



DexTech
Know-how in Translational Research

DexTech Medical AB
Interim report July 1- September 30, 2024

By "Company" or "DexTech" is meant DexTech Medical AB with organization number 556664-6203.

Summary of the first quarter (2024-07-01 – 2024-09-30)

- Net sales amounted to MSEK 0,0 (0,0)
- Operating profit/loss amounted to MSEK -1,3 (-1,1)
- Earnings per share* SEK -0.06 (-0.05)
- Cash and cash equivalents at the end of the period amounted to MSEK 17,9 (19,0)

** Before and after dilution. Earnings per share: Profit for the period divided by the average number of shares 18,485,857. For the comparison period, the average number of shares was 18,485,857. Amounts in brackets refer to the corresponding period last year.*

Comments from the CEO

The latest results from the Company's ongoing myeloma study, which was announced in August, showed that three out of four patients had stable disease after completing treatment. Stable disease means a slowing down of the course of the disease where the cancer does not progress. The patients who can be included in the study (inclusion criteria), must have relapsed/treatment-resistant disease and received 1-5 prior lines of therapy. The results are very important and promising, indicating that OsteoDex can slow relapsed/treatment-resistant disease. In addition, a clear decreasing effect on biomarkers related to bone cells, especially osteoclasts activity (bone resorption) is noted. Significantly, no OsteoDex related serious adverse events (SAEs) have been noted. The study is now progressing towards the two higher dose ranges of 6mg/kg and 9mg/kg. Patients who achieve stable disease after completion of treatment will be followed up until new progression, according to the approved amendment, which provides information on how long the treatment effect lasts.

General information about the study: Conducted at Uddevalla Hospital, Dr Dorota Knut, and Dr Katarina Uttervall dept. Haematology/HERM, Karolinska University Hospital, Huddinge, Katarina Uttervall is principal investigator (PI). Biomarkers are analysed at the Central Laboratory, Karolinska University Hospital, NKS, Solna. The primary objective is to confirm safety and tolerability and as a secondary objective to determine treatment response. Documentation of quality of life will also be done (QoL scores).

Anders R Holmberg

Significant events during the interim period (July 2024 - September 2024)

On August 12, DexTech Medical announced new positive results from the myeloma study. The Phase 1 study examines the effect of OsteoDex on patients with progressive multiple myeloma (MM). Progressive disease means that the disease progresses and does not respond to existing treatment. The first dose group (3mg/kg) is now ready and the DMC (Data Monitoring Committee) has approved the start of dose group 2 (6mg/kg). DMC assesses all analysis results to decide on the next higher dose. No side effects related to OsteoDex have been noted. All patients show a decrease in skeletal biomarkers. Three out of four patients have stable disease after completion of treatment (stable = no progression of the disease). Patients with stable disease will be followed up until new progress according to the approved amendment, which provides information on how long the treatment effect lasts.

Events after the end of the interim period

No events after the end of the interim period to report.

Financial overview

	Quarter 1	
	2024-07-01 2024-09-30	2023-07-01 2023-09-30
Net sales, TSEK	–	–
Profit after net financial items, SEK thousand	-1 139	-917
Earnings per share SEK*	-0,06	-0,05
* before and after dilution		
	2024-09-30	2024-06-30
Cash and cash equivalents SEK thousand	17 991	19 043
Balance sheet total TSEK	29 156	30 588
Equity ratio %	98	97

Results, The first quarter, July – September 2024

Turnover and earnings

The company had no sales during the first quarter. Operating profit amounted to MSEK -1,3 (-1,1). During the first quarter, costs of MSEK 0,6 (1,6) were capitalized for drug development and patents. Operating expenses amounted to MSEK 1,9 (2,7) and consist of personnel costs MSEK 0,2 (0,2), other external expenses MSEK 0,7 (1,8) and depreciation MSEK 0,9 (0,7). Other external costs include hospital costs MSEK 0,1, costs for patents MSEK 0,1 and regulatory control MSEK 0,3 regarding the MM-study. Profit after tax amounted to MSEK -1,1 (-0,9).

Liquidity and financing

Cash and cash equivalents at the end of the interim period amounted to SEK 18.0 (19.0) million.

Cash flow for the period amounted to SEK -1.1 (-1.6) million.

Financing is done with equity. Equity at the end of the interim period amounted to SEK 28.5 (29.6) million, corresponding to SEK 1.54 (1.60) per share. The equity/assets ratio was 98 (97) percent.

Working capital

In December 2021, DexTech carried out a rights issue that raised SEK 46.3 million before issue costs. Net proceeds of SEK 37.1 million to DexTech after issue costs of SEK 9.2 million. The Rights Issue 2021 ensured continued operations until the end of 2025. The goal is for license revenues to finance operations thereafter.

Activities

DexTech Medical, org.nr 556664-6203 based in Stockholm, Sweden, develops drug candidates with applications in urological oncology, primarily prostate cancer. Operations commenced on August 9, 2004 and the Company was listed on the Spotlight Stock Market on June 19, 2014.

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The company has a strong clinical foundation with valuable specialist expertise, from research laboratory and manufacturing to clinical oncology. Research and development is conducted cost-effectively through collaboration in a global network.

Based on a proprietary patented technology platform, GuaDex, the Company has developed four different drug candidates, OsteoDex, SomaDex, CatDex & GuaDex and a PSMA-binding conjugate, with patents/patent applications in several key markets.

- The company's lead candidate, *OsteoDex*, for the treatment of bone metastases in castration-resistant prostate cancer, CRPC, has after extensive preclinical studies shown strong tumoricidal effect and potent inhibition of bone degradation. After a successful phase I/IIa study where the results show high tolerability with only mild side effects and a clear effect in the highest dose group, a clinical phase IIb study (efficacy study) was initiated in the autumn of 2014. The full Phase IIb clinical study report (CSR) from the Phase IIb study for OsteoDex was completed in December 2018 and in June DexTech's Phase IIb study was completed with the receipt of 2-year follow-up results from the last patients. The study, which was conducted in Sweden, Finland, Estonia and Latvia, included 55 well-defined patients with castration-resistant prostate cancer with bone metastases (mCRPC).
- *SomaDex* for the treatment of acromegaly, neuroendocrine tumors and palliative care in advanced prostate cancer. SomaDex is a drug candidate based on an endogenous hormone, somatostatin, for the treatment of acromegaly, neuroendocrine tumors and palliative treatment in advanced prostate cancer. SomaDex has undergone a Phase I clinical study (in Sweden/Finland) and a Phase II pilot study in Mexico. The studies showed that SomaDex has few and mild side effects (phase I) and has a palliative effect in advanced prostate cancer (pilot study).
- *CatDex & GuaDex*: *GuaDex* is the so-called technology platform and is a charge-modified dextran molecule with tumor-toxic properties (kills tumor cells) and is a development of CatDex.
- *PSMA-binding conjugate*, for target-specific treatment of mCRPC that overexpresses PSMA (prostate specific membrane antigen). The compound is based on the platform, GuaDex.

DexTech's goal is to out-license each drug candidate no later than after completion of the phase II study.

The technology platform, which can be likened to a "Lego box" with multiple opportunities to build new molecules, can also be out-licensed.

The following parameters have been important for DexTech's positive development to date:

- modified generics with well-documented mechanisms of action that are patented, entailing a lower risk in clinical development;
- early proof-of-concept data;
- strong clinical foundation with daily contact in clinical oncology;
- networked, academically and commercially;
- minimized fixed costs;
- Capital has been dedicated to drug development and patents.

Prostate cancer

- Prostate cancer is the most common form of cancer in men in the Western world.
- About 25% of those who have prostate cancer develop incurable castration-resistant prostate cancer (CRPC) with bone metastases.
- Today, there are only a handful of approved drugs that can prolong the lives of these patients. All of these drugs have more or less serious side effects. Each of these drugs currently has, or is expected to achieve, sales of over USD 1 billion annually, so-called blockbusters.
- After a limited time, CRPC becomes resistant to the respective drug, which means that the need for new complementary life-prolonging drugs is great.
- DexTech's lead candidate, OsteoDex, has the potential to become such a complementary drug.

The Phase IIb study

The original study protocol with ID ODX-002, was approved by the Swedish and Danish Medical Products Agencies in October 2014 (a placebo-controlled randomized multicenter phase II study) regarding OsteoDex for the treatment of castration-resistant prostate cancer with bone metastases (CRPC). On October 27, 2015, DexTech decided to change the study design and give all study patients active substance (OsteoDex). This is as a result of discussions with the Medical Products Agency in Uppsala and advice from "BigPharma". The study design was changed to active treatment for all patients. DexTech thus gains faster knowledge about the tumor-inhibiting effect in relation to dose, the efficacy parameter requested by prospective licensees. DexTech also responded to patients' requests for access to the active substance and thus avoid the risk of randomization to the placebo group. A decision to approve the new study protocol with ID ODX-003 was given by the Medical Products Agency in Uppsala on February 28, 2016.

The primary objective of the Phase II study was to document the efficacy of OsteoDex in the treatment of CRPC. The study included 55 well-defined CRPC patients. Patients were divided between three treatment arms (blinded distribution, 3 ascending dose levels of OsteoDex). The treatment was given for 5 months where OsteoDex was administered every two weeks. The study was conducted in Sweden (Norrländ University Hospital in Umeå, Södersjukhuset in Stockholm and University Hospital in Örebro), in Finland (Tampere University Hospital), in Estonia (East Tallin Central Hospital and Tartu University Hospital) and in Latvia (Riga East University Hospital and Daugavpils Regional Hospital). The first patient received his first treatment in September 2016 at Södersjukhuset in Stockholm.

In connection with these changes, the company chose to change the study organization by recruiting Crown-CRO Oy as GCP manager (good clinical practice) for the OsteoDex study. Crown-CRO Oy specializes in oncology studies in the Nordic and Baltic countries. Crown-CRO Oy replaces the company's former partner SynteractHCR.

In June 2018, the last patients in DexTech's phase IIb study for OsteoDex were completed. The work was then focused on the completion of the formal study report.

At the beginning of October 2018, DexTech was able to present the first results from the completed phase IIb study for OsteoDex. The results obtained meet the primary objective of the protocol.

The Clinical Study Report (CSR) shows that 51 percent of patients completed the treatment (5 months, dose every two weeks). Of these, 52% showed stable disease (improved/unchanged) regarding bone metastasis. 35% of patients who completed treatment had a reduced tumour burden in the bones. The majority of the patients who had a reduced tumour burden in the skeleton had been treated with and no longer responded to two or more of the currently available drugs (docetaxel, cabazitaxel, abiraterone, enzalutamide, radium-223 dichloride) prior to enrolment in the study. This finding is of great importance for the continued clinical development of OsteoDex as the current patient group represents a significant so-called "unmet medical need". The results show that OsteoDex has a significant inhibitory effect on the vicious cycle ("vicious circle") in the skeleton, i.e. the biological process that drives this disease and thus also to shortened survival. More than 50% of patients showed marked decreases in the levels of markers related to bone metabolism and a particularly marked decrease was noted in 67% of patients for the marker CTX, which reflects bone degradation. The effect on this marker and other markers related to bone metastasis reflects the biological effect of the OsteoDex molecule. Tolerability was remarkably good with only few side effects. No patients needed to discontinue treatment due to adverse events and no OsteoDex-related serious adverse events (SAEs) were noted. The three dose arms in the protocol show equivalent treatment effect. The interpretation is that even the lower doses are sufficient to saturate the metastasis areas in the bones.

DexTech has previously reported promising follow-up results from the company's Phase IIb study of OsteoDex for the treatment of castration-resistant metastatic prostate cancer (mCRPC). Patients were then followed for survival for 24 months after completion of OsteoDex treatment. The results as of October 14, 2020 showed the following: of the patients who had stable (unchanged) bone metastasis disease at the end of treatment, 58% were alive, of the patients who had discontinued or discontinued treatment with progressive disease (progressive disease progression) were alive, and of the patients who had objective regression of bone metastases (reduction of existing bone metastases) at the end of treatment, 86% were alive. The results indicate prolonged survival after OsteoDex treatment.

DexTech announced on June 12, 2020 that the randomized phase IIb study for the treatment of bone metastatic castration-resistant prostate cancer (mCRPC) was completed with the receipt of 2-year follow-up results from the last patients.

DexTech Medical

The study's primary endpoints regarding markers of bone metabolism had been well achieved. A clear majority of patients showed a reduction in their bone markers in blood from the given treatment with OsteoDex. The treatment was very well tolerated (few and mild side effects) and good disease-inhibiting effect was seen even in the lowest doses. Slowing and regression of the disease was also seen in patients whose disease progressed after treatment with several of the other available medications for castration-resistant prostate cancer.

The study's secondary endpoints include overall survival that was studied through 24 months of follow-up after completion of treatment. Of the patients who responded to treatment, with slowing or stabilisation of the disease, the median survival had not yet been achieved (> 27 months, thus a positive result), compared to 14 months for the other patients (significance, $p < 0.05$). The 2-year survival rate after study entry was 65% for patients who responded to treatment, with disease slowing or stabilisation, compared to 28% for other patients (significance, $p < 0.05$).

The results of the study were very positive and show that OsteoDex effectively slows down the tumor disease. Data regarding overall survival should be seen as an indication, as these data, for natural reasons, need to be confirmed in a significantly larger, so-called Phase-III study.

None of the modern drugs are curative for castration-resistant prostate cancer and there is therefore a great need (unmet need) for new potent and tolerable drugs. OsteoDex has a clear potential to fill this need.

The continued clinical development of OsteoDex will be carried out by or together with a prospective licensee.

Preclinical research

OsteoDex has a mechanism of action against cancer cells that is general, and therefore other cancers have also been investigated as possible indications in addition to mCRPC, i.e. breast cancer, lung cancer and multiple myeloma.

Breast cancer

There are significant similarities between castration-resistant prostate cancer and advanced breast cancer in terms of propensity to metastasize to the bones. DexTech's preclinical studies conducted so far have clearly shown that OsteoDex has promising potential for the treatment of this form of cancer as well. The value of the breast cancer drug market (total sales) in the United States, Western Europe and Japan is estimated to be more than USD 15 billion by 2022 (Decision Resources 2013). The expanded preclinical program is part of the company's strategy to demonstrate OsteoDex's potential beyond the indication of castration-resistant prostate cancer.

Lung cancer

DexTech has previously announced data from preclinical studies regarding the effect of OsteoDex on the most common form of lung cancer, so-called non-small cell lung cancer (NSCLC). In conducted in vitro trials at Karolinska Institutet, OsteoDex shows a robust cell-killing effect in non-small cell lung cancer (NSCLC). The cell-killing effect was found to be completely on par with that seen in castration-resistant prostate cancer and breast cancer.

Lung cancer is divided into two main groups; non-small cell lung cancer and small cell lung cancer. Approximately 80 percent of all lung cancer cases are non-small cell lung cancer (NSCLC), which in turn is divided into several subgroups. Globally, >1.5 million people are diagnosed with lung cancer every year, and the vast majority of these die from it. The lack of active and well-tolerated drugs is strikingly great.

Multiple Myeloma

DexTech has conducted an extensive preclinical program regarding the effect of OsteoDex on multiple myeloma. In vitro experiments conducted at Karolinska Institutet show that OsteoDex has a robust cell-killing effect on myeloma cells. The cell-killing effect has been shown to be superior to the standard drug Melphalan.

MM is a form of blood cancer that starts in the bone marrow and causes the breakdown of the bones. The disease is incurable and the treatments that are currently available are used to, as far as possible, slow down the progression. The treatments often have severe side effects.

The company sees OsteoDex as very promising for the treatment of MM and has therefore decided to conduct a phase 1 study regarding the effect of OsteoDex on patients with multiple myeloma. This is

DexTech Medical

based on OsteoDex's dual mechanism of action, inhibition of bone-degrading cells and tumor cell toxicity as well as with mild side effects, verified in clinical results.

On August 10, 2022, the Swedish Medical Products Agency approved and granted permission to conduct the phase 1 study regarding the effect of OsteoDex on patients with multiple myeloma.

DexTech announced on March 27, 2023 that the Company's Phase 1 study regarding the effect of OsteoDex on patients with multiple myeloma (MM) has been initiated and recruitment of patients has begun. The study includes 20 patients and is initially being conducted at three hospitals in Sweden: Karolinska University Hospital Huddinge, Uddevalla Hospital and Södersjukhuset in Stockholm. Another center in Sweden may be connected at a later date.

The study is expected to be completed in Q2, 2025. The Principal Investigator (PI) is Dr Katarina Uttervall, MD, PhD, Department of Hematology/HERM, Karolinska University Hospital Huddinge. Analysis of main blood markers takes place at the Central Laboratory, Karolinska University Hospital Solna, NKS. In accordance with the treatment schedule, OsteoDex is given every two weeks. The inclusion criteria include adult MM patients with *relapsed/treatment-resistant disease*, who received 1–5 prior lines of therapy. The primary objective is to confirm safety and tolerability. The secondary objective is to determine treatment response, change in the level of disease-related biomarkers, and documentation of quality of life.

PSMA-binding association

In June 2016, DexTech filed a patent application for important innovation regarding companion diagnostics and target-specific treatment of prostate cancer.

It is well known that prostate cancer cells on their surface overexpress (present in larger quantities) the protein PSMA (prostate-specific membrane antigen, i.e. PSMA is found in greater quantities on the surface of the tumor cell). Extensive international research activity is underway to produce molecules that can bind specifically to PSMA and thus be used as carriers of cancer cell-killing substances (radioactive isotopes, cytostatics, etc.) for so-called target-specific treatment of prostate cancer. Such molecules (including antibodies to PSMA) have been produced in several laboratories, but there are still challenges regarding production for clinical use, shelf life, patent protection, regulatory requirements, etc.

DexTech has developed a new PSMA-binding compound with the help of the company's technology platform. The new substance has unique properties in that it has multiple PSMA-binding parts and can carry a larger load of cell-killing substances than has been possible with PSMA-specific molecules produced so far. The production of the new substance can be relatively easily adapted to the company's GMP platform (i.e. manufacturing that is approved for clinical use). The current patent application complements and strengthens the company's other patents. DexTech intends to seek a development partner for the pre-clinical/clinical development of the new drug candidate.

In June 2016, DexTech filed a patent application for an important innovation (patent family 4) regarding diagnosis (so-called companion diagnostics) and target-specific treatment of prostate cancer, PSMA. This application was approved for a patent in Finland in June 2018. In the autumn of 2017, DexTech filed an international patent application (so-called PCT application). Patents have now been granted in Europe, Israel, Canada and Japan.

Patent

DexTech's patent portfolio includes four patent families and a new application for GMP manufacturing of OsteoDex (October 2023). Patents/applications provide strong protection of the Company's drug candidates and the Company's technology platform. The portfolio has a relevant geographical spread for DexTech. The Company's four patent families/patent applications are strongly related and each patent family is therefore relevant for all of the Company's drug candidates as well as for the platform, GuaDex. Patent applications are filed in countries where there is advanced pharmaceutical research and development and in countries that are larger markets for pharmaceutical products.

Patent family 1 - filed in 1999

Patent family 1 describes how the positively charged substance, CatDex, is selectively enriched in the tumor tissue, i.e. selectively relative to normal tissue.

Patent family 1 includes approved patents in Australia, Canada, the United States, and Europe (registered in Belgium, Switzerland, Germany, France, the United Kingdom, Italy, and Sweden). The patent was valid until October 12, 2019.

DexTech Medical

Patent family 2 filed in 2008

Patent family 2, the GuaDex patent, a further development of patent family 1, describes its tumor cell-killing properties against a number of different tumors, tumor cell cultures.

Patent family 2 includes approved patents in China, Finland, Israel, the United States, Mexico, Canada, Japan, and Europe (registered in Switzerland, Germany, France, the United Kingdom, Italy, and Sweden). The patent is valid until March 6, 2028.

Patent family 3 - filed in 2008

Patent family 3, the OsteoDex patent, is a GuaDex molecule with an additional component, a bisphosphonate, which has selectivity for the skeleton, i.e. where the metastasis is located.

Patent family 3 includes approved patents in China, Japan, Canada, Israel, Mexico, Brazil and Europe (registered in Switzerland, Germany, France, United Kingdom, Italy and Sweden). The patents are valid until April 7, 2028.

Patent family 4 - filed in 2016

In June 2016, DexTech filed a patent application for an important innovation (patent family 4) regarding diagnosis (so-called companion diagnostics) and target-specific treatment of prostate cancer, PSMA. This application was approved for a patent in Finland in June 2018. In the autumn of 2017, DexTech filed an international patent application (so-called PCT application). The application has been approved and patents have been granted in Europe, Israel, Canada and Japan. The patents are valid until 2036.

Patent family 5 - filed in 2023

The company has filed a new patent application with the European Patent Office regarding GMP manufacturing of OsteoDex (GMP= good manufacturing practice). Granted application means patent protection until about 2044. Access to GMP manufacturing is a prerequisite for conducting clinical research.

Prospects

DexTech's lead drug candidate OsteoDex has a unique dual mode of action, tumor-specific denaturation and inhibition of bone resorbing cells (osteoclasts). OsteoDex has been studied in a clinical phase II study with good results. There are significant similarities between bone metastases from mCRPC and Multiple Myeloma, such as growth site, bone degradation, and stimulation from osteoclasts.

These similarities have motivated DexTech's studies of OsteoDex's effects on Multiple Myeloma. In extensive preclinical studies conducted at Karolinska Institutet in Stockholm, the company has shown that OsteoDex has a very pronounced tumor cell-killing effect, which has been demonstrated on various Multiple Myeloma cell lines. OsteoDex shows strong efficacy even at low concentrations. Even compared to Melphalan, which is a proven standard drug for the treatment of multiple myeloma (MM), OsteoDex's effect is strikingly strong

The project is now being developed into clinical research and a formal protocol is being prepared. On August 10, 2022, the Swedish Medical Products Agency approved and granted the application for a phase 1 study regarding the effect of OsteoDex on patients with multiple myeloma. The study will include 20 patients and will be conducted at 3 hospital centers in Sweden. The study is expected to be completed in Q2 2025.

The intention is that the study will provide proof of concept and thus further verify OsteoDex's value as a potential cancer drug. The market for the new indication is estimated to be twice as large as that for mCRPC. The Rights Issue 2021 finances the Multiple Myeloma study and ensures continued operation until the end of 2025.

The continued clinical development of OsteoDex with the indication mCRPC, i.e. towards phase III, is very resource-intensive and requires large investments and will be carried out by a prospective larger partner. One of the motives/requirements for such an investment is patent protection, i.e. long market exclusivity. With the new synthesis patent application approved, the requirement for long-term market exclusivity is met.

Organization

Anders R Holmberg is the CEO. The Board of Directors consists of Chairman of the Board Andreas Segerros and Board members Per-Olov Asplund, Peter Benson, Rolf Eriksson, and Svante Wadman.

DexTech Medical

Financial information

AGM*	31 October 2024
Half-year report 2024/2025	February 27, 2025
Q3 report 2024/2025	April 29, 2025
Year-end report 2024/2025	August 30, 2025

* The Annual General Meeting will be held in Stockholm on October 31, 2024.

Contact

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This information is such information that DexTech Medical AB is required to disclose in accordance with the EU Market Abuse Regulation. The information was submitted for publication on October 24, 2024 through the care of the above contact persons.

Stockholm October 24, 2024

DexTech Medical AB

Board of Directors

This report has not been reviewed by the Company's auditor.

This report is an in-house translation of the original report in Swedish

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SUMMARY OF INCOME STATEMENTS

KSEK	Quarter 1	
	2024-07-01	2023-07-01
	2024-09-30	2023-09-30
Net sales	-	-
Work performed by the company for its own use and capitalized	585	1 646
Operating expenses	-1 878	-2 732
Operating profit/loss	-1 293	-1 086
Net financial profit/loss	154	169
Profit/loss before tax	-1 139	-917
Tax	-	-
Net profit/loss	-1 139	-917
Earnings per share, SEK *	-0,06	-0,05
Average number of shares, thousand *	18 485 857	18 485 857

* Before and after dilution.

SUMMARY BALANCE SHEETS

KSEK	2024-09-30	2024-06-30
Assets		
Intangible assets	10 572	10 907
Financial assets	1	1
Receivables	592	637
Cash and cash equivalents	17 991	19 043
Total assets	29 156	30 588
Equity and liabilities		
Equity	28 469	29 608
Current liabilities	687	980
Total equity and liabilities	29 156	30 588

SUMMARY CASH FLOW ANALYSIS

KSEK	2024-07-01	2023-07-01
	2024-09-30	2023-09-30
Cash flow from operating activities	-466	35
Cash flow from investing activities	-586	-1 646
Cash flow for the period	-1 052	-1 611
Cash and cash equivalents at the beginning of the period	19 043	25 236
Cash and cash equivalents at the end of the period	17 991	23 624