Martin Welschof, CEO:

"BioInvent further strengthened its financial position in the third quarter through a directed share issue. With this solid foundation, we have continued our strong clinical progress and look forward to a number of significant drug development milestones."

BioInvent at a glance as of September 30, 2022

5	10+	93	1,664
projects in clinical development	Licensing, supply and collaboration agreements	employees (full time equivalent)	SEKm in liquid funds etc

FINANCIAL INFORMATION

Third quarter 2022

- Net sales SEK 17.9 (3.0) million.
- Profit/loss after tax SEK -63.9 (-62.6) million.
- Profit/loss after tax per share before and after dilution SEK -1.00 (-1.07).
- Cash flow from operating activities SEK 172.8 (-57.5) million.

January – September 2022

- Net sales SEK 305.5 (14.5) million.
- Profit/loss after tax SEK 35.8 (-199.7) million.
- Profit/loss after tax per share before and after dilution SEK 0.59 (-3.79).
- Cash flow from operating activities SEK 30.4 (-170.1) million.
- Liquid funds, current and long-term investments as of September 30, 2022: SEK 1,664.3 (1,445.3) million.

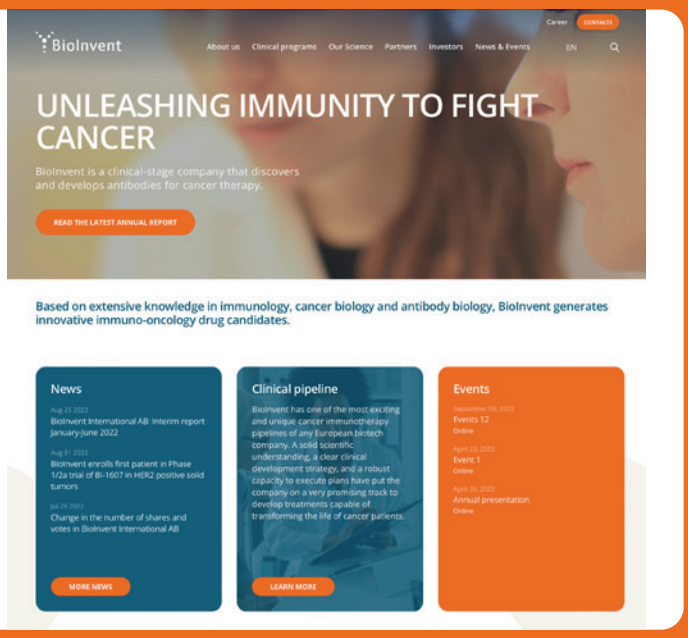
The information was submitted for publication, through the agency of the contact person set out on page 23, at 8:00 a.m. CEST on October 27, 2022.

Q3 Highlights

EVENTS IN THE THIRD QUARTER

- (R) BioInvent successfully carried out a directed share issue of approximately SEK 300 million
- (R) Natalie Berner of Redmile and Nanna Lüneborg of Forbion elected as new Board members of BioInvent
- BioInvent received the upfront payment of MUSD 25 from the option and license agreement with Exelixis
- First patient enrolled in Phase 1/2a trial evaluating BI-1607 for the treatment of HER2 positive solid tumors
- BioInvent completed the planned dose-escalation in Phase 1/2a trial of BI-1808 in advanced malignancies
- CASI Pharmaceuticals and BioInvent dosed first patient in BI-1206 Phase 1 clinical trial for the treatment of relapsed/refractory non-Hodgkin's lymphoma in China

(R)= Regulatory event



Visit our new web site

On October 21, BioInvent launched its new web site. The site has been developed to better reflect the strong progress the company has undergone the past couple of years. The new site also makes it easier for you to find the information you are looking for. We hope you will enjoy it.

https://bioinvent.com

Martin Welschof
CEO

Share issue provides foundation for major clinical milestones

BioInvent further strengthened its financial position in the third quarter through a directed share issue. With this solid foundation, we have continued our strong clinical progress and look forward to several significant drug development milestones.

BioInvent received proceeds of approximately SEK 300 million from the share issue, before transaction costs. A number of international and Swedish investors participated, including new investors such as AXA Investment Managers and a US institutional investor and existing shareholders such as Forbion, HBM Healthcare Investments, Redmile Group, Invus, the Fourth National Swedish Pension Fund and Swedbank Robur Fonder. Demand for the new shares, at a price corresponding to a premium compared to the closing price on the day of the announcement, exceeded the size of the directed share issue.

Our strategy is to finance the company from a position of strength, and this was an ideal opportunity to do so given our strong clinical progress, and the deal with the US biotech company Exelixis in June. We now have an even stronger investor base, and our financial position enables us to deliver on pipeline development milestones with multiple drug candidates. I am particularly pleased that we were able to execute this financing at a time of market turbulence, and that our position is strengthened during a potentially extended period of uncertainty.

MOVING FORWARD

Our clinical pipeline of exciting novel and first-in-class immuno-modulatory antibodies for cancer therapy continues to make strong progress.

Together with our partner CASI Pharmaceuticals, we dosed the first patient in a Phase 1 dose-escalation and expansion study in China of our lead drug candidate BI-1206. This study will examine the FcγRIIB-targeting monoclonal antibody in combination with rituximab in patients with Non-Hodgkin's Lymphoma (NHL). The study is designed to assess the safety, tolerability, pharmacology, and clinical activity of BI-1206, and marks an expansion of the ongoing clinical program. The study will generate valuable information and has the potential to provide further evidence of clinical activity in the treatment of relapsed or refractory NHL.

We have completed the planned dose escalation part of the Phase 1/2a trial of the anti-TNFR2 drug candidate BI-1808. BI-1808 was shown to be safe and well tolerated with no serious adverse events or dose-limiting toxicity observed during dose-escalation. Furthermore, we have seen first signs of efficacy with BI-1808 as a single agent.

Given the positive safety and tolerability profile observed so far, a higher dose of BI-1808 as single agent will be tested to explore the effect of higher exposure. Completion of dose escalation also triggered the start of combination study of BI-1808 and pembrolizumab.

These interim results are a further reinforcement of the very promising data generated so far on BI-1808. Furthermore, translational data have shown similar biomarker correlations in patient samples as we have previously observed in the preclinical setting.

A FIFTH CLINICAL TRIAL

Our second anti-FcγRIIB antibody, BI-1607, is also making good progress, with the initiation of a Phase 1/2a trial in combination with trastuzumab in HER2+ solid tumors. We are currently in the dose escalation part of the study and the selected dose of BI-1607 will be studied in a subsequent Phase 2a part of the trial along with trastuzumab in advanced breast, metastatic gastric and gastroesophageal junction HER2+ cancers.

This marks BioInvent's fifth clinical trial, with four distinct drug candidates, and it is a further demonstration of the productivity of our technology platform. Another important clinical milestone, the start of the subcutaneous formulation Phase 1 study with BI-1206, is expected by the end of 2022.

We are looking forward to reviewing these highlights, and upcoming news flow, with you at our planned R&D Day in Stockholm on December 8. More information on this event will be provided shortly.

Next year promises to be highly exciting as we plan to report data from several clinical trials with potentially significant progress towards helping patients in need of effective cancer treatments. I would like to take this opportunity to thank you once again for your continuing support, and I look forward to speaking regularly as we progress our drug candidates towards market.

Martin Welschof, CEO

Pipeline with five clinical programs

BioInvent is focused on developing novel immuno-modulatory antibodies for cancer therapy. These innovative antibodies may significantly improve the efficacy of currently available checkpoint inhibitor and/or activate anti-cancer immunity in currently non-responding patients.

Target: FcγRIIB	Indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
BI-1206/rituximab	NHL (MCL, MZL, iFL)					CASI
BI-1206/pembrolizumab	Solid tumors					CASI, MSD*
BI-1607/ trastuzumab	Solid tumors					

Target: TNFR2 and CTLA-4						
BI-1808 (TNFR2)	Solid tumors					MSD*
BT-001 (CTLA-4, GM-CSF)	Solid tumors					transgene, MSD*
BI-1910 (TNFR2)	Solid tumors					

Completed
Ongoing
Up-coming

* Clinical supply and collaboration agreement

Clinical programs

BioInvent has one of the most exciting and unique cancer immunotherapy pipelines of any European biotech company. A solid scientific understanding, a clear clinical development strategy, and a robust capacity to execute plans have put the company in on very promising track to develop treatments capable of transforming the life of cancer patients.

BI-1206

BI-1206 is BioInvent's most advanced drug candidate and is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab, drugs with a combined global sales of approximately USD 21 billion annually. The drug candidate is evaluated in two separate clinical trials, one for the treatment of non-Hodgkin's lymphoma (NHL, a type of blood cancer) and one for the treatment of solid tumors.

BI-1206 in NHL

In December 2021, positive interim Phase 1 data were presented suggesting that BI-1206 restores the activity of rituximab in relapsed NHL patients. The quality of the responses is particular impressive with patients still doing well two years after ending cancer treatment.

BI-1206 in solid tumors

For the solid tumor setting, early observations from clinical Phase 1 are that BI-1206 in combination with pembrolizumab may stem and reverse metastatic disease progression in patients who have previously progressed on PD-1/PDL-1 therapies and other prior treatments.

BI-1808

BI-1808 is aimed for the treatment of solid tumor disease such as non-small cell lung cancer (NSLC) and ovarian cancer. It is currently evaluated in a clinical Phase 1/2a trial which will study BI-1808 as a single agent as well as in combination with pembrolizumab. Interim results in September 2022 displayed favorable tolerability and three disease stabilizations.

The anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate. TNFR2 has been shown to be important for tumor expansion and survival, representing a new and promising target for cancer immunotherapy.

BT-001

BT-001 is a drug candidate being developed in collaboration with the French biotech company Transgene. BT-001 is an oncolytic virus armed with BioInvent's anti-CTLA-4 antibody. When the virus is infecting the tumor cells it releases the anti-CTLA-4 locally in the tumor, decreasing the risk for systemic side-effects. In June 2022, positive data were presented from the ongoing clinical Phase 1/2a study.

BI-1607

BI-1607 is an FcγRIIB-blocking antibody but differs from BI-1206 in that it has been engineered for reduced Fc-binding to FcγRs. Preclinical proof-of-concept data indicate that combined treatment with BI-1607 may both enhance efficacy of current anti-HER2 regimens and increase response rates in patients no longer responding to anti-HER2-directed therapies such as trastuzumab. A Phase 1/2a study is ongoing since July 2022.

BI-1206 in non-Hodgkin's lymphoma

BI-1206 is a high-affinity monoclonal antibody that selectivity binds to FcγRIIB (CD32B), the only inhibitory member of the FcγR family. FcγRIIB is overexpressed in several forms of NHL and overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma. By blocking FcγRIIB, BI-1206 is expected to recover and enhance the activity of rituximab or other anti-CD20 monoclonal antibodies in the treatment of these diseases. The combination of the two drugs could provide a new and important option for patients suffering from NHL and represents a substantial commercial opportunity.

Status: clinical phase 1/2a study with BI-1206 in combination with rituximab for the treatment of non-Hodgkins lymphoma (NHL) (NCT03571568)	In May 2022, BioInvent announced that BI-1206 is allowed to progress into the expansion phase of the Phase 1/2a trial, following a positive End-of-Phase 1 meeting with the US FDA. The ongoing expansion Phase 2a part of the study started dosing patients at 100 mg of BI-1206. Once the Phase 1/2a data package is completed, the plan is to move forward with a randomized, controlled, potentially pivotal Phase 2 study. In December 2021, positive interim top-line data were presented showing increased response levels and sustained complete responses in the ongoing clinical Phase 1/2a study of BI-1206 in combination with rituximab for the treatment of non-Hodgkin's lymphoma (NHL). The response rate for follicular lymphoma was particularly impressive: of nine evaluable patients, three developed a complete response, three developed a partial response and one patient had stable disease at the cut-off date, giving an objective response rate (ORR) of 67% and 78% disease control rate (DCR). Overall, the study provided an ORR of 54%, with three complete responses and four partial responses in 13 patients evaluated for therapeutic benefit for the three indications (mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma) enrolled. The treatment stabilized disease in one additional patient, giving an overall DCR of 62% (8 out of 13 patients). All three complete responses have been sustained for extended periods, with the longest complete response enduring beyond 36 months. In two patients, complete responses have lasted beyond 12 and 24 months after end of treatment. Previous rituximab treatments without BI-1206 had failed in these patients, prior to participation in the trial all patients had relapsed on earlier lines of rituximab-containing treatments.
Study design	The Phase 1/2a study is divided into two parts: 1) Phase 1, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase 2a dose (RP2D); and 2) Phase 2a, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma. Patients in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Those who show clinical benefit at week 6 continue onto maintenance therapy and receive BI-1206 and rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 1 year from first dose of BI-1206.
Orphan Drug Designation for the treatment of FL and MCL	In January 2022, BI-1206 was granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of follicular lymphoma (FL), the most common form of slow-growing Non-Hodgkin lymphoma. The FDA's Office of Orphan Drug Products grants orphan status to support the development of medicines for rare disorders that affect fewer than 200,000 people in the U.S. Since 2019, BI-1206 has ODD for mantle cell lymphoma.
Clinical development in China with BI-1206 in combination with rituximab and as single-agent	In September 2022, the first patient was enrolled in China to a Phase 1 dose-escalation and expansion study of BI-1206. The study will assess the safety, tolerability, pharmacology, and clinical activity of BI-1206. The patient was enrolled at Henan Cancer Hospital. CASI is performing clinical Phase 1 trials with the aim to further evaluate the PK profile of BI-1206 in combination with rituximab in NHL (mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma) to assess safety and tolerability, select the Recommended Phase 2 Dose and assess early signs of clinical efficacy as part of its development program for BI-1206 in China and associated markets.
Outlook	BioInvent's Phase 1 trial of the subcutaneous formulation of BI-1206 is on track to begin in H2 2022 and the first results are expected in H1 2023.
Out-licensing and partnering	Since October 2020, BioInvent has a licensing agreement in place with CASI Pharmaceuticals for the China region. Under the terms of the agreement, BioInvent and CASI will develop BI-1206 in both hematological and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent received USD 12 million upfront in combination of cash and equity investment and eligible to receive up to USD 83 million in milestone payments, plus tiered royalties.

BI-1206 in solid tumors

BI-1206 is a high-affinity monoclonal antibody that selectivity binds to FcγRIIB (CD32B), the only inhibitory member of the FcγR family. The ongoing clinical program is based on BioInvent's preclinical data demonstrating the ability of BI-1206 to address an important mechanism of resistance to PD-1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors.

Status: clinical phase 1/2a study with BI-1206 in combination with pembrolizumab (NCT04219254)	Early observations indicate that BI-1206 in combination with pembrolizumab may reverse metastatic disease progression in patients who have previously progressed on PD-1/PDL-1 therapies. Aside infusione related reactions, no major safety concerns have been observed and dose-escalation will continue. Current patient cohort is dosed at 2 mg/kg.
Study design	The Phase 1/2a is a multicenter, dose-finding, open-label study of BI-1206 in combination with pembrolizumab (Keytruda®) in patients with advanced solid tumors. Patients in the study will previously have received treatment with PD-1/PD-L1 immune checkpoint inhibitors. It is conducted at several sites across the US and Europe and will assess potential signs of antitumoral activity, as well as exploring the expression of potential immunological markers that might be associated, and eventually predict clinical responses. The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BI-1206 in combination with Keytruda. The Phase 1 part is a dose escalation study with the aim to determine the recommended Phase 2 dose (RP2D) of BI-1206 in combination with Keytruda. The Phase 2a part will study the BI-1206/Keytruda combination treatment in patients with advanced lung cancer, melanoma and other types of malignancies.
Positive early clinical data	As of the fourth quarter 2021, eleven patients in three dose cohorts have been treated with BI-1206 in combination with pembrolizumab. During the study period, a patient with stage IV sarcoma was able to stop all pain medication, the coughing disappeared, and the shortness of breath markedly improved. From the time of ending participation in the BI-1206 study, the patient did not receive any other anti-cancer treatment and showed on a scan performed in September 2021 that some metastatic lesions have disappeared, some are smaller, and others have not changed. No lesions have grown, and no new lesions are evident. Another patient, with uveal melanoma, demonstrated a partial response and is still on treatment with the combination of BI-1206 and pembrolizumab. Metastatic uveal melanoma is a difficult-to-treat disease, with median overall survival of approximately 13.4 months, with only 8% of patients surviving after 2 years. (Uveal melanoma: epidemiology, etiology, and treatment of primary disease, Krantz et al, Clin Ophthalmology 31 Jan 2017.)
Outlook	A Phase 1 trial with a subcutaneous formulation of BI-1206 is expected to begin in H1 2023. This new formulation is expected to circumvent infusion relatwed reactions.
Out-licensing and partnering	In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BioInvent's BI-1206 and MSD's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial for patients with solid tumors. Under the agreement, MSD supplies Keytruda which supports the evaluation of BI-1206 for the treatment of solid tumors in combination with one of the most successful immuno-oncology drugs.

BI-1808 in solid tumors and CTCL

The anti-TNFR2 antibody BI-1808 is part of BioInvent's tumor-associated regulatory T cells (Treg)-targeting program. TNFR2 is particularly upregulated on Tregs of the tumor micro environment and has been shown to be important for tumor growth and survival, representing a new and promising target for cancer immunotherapy. Two different types of TNFR2 targeting antibodies are being developed by BioInvent. In addition to BI-1808, the company also has BI-1910 (a TNFR2 agonist) in late-stage IND-enabling preclinical studies.

Status: Clinical phase 1/2a study (NCT04752826)	In September 2022, the planned dose escalation part of the Phase 1/2a trial was completed. Given the positive safety and tolerability profile observed, a higher dose of BI-1808 as single agent will be tested to explore the effect of higher exposure. In the ongoing study, BI-1808 was shown to be safe and well tolerated with no serious adverse events or dose-limiting toxicity observed during dose-escalation. Only grade 1 and 2 adverse events related or possibly related to BI-1808 were observed during treatment. Three disease stabilizations were observed during the escalation process. Completion of the planned dose escalation phase of BI-1808 as single agent triggered the initiation of cohorts of BI-1808 in combination with Keytruda. At the AACR (American Association for Cancer Research) annual meeting in April 2022 (AACR22) exciting translational data were presented. In vivo studies using experimental cancer models show a clear relationship between dose, receptor occupancy (RO) and efficacy. Furthermore, correlations between dose, RO and soluble TNFR2 have been observed in patients in the ongoing Phase 1/2a clinical trial. Results from toxicological studies demonstrate a very good tolerability profile and there have been no safety concerns in the clinical trial to date. In April 2021, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug (IND) for the BI-1808 Phase 1/2a clinical study. The study is currently conducted in Denmark, Hungary, Sweden and the United Kingdom.
Study design	Since January 2021, patient enrollment is ongoing in Europe. During the first part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent and in combination with the anti-PD-1 therapy Keytruda will be evaluated in patients with advanced solid tumors and CTCL. In the subsequent part of the Phase 1/2a study, BI-1808 as single-agent and in combination with the anti-PD-1 therapy Keytruda will be further evaluated in expansion cohorts in patients with ovarian cancer, non-small cell lung cancer and CTCL. The study is expected to enroll a total of approximately 120 patients.
Outlook	Further results from the Phase 1 single-agent study are expected in H1 2023. First data from the Keytruda combination study are expected in H2 2023.
Out-licensing and partnering	Since August 2021, BioInvent has a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BI-1808 and MSD's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial in patients with advanced solid tumors. Under the agreement, MSD supplies Keytruda which supports the evaluation of BI-1808 in combination with the most successful immuno-oncology drug in the market.

BT-001 in solid tumors

BT-001 is an oncolytic virus developed with Transgene's Invir.IO™ platform, engineered to express both a Treg-depleting human recombinant anti-CTLA-4 antibody generated by BioInvent's proprietary n-CoDeR/F.I.R.S.T platforms, and the human GM-CSF cytokine. The differentiated and potent anti-CTLA-4 mAb was generated using BioInvent's proprietary n-CoDeR/F.I.R.S.T platforms. The use of an oncolytic virus to deliver the anti-CTLA-4 directly in the tumor microenvironment allows high intratumoral antibody concentrations, eliciting a stronger and more effective antitumoral response. Reducing systemic exposure to low levels, enhances safety and tolerability of the anti-CTLA-4 antibody.

Status: Clinical phase 1/2a study (NCT04725331)	In June 2022, BioInvent and partner Transgene announced positive progress and safety data in the ongoing Phase 1/2a trial evaluating BT-001 in patients with solid tumors, including melanoma. The initial data generated in Phase 1 part A, demonstrated that BT-001 alone is well tolerated, with first signs of anti-tumor activity in a hard-to-treat population and confirmed the mechanism of action of BT-001 as a single agent. The initial findings are as follows: - After administration, the virus was found in the tumors after several days. This suggests that BT-001 is able to persist and replicates within tumors. - This finding is consistent with the expression of the anti-CTLA-4 observed in the tumor with no detectable systemic exposure. - No spreading in blood or biological fluids has been detected, suggesting high tumor specificity. - Tumor shrinkage was observed in one patient in the first cohort. In January 2022, BioInvent and Transgene published preclinical proof-of-concept data in the Journal of Immunotheray of Cancer (JITC) that demonstrate that their co-developed clinical stage product, based on Transgene's patented oncolytic vector and encoding BioInvent's proprietary anti-CTLA-4 antibody, has the potential to provide greater therapeutic benefit than systemically administered anti-CTLA-4 antibodies. Systemically administered anti-CTLA-4 antibodies, such as the approved ipilimumab, have demonstrated siginificant efficacy but also limiting toxicity. The JITC paper is titled 'Vectorized Treg-depleting αCTLA-4 elicits antigen cross-presentation and CD8+ T cell immunity to reject "cold" tumors' and can be accessed here: https://jitc.bmj.com/content/jitc/10/1/e003488.full.pdf. Preclinical data were also presented at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) in November 2021 and at the AACR (American Academy for Cancer Research) in April 2022. Since March 2021, patients are enrolled to the ongoing Phase 1/2a open-label, multicenter, dose-escalation study evaluating BT-001 as a single agent and in combination with pembrolizumab. The study is currently enrolling patients at sites in France and Belgium.
Study design	The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BT-001 alone and in combination with pembrolizumab. The ongoing Phase 1 component of the study is divided into two parts: Part A will evaluate intra-tumoral injections of BT-001 as single agent in up to 42 patients with advanced solid tumor disease. The first two dose levels have been successfully completed, with 12 patients dosed to date. The highest dose cohort is currently enrolling patients. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab in several cohorts of up to 12 patients each. The subsequent Phase 2a component of the study will evaluate the combination regimen in several patient cohorts with different tumor types. These expansion cohorts will offer the possibility of exploring the activity of this approach to treat other malignancies not traditionally addressed with this type of treatment.
Outlook	The part A of the Phase I trial (single agent, dose escalation part) is expected to be completed by the end of 2022. The Phase 1 study part B, i.e. BT-001 in combination with pembrolizumab, is planned to start in H1 2023.
Out-licensing and partnering	In June 2022, BioInvent and Transgene announced a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the oncolytic virus BT-001 in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a Phase 1/2a clinical trial for the treatment of patients with solid tumors. Under the terms of the supply agreement, MSD will provide pembrolizumab to be used in combination with BT-001 in the ongoing Phase 1/2a clinical trial. Since 2017, BioInvent and Transgene collaborate on the development of the drug candidate BT-001 which encodes both a differentiated and proprietary anti-CTLA-4 antibody and the GM-CSF cytokine. Transgene is contributing its proprietary oncolytic virus (OV) platform Invir.IO™, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an anti-CTLA-4 antibody, which will further boost immune response against the tumor. The research and development costs as well as revenue and royalties are shared 50:50.

BI-1607

BI-1607 is an FcγRIIB-blocking antibody but differs from BI-1206 in that it has been engineered for reduced Fc-binding to FcγRs. Preclinical proof-of-concept data indicate that combined treatment with BI-1607 may both enhance efficacy of current anti-HER2 regimens and increase response rates in patients no longer responding to anti-HER2-directed therapies such as trastuzumab. In analogy with BI-1206 (BioInvent's other clinical-stage FcγRIIB antibody), BI-1607 is intended to be used to enhance the efficacy and overcome resistance to existing cancer treatments.

Status	In July 2022, the first patient was enrolled to the ongoing clinical Phase 1/2a study.
Study design	The first-in-human Phase 1 trial is a dose escalation study of BI-1607 in combination with trastuzumab in HER2+ advanced or metastatic solid tumors. The selected dose of BI-1607 will be studied in a subsequent Phase 2a part of the trial along with trastuzumab in advanced breast, metastatic gastric and gastroesophageal junction HER2+ cancers. The Phase 1 part of the study is expected to recruit between 12 and 26 subjects, whereas the Phase 2a aims to recruit 30 patients, in two cohorts of 15 subjects each (one cohort in breast and one in gastric and gastroesophageal cancers). The study is carried out at 7-12 sites in Spain, the UK, Germany, and in the U.S. Preclinical data presented at this year's AACR, indicate that treatment with BI-1607 enhances the efficacy of current anti-HER2 regimens such as trastuzumab. HER2 is a driver of tumor formation and growth in approximately 20% of breast cancers, the most common cancer worldwide in women, and in gastric and gastroesophageal junction adenocarcinoma.
Outlook	First results from the ongoing Phase 1 study are expected H2 2023.

Preclinical programs

BioInvent's preclinical research is focused on developing novel immuno-modulatory antibodies for cancer therapy. Such antibodies may significantly improve efficacy of currently available checkpoint inhibitor therapies and/or activate anti-cancer immunity in currently non-responding patients and cancer types.

The Preclinical team at BioInvent is highly involved in all steps in a project – from idea to pulling out desired antibodies from our n-CoDeR library, functionally test these in predictive cancer models, as well as in developing biomarkers for the clinic.

The flexibility of the team and the close communication between the Preclinical, Translational and Core Research Teams and Clinical Development assures rapid adjustments to answer the most critical questions to advance our pipeline.

The strength of the company's technology platform with its development tool F.I.R.S.T™ and the n-CoDeR® antibody library is a strong driver in the discovery phase where the company currently is working on a number of promising candidates.

BI-1910

Two different types of TNFR2 targeting antibodies are being developed by BioInvent. BI-1910 is a drug candidate in preclinical development, besides BI-1808 currently in clinical development. BI-1910 is an agonist, immune-activating TNFR2 antibody whilst BI-1808 is a ligand blocking antibody.

Preclinical data has been presented at AACR 2020 showing that an immune-activating BI-1910 surrogate antibody regress large established tumors and synergize with anti-PD-1 therapy. Further mode-of-action analyses demonstrate that the BI-1910 surrogate antibody increases intratumoral CD8+ T effector cells and induces long-lasting T cell memory. BI-1910 is expected to enter clinical development during H2 2023.

Strategic collaborations

BioInvent collaborates with a number of important players within the pharmaceutical industry and within academia. The collaborations with other pharmaceutical companies focus on commercial partnerships for BioInvent's clinical assets. The further the clinical programs have advanced, the greater is the chance of establishing partnerships that bring real value to BioInvent. Academic partnerships, on the other hand, allow BioInvent to tap into world class scientific expertise to advance the company's early programs, and potentially to acquire high quality early assets that could be of interest to BioInvent for further development.

COLLABORATIONS WITH LEADING PHARMACEUTICAL COMPANIES

For its clinical programs, BioInvent has different kinds of collaborations with leading pharmaceutical companies such as CASI, MSD, and Transgene, see pages 7 to 10 for details. The most recent collaboration was established in August 2021, when BioInvent signed a supply and collaboration agreement with MSD to support the expansion of the clinical trial program with anti-TNFR2 antibody BI-1808. The agreement with MSD gives BioInvent the opportunity to explore the potential synergistic activity of BI-1808 in combination with pembrolizumab. As MSD carefully reviews programs before establishing such agreements, this provides further validation of the high quality of the TNFR2 program.

SIX CLINICAL PROJECTS OUTLICENSED

BioInvent currently has six clinical projects outlicensed to other companies. Long-term, these projects hold real financial potential. In the short term, say five years, BioInvent may receive minor clinical milestone payments, but the real upside in these projects lies in commercial milestones and potential royalties five to ten years from now. It is impossible to know if any of BioInvent's external projects will go all the way to market but statistically it is highly probable that at least one or two will be successful.

R&D PARTNERSHIPS

BioInvent has also signed early research and development partnerships focused on the identification and development of novel antibodies for use in immuno-oncology therapeutics. Agreements have been signed with both Exelixis and Pfizer, with potential future development milestones and royalties.

BIOINVENT'S OUT-LICENSING AGREEMENTS FOR PROJECTS IN CLINICAL DEVELOPMENT

Program	Target	Primary indication	Phase 1	Phase 2	Phase 3	Market	Partner
MT-2990	anti-IL33	Endometriosis					Mitsubishi Tanabe
TAK-079	anti-CD38	Myastenia Gravis					Takeda
Orticumab	anti-ApoB100	Psoriasis					Abcentra
TAK-169/MT-0169	anti-CD38	Multiple Myeloma					Molecular Templates
DS-1055	anti-GARP	Solid tumor					Daiichi-Sankyo
HMI-115	anti-PRLR	Endometriosis					Hope Medicine/Bayer

BioInvent's external projects are a seal of excellence for the quality of the company's research and development capabilities.

Financial information

REVENUES AND RESULT

Figures in parentheses refer to the outcome for the corresponding period in the preceding year.

Third quarter

Net sales amounted to SEK 17.9 million (3.0). Revenues for the period were mainly derived from production of antibodies for clinical studies, and revenues from research funding. Revenues for the corresponding period 2021 were mainly derived from production of antibodies for clinical studies.

The Company's total costs amounted to SEK 88.1 million (65.5). Operating costs are divided between external costs of SEK 61.3 million (44.6), personnel costs of SEK 23.2 million (17.0) and depreciation of SEK 3.6 million (3.9).

Research and development costs amounted to SEK 77.7 million (57.7). Sales and administrative costs amounted to SEK 10.4 million (7.8).

Profit/loss after tax amounted to SEK -63.9 million (-62.6). The net financial items amounted to SEK 5.3 million (-0.2). Profit/loss per share before and after dilution amounted to SEK -1.00 (-1.07).

January - September

Net sales amounted to SEK 305.5 million (14.5). Revenues for the period were mainly derived from an upfront fee of USD 25 million when an exclusive option and license agreement was entered into with Exelixis to develop novel antibody-based immuno-oncology therapies, a EUR 0.5 million milestone payment under the collaboration with Bayer Healthcare/Hope Medicine related to the initiation of a Phase 2 clinical trial, production of antibodies for clinical studies, and revenues from research funding. Revenues for the corresponding period 2021 were mainly derived from production of antibodies for clinical studies and revenues from research funding.

The Company's total costs amounted to SEK 276.5 million (215.4). Operating costs are divided between external costs of SEK 191.0 million (145.3), personnel costs of SEK 74.8 million (59.2) and depreciation of SEK 10.7 million (10.9).

Research and development costs amounted to SEK 241.0 million (187.9). Sales and administrative costs amounted to SEK 35.5 million (27.5).

Profit/loss after tax amounted to SEK 35.8 million (-199.7). The net financial items amounted to SEK 7.5 million (-0.2). Profit/loss per share before and after dilution amounted to SEK 0.59 (-3.79).

FINANCIAL POSITION AND CASH FLOW

On July 12, 2022, BioInvent successfully completed a directed share issue of SEK 298.9 million before transaction costs. A number of international and Swedish investors participated in the directed share issue, including new investors such as AXA Investment Managers and a US institutional investor and the existing shareholders Forbion, HBM Healthcare Investments, Redmile Group, Invus, the Fourth National Swedish Pension Fund and Swedbank Robur Fonder, with demand for the new shares exceeding the size of the directed share issue. 6,496,788 new shares were issued based on the authorization granted by the AGM on April 28, 2022.

The share capital consists of 64,967,884 shares after completion of the directed share issue.

As of September 30, 2022, the Group's liquid funds, current and long-term investments amounted to SEK 1,664.3 million (1,445.3). Amount as of September 30, 2022, does include upfront fee from Exelixis SEK 255.8 million (USD 25 million) received in July 2022, and net capital from the directed share issue SEK 279.8 million, also received in July 2022. The cash flow from operating activities for the January-September period amounted to SEK 30.4 million (-170.1).

The shareholders' equity amounted to SEK 1,684.3 million (1,445.5) at the end of the period. The Company's share capital was SEK 13.0 million. The equity/assets ratio at the end of the period was 96 (95) percent. Shareholders' equity per share amounted to SEK 25.92 (24.72).

INVESTMENTS

Investments for the January-September period in tangible fixed assets amounted to SEK 6.2 million (10.3).

PARENT COMPANY

All operations of the Group are conducted by the Parent Company. Except for financial leases, the Group's and the Parent Company's financial statements coincide in every material way.

ORGANIZATION

As of September 30, 2022, BioInvent had 93 (85) employees (full time equivalent). 84 (76) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 68 in the Company's annual report 2021. Otherwise there are no transactions with related parties, in accordance with IAS 24, to report.

RISK FACTORS

The Company's operations are associated with risks related to factors such as pharmaceutical development, clinical trials and product responsibility, commercialization and partners, competition, intellectual property protection, compensation for pharmaceutical sales, qualified personnel and key individuals, additional financing requirements, currency risk and interest risk. The risks summarize the factors of significance for BioInvent and thus an investment in the BioInvent share.

At the beginning of 2022, the relation between Russia and Ukraine have deteriorated sharply, and on February 24, Russia invaded Ukraine. The situation is characterized by great uncertainty and the course of events is unpredictable. The market reactions on the development have been strongly negative, which is shown through significant price drops in the stock markets in the countries concerned, but also in other markets, including the Swedish market. In addition, the United States and Europe have imposed economic sanctions on Russia. In relation to BioInvent's operations, in the form of ongoing clinical trials and the results of these, this has so far not been affected in any material way. However, it cannot be completely ruled out that the situation in the world will change, which may also have an impact on BioInvent's operations, primarily in the form of delays in the company's ongoing clinical trials and clinical trials that will soon be initiated. If such an impact on the operation is expected to arise, BioInvent will provide updates as necessary.

For a more detailed description of risk factors, see section "Risks and Risk Management", page 50, in the Company's annual report 2021.

Consolidated statement of comprehensive income in brief for the Group (SEK thousand)

	3 MONTHS 2022 JULY-SEP.	3 MONTHS 2021 JULY-SEP	9 MONTHS 2022 JAN.-SEP.	9 MONTHS 2021 JAN.-SEP.	12 MONTHS 2021 JAN.-DEC.
Net sales	17,920	2,993	305,486	14,481	19,384
Operating costs					
Research and development costs	-77,675	-57,642	-240,945	-187,889	-258,337
Sales and administrative costs	-10,432	-7,819	-35,523	-27,477	-39,438
Other operating income and costs	1,035	38	-676	1,382	41
	-87,072	**-65,423**	**-277,144**	**-213,984**	**-297,734**
Operating profit/loss	**-69,152**	**-62,430**	**28,342**	**-199,503**	**-278,350**
Profit/loss from financial investments	5,284	-175	7,490	-181	-94
Profit/loss before tax	**-63,868**	**-62,605**	**35,832**	**-199,684**	**-278,444**
Tax	-	-	-	-	-
Profit/loss	**-63,868**	**-62,605**	**35,832**	**-199,684**	**-278,444**
Other comprehensive income					
Items that have been or may be reclassified subsequently to profit or loss	-	-	-	-	-
Comprehensive income	**-63,868**	**-62,605**	**35,832**	**-199,684**	**-278,444**
Other comprehensive income attributable to parent Company's shareholders	-63,868	-62,605	35,832	-199,684	-278,444
Profit/loss per share, SEK					
Before dilution	-1.00	-1.07	0.59	-3.79	-5.14
After dilution	-1.00	-1.07	0.59	-3.79	-5.14

Consolidated statement of financial position in brief for the Group (SEK thousand)

	2022 SEP. 30	2021 SEP. 30	2021 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	22,857	30,724	27,433
Tangible fixed assets - other	21,723	20,928	21,651
Financial fixed assets - long-term investments	440,972	188,802	282,208
Total fixed assets	**485,552**	**240,454**	**331,292**
Inventories	11,238	13,129	16,848
Current receivables	34,948	10,084	16,342
Current investments	527,049	-	172,074
Liquid funds	696,315	1,256,516	910,755
Total current assets	**1,269,550**	**1,279,729**	**1,116,019**
Total assets	**1,755,102**	**1,520,183**	**1,447,311**
SHAREHOLDERS' EQUITY			
Total shareholders' equity	**1,684,259**	**1,445,495**	**1,366,987**
LIABILITIES			
Lease liabilities	17,058	23,004	21,532
Total long term liabilities	**17,058**	**23,004**	**21,532**
Lease liabilities	6,521	6,939	6,835
Other liabilities	47,264	44,745	51,957
Total short term liabilities	**53,785**	**51,684**	**58,792**
Total shareholders' equity and liabilities	**1,755,102**	**1,520,183**	**1,447,311**

Statement of changes in equity for the Group (SEK thousand)

	2022 JULY-SEP.	2021 JULY-SEP	2022 JAN.-SEP.	2021 JAN.-SEP.	2021 JAN.-DEC.
Shareholders' equity at beginning of period	**1,467,374**	**1,508,118**	**1,366,987**	**743,499**	**743,499**
Comprehensive income					
Profit/loss	-63,868	-62,605	35,832	-199,684	-278,444
Comprehensive other income	-	-	-	-	-
Total comprehensive income	**-63,868**	**-62,605**	**35,832**	**-199,684**	**-278,444**
Total, excluding transactions with equity holders of the Company	**1,403,506**	**1,445,513**	**1,402,819**	**543,815**	**465,055**
Transactions with equity holders of the Company					
Employee options program	904	-18	1,591	886	1,138
Directed share issue	279,849		279,849	900,794	900,794
Shareholders' equity at end of period	**1,684,259**	**1,445,495**	**1,684,259**	**1,445,495**	**1,366,987**

The share capital as of September 30, 2022 consists of 64,967,884 shares and the share's ratio value was 0.20. The directed new share issue carried out in July 2022 raised SEK 298.9 million before issue expenses and SEK 279.8 million after issue expenses.

Consolidated statement of cash flows in brief for the Group (SEK thousand)

	2022 JULY-SEP.	2021 JULY-SEP	2022 JAN.-SEP.	2021 JAN.-SEP.	2021 JAN.-DEC.
Operating activities					
Operating profit/loss	-69,152	-62,430	28,342	-199,503	-278,350
Depreciation	3,646	3,881	10,705	10,927	14,610
Adjustment for other non-cash items	904	-18	1,591	886	1,138
Interest received and paid	-121	-18	-436	-154	-269
Cash flow from operating activities before changes in working capital	**-64,723**	**-58,585**	**40,202**	**-187,844**	**-262,871**
Changes in working capital	237,494	1,090	-9,763	17,739	17,028
Cash flow from operating activities	**172,771**	**-57,495**	**30,439**	**-170,105**	**-245,843**
Investment activities					
Acquisition of tangible fixed assets	-1,254	-5,473	-6,201	-10,294	-13,260
Changes of financial investments	-344,669	-188,802	-513,739	-188,802	-454,282
Cash flow from investment activities	**-345,923**	**-194,275**	**-519,940**	**-199,096**	**-467,542**
Cash flow from operating activities and investment activities	**-173,152**	**-251,770**	**-489,501**	**-369,201**	**-713,385**
Financing activities					
Directed share issue	279,849		279,849	900,794	900,794
Amortization of lease liability	-1,606	-1,375	-4,788	-4,347	-5,924
Cash flow from financing activities	**278,243**	**-1,375**	**275,061**	**896,447**	**894,870**
Change in liquid funds	**105,091**	**-253,145**	**-214,440**	**527,246**	**181,485**
Opening liquid funds	591,224	1,509,661	910,755	729,270	729,270
Liquid funds at end of period	**696,315**	**1,256,516**	**696,315**	**1,256,516**	**910,755**
Liquid funds, specification:					
Cash and bank	696,315	1,256,516	696,315	1,256,516	910,755
	696,315	**1,256,516**	**696,315**	**1,256,516**	**910,755**

Key financial ratios for the Group

	2022 SEP. 30	2021 SEP. 30	2021 DEC. 31
Shareholders' equity per share at end of period, SEK	25.92	24.72	23.38
Number of shares at end of period (thousand)	64,968	58,471	58,471
Equity/assets ratio, %	96.0	95.1	94.5
Number of employees at end of period	93	85	84

Consolidated income statement in brief for the Parent Company (SEK thousand)

	3 MONTHS 2022 JULY-SEP.	3 MONTHS 2021 JULY-SEP	9 MONTHS 2022 JAN.-SEP.	9 MONTHS 2021 JAN.-SEP.	12 MONTHS 2021 JAN.-DEC.
Net sales	17,920	2,993	305,486	14,481	19,384
Operating costs					
Research and development costs	-77,893	-57,606	-241,597	-187,778	-258,521
Sales and administrative costs	-10,451	-7,815	-35,580	-27,467	-39,454
Other operating income and costs	1,035	38	-676	1,382	41
	-87,309	**-65,383**	**-277,853**	**-213,863**	**-297,934**
Operating profit/loss	**-69,389**	**-62,390**	**27,633**	**-199,382**	**-278,550**
Profit/loss from financial investments	5,440	19	7,987	148	420
Profit/loss after financial items	**-63,949**	**-62,371**	**35,620**	**-199,234**	**-278,130**
Tax	-	-	-	-	-
Profit/loss	**-63,949**	**-62,371**	**35,620**	**-199,234**	**-278,130**
Other comprehensive income	**-**	**-**	**-**	**-**	**-**
Comprehensive income	**-63,949**	**-62,371**	**35,620**	**-199,234**	**-278,130**

Consolidated balance sheet in brief for the Parent Company (SEK thousand)

	2022 SEP. 30	2021 SEP. 30	2021 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	21,723	20,928	21,651
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	440,972	188,802	282,208
Total fixed assets	**463,382**	**210,417**	**304,546**
Current assets			
Inventories	11,238	13,129	16,848
Current receivables	34,636	11,622	16,030
Current investments	527,049	6,000	172,074
Cash and bank	696,315	1,250,516	910,755
Total current assets	**1,269,238**	**1,281,267**	**1,115,707**
Total assets	**1,732,620**	**1,491,684**	**1,420,253**
SHAREHOLDERS' EQUITY			
Restricted equity	40,687	39,387	39,387
Non-restricted equity	1,644,020	1,406,904	1,328,260
Total shareholders' equity	**1,684,707**	**1,446,291**	**1,367,647**
LIABILITIES			
Short term liabilities	47,913	45,393	52,606
Total short term liabilities	**47,913**	**45,393**	**52,606**
Total shareholders' equity and liabilities	**1,732,620**	**1,491,684**	**1,420,253**

Lund, October 27, 2022

Martin Welschof
CEO

Review report

INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on September 30, 2022 and for the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the 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 the International Standards on Auditing, ISA, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

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, for the group's part according to IAS 34 and the Annual Accounts Act and for the parent Company's part according to the Annual Accounts Act.

Malmö, October 27, 2022
KPMG AB

Linda Bengtsson
Authorized Public Accountant

Information notes

NOTE 1 ACCOUNTING PRINCIPLES

This interim report in brief for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting and applicable parts of the Annual Accounts Act. The interim report of the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act. For the Group and the Parent Company, the same accounting policies and accounting estimates and assumptions were applied to this interim report as were used in the preparation of the most recent annual report.

Changes in IFRS standards entered into force in 2022 has had no material impact on the financial statements. The financial statements of the Parent Company coincide in every material way with the consolidated financial statements.

The definition of alternative performance measures not defined by IFRS is unchanged from those presented in the most recent annual report.

In June 2022, BioInvent entered into an agreement with Exelixis that granted BioInvent the right to receive an upfront fee of USD 25 million in consideration for Exelixis receiving rights to select three target identified using BioInvent's proprietary F.I.R.S.T platform and n-CoDeR library. The grant of these rights has been deemed to constitute a separate performance obligation that was satisfied in connection with Exelixis gaining access to the targets in June 2022. The full amount of USD 25 million has therefore been recognized as revenue in the second quarter. For more detailed information about the Group's accounting principles regarding revenues, see Note 1 Accounting principles, page 64, in the Company's annual report 2021.

NOTE 2 NET REVENUE

SEK THOUSAND	2022 JULY-SEP.	2021 JULY-SEP	2022 JAN.-SEP.	2021 JAN.-SEP.	2021 JAN.-DEC.
Revenue by geographical region:					
Sweden	3,705	2,595	22,634	9,409	13,515
Europe	10,238	353	18,681	3,843	4,213
USA	3,977	45	264,171	1,229	1,656
Other countries	-	-	-	-	-
	17,920	**2,993**	**305,486**	**14,481**	**19,384**
Revenue consists of:					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	4,417	-	260,180	-	-
Revenue from technology licenses	-	-	5,221	-	-
Revenue from external development projects	13,503	2,993	40,085	14,481	19,384
	17,920	**2,993**	**305,486**	**14,481**	**19,384**

The net revenue of the Group and the Parent Company coincide.

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

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

(R)= Regulatory event

Other information

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on April 27, 2023 at 4 p.m. Elite Hotel Ideon, Scheelevägen 27, Lund. Notice to attend will be announced in Post- och Inrikes Tidningar and on the Company website.

FINANCIAL CALENDAR

- Year-end report: February 22, 2023
- Interim report Q1: April 26, 2023
- Interim report Q2: August 30, 2023
- Interim report Q3: October 26, 2023

CONTACT

Any questions regarding this report will be answered by Cecilia Hofvander, Senior Director Investor Relations, +46 (0)46 286 85 50, cecilia.hofvander@bioinvent.com.

The report is also available at www.bioinvent.com.

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FORWARD LOOKING INFORMATION

This interim report contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual out-come may deviate significantly from the scenarios described in this interim report.

TRADEMARKS