BioInvent

UNLEASHING IMMUNITY TO FIGHT CANCER

INTERIM REPORT Q3, 2023

Martin Welschof, CEO:

"In the third quarter of 2023, BioInvent achieved a significant landmark with the recruitment of the first patient to the BI-1808 single agent Phase 2a study. BI-1808 can potentially become a novel checkpoint inhibitor and thus play an important role in the context of immune oncology. BioInvent is leading the field of companies aiming to unlock the value of TNFR2 in cancer therapy."

THIRD QUARTER 2023

- Net sales SEK 26.8 (17.9) million.
- Profit/loss after tax SEK -71.1 (-63.9) million.
- Profit/loss after tax per share before and after dilution SEK -1.08 (-1.00).
- Cash flow from operating activities SEK -106.2 (172.8) million.

JANUARY – SEPTEMBER 2023

- Net sales SEK 56.1 (305.5) million.
- Profit/loss after tax SEK -233.1 (35.8) million.
- Profit/loss after tax per share before and after dilution SEK -3.55 (0.59).
- Cash flow from operating activities SEK -269.3 (30.4) million.
- Liquid funds, current and long-term investments as of September 30, 2023: SEK 1,357.5 (1,664.3) million.

BioInvent in numbers, September 30, 2023

- 5 projects in clinical development
- 10+ development agreements
- 108 employees (FTE)
- SEK 1,358 in liquid funds & investments
- SEK 1,098 m in market cap

Highlights

EVENTS IN THE THIRD QUARTER

- BioInvent announced it will hold two poster presentations at SITC 38th Annual Meeting in November 2023; single agent data for BI-1808 and preclinical data for BI-1910
- The first patient was recruited in the Phase 2a trial of single agent BI-1808 for the treatment of advanced malignancies
- The subcutaneous arm of Phase 1/2 trial with BI-1206 in solid tumors was initiated
- A research milestone event was achieved in the collaboration with Exelixis, triggering a USD 1 million milestone payment
- The dose-escalation part of the BI-1607 study was completed without any safety concerns. First clinical data to be presented at the San Antonio Breast Cancer Symposium on December 6, 2023.

EVENTS AFTER THE END OF THE PERIOD

- BioInvent and Transgene announced that the first patient had been treated in Part B of Phase 1 trial assessing the novel oncolytic virus BT-001 in combination with KEYTRUDA® (pembrolizumab)

BioInvent initiates Phase 2 study for BI-1808 as a single agent

In the third quarter of 2023, BioInvent achieved a significant landmark with the recruitment of the first patient to the BI-1808 single agent Phase 2a study. BI-1808 can potentially become a novel checkpoint inhibitor and thus play an important role in the context of immune oncology. BioInvent is leading the field of companies aiming to unlock the value of TNFR2 in cancer therapy.

During the quarter, our clinical programs continue to move forward, and we are anticipating a significant number of major milestones throughout 2023 and 2024. Currently, we have four drug candidates in five ongoing clinical programs and will soon be expanding the pipeline further.

STRONG INTERIM BI-1808 SAFETY DATA

Earlier this year, we reported strong interim safety data on BI-1808 as a single agent from the Phase 1/2 study. This study is investigating the use of BI-1808 as a single agent and in combination with pembrolizumab in patients with advanced malignancies, whose disease has continued to progress after standard therapy. The clinical data are highly encouraging, and we are excited to further investigate the safety and efficacy profile of our antibody in a larger number of patients, and different clinical settings. We are now enlarging the scope of BI-1808 towards first line treatment and indications such as melanoma and other forms of T cell lymphomas.

ENROLLMENT OF FIRST PATIENT IN BI-1206 SUBCUTANEOUS ADMINISTRATION

During the quarter, we enrolled the first patient in a Phase 1/2 trial of a subcutaneous (SC) formulation of our lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, in combination with pembrolizumab in solid tumors. The intravenous part of the study has already generated early signs of efficacy in the form of two long-lasting partial responses and two cases of stable disease.

Martin Welschof, CEO

SIX KEY CATALYSTS EXPECTED IN H2 2023

BI-1206 + Keytruda	BI-1808 single agent	BI-1808 single agent	BT-001 + Keytruda	BI-1607 + trastuzumab	BI-1910 single agent
Start of Phase 1 - SC	Start of Phase 2a Part A	Phase 1 data at SITC	Start of combination study with Keytruda	Phase 1 data at SABCS	Start Phase 1/2a
✓	✓		✓		

BI-1206 SC IN COMBINATION WITH RITUXIMAB

We are currently compiling the emerging data from the two ongoing trials where patients are being administered with the subcutaneous formulation: for the treatment of NHL and solid tumors. For the NHL study, we can now say that BI-1206 can be safely administered at doses of 150 mg SC. We plan however to accumulate more data points, so the data will be compiled and presented in H1 2024.

INITIATION OF THE COMBINATION PART IN THE BT-001 STUDY

Together with our partner Transgene, we have initiated the combination part of the trial of the oncolytic virus BT-001 for the treatment of solid tumors. Previously reported Phase 1 data have confirmed the mechanism of action of BT-001 as a single agent and demonstrated first signs of anti-tumor activity.

MILESTONE PAYMENT FROM EXELIXIS

The payment of a milestone of USD 1 million by Exelixis, Inc. is an important validation of our technology platform and the work being carried out under our collaboration and license agreement. The collaboration with Exelixis is a good example of how our cancer immunology expertise and discovery platform can accelerate drug discovery both for ourselves and for our partners.

UPCOMING PRESENTATIONS THIS YEAR

We will be holding two presentations on our anti-tumor necrosis factor receptor 2 (TNFR2) programs at the Society of Immunotherapy for Cancer (SITC) 38th Annual Meeting, which is being held November 3-5, 2023, in San Diego, California. The posters will showcase the latest data from a clinical Phase 1 trial evaluating the first-in-class antibody BI-1808 as single agent, as well as preclinical data for BI-1910, which has received Investigational New Drug approval and is expected to enter clinical development by the end of this year.

Furthermore, on December 6, 2023, we will present the first clinical Phase 1 data for our second anti-FcγRIIB antibody BI-1607 at the San Antonio Breast Cancer Symposium being held in Texas, US.

MULTIPLE VALUE-INFLECTION POINTS

This sets the stage for what will be a busy end to the year for BioInvent – which will continue through 2024.

In H1 2024, we expect to report data on the combination of BI-1808 with pembrolizumab from the Phase 1 part of the trial in advanced malignancies and on the dose-escalation of BI-1206 administered subcutaneously in combination with rituximab.

It promises to be an exciting time ahead and I am very excited to see more data on our novel and first-in-class immuno-modulatory antibodies for cancer therapy. These achievements are only possible thanks to the dedication of the team at BioInvent, and the continuing support of our loyal investors and partners.

I would like to take this moment to thank all of you for the strong collaboration, and I look forward to further updating you again in a few months' time.

Martin Welschof, CEO
October 2023

Pipeline with five proprietary clinical programs

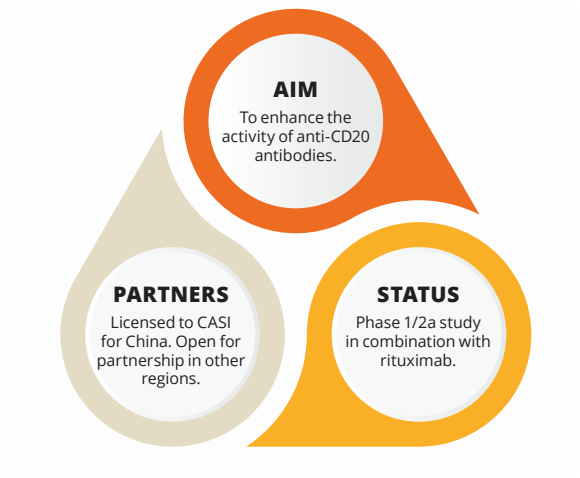
BioInvent is focused on developing novel immuno-modulatory antibodies for cancer therapy. These innovative antibodies may significantly improve the efficacy of currently available checkpoint inhibitor and/or activate anti-cancer immunity in currently non-responding patients.

FOUR DRUG CANDIDATES IN FIVE PROPRIETARY CLINICAL STUDIES

Candidate drug	Combination agent	Target	Indication	Phase 1	Phase 2	Partner
BI-1206	Rituximab	FcγRIIB	NHL			CASI
BI-1206	Pembrolizumab	FcγRIIB	Solid tumor			CASI
BI-1607	Trastuzumab	FcγRIIB	Solid tumor			
BI-1808	Single agent/Pembrolizumab	TNFR2	Solid tumor			
BT-001	Pembrolizumab	CTLA-4	Solid tumor			transgene

BI-1206 in non-Hodgkin's lymphoma

BI-1206 selectivity binds to FcγRIIB (CD32B), which is overexpressed in several forms of non-Hodgkin's lymphoma (NHL). Overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL. By blocking FcγRIIB, BI-1206 is expected to recover and enhance the activity of rituximab and other anti-CD20 monoclonal antibodies. The combination of the two drugs could provide a new and important option for patients suffering from NHL and represents a substantial commercial opportunity. Clinical phase 1/2a study is ongoing with BI-1206 in combination with rituximab.



STATUS

Clinical Phase 1/2a study (NCT03571568) ongoing

A subcutaneous (SC) formulation is being developed in parallel to the intravenous (IV) and patient recruitment to the study with BI-1206 SC as well as BI-1206 IV is ongoing. For SC, it has so far been shown that a dose of 150 mg can be safely administered. The dose is predicted to provide drug exposure at levels at which responses have already been observed IV.

QUALITY OF RESPONSES PARTICULARLY IMPRESSIVE

All patients in the ongoing study of BI-1206 have previously been treated with one or multiple rituximab containing treatments and classified as refractory or relapsed. In the intravenous (IV) dose escalation cohort, responses have been observed across the dose range of 30-100 mg, including 4 complete responders (CR), 3 partial responders (PR) and 4 cases of stable disease (SD) out of 15 evaluable patients. Among the CR population, responses have been long-lasting, three of them lasting years after end of treatment, while the 4th is still on treatment. As of June 2023, the median duration of complete response was 2.5 years, with three patients still ongoing. No maximum tolerated dose has been defined, and Phase 2a dose IV expansion cohort is currently enrolling patients.

The presented data are highly encouraging and show the benefit of BI-1206 in rescuing rituximab treatment in advanced NHL. The quality of the responses is particular impressive.

STUDY DESIGN

The Phase 1/2a study (NCT03571568) is divided into two parts, each with a subcutaneous (SC) and intravenous infusion (IV) arm:

1) Phase 1, with dose escalation cohorts using a 3+3 (IV) or Bayesian logistic regression model, BLRM (SC) 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.

CLINICAL DEVELOPMENT IN CHINA

CASI is performing the trials with the aim to further evaluate the pharmacokinetic profile of BI-1206 in combination with rituximab in NHL, 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.

ODD FOR THE TREATMENT OF FL AND MCL

BI-1206 has been granted Orphan Drug Designation (ODD) by FDA for the treatment of follicular lymphoma (FL), the most common form of slow-growing Non-Hodgkin's lymphoma, as well as for the more difficult-to-treat form mantle cell lymphoma.

OUT-LICENSING AND PARTNERING

Since October 2020, BioInvent has a licensing agreement in place with CASI Pharmaceuticals for China, Hong Kong, Macau and Taiwan. Under the terms of the agreement, BioInvent and CASI 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.

In January 2023, BioInvent was selected as partner of The Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP), aimed at advancing the company's program to treat blood cancers. The partnership gives access to the unique scientific, clinical and drug development expertise of LLS and also entailed a strategic capital equity investment from LLS TAP of USD 3 million.

OUTLOOK

First results from the Phase 1 trial of the subcutaneous formulation of BI-1206 are expected in H1 2024.

BI-1206 in solid tumors

BI-1206 selectively 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) ongoing

The ongoing study is recruiting patients with advanced solid tumors who had progressed on prior treatments including PD-1/PD-L1 immune checkpoint inhibitors. Patients receive a three-week cycle of BI-1206 in combination with pembrolizumab for up to two years, or until disease progression. In September 2023, the first patient was recruited to a subcutaneous (SC) arm of the Phase 1/2a study.

INTERIM RESULTS

As reported on June 7, 2023, the Phase 1, IV arm of the study has already generated early signs of efficacy, e.g., two long-lasting partial responses and two patients displaying stable disease, out of a total of 18 evaluable patients having received BI-1206 in combination with pembrolizumab. Both responding patients have melanoma, and both had previously been treated with immune checkpoint inhibitors.

These long-lasting responses in hard-to-treat metastatic diseases, in patients who had previously progressed after treatment with anti-PD1/PDL1 agents, strongly suggest that BI-1206 is enhancing and recovering the activity of pembrolizumab (an anti-PD1 agent).

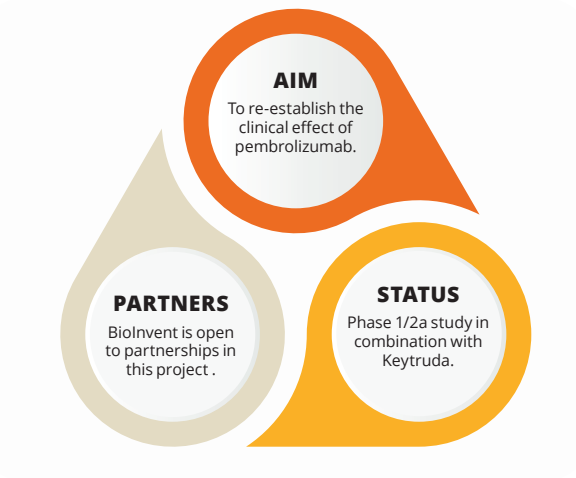
STUDY DESIGN

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.

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.

OUTLOOK

Further Phase 1 clinical data of BI-1206 is expected in 2024.

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

A clinical Phase 1/2a study evaluating BI-1607 in combination with trastuzumab is ongoing (NCT05555251)

The dose-escalation part of the study has been completed, without any safety concerns. Predicted PK profile, adequate exposure and full receptor occupancy during the full treatment interval were observed at higher doses. Exploratory work at intermediate dose levels is now being conducted to determine the best dose to move forward in subsequent studies.

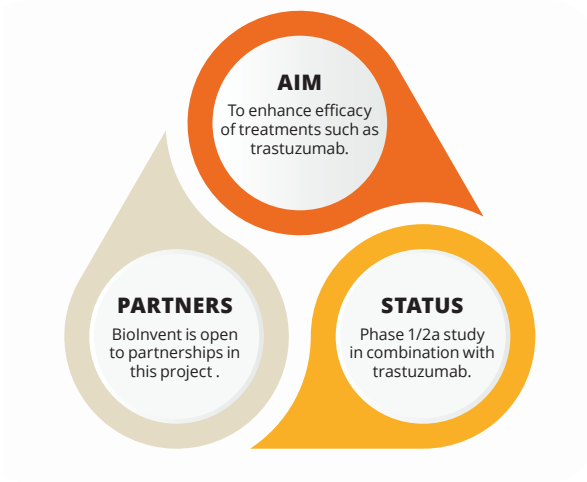
STUDY DESIGN

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 planned to be carried out at 7-12 sites in Spain, the UK, Germany, and in the U.S.

OUTLOOK

First data from the ongoing clinical study will be presented in a poster with the title "Phase 1/2a Open-label Clinical Trial of BI-1607, an Fc Engineered Monoclonal Antibody to CD32b (FcγRIIB), in Combination with Trastuzumab in Subjects with HER2-positive Advanced Solid Tumors – CONTRAST" at the San Antonio Breast Cancer Symposium in Texas, US, on December 6, 2023.



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 microenvironment 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) which is planned to initiate clinical development during the year.

STATUS

Clinical Phase 1/2a study (NCT04752826) ongoing
In September 2023, the company announced recruitment of the first patient in the single agent Phase 2a part of its Phase 1/2a trial of its first-in-class anti-TNFR2 antibody BI-1808 in advanced malignancies.

Phase 1 dose-escalation of BI-1808 in combination with pembrolizumab (Keytruda) is ongoing since September 2022.

STRONG INTERIM DATA

In June 2023, BioInvent reported strong interim safety data on BI-1808 as a single agent, from the dose-escalation, multicenter, first-in-human, consecutive-cohort, open-label study. The trial is investigating the use of BI-1808 as a single agent and in combination with pembrolizumab in subjects with advanced malignancies, whose disease has progressed after standard therapy.

Stable disease as best response was observed in six subjects during the single agent dose escalation part. The efficacy of BI-1808 as single agent will now be further explored in the Phase 2a part of the trial in a larger sample of patients. In addition to the originally planned expansion cohorts in lung cancer, ovarian cancer and cutaneous T cell lymphoma (CTCL), BioInvent plans to enlarge the scope of the signal seeking cohorts to include new cohorts in melanoma and other forms of T cell lymphomas. This is driven by the exciting data observed so far.

STUDY DESIGN

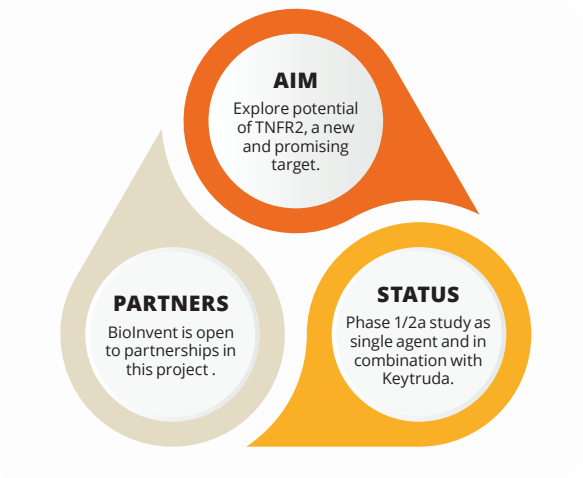
During the first part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent and in combination with the anti-PD-1 therapy Keytruda will be evaluated in patients with advanced solid tumors and T cell lymphoma. In the subsequent part of the Phase 1/2a study, BI-1808 as single-agent and in combination with the anti-PD-1 therapy Keytruda is evaluated in expansion cohorts in patients with the selected indications. The study is expected to enroll a total of approximately 180 patients.

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.

OUTLOOK

The company will hold two poster presentations on both of its anti-tumor necrosis factor receptor 2 (TNFR2) programs at the Society of Immunotherapy for Cancer (SITC) 38th Annual Meeting, held November 3-5, 2023, in San Diego, California. The posters will showcase the latest data from a clinical Phase 1 trial evaluating BI-1808 as single agent, as well as preclinical data for BI-1910. BI-1910 has received an IND approval and is expected to enter clinical development H2 2023.



Titles and numbers of the poster presentations are as follows:
BI-1808: Phase 1/2a Clinical Trial of BI-1808, a Monoclonal Antibody to Tumor Necrosis Factor Receptor 2 (TNFR2) as Single Agent and in Combination with Pembrolizumab. Number: 757
BI-1910: Preclinical development of an agonistic anti-TNFR2 antibody (BI-1910) for cancer immunotherapy. Number: 1368
For further information about the conference, please refer to Home - SITC 2023 (sitcancer.org).

First data from the BI-1808 and Keytruda combination study are expected in H1 2024.

BT-001 in solid tumors

BT-001 is an oncolytic virus developed with Transgene's Invir.IO™ platform and BioInvent's proprietary n-CoDeR/F.I.R.S.T platforms. The use of an oncolytic virus to deliver an anti-CTLA-4 antibody 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.

BT-001 is engineered to express both a Treg-depleting human recombinant anti-CTLA-4 antibody and a 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.

STATUS

Clinical phase 1/2a study (NCT04725331) ongoing

In October 2023, BioInvent and Transgene announced that the first patient of the Phase 1 part B clinical trial evaluating the combination of BT-001 and MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) had been dosed.

POSITIVE INTERIM RESULTS

In May 2023, the company announced positive data from the ongoing Phase 1/2a study. Treatment with single agent BT-001 in 18 patients has been completed with no safety concerns reported. Patients had at least one accessible superficial lesion and were studied in three dose-escalating cohorts. BT-001 stabilized the injected lesions in eleven patients in total: two at the 10^6 pfu dose (n=6), five at 10^7 pfu (n=6) and four at 10^8 pfu (n=6). Furthermore, objective antitumor activity, defined as decrease of injected lesion size of 50% or more, was observed in one patient in the 10^6 pfu cohort (n=6) and one patient in the 10^7 pfu cohort (n=6). Previously reported Phase 1 data confirmed the mechanism of action of BT-001 as a single agent and demonstrated first signs of anti-tumor activity.

STUDY DESIGN

The ongoing Phase 1/2a (NCT: 04725331) study is a multicenter, open label, dose-escalation trial evaluating BT-001 as a single agent and in combination with pembrolizumab (anti-PD-1 treatment). Patient inclusions are ongoing in Europe (France, Belgium) and the trial has been authorized in the US.

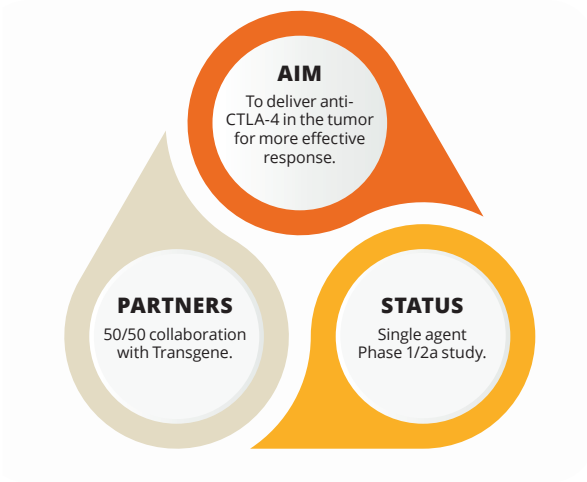
This Phase 1 is divided into two parts. In part A, patients with metastatic/advanced tumors received single agent, intra-tumoral administrations of BT-001. Part B is exploring intra-tumoral injections of BT-001 in combination with KEYTRUDA. In this part, KEYTRUDA is being provided to the trial by MSD (a tradename of Merck & Co., Inc., Rahway, NJ, USA).

The Phase 2a will evaluate the combination regimen in several patient cohorts with selected 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 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.

OUTLOOK

The inclusion of the last patient in Part B of the Phase 1 study, evaluating the combination of BT-001 and KEYTRUDA® is expected in H1 2024.

Discovery and preclinical development

BioInvent's discovery and 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.

Traditionally, drug discovery work is carried out according to a hypothesis in which first a receptor is found that is believed to be suitable for antibody drugs. The search then begins for antibodies that bind to this receptor. However, by combining new techniques looking simultaneously for both antibodies and the receptors they bind to, it is possible to find many more functioning antibodies than previously.

What BioInvent does is find antibodies against large amounts of different receptors on the cell and look at these antibodies' function directly. The strategy is to test how the antibodies work without any prior assumptions; for example, whether it can kill a tumor cell. Once we have identified which antibodies work, various tests are carried out to determine which receptor they bind to. By doing this, we have found antibodies that bind to cancer cells but not to normal cells in healthy individuals.

The process of looking for antibodies and targets simultaneously, rather than first finding a target and then looking for a suitable antibody is central in BioInvent's F.I.R.S.T™ platform. It is this strategy, combined with new techniques, that is enabling many more antibodies to be found than before. This method is important for the development of future antibody drugs that can be used to treat many different diseases.

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 testing 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.

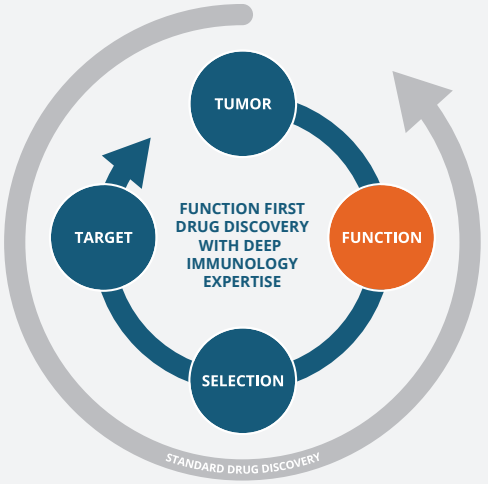
The strength of the company's technology platform with its development tool F.I.R.S.T™ and the n-CoDeR® antibody library is a strong driver in the discovery phase where the company currently is working on a number of promising candidates.

FUNCTION FIRST DRUG DISCOVERY

In our drug discovery process, we start from what matters the most, namely the function. While other companies focus on the targets and test function at the end, we do it the other way round.

Our approach contrasts with the more commonly used target-focused approach, where a target is picked on beforehand and consequently, functionality is restricted to this specified target. BioInvent applies a function-first approach, meaning it discovers the most functional antibodies to unknown targets, which can then be identified in a subsequent step.

As such, BioInvent's approach discovers highly efficacious antibodies to targets that have not previously been pursued in cancer immunotherapy, as well as uniquely functional antibodies to validated targets. This is exemplified in, e.g., the company's BI-1808 first-in-class anti-TNFR2 antibody and the strongly Treg-depleting anti-CTLA-4 antibody that has been vectorized in the BT-001 program.



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.

SIX OUTLICENSED PROJECTS IN CLINICAL STUDIES

Project	Target	Primary indication	Phase 1	Phase 2	Phase 3	Market	Licensee
MT-2990	anti-IL33	Endometriosis					Mitsubishi Tanabe
TAK-079	anti-CD38	ITP					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

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 6 to 10 for details. BioInvent has three supply and collaboration agreements with MSD to support the expansion of the clinical trial programs for the anti-FcγRIIB antibody BI-1206, the anti-TNFR2 antibody BI-1808 and the oncolytic virus BT-001. The agreements with MSD give BioInvent the opportunity to explore the potential synergistic activity of its proprietary drug candidates in combination with pembrolizumab. As MSD carefully reviews programs before establishing such agreements, this provides further validation of the high quality of the programs.

STRATEGIC CLINICAL COLLABORATIONS

In January 2023, BioInvent was selected as partner of The Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP) and received a strategic equity investment of USD 3 million to support clinical advancement of BI-1206 in Non-Hodgkin's Lymphoma and BI-1808 in cutaneous T-cell lymphoma. LLS TAP is a strategic funding initiative to accelerate innovative blood cancer therapeutics worldwide.

R&D PARTNERSHIPS FOR THE FUTURE

BioInvent has also signed early research and development partnerships focused on the identification and development of novel antibodies for use in immuno-oncology therapeutics. The latest agreement was signed in July 2022, with the US company Exelixis. BioInvent received an upfront fee of $25 million in exchange for rights to select targets identified using BioInvent's proprietary F.I.R.S.T platform and n-CoDeR library. Exelixis will have the right to exercise an option to in-license any of the target programs upon identification of a development candidate directed to that target. Upon option exercise, Exelixis will pay BioInvent an option exercise fee and will assume responsibility for all future development and commercialization activities for the development candidate. In addition, BioInvent will be eligible for success-based development and commercialization milestones, as well as tiered royalties on the annual net sales of any products that are successfully commercialized under the collaboration.

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 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.

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 26.8 million (17.9). Revenues for the period were mainly derived from a USD 1 million (SEK 11.1 million) milestone payment from Exelixis, when a research milestone had been achieved in the development of an antibody, as well as revenues from production of antibodies for clinical studies and revenues from research services.

Revenues for the corresponding period 2022 were mainly derived from production of antibodies for clinical studies and revenues from research services. See also note 2.

The Company's total costs amounted to SEK 108.0 million (88.1). These are divided between external costs of SEK 76.4 million (61.3), personnel costs of SEK 27.4 million (23.2) and depreciation of SEK 4.2 million (3.6).

Research and development costs amounted to SEK 96.7 million (77.7). Sales and administrative costs amounted to SEK 11.3 million (10.4).

Profit/loss after tax amounted to SEK -71.1 million (-63.9). The net financial items amounted to SEK 10.3 million (5.3). Profit/loss per share before and after dilution amounted to SEK -1.08 (-1.00).

January - September

Net sales amounted to SEK 56.1 million (305.5). Revenues for the period were mainly derived from a USD 1 million (SEK 11.1 million) milestone payment from Exelixis, when a research milestone had been achieved in the development of an antibody, as well as revenues from production of antibodies for clinical studies and revenues from research services.

Revenues for the corresponding period 2022 were mainly derived from an upfront fee of USD 25 million (SEK 255.8 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 (SEK 5.2 million) milestone payment under the collaboration with Bayer Healthcare/Hope Medicine related to the initiation of a Phase 2 clinical trial, as well as revenues from production of antibodies for clinical studies and revenues from research services. See also note 2.

The Company's total costs amounted to SEK 315.3 million (276.5). These are divided between external costs of SEK 217.0 million (191.0), personnel costs of SEK 86.1 million (74.8) and depreciation of SEK 12.2 million (10.7).

Research and development costs amounted to SEK 278.8 million (241.0). Sales and administrative costs amounted to SEK 36.5 million (35.5).

Profit/loss after tax amounted to SEK -233.1 million (35.8). The net financial items amounted to SEK 25.9 million (7.5). Profit/loss per share before and after dilution amounted to SEK -3.55 (0.59).

FINANCIAL POSITION AND CASH FLOW

On January 17, 2023 BioInvent announced that it had been selected as partner of The Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP), aimed at advancing the company's program to treat blood cancers. The partnership include access to the unique scientific, clinical and drug development expertise of LLS as well as a strategic capital equity investment from LLS TAP of USD 3 million (SEK 31.3 million before issue expenses). 836,478 new shares were issued based on the authorization granted by the AGM on April 28, 2022.

The share capital consists of 65,804,362 shares as of September 30, 2023.

As of September 30, 2023, the Group's liquid funds, current and long-term investments amounted to SEK 1,357.5 million (1,664.3). The cash flow from operating activities for the January-September period amounted to SEK -269.3 million (30.4).

The shareholders' equity amounted to SEK 1,406.3 million (1,684.3) at the end of the period. The Company's share capital was SEK 13.2 million. The equity/assets ratio at the end of the period was 95 (96) percent. Shareholders' equity per share amounted to SEK 21.37 (25.92).

INVESTMENTS

Investments for the January-September period in tangible fixed assets amounted to SEK 10.6 million (6.2).

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, 2023, BioInvent had 108 (93) employees (full time equivalent). 97 (84) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 63 in the Company's annual report 2022. 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.

For a more detailed description of risk factors, see section "Risks and Risk Management", page 47, in the Company's annual report 2022.

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

	3 MONTHS 2023 JULY-SEP.	3 MONTHS 2022 JULY-SEP.	9 MONTHS 2023 JAN.-SEP.	9 MONTHS 2022 JAN.-SEP.	12 MONTHS 2022 JAN.-DEC.
Net sales	26,797	17,920	56,142	305,486	326,126
Operating costs					
Research and development costs	-96,729	-77,675	-278,837	-240,945	-325,929
Sales and administrative costs	-11,270	-10,432	-36,470	-35,523	-50,750
Other operating income and costs	-116	1,035	151	-676	-368
	-108,115	**-87,072**	**-315,156**	**-277,144**	**-377,047**
Operating profit/loss	**-81,318**	**-69,152**	**-259,014**	**28,342**	**-50,921**
Profit/loss from financial investments	10,252	5,284	25,869	7,490	8,418
Profit/loss before tax	**-71,066**	**-63,868**	**-233,145**	**35,832**	**-42,503**
Tax	-	-	-	-	-
Profit/loss	**-71,066**	**-63,868**	**-233,145**	**35,832**	**-42,503**
Other comprehensive income					
Items that have been or may be reclassified subsequently to profit or loss	-	-	-	-	-
Comprehensive income	**-71,066**	**-63,868**	**-233,145**	**35,832**	**-42,503**
Other comprehensive income attributable to parent Company's shareholders	-71,066	-63,868	-233,145	35,832	-42,503
Profit/loss per share, SEK					
Before dilution	-1.08	-1.00	-3.55	0.59	-0.69
After dilution	-1.08	-1.00	-3.55	0.59	-0.69

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

	2023 SEP. 30	2022 SEP. 30	2022 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	21,064	22,857	26,543
Tangible fixed assets - other	29,303	21,723	25,469
Financial fixed assets - long-term investments	203,776	440,972	576,140
Total fixed assets	**254,143**	**485,552**	**628,152**
Inventories	13,315	11,238	11,506
Current receivables	61,838	34,948	55,075
Current investments	563,952	527,049	502,434
Liquid funds	589,795	696,315	515,047
Total current assets	**1,228,900**	**1,269,550**	**1,084,062**
Total assets	**1,483,043**	**1,755,102**	**1,712,214**
SHAREHOLDERS' EQUITY			
Total shareholders' equity	**1,406,269**	**1,684,259**	**1,606,122**
LIABILITIES			
Lease liabilities	13,458	17,058	18,773
Total long term liabilities	**13,458**	**17,058**	**18,773**
Lease liabilities	7,741	6,521	8,190
Other liabilities	55,575	47,264	79,129
Total short term liabilities	**63,316**	**53,785**	**87,319**
Total shareholders' equity and liabilities	**1,483,043**	**1,755,102**	**1,712,214**

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

	2023 JULY-SEP.	2022 JULY-SEP.	2023 JAN.-SEP.	2022 JAN.-SEP.	2022 JAN.-DEC.
Shareholders' equity at beginning of period	**1,476,329**	**1,467,374**	**1,606,122**	**1,366,987**	**1,366,987**
Comprehensive income					
Profit/loss	-71,066	-63,868	-233,145	35,832	-42,503
Comprehensive other income	-	-	-	-	-
Total comprehensive income	**-71,066**	**-63,868**	**-233,145**	**35,832**	**-42,503**
Total, excluding transactions with equity holders of the Company	**1,405,263**	**1,403,506**	**1,372,977**	**1,402,819**	**1,324,484**
Transactions with equity holders of the Company					
Employee options program	1,006	904	2,333	1,591	1,789
Directed share issue		279,849	30,959	279,849	279,849
Shareholders' equity at end of period	**1,406,269**	**1,684,259**	**1,406,269**	**1,684,259**	**1,606,122**

The share capital as of September 30, 2023 consists of 65,804,362 shares and the share's ratio value was 0.20. The directed new share issue carried out in January 2023 raised SEK 31.3 million before issue expenses and SEK 31.0 million after issue expenses. 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)

	2023 JULY-SEP.	2022 JULY-SEP.	2023 JAN.-SEP.	2022 JAN.-SEP.	2022 JAN.-DEC.
Operating activities					
Operating profit/loss	-81,318	-69,152	-259,014	28,342	-50,921
Depreciation	4,235	3,646	12,195	10,705	14,724
Adjustment for other non-cash items	1,006	904	2,333	1,591	1,789
Interest received and paid	3,582	-121	7,682	-436	-44
Cash flow from operating activities before changes in working capital	**-72,495**	**-64,723**	**-236,804**	**40,202**	**-34,452**
Changes in working capital	-33,748	237,494	-32,496	-9,763	-6,775
Cash flow from operating activities	**-106,243**	**172,771**	**-269,300**	**30,439**	**-41,227**
Investment activities					
Acquisition of tangible fixed assets	-2,749	-1,254	-10,550	-6,201	-12,377
Changes of financial investments	126,606	-344,669	323,876	-513,739	-616,471
Cash flow from investment activities	**123,857**	**-345,923**	**313,326**	**-519,940**	**-628,848**
Cash flow from operating activities and investment activities	**17,614**	**-173,152**	**44,026**	**-489,501**	**-670,075**
Financing activities					
Directed share issue		279,849	30,959	279,849	279,849
Amortization of lease liability	-1,934	-1,606	-5,764	-4,788	-6,362
Cash flow from financing activities	**-1,934**	**278,243**	**25,195**	**275,061**	**273,487**
Change in liquid funds	**15,680**	**105,091**	**69,221**	**-214,440**	**-396,588**
Opening liquid funds	570,567	591,224	515,047	910,755	910,755
Accrued interest on investments classified as liquid funds	3,548		5,527		880
Liquid funds at end of period	**589,795**	**696,315**	**589,795**	**696,315**	**515,047**
Liquid funds, specification:					
Cash and bank	589,795	696,315	589,795	696,315	515,047
	589,795	**696,315**	**589,795**	**696,315**	**515,047**

Key financial ratios for the Group

	2023 SEP. 30	2022 SEP. 30	2022 DEC. 31
Shareholders' equity per share at end of period, SEK	21.37	25.92	24.72
Number of shares at end of period (thousand)	65,804	64,968	64,968
Equity/assets ratio, %	94.8	96.0	93.8
Number of employees at end of period	108	93	94

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

	3 MONTHS 2023 JULY-SEP.	3 MONTHS 2022 JULY-SEP.	9 MONTHS 2023 JAN.-SEP.	9 MONTHS 2022 JAN.-SEP.	12 MONTHS 2022 JAN.-DEC.
Net sales	26,797	17,920	56,142	305,486	326,126
Operating costs					
Research and development costs	-96,878	-77,893	-279,283	-241,597	-326,368
Sales and administrative costs	-11,283	-10,451	-36,509	-35,580	-50,788
Other operating income and costs	-116	1,035	151	-676	-368
	-108,277	**-87,309**	**-315,641**	**-277,853**	**-377,524**
Operating profit/loss	**-81,480**	**-69,389**	**-259,499**	**27,633**	**-51,398**
Profit/loss from financial investments	10,398	5,440	26,345	7,987	9,068
Profit/loss after financial items	**-71,082**	**-63,949**	**-233,154**	**35,620**	**-42,330**
Tax	-	-	-	-	-
Profit/loss	**-71,082**	**-63,949**	**-233,154**	**35,620**	**-42,330**
Other comprehensive income	**-**	**-**	**-**	**-**	**-**
Comprehensive income	**-71,082**	**-63,949**	**-233,154**	**35,620**	**-42,330**

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

	2023 SEP. 30	2022 SEP. 30	2022 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	29,303	21,723	25,469
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	203,776	440,972	576,140
Total fixed assets	**233,766**	**463,382**	**602,296**
Current assets			
Inventories	13,315	11,238	11,506
Current receivables	62,490	34,636	55,450
Current investments	563,952	527,049	502,434
Cash and bank	589,795	696,315	515,047
Total current assets	**1,229,552**	**1,269,238**	**1,084,437**
Total assets	**1,463,318**	**1,732,620**	**1,686,733**
SHAREHOLDERS' EQUITY			
Restricted equity	40,854	40,687	40,687
Non-restricted equity	1,366,239	1,644,020	1,566,268
Total shareholders' equity	**1,407,093**	**1,684,707**	**1,606,955**
LIABILITIES			
Short term liabilities	56,225	47,913	79,778
Total short term liabilities	**56,225**	**47,913**	**79,778**
Total shareholders' equity and liabilities	**1,463,318**	**1,732,620**	**1,686,733**

Lund, October 26, 2023

Martin Welschof
CEO

Review report

INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on September 30, 2023 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 26, 2023

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 2023 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 60, in the Company's annual report 2022.

NOTE 2 NET REVENUE

SEK THOUSAND	2023 JULY-SEP.	2022 JULY-SEP.	2023 JAN.-SEP.	2022 JAN.-SEP.	2022 JAN.-DEC.
Revenue by geographical region:					
Sweden	5,602	3,705	13,132	22,634	25,634
Europe	1,298	10,238	4,320	18,681	27,102
USA	19,897	3,977	38,690	264,171	273,390
Other countries	-	-	-	-	-
	26,797	**17,920**	**56,142**	**305,486**	**326,126**
Revenue consists of:					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	18,988	4,417	37,307	260,180	268,753
Revenue from technology licenses	-	-	-	5,221	5,221
Revenue from external development projects	7,809	13,503	18,835	40,085	52,152
	26,797	**17,920**	**56,142**	**305,486**	**326,126**

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

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- BioInvent and Transgene announced that the first patient had been treated in Part B of Phase 1 trial assessing the novel oncolytic virus BT-001 in combination with KEYTRUDA® (pembrolizumab)

Other information

ANNUAL GENERAL MEETING

The Annual General Meeting will be held on May 3, 2024, 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, 2024
- Interim report Q1: April 24, 2024
- Interim report Q2: August 29, 2024
- Interim report Q3: October 31, 2024

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.

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