 2020

The Annual General Meeting on June 24, 2020 resolved to establish a long-term incentive program ("Warrant Program 2020") aimed at the CEO of the company. Warrant Program 2020 should be seen as a supplementary program aimed exclusively at the company's CEO, who did not participate in Warrant Program 2018. The program, which includes a maximum of 250,000 subscription warrants, will result in a smaller dilution for the company's shareholders since the company canceled approximately 408,000 subscription warrants from Warrant Program 2018 in conjunction with the 2020 Annual General Meeting. The maximum of 250,000 subscription warrants entitle the holder to subscribe for a maximum of 370,000 shares (after the completion of the rights issue in June 2020). The subscription period will extend from 15 May 2023 to 15 July 2023. The subscription price for shares subscribed for with the support of the subscription warrants was set at SEK 30.3 per share. In August, the CEO subscribed for all 250,000 subscription warrants at a price corresponding to SEK 0.24 per subscription warrant, generating SEK 60,000 in warrant premiums. The subscription warrants were transferred at market value.

WARRANT PROGRAM 2018

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

In early February 2020 and in May 2020, 207,287 subscription warrants were repurchased by Isofol. These subscription warrants were attributable to individuals who had terminated their employment with Isofol. The repurchase took place at market value, calculated according to the Black & Scholes model. The market valuation was performed by an external valuation consultant. The repurchase pertained to Warrant Programs 2018/2022 and 2018/2023 issued in January 2019.

Of the total number of warrants, approximately 408,000 subscription warrants remained that had not been transferred or repurchased by participants whose employment with the company had ended. In conjunction with the 2020 Annual General Meeting, all outstanding subscription warrants in the Warrant Program 2018 that were not allotted to a holder were canceled.

The company's management and employees paid the warrant proceeds in 2019, pertaining to Warrant Program 2018, through a cash payment and a loan from the company. The loan will be paid off over three years.

Group and Parent Company TSEK	2021	2020
Subscription warrants, proceeds	-	-
Loan to management and employees	-	-
Repayment from management and employees	55	305
Repurchase of subscription warrants	-	-57
Issued subscription warrants, CEO	-	60
Total	**55**	**308**

In November 2020, subscription warrants were repurchased from a senior executive who had terminated his employment with Isofol Medical AB (publ). The repurchase was based on a market valuation in accordance with a Black & Scholes calculation performed by Grant Thornton Sweden AB. The repurchase comprised a total of 117,534 warrants at a total cost of SEK 73,460 and pertained to Warrant Program 2018. In conjunction with the repurchase, all repurchased subscription warrants were transferred at market value to the newly appointed Chief Commercial Officer (CCO), Tony Gustavsson.

Upon full exercise of all warrant programs issued for the subscription of shares, a total of 2,359, 980 shares will be issued, corresponding to a dilution of approximately 1.5%.

Key figures and definitions

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

TSEK	Sep 30, 2021	Sep 30, 2020	Dec 31, 2020
Equity	379,403	121,226	66,567
Total assets	**453,923**	**187,600**	**148,130**
Solvency	**83.6%**	**64.6%**	**44.9%**
Cash and cash equivalents	420,861	153,612	116,393
Working capital	372,673	114,397	59,717

Solvency
Solvency is calculated by comparing equity in relation to total assets and is thus a measure of the proportion of assets that are financed with equity.

Equity
Equity consists of share capital, other contributed capital and retained earnings, including the Group's result for the year.

Cash and cash equivalents
Cash and cash equivalents comprises cash and bank balances, immediately available bank balances and other money market instruments with original maturities of less than three months.

Working capital
Working capital consists of the Group's current assets less current liabilities.

Earnings per share
The result for the period divided by the weighted average number of shares during the period, before and after dilution.

To calculate earnings per share after dilution, the weighted average number of outstanding ordinary shares is adjusted for the dilution effect of all potential ordinary shares. These potential ordinary shares are attributable to the warrants included in Warrant Program 2018 (series 2018/2022 and series 2018/2023) and Warrant Program 2020. If the result for the period is negative, the warrants are not considered dilutive.

The Board's certification

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

Gothenburg, November 11, 2021

Pär-Ola Mannefred
Chairman

Magnus Björsne
Board member

Paula Boultbee
Board member

Alain Herrera
Board member

Anna Belfrage
Board member

Robert Marchesani
Board member

Aram Mangasarian
Board member

Lennart Jeansson
Board member

Ulf Jungnelius
CEO

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, 2021

KPMG AB

Jan Malm
Authorized Public Accountant

Financial reports

The following reports are scheduled for publication:

Year-end report 2021	February 25, 2022
Annual Report 2021	April 2022
Interim report January-March 2022	May 12, 2022
Interim report April-June 2022	August 23, 2022
Interim report July-September 2022	November 10, 2022
Year-end report 2022	February 23, 2023

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

Calendar

The next Annual General Meeting is scheduled to be held:

Annual General Meeting 2022	May 19, 2022

For further information, contact:

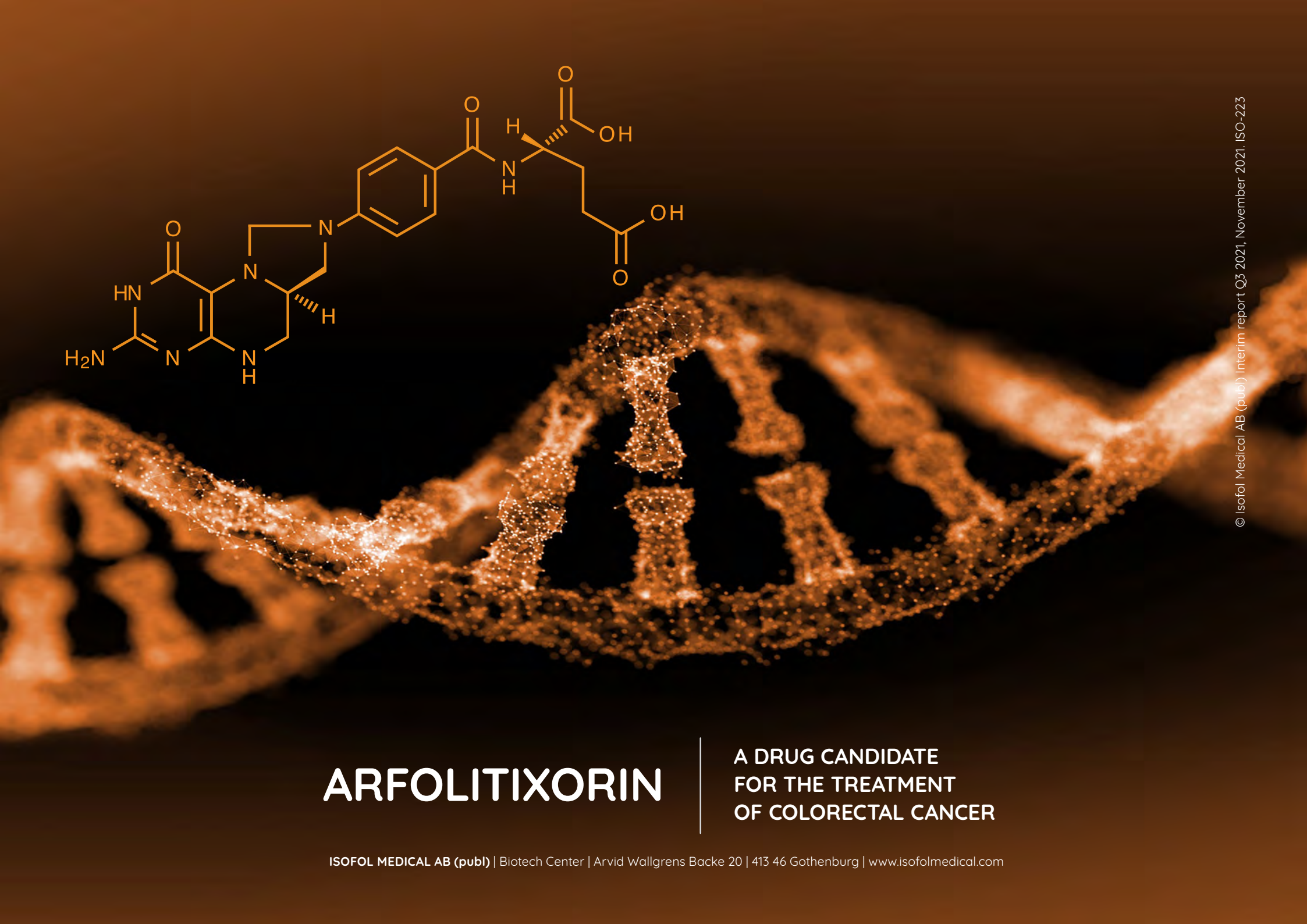
Ulf Jungnelius, CEO
Telephone: +46 709 16 89 55
Email: jungnelius@isofolmedical.com

Gustaf Albèrt, CFO, Deputy CEO
Telephone: +46 709 16 83 02
Email: gustaf.albert@isofolmedical.com

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

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

The information was submitted for publication, through the agency of the contact person set out above, at 8:00 CET, on November 11, 2021.



ARFOLITIXORIN

A DRUG CANDIDATE FOR THE TREATMENT OF COLORECTAL CANCER

ISOFOL MEDICAL AB (publ) | Biotech Center | Arvid Wallgrens Backe 20 | 413 46 Gothenburg | www.isofolmedical.com