BioInvent Q4

YEAR-END REPORT JANUARY 1 - DECEMBER 31, 2021

BioInvent's CEO:

"The past year was very exciting for BioInvent. Two of our clinical trials provided highly encouraging results in 2021 at the same time as we expanded our pipeline of clinical programs with the initiation of two additional programs and the submission of one clinical trial application, more than doubling the portfolio."

Events in the fourth quarter

- (R) Positive interim data from BI-1206 Phase 1 in NHL show increased and sustained responses in relapsed patients. Particularly impressive outcome in follicular lymphoma:
  - Objective response rate (ORR) 67%
  - Disease control rate (DCR) 78%
  - Complete responses with duration of 12, 24 and 36 months.
- (R) Positive early clinical data presented from the ongoing BI-1206 Phase 1 study of BI-1206 in combination with pembrolizumab for the treatment of solid tumors.
- BioInvent and CASI Pharmaceuticals announced CTA approval for clinical studies of BI-1206 in NHL in China.
- BioInvent advanced to the Nasdaq Stockholm's Mid Cap segment.

Events after the period

- (R) Orphan Drug Designation granted to BI-1206 for the treatment of follicular lymphoma.
- BioInvent and Transgene published preclinical BT-001 proof-of-concept data in the *Journal of ImmunoTherapy of Cancer (JITC).*
- BI-1607 CTA approval received.
- Marie Moores was appointed Chief Operating Officer.

Financial information

Fourth quarter 2021

- Net sales SEK 4.9 (98.7) million.
- Loss after tax SEK -78.8 (28.5) million.
- Loss after tax per share before and after dilution SEK -1.35 (0.74).
- Cash flow from operating activities SEK -75.7 (29.2) million.

January – December 2021

- Net sales SEK 19.4 (147.4) million.
- Loss after tax SEK -278.4 (-76.3) million.
- Loss after tax per share before and after dilution SEK -5.14 (-2.66).
- Cash flow from operating activities SEK -245.8 (-62.6) million.
- Liquid funds, current and long-term investments as of December 31, 2021: SEK 1,365.0 (729.3) million.

(R)= Regulatory event

The information was submitted for publication, through the agency of the contact person set out on page 22, at 8:00 a.m. CET on February 23, 2022.

"Two separate clinical trials of our lead antibody BI-1206, provided highly encouraging results in 2021. The two clinical trials target non-Hodgkin's lymphoma and solid tumors, respectively."

Comments from the CEO.

The past year was very exciting for BioInvent. Two of our clinical trials provided highly encouraging results in 2021 at the same time as we expanded our pipeline of clinical programs with the initiation of two additional programs and the submission of one clinical trial application, more than doubling the portfolio.

To realize and manage our clinical ambitions, we significantly strengthened our regulatory and clinical organization, as well as expanding the overall organization. BioInvent is rapidly becoming a truly international and diverse company, and we now count over ten nationalities in our organization.

The record financing in February 2021 has given BioInvent a strong financial position, which supports our ambitious clinical development programs. With the directed share issue, we also expanded our base of powerful international biotech investors – a clear reflection of our increasing international visibility.

HIGHLY ENCOURAGING RESULTS FOR BI-1206

Two separate clinical trials of our lead antibody BI-1206 (anti-FcγRIIB), provided highly encouraging results in 2021. The two clinical trials target non-Hodgkin's lymphoma and solid tumors, respectively.

BI-1206 in non-Hodgkin's lymphoma

At the American Society of Hematology Annual Meeting in December 2021, we presented an update on the results of our clinical trial which combines BI-1206 and rituximab to treat patients with non-Hodgkin's lymphoma. The results show that the combination of BI-1206 and rituximab slow tumor growth in more than 60 percent of the cases (8 out of 13 patients). In 7 out of the 13 patients, partial or complete tumor shrinkage has been observed. Even more remarkable, one of the first patients in the trial today is living tumor-free, without treatment, three years after the start of the trial.

The response rate is highly encouraging and especially notable since only patients with advancing tumor disease, despite previous treatments with rituximab, were included in the trial. The results so far seem to indicate that BI-1206 not only restores the anti-tumor response of rituximab but does so in a safe and prolonged manner in patients.

BI-1206 in advanced solid tumors

The ability of BI-1206 to block resistance mechanisms has also been observed in our clinical trial in advanced solid tumors. Using BI-1206 in combination with pembrolizumab, Merck's widely used anti-PD-1 checkpoint inhibitor, we have already noted the shrinkage of tumors in two late-stage solid cancer patients who had previously received pembrolizumab treatment without any success.

Further exploration of BI-1206

While it is still early days, the observation that BI-1206 seems able to restore the efficacy of two leading antibody treatments in both blood cancer and solid tumors is very encouraging, and in line with our understanding of its mode of action. During 2022, we will start evaluating a subcutaneous formulation which could further improve the use of BI-1206. Furthermore, our partner CASI Pharmaceuticals is positioned to commence parallel clinical development of BI-1206 in China following approval of CASI's Clinical Trial Application in December 2021.

BI-1206 granted a second Orphan Drug Designation
In early 2022, BI-1206 was granted its second Orphan Drug Designation (ODD) by the FDA, adding the treatment of follicular lymphoma to mantle cell lymphoma, which received an ODD in 2019. Follicular lymphoma is the most common form of slow-growing non-Hodgkin's lymphoma, a type of white blood cell cancer.

An Orphan Drug Designation entails several benefits in terms of reduced application fees, help with inspections, specific scientific advice, and potentially longer marketing exclusivity if "clinical superiority" is demonstrated at the time of approval.

EXPANDING CLINICAL PIPELINE

BioInvent has also expanded its pipeline further with the ongoing clinical trials for BI-1808 and BT-001.

Leading the field with BI-1808
In April 2021, the FDA approved the Investigational New Drug (IND) for the BI-1808 study which is recruiting patients in Europe since January 2021. BI-1808 targets the TNF2 receptor (TNFR2), a protein that is important for tumor expansion and survival and a target that is increasingly attracting global interest – with BioInvent leading the field. The ongoing trial will explore the safety and efficacy of BI-1808 both as single agent and in combination with pembrolizumab. In August 2021, we signed a second clinical trial collaboration and supply agreement with Merck, securing access to Keytruda® (pembrolizumab) for the continued clinical development of BI-1808. The first Phase 1 data are expected mid-2022.

BT-001 data published in high-impact journal
Recruitment in the ongoing Phase 1/2a clinical study of our oncolytic virus BT-001, armed with an anti-CTLA-4 antibody, is ongoing. Together with our partner, Transgene, we shared our preclinical proof-of-concept data on BT-001 with research and clinical research colleagues at the Society for ImmunoTherapy of Cancer meeting in November 2021 and through a peer-reviewed paper in the Journal of ImmunoTherapy of Cancer in January 2022. The data showed that the anti-CTLA-4 antibody in BT-001 reduces systemic toxicity, addresses 'cold tumors' and provides excellent tumor-selective Treg depletion. We look forward to the initial Phase 1 data that are expected in the first half of 2022.

BI-1607 CTA approval
We received the approval of the Clinical Trial Application (CTA) for our second FcγRIIB-targeted antibody, BI-1607, in January 2022 which extends the BioInvent pipeline to four drug candidates in five trials. The BI-1607 study start is planned for the second quarter 2022.

AN INCREASINGLY ATTRACTIVE EMPLOYER

BioInvent's ability to attract talented colleagues to our company continues to grow with the successful progress of our preclinical and clinical programs. In 2021, we employed several new colleagues, expanding our organization to 90 people at the end of the year. As an example, to realize and manage our clinical ambitions, seven people joined our regulatory and clinical teams. BioInvent is rapidly becoming a truly international and diverse company and we now count over ten nationalities in our organization.

Recently, we also recently strengthened our senior management team with the appointment of Marie Moores as Chief Operating Officer. Marie's primary focus will be to get involved in all operational aspects including quality assurance as well as commercial strategy planning such as further developing the target product profiles for BioInvent's drug candidates. Such profiles guide our research and development (R&D), frame development in relation to compilation of product dossiers and set internal R&D targets that optimize the development opportunities.

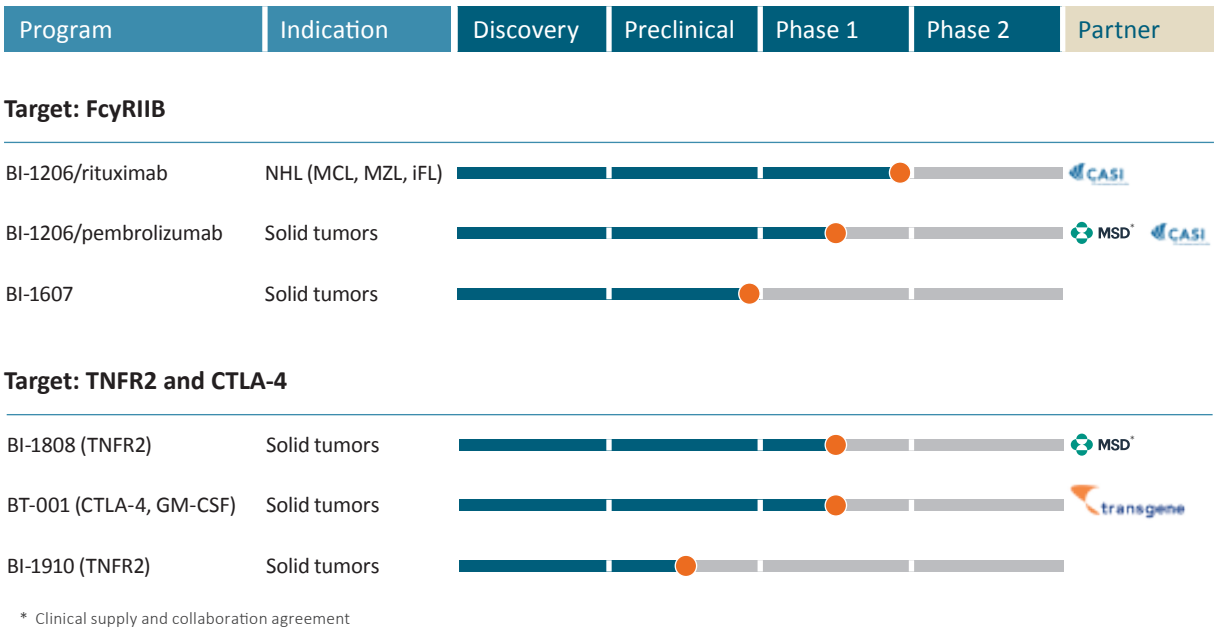
OUTLOOK

Let me end by addressing BioInvent's employees. The progress we achieved in 2021 was made possible by your commitment and talented efforts. BioInvent is increasingly recognized by investors, partners and collaborators as a clinical-stage oncology antibody innovator and a manufacturer that can develop and produce clinical grade material for our ongoing and forthcoming trials. Our sincere thanks also to our shareholders for the confidence you have placed in us and for your continued support on our mission of improving the lives of patients. In 2022, we will continue to build on this attractive position, and continue to advance our very promising clinical pipeline.

Martin Welschof
CEO

Pipeline with four clinical programs.

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



* Clinical supply and collaboration agreement

Discovery.

At BioInvent, we combine deep immunological understanding with target agnostic screening (the target structure is identified only when functional activity is verified) to identify the clinically most relevant targets and antibodies for cancer immunotherapy. Patient tissue, alongside our F.I.R.S.T™ technology platform and the human antibody library n-CoDeR®, are cornerstones in this process.

TECHNOLOGY PLATFORMS

The unique development tool F.I.R.S.T™, where patient material is the foundation throughout the development process, simultaneously identifies the clinically most relevant targets in a disease model and matching antibodies. The proprietary antibody library n-CoDeR® contains antibodies that bind specifically and strongly to their targets.

TUMOR-ASSOCIATED MYELOID CELLS (TAM)

Myeloid cells are a key part of our innate, non-specific, immune system but can also be "hijacked" by tumors to support the growth and spread of cancer. Antibody-mediated "reprogramming" of immunosuppressive tumor-associated myeloid cells (TAMs) to become effector cells that can help to eliminate cancer cells is an attractive therapy concept and a field of research where BioInvent and its partners are at the forefront.

BioInvent has so far received USD 6.6 million in milestone payments besides research funding for an R&D collaboration with Pfizer 2017-2020 on the selection of TAM targets. Pfizer has selected its targets and BioInvent is eligble for potential future development milestones in excess of USD 100 million if one antibody is developed through to commercialization, and up to double digit royalties on future sales.

REGULATORY T CELLS (TREGS)

Normally, Tregs suppress undesirable activation of the immune system, but unfortunately also enable tumors to evade the body's immune system in cancer. There are many publications showing a clear correlation between the number of Tregs in cancer patients and poor prognosis.

BioInvent is developing antibodies specifically targeting regulatory T cells and tumor-associated myeloid cells, both of which are strongly immunosuppressive, with the aim to deplete or re-educate these cells for enhanced immune-mediated cancer rejection.

Clinical programs

Andres McAllister
Chief Medical Officer

"BioInvent is the first company to be able to exclusively recognize and block the FcγRIIB receptor. Restoring or enhancing the activity of rituximab will have a major impact on the treatment algorithm, spanning from last resorts of therapeutic intervention, to potentially all lines of treatment. The fact that we are observing long-lasting complete responses speaks loudly about the potential of BI-1206, and how this could help shift the treatment paradigm to chemotherapy-free regimens."

BI-1206 in non-Hodgkin's lymphoma.

Target: **FcyRIIB** Status: **Phase 1** Partner: **CASI Pharmaceuticals, Inc.**

PROJECT STATUS AND OUTLOOK

Data suggest that BI-1206 restores activity of rituximab in relapsed NHL patients. The response rate for follicular lymphoma is particularly impressive.
At the ASH (American Society of Hematology) conference 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 (NCT03571568) 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 complete responses have been sustained for extended periods, with the longest complete response enduring beyond 36 months. In two additional 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.

BI-1206 Orphan Drug Designation for the treatment of FL
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. ODD provides benefits, including market exclusivity upon regulatory approval, exemption of FDA biologic license application fee and tax credits for qualified clinical trials. BI-1206 previously received ODD from the FDA for the treatment of mantle cell lymphoma in January 2019.

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.

Initiation of Phase 2 part expected H1, 2022
The end of Phase 1 meeting with the FDA and the determination of the recommended Phase 2 dose (RP2D) and progression to the expansion Phase 2a part of the study, is expected during H1 2022.

Clinical development in China
The Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA), China's medical product regulator, approved in December 2021 a Clinical Trial Application (CTA) submitted by BioInvent's licensee in China, CASI Pharmaceuticals (CASI). The CTA is for the initiation of two clinical trials of BI-1206 in patients with non-Hodgkin's Lymphoma (NHL) in China.

CASI is planning Phase 1 trials of BI-1206 as a single agent with the aim to evaluate the PK profile and 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. The studies are expected to start in H1 2022.

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.

Target: **FcyRIIB** Status: **Phase 1** Partner: **CASI Pharmaceuticals, Inc.**

PROJECT STATUS AND OUTLOOK

Positive early clinical data presented
Early observations 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. No major safety concerns have been noted and dose-escalation will continue. Next patient cohort will be dosed at 2 mg/kg.

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 [1)].

Ongoing Phase 1/2a multicenter
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.

Evaluation of safety and tolerability
The overall objective of the Phase 1/2a study (NCT04219254) 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.

1) Uveal melanoma: epidemiology, etiology, and treatment of primary disease, Krantz et al, Clin Ophthalmology 31 Jan 2017.

OUT-LICENSING AND PARTNERING

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206 and Merck's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial for patients with solid tumors. Under the agreement, Merck 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.

Target: **TNFR2** Status: **Phase 1**

PROJECT STATUS AND OUTLOOK

Initial Phase 1 data expected mid-2022
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, the United Kingdom and Russia.

Since January 2021, patient enrollment is ongoing in Europe to the first part of the Phase 1/2a study evaluating 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 in patients with ovarian cancer, non-small cell lung cancer and CTCL. The study (NCT04752826) is expected to enroll a total of approximately 120 patients. The initial Phase 1 data are expected mid-2022.

Dose escalation to determine the recommended single agent Phase 2 dose
The ongoing Phase 1 component of the study is divided into two parts: Part A is a dose escalation study of BI-1808 to assess safety, tolerability, pharmacokinetics/pharmacodynamics, and to determine the recommended single agent Phase 2 dose (RP2D). Part B will explore the safety and tolerability of BI-1808 in combination with Keytruda.

The subsequent Phase 2a component consists of expansion cohorts to assess signs of efficacy of BI-1808 as single agent, as well as in combination with Keytruda in lung cancer- and ovarian cancer patients. Another cohort will explore the activity as single agent in cutaneous T-cell lymphoma (CTCL).

OUT-LICENSING AND PARTNERING

As communicated in August 2021, BioInvent has entered into a second clinical trial collaboration and supply agreement with Merck. This time to evaluate the combination of BioInvent's BI-1808 and Merck's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial in patients with advanced solid tumors. Under the agreement, Merck supplies Keytruda which supports the evaluation of BI-1808 in combination with one of the most successful immuno-oncology drugs on the market.

BT-001 in solid tumors.

Target: **CTLA-4, GM-CSF** Status: **Phase 1** Partner: **Transgene**

PROJECT STATUS AND OUTLOOK

Preclinical proof-of-concept data published in JITC
In January 2022, BioInvent and Transgene published preclinical proof-of-concept data 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 substantial efficacy but also clinically 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.

Additional preclinical data on BT-001 were presented at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) in November 2021.

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 (NCT04725331) is currently enrolling patients at sites in France and Belgium. Initial Phase 1 data is expected H1 2022.

Evaluating the safety and tolerability
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. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab in several cohorts of up to 12 patients each.

Exploring the activity in Phase 2a
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.

OUT-LICENSING AND PARTERING

Since 2017, BioInvent and Transgene collaborate on the development of oncolytic virus (OV) drug candidates aimed at treating solid tumors, with the potential to be significantly more effective than the combination of a virus and an antibody as single agents. The clinical drug candidate BT-001 encode 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 from drug candidates generated from the collaboration, are shared 50:50.

Preclinical programs

Ingrid Teige
Head of Preclinical

"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 and is key to sustain the creative and high-energy spirit at BioInvent."

BI-1607.

Target: **FcyRIIB** Status: **Ready for Clinical Phase 1**

PROJECT STATUS AND OUTLOOK
In January 2022, the Clinical Trial Application (CTA) submitted in December for the novel, fully human FcyRIIB-blocking antibody, BI-1607, was approved. Patient recruitment is planned start during Q2, 2022.

BI-1607 targets FcyRIIB but is modified in its Fc region to alter its affinity for Fc receptors. By selectively blocking FcyRIIB, BI-1607 enhances the activity of other therapeutic monoclonal antibodies, whose mechanism-of-action involves depletion of tumors or immune suppressive cells. Understanding the biology of FcR/Fc interactions was essential for generating BI-1607, which has a clearly differentiated profile from BioInvent's lead drug candidate BI-1206.

BioInvent intends to explore the activity of BI-1607 in advanced solid tumors and antibody combinations supported by strong preclinical data.

BACKGROUND
Understanding mechanisms and overcoming resistance to distinct classes of antibody drugs has the potential to further improve cancer outcomes. BI-1607 is a novel, fully human FcγRIIB-blocking antibody with a novel mechanism-of-action, designed to enhance FcγR-dependent antitumor immunity. It blocks the inhibitory signaling of FcγRIIB in immune cells, with the potential of increasing therapeutic activity of other Fc-dependent therapeutic antibodies.

BI-1910.

Target: **TNFR2** Status: **Preclinical**

PROJECT STATUS AND OUTLOOK
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 was 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.

BACKGROUND
BioInvent has identified tumor necrosis factor receptor 2 (TNFR2), a member of the so-called TNFR superfamily (TNFRS) as an attractive target for cancer therapy. TNFR2 is particularly upregulated on tumor-associated regulatory T cells (Tregs) and has been shown to be important for their expansion and survival. As a part of its Treg program, BioInvent identified and characterized a wide panel of TNFR2-specific antibodies, generated from its proprietary n-CoDeR® library and unique F.I.R.S.T™ discovery tool, of which BI-1808 and BI-1910 are the lead development candidates.

BioInvent is in a very attractive position with several value drivers.

All pharmaceutical development is associated with risk. BioInvent manages these risks by a stringent portfolio management, a diversified approach to drug candidates and mechanisms of action, and by targeting a very attractive space in the pharmaceutical landscape. Partnerships within the big pharma community, solid ownership and a strong cash position give BioInvent a solid platform to continue its transformation.

STRINGENT PORTFOLIO MANAGEMENT

BioInvent has four ongoing clinical programs and a fifth to come, where each program has its own individual mechanism of action. In this way, the company is not dependent on the success of one individual program or one single technology. In the Discovery phase, BioInvent applies a stringent process in order to make sure that all of the company's drug candidates have a smart design and high commercial potential for successful partnering at the optimal time for each project.

The company's Discovery engine not only generates new drug candidates, it also offers ample opportunity for successful collaborations and partnering.

ATTRACTIVE SPACE IN THE PHARMACEUTICAL LANDSCAPE

BioInvent targets a commercially very attractive space in the pharmaceutical landscape – with potential to expand into new territories. BI-1206 is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab, drugs with combined global sales of approximately USD 21 billion annually. BI-1206 also has the potential to expand beyond the treatment of cancer.

BioInvent has a strong deal-making track record, and has ongoing collaborations with companies such as CASI, Pfizer, Merck, Daiichi and Mitsubishi Tanabe. The CASI deal amounts to USD 83 million in potential milestone payments as well as royalties on future sales and is restricted to the commercialization in China.

BIG PHARMA PARTNERS AND SOLID OWNERSHIP

BioInvent has established partnerships with several big pharma companies, who not only contribute to the validation of the company's clinical concepts but also has the financial strength to bring drug candidates to market.

The company also has strong and long-term institutional specialist and generalist owners, something which brings stability and further enhances the ability to develop new and unique drug candidates. BioInvent also has a proven track record of its financing activities and has a solid cash position, providing strength and flexibility in the continued transformation of the company.

Financial information

Financial information.

REVENUES AND RESULT

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

Fourth quarter

Net sales amounted to SEK 4.9 million (98.7). Revenues for the period were mainly derived from production of antibodies for clinical studies. Revenues for the corresponding period 2020 were mainly derived from upfront payment of $5 million in connection with licensing of BI-1206 to CASI Pharmaceuticals for the Greater China region, a $3 million milestone payment related to selection of antibodies under the collaboration with Pfizer, a €2 million milestone payment under the collaboration with Daiichi Sankyo related to the initiation of a Phase I clinical trial, and also revenues from production of antibodies for clinical studies.

The Company's total costs amounted to SEK 82.4 million (69.5). Operating costs are divided between external costs of SEK 52.8 million (46.0), personnel costs of SEK 25.9 million (20.4) and depreciation of SEK 3.7 million (3.1).

Research and development costs amounted to SEK 70.4 million (60.1). Sales and administrative costs amounted to SEK 12.0 million (9.4).

Profit/loss after tax amounted to SEK -78.8 million (28.5). The net financial items amounted to SEK 0.1 million (-0.9). Profit/loss per share before and after dilution amounted to SEK -1.35 (0.74).

January - December

Net sales amounted to SEK 19.4 million (147.4). Revenues for the period were mainly derived from production of antibodies for clinical studies. Revenues for the corresponding period 2020 were mainly derived from upfront payment of $5 million in connection with licensing of BI-1206 to CASI Pharmaceuticals for the Greater China region, a $3 million milestone payment related to selection of antibodies under the collaboration with Pfizer, a €2 million milestone payment under the collaboration with Daiichi Sankyo related to the initiation of a Phase I clinical trial, and also revenues from production of antibodies for clinical studies and revenues from research funding.

The Company's total costs amounted to SEK 297.8 million (223.6). Operating costs are divided between external costs of SEK 198.1 million (144.0), personnel costs of SEK 85.1 million (67.6) and depreciation of SEK 14.6 million (12.0). In January 2021, BioInvent announced that it had restructured a clinical development agreement with Cancer Research UK (CRUK) for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces Bioinvent's obligations to CRUK. This cost is included in external costs for the first quarter.

Research and development costs amounted to SEK 258.3 million (191.4). Sales and administrative costs amounted to SEK 39.5 million (32.2).

Loss after tax amounted to SEK -278.4 million (-76.3). The net financial items amounted to SEK -0.1 million (-0.9). Loss per share before and after dilution amounted to SEK -5.14 (-2.66).

FINANCIAL POSITION AND CASH FLOW

On February 23, 2021, BioInvent successfully completed a directed share issue of approximately SEK 962 million before transaction costs. Investors in the directed share issue are a range of international and Swedish investors, including Redmile Group, LLC., Invus, HBM Healthcare Investments, The Fourth National Swedish Pension Fund, Swedbank Robur Fonder and Van Herk Investments. 2,834,399 new shares were issued based on the authorization granted by the EGM on November 27, 2020, and 16,260,601 new shares were issued after approval at an EGM held on March 23, 2021.

The share capital consists of 58,471,096 shares.

As of December 31, 2021, the Group's liquid funds, current and long-term investments amounted to SEK 1,365.0 million (729.3). The cash flow from operating activities for the January-December period amounted to SEK -245.8 million (-62.6).

The shareholders' equity amounted to SEK 1,367.0 million (743.5) at the end of the period. The Company's share capital was SEK 11.7 million. The equity/assets ratio at the end of the period was 94 (93) percent. Shareholders' equity per share amounted to SEK 23.38 (18.88).

INVESTMENTS

Investments for the January-December period in tangible fixed assets amounted to SEK 13.3 million (6.7).

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 December 31, 2021, BioInvent had 84 (72) employees. 75 (65) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 47 in the Company's annual report 2020.

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.

Covid-19 is continuing to create many uncertainties in the world and healthcare is no exception. As we have previously communicated, BioInvent has taken all the necessary precautions with regards to Covid-19 and we remain on track with our clinical trials and results. As the situation is still evolving, timelines may be impacted in geographic areas most severely affected, and we will provide updates as necessary.

For a more detailed description of risk factors, see section "Risks and Risk Management", page 31, in the Company's annual report 2020.

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

	3 MONTHS 2021 OCT.-DEC.	3 MONTHS 2020 OCT.-DEC.	12 MONTHS 2021 JAN.-DEC.	12 MONTHS 2020 JAN.-DEC.
Net sales	4,903	98,743	19,384	147,372
Operating costs				
Research and development costs	-70,448	-60,077	-258,337	-191,421
Sales and administrative costs	-11,961	-9,456	-39,438	-32,155
Other operating income and costs	-1,341	198	41	730
	-83,750	**-69,335**	**-297,734**	**-222,846**
Operating profit/loss	**-78,847**	**29,408**	**-278,350**	**-75,474**
Profit/loss from financial investments	87	-888	-94	-859
Profit/loss before tax	**-78,760**	**28,520**	**-278,444**	**-76,333**
Tax	-	-	-	-
Profit/loss	**-78,760**	**28,520**	**-278,444**	**-76,333**
Other comprehensive income				
Items that have been or may be reclassified subsequently to profit or loss	-	-	-	-
Comprehensive income	**-78,760**	**28,520**	**-278,444**	**-76,333**
Other comprehensive income attributable to parent Company's shareholders	-78,760	28,520	-278,444	-76,333
Profit/loss per share, SEK				
Before dilution	-1.35	0.74	-5.14	-2.66
After dilution	-1.35	0.74	-5.14	-2.66

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

	2021 DEC. 31	2020 DEC. 31
ASSETS		
Intangible fixed assets	0	0
Tangible fixed assets - leases	27,433	12,834
Tangible fixed assets - other	21,651	16,762
Financial fixed assets - long-term investments	282,208	-
Total fixed assets	**331,292**	**29,596**
Inventories	16,848	4,079
Current receivables	16,342	39,695
Current investments	172,074	-
Liquid funds	910,755	729,270
Total current assets	**1,116,019**	**773,044**
Total assets	**1,447,311**	**802,640**
SHAREHOLDERS' EQUITY		
Total shareholders' equity	**1,366,987**	**743,499**
LIABILITIES		
Lease liabilities	21,532	5,632
Total long term liabilities	**21,532**	**5,632**
Lease liabilities	6,835	5,972
Other liabilities	51,957	47,537
Total short term liabilities	**58,792**	**53,509**
Total shareholders' equity and liabilities	**1,447,311**	**802,640**

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

	2021 OCT.-DEC.	2020 OCT.-DEC.	2021 JAN.-DEC.	2020 JAN.-DEC.
Shareholders' equity at beginning of period	**1,445,495**	**653,800**	**743,499**	**169,436**
Comprehensive income				
Profit/loss	-78,760	28,520	-278,444	-76,333
Comprehensive other income	-	-	-	-
Total comprehensive income	**-78,760**	**28,520**	**-278,444**	**-76,333**
Total, excluding transactions with equity holders of the Company	**1,366,735**	**682,320**	**465,055**	**93,103**
Transactions with equity holders of the Company				
Employee options program	252	125	1,138	-41
Directed share issues and rights issue				589,383
Directed share issue		61,054	900,794	61,054
Shareholders' equity at end of period	**1,366,987**	**743,499**	**1,366,987**	**743,499**

The share capital as of December 31, 2021 consists of 58,471,096 shares and the share's ratio value was 0.20. The directed new share issue carried out in March 2021 raised approximately SEK 961.6 million before issue expenses and approximately SEK 900.8 million after issue expenses.

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

	2021 OCT.-DEC.	2020 OCT.-DEC.	2021 JAN.-DEC.	2020 JAN.-DEC.
Operating activities				
Operating profit/loss	-78,847	29,408	-278,350	-75,474
Depreciation	3,683	3,108	14,610	12,004
Adjustment for other non-cash items	252	125	1,138	-41
Interest received and paid	-115	-105	-269	-307
Cash flow from operating activities before changes in working capital	**-75,027**	**32,536**	**-262,871**	**-63,818**
Changes in working capital	-711	-3,336	17,028	1,196
Cash flow from operating activities	**-75,738**	**29,200**	**-245,843**	**-62,622**
Investment activities				
Acquisition of tangible fixed assets	-2,966	-1,615	-13,260	-6,700
Acquisition of financial investments	-265,480	-	-454,282	-
Cash flow from investment activities	**-268,446**	**-1,615**	**-467,542**	**-6,700**
Cash flow from operating activities and investment activities	**-344,184**	**27,585**	**-713,385**	**-69,322**
Financing activities				
Directed share issues and rights issue				589,383
Directed share issue		61,054	900,794	61,054
Amortization of lease liability	-1,577	-1,467	-5,924	-5,820
Cash flow from financing activities	**-1,577**	**59,587**	**894,870**	**644,617**
Change in liquid funds	**-345,761**	**87,172**	**181,485**	**575,295**
Opening liquid funds	1,256,516	642,098	729,270	153,975
Liquid funds at end of period	**910,755**	**729,270**	**910,755**	**729,270**
Liquid funds, specification:				
Cash and bank	910,755	729,270	910,755	729,270
	910,755	**729,270**	**910,755**	**729,270**

Key financial ratios for the Group

	2021 DEC. 31	2020 DEC. 31
Shareholders' equity per share at end of period, SEK	23.38	18.88
Number of shares at end of period (thousand)	58,471	39,376
Equity/assets ratio, %	94.5	92.6
Number of employees at end of period	84	72

Shareholders' equity per share and number of shares at end of period has been adjusted as if the reverse split in 2020 had been completed January 1, 2020.

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

	3 MONTHS 2021 OCT.-DEC.	3 MONTHS 2020 OCT.-DEC.	12 MONTHS 2021 JAN.-DEC.	12 MONTHS 2020 JAN.-DEC.
Net sales	4,903	98,743	19,384	147,372
Operating costs				
Research and development costs	-70,743	-60,133	-258,521	-191,649
Sales and administrative costs	-11,987	-9,461	-39,454	-32,175
Other operating income and costs	-1,341	198	41	730
	-84,071	**-69,396**	**-297,934**	**-223,094**
Operating profit/loss	**-79,168**	**29,347**	**-278,550**	**-75,722**
Profit/loss from financial investments	272	-819	420	-528
Profit/loss after financial items	**-78,896**	**28,528**	**-278,130**	**-76,250**
Tax	-	-	-	-
Profit/loss	**-78,896**	**28,528**	**-278,130**	**-76,250**
Other comprehensive income	**-**	**-**	**-**	**-**
Comprehensive income	**-78,896**	**28,528**	**-278,130**	**-76,250**

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

	2021 DEC. 31	2020 DEC. 31
ASSETS		
Intangible fixed assets	0	0
Tangible fixed assets	21,651	16,762
Financial fixed assets - Shares in subsidiaries	687	687
Financial fixed assets - long-term investments	282,208	-
Total fixed assets	**304,546**	**17,449**
Current assets		
Inventories	16,848	4,079
Current receivables	16,030	41,233
Current investments	172,074	-
Cash and bank	910,755	729,270
Total current assets	**1,115,707**	**774,582**
Total assets	**1,420,253**	**792,031**
SHAREHOLDERS' EQUITY		
Restricted equity	39,387	106,445
Non-restricted equity	1,328,260	637,400
Total shareholders' equity	**1,367,647**	**743,845**
LIABILITIES		
Short term liabilities	52,606	48,186
Total short term liabilities	**52,606**	**48,186**
Total shareholders' equity and liabilities	**1,420,253**	**792,031**

The board of directors and the CEO hereby ensure that this interim report for the period January 1, 2021 – December 31, 2021 provides a fair overview of the operations, financial position and performance of the Company and the Group and describes the material risks and uncertainty factors faced by the Company and the companies included in the Group.

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

Lund, February 23, 2022

Leonard Kruimer
Chairman of the Board

Vessela Alexieva
Board member

Kristoffer Bissessar
Board member

Dharminder Chahal
Board member

Thomas Hecht
Board member

Vincent Ossipow
Board member

Bernd Seizinger
Board member

Martin Welschof
CEO

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 2021 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.

For more detailed information about the Group's accounting principles regarding revenues, see Note 1 Accounting principles, page 43, in the Company's annual report 2020.

NOTE 2 NET REVENUE

SEK THOUSAND	2021 OCT.-DEC.	2020 OCT.-DEC.	2021 JAN.-DEC.	2020 JAN.-DEC.
Revenue by geographical region:				
Sweden	4,107	230	13,515	2,747
Europe	370	6,317	4,213	34,269
USA	426	71,529	1,656	89,689
Japan	-	20,667	-	20,667
Other countries	-	-	-	-
	4,903	**98,743**	**19,384**	**147,372**
Revenue consists of:				
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	70,015	-	76,713
Revenue from technology licenses	-	20,667	-	20,667
Revenue from external development projects	4,903	8,061	19,384	49,992
	4,903	**98,743**	**19,384**	**147,372**

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- R) Orphan Drug Designation granted to BI-1206 for the treatment of follicular lymphoma.
- BioInvent and Transgene published preclinical BT-001 proof-of-concept data in the *Journal of ImmunoTherapy of Cancer* (JITC).
- BI-1607 CTA approval received.
- Marie Moores was appointed Chief Operating Officer.

(R)= Regulatory event

Other information.

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on April 28, 2022 at 4 p.m. Elite Hotel Ideon, Scheelevägen 27, Lund. Notice to attend will be announced in the Swedish press in Post- och Inrikes Tidningar and on the Company's website.

The Board of Directors and the CEO do not propose the payment of any dividend for the 2021 business year.

FINANCIAL CALENDAR

- Annual report expected to be available on the website 7 April 2022.
- Interim reports April 27, August 25, October 27, 2022

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.

BioInvent International AB (publ)
Co. reg. no. 556537-7263
Address: Ideongatan 1, 223 70 Lund
Tel.: +46 (0)46 286 85 50

FORWARD LOOKING INFORMATION

This financial statement 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 Year-end report.