BioInvent

UNLEASHING IMMUNITY TO FIGHT CANCER

INTERIM REPORT Q2, 2023

Martin Welschof, CEO:

"In the quarter, we had impressive early signals of efficacy in the Phase 1/2 trial of our lead drug candidate, the novel anti-FcgRIIB antibody BI-1206, in combination with rituximab in non-Hodgkin's lymphoma (NHL). A fourth complete response was observed in the 100 mg dose expansion cohort in the intravenous arm of the study."

SECOND QUARTER 2023

- Net sales SEK 13.1 (270.9) million.
- Profit/loss after tax SEK -88.3 (167.4) million.
- Profit/loss after tax per share before and after dilution SEK -1.34 (2.86).
- Cash flow from operating activities SEK -84.1 (62.5) million.

JANUARY – JUNE 2023

- Net sales SEK 29.3 (287.6) million.
- Profit/loss after tax SEK -162.1 (99.7) million.
- Profit/loss after tax per share before and after dilution SEK -2.47 (1.71).
- Cash flow from operating activities SEK -163.1 (-142.3) million.
- Liquid funds, current and long-term investments as of June 30, 2023: SEK 1,461.7 (1,214.6) million.

BioInvent in numbers, June 30, 2023

- 5 projects in clinical development
- 10+ development agreements
- 103 employees (FTE)
- SEK 1,462 m in liquid funds & investments
- SEK 1,187 m in market cap

Highlights

EVENTS IN THE SECOND QUARTER

- (R) A fourth complete response was announced in Phase 1/2 trial with BI-1206 in non-Hodgkin's lymphoma
- Management was strengthened with the appointment of Ingunn Munch Lindvig as Senior Vice President Regulatory Affairs
- (R) BioInvent and Transgene reported positive Phase 1a data on oncolytic virus BT-001 in solid tumors
- IND approval obtained for clinical trial with anti-TNFR2 antibody BI-1910
- (R) Additional efficacy data announced from intravenous part of Phase 1/2 trial with BI-1206 in solid tumors
- Abstract Presentation of BI-1206 at the 17th International Conference of Malignant Lymphoma 2023
- (R) Strong interim safety data and early signs of efficacy reported in Phase 1/2a trial with anti-TNFR2 antibody BI-1808 in advanced malignancies

EVENTS AFTER THE END OF THE PERIOD

- The dose-escalation part of the BI-1607 study was completed without any safety concerns. Exploratory work at intermediate dose levels is now being conducted to determine the best dose to move forward in subsequent studies.

(R)= Regulatory event

New data underline the potential in our broadening pipeline

BioInvent made significant advances in the second quarter of 2023, reporting strong data on our lead drug candidate BI-1206, both in NHL and solid tumors, and continued to move our other candidates through clinical development. We are very encouraged by these data and the potential of our novel immune-modulatory antibodies to significantly improve options for cancer patients in urgent need of improved treatments, and shortly, we will have five drug candidates being investigated in six different clinical trials.


Martin Welschof, CEO

ENCOURAGING DATA ON BI-1206

In the quarter, we had impressive early signals of efficacy in the Phase 1/2 trial of our lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, in combination with rituximab in non-Hodgkin's lymphoma (NHL). A fourth complete response was observed in the 100 mg dose expansion cohort in the intravenous (IV) arm of the study which, in addition to the previously reported positive results, is very encouraging news for NHL patients.

BioInvent is currently also recruiting patients to a second arm of the NHL study where the drug is administered subcutaneously (SC), an administration route significantly more convenient for both patients and healthcare professionals. Given the positive results observed with the IV infusion, recruitment was slow in the lower doses of the SC arm, due to investigators giving priority to IV administration. However, since we are now at dose levels comparable to those of the IV infusion, enrollment rates in the SC arm have increased remarkably in the past few months. We are looking forward to sharing the data during the second half of this year.

Six additional patients have been treated in the IV arm of the Phase 1/2 trial of BI-1206 in combination with KEYTRUDA® (pembrolizumab) against solid tumors. Besides the patients previously reported, new data in June 2023 showed one patient

SIX KEY CATALYSTS EXPECTED IN H2 2023

BI-1206 + rituximamb	BI-1206 + Keytruda	BI-1808 single agent	BT-001 + Keytruda	BI-1607 + trastuzumab	BI-1910 single agent
Preliminary results Phase 1 – SC	Start of Phase 1 - SC	Start of Phase 2a Part A	Start of combination study with Keytruda	Preliminary results Phase 1	Start Phase 1/2a

experiencing long-lasting stable disease, with more than 80 weeks of treatment in the study, and another patient experiencing a partial response. The patient previously observed with a partial response is still responding and on treatment after more than 90 weeks.

This data further reinforces the promising profile of BI-1206. We are also investigating subcutaneous administration in solid tumors, and the first patient in this arm of the study is expected to be recruited within a short time.

STRONG PIPELINE PROGRESS

There were also strong interim safety data and early signs of efficacy in our Phase 1/2a trial of the first-in-class anti-TNFR2 antibody BI-1808 in advanced malignancies. No significant safety concerns were observed in relation to the administration of BI-1808 as single agent. Stable disease has been observed in six patients so far. Data from the arm of the trial investigating BI-1808 in combination with pembrolizumab are expected in the first half of 2024.

We have received Investigational New Drug (IND) approval for BI-1910, which will become our second anti-tumor necrosis factor receptor 2 (TNFR2) program to enter clinical development, with the first patient expected to be treated in a Phase 1/2a trial in the second half 2023. BI-1910 will become the fifth drug candidate in clinical development, in six different trials, reflecting the productivity of BioInvent's technology platform and its potential to intervene profoundly in the tumor microenvironment and significantly improve treatment for cancer patients.

Together with our partner Transgene, we reported positive Phase 1a data on the oncolytic virus BT-001 for the treatment of solid tumors. Treatment with single agent BT-001 in 18 patients has now been completed with no safety concerns reported. Based on these results, the independent Safety Review Committee has approved initiation of the combination part of the trial with pembrolizumab, with the first patient expected to be enrolled in the second half of 2023.

STRENGTHENED MANAGEMENT AND ESG TRANSPARENCY

The management team was strengthened with the appointment of Ingunn Munch Lindvig as Senior Vice President Regulatory Affairs. Ingunn is a very experienced regulatory affairs leader who has worked across all stages of product development and has hands-on experience of the US and EU regulatory systems, which will be critical as we progress our pipeline to later development stages.

We are also have been certified as a Nasdaq ESG Transparency Partner 2022. This is granted to companies with a high level of transparency regarding Environmental, Social and Governance issues (ESG) and is a recognition of BioInvent's commitment to sustainable development in our work.

The next few months are expected to be very busy at BioInvent, with several data readouts and other clinical trial milestones approaching. Our next investor event will be Börsveckan Småbolagsdag event in Stockholm on September 6, and we hope to see many of you there. As always, I would like to thank all our employees, patients and investors, without the support of whom this work would not be possible. I look forward to updating you again in October with our third quarter interim report.

Martin Welschof, CEO
August 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	FcyRIIB	NHL			CASI
BI-1206	Pembrolizumab	FcyRIIB	Solid tumor			CASI
BI-1607	Trastuzumab	FcyRIIB	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 is ongoing. The starting dose of 150 mg is predicted to provide drug exposure at levels at which responses have already been observed. The adaptive study design implemented will allow for efficient escalation to higher doses.

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 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

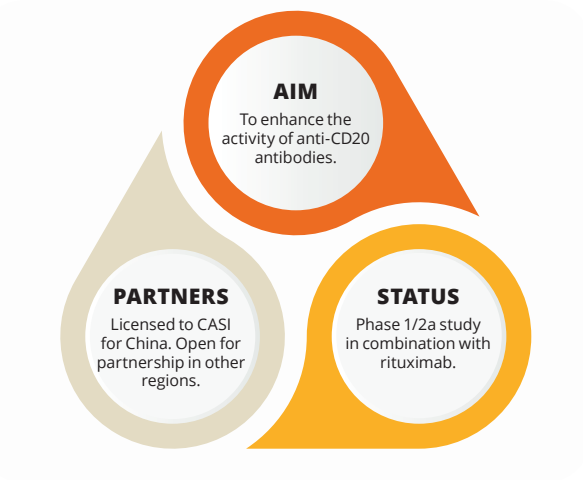
CASI is performing the trials with the aim to further evaluate the pharmacokinetic profile of BI-1206 in combination with rituximab in NHL, to assess safety and tolerability, select the Recommended Phase 2 Dose and assess early signs of clinical efficacy as part of its development program for BI-1206 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 H2 2023.

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)

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.

INTERIM RESULTS

In June 2023, the company announced additional efficacy data from intravenous (IV) part of the Phase 1/2 trial with BI-1206 in solid tumors. In addition to the patients previously reported, (1 case of pseudo progression and 1 partial response (PR), new data show one patient experiencing a long-lasting stable disease, with more than 80 weeks of treatment in the study, and another patient experiencing a PR. Both patients have melanoma, and both had previously been treated with immune checkpoint inhibitors. The latter had progressed after previous lines of those agents. The first PR observed is still responding and has been on treatment for more than 90 weeks.

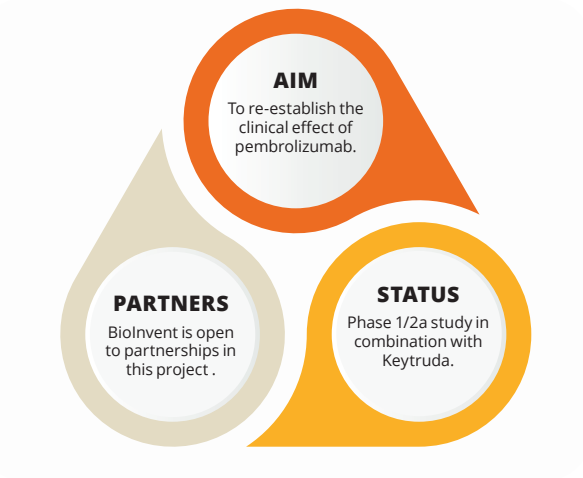
These long-lasting responses in hard-to-treat metastatic diseases, in patients who had previously progressed after treatment with anti-PD1/PDL1 agents, strongly suggest that BI-1206 is enhancing and recovering the activity of pembrolizumab (an anti-PD1 agent).

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.

BI-1206 are also investigated with a more flexible subcutaneous method of administration for the treatment of solid tumors. The first patient is expected to be enrolled shortly.



OUT-LICENSING AND PARTNERING

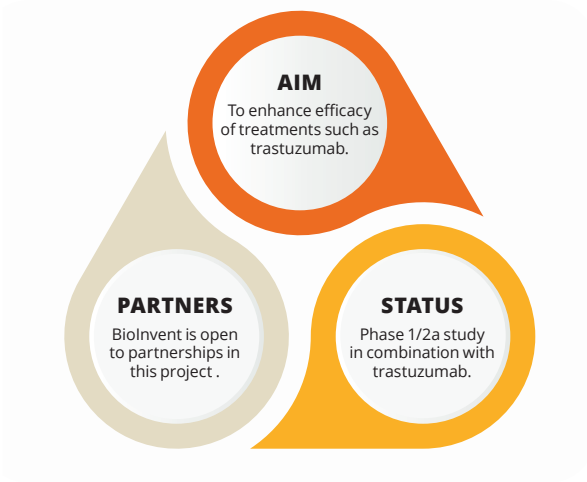
In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BioInvent's BI-1206 and MSD's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial for patients with solid tumors.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

A Phase 1 trial with a subcutaneous formulation of BI-1206 is expected to begin in H2 2023.

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. 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 results from the ongoing Phase 1 study are expected H2 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

Given the positive safety and tolerability profile observed, a higher dose (1000 mg) of BI-1808 as single agent has been tested to explore the effect of higher exposure. The planned dose escalation part of the Phase 1/2a trial was completed in 2022. Evaluation of BI-1808 in combination with pembrolizumab (Keytruda) is ongoing since September 2022.

STRONG INTERIM DATA

In June 2023, the company announces strong interim safety data from the ongoing Phase 1/2a trial. No significant safety concerns were observed in relation to the administration of BI-1808 as single agent in Phase 1, Part A of the trial. A total 24 subjects were dosed with a range of 25-1000 mg with 22 patients evaluable for efficacy. The BI-1808 infusions were well tolerated and no dose limiting toxicity or serious adverse events related to BI-1808 were observed, at any dose level.

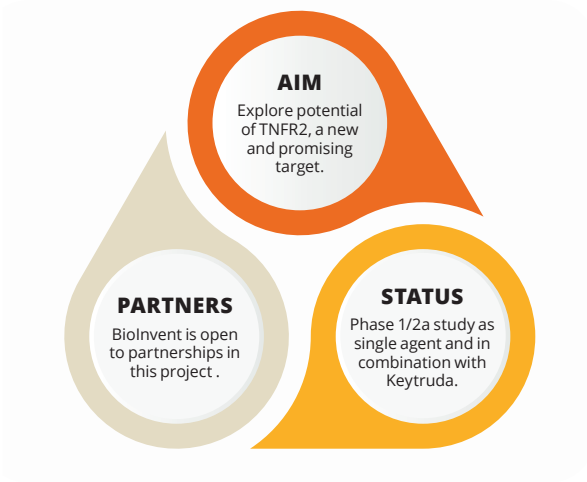
Stable disease has been observed in six patients subjects so far - 1 in the 25 mg cohort, 3 subjects at 75 mg, 1 at 225 mg and 1 at 1000 mg. The efficacy of BI-1808 as single agent and in combination with pembrolizumab will be further explored in the subsequent Phase 2a part of the trial, which is intended to enroll pre-defined malignancies and a larger sample size.

STUDY DESIGN

Since January 2021, patient enrollment is ongoing in Europe. During the first part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent and in combination with the anti-PD-1 therapy Keytruda will be evaluated in patients with advanced solid tumors and CTCL. In the subsequent part of the Phase 1/2a study, BI-1808 as single-agent and in combination with the anti-PD-1 therapy Keytruda will be further evaluated in expansion cohorts in patients with ovarian cancer, non-small cell lung cancer and CTCL. The study is expected to enroll a total of approximately 120 patients.

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

Phase 2a Part A (single agent) is planned to start during H2 2023. First data from the 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

The ongoing Phase 1/2a open-label, multicenter, dose-escalation study is currently evaluating BT-001 as single agent and in combination with pembrolizumab (Part B) for the treatment of patients with solid tumors.

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.

Based on these results, the independent Safety Review Committee approved initiation of the combination part of the trial with pembrolizumab.

STUDY DESIGN

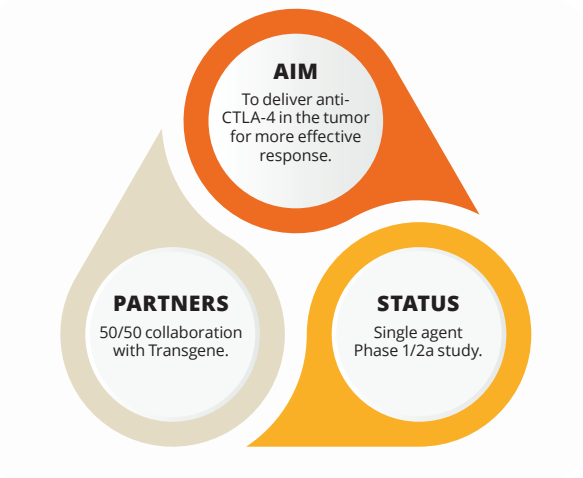
The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BT-001 alone and in combination with pembrolizumab. The ongoing Phase 1 component of the study is divided into two parts: Part A evaluates intra-tumoral injections of BT-001 as single agent in 18 patients with advanced solid tumor disease. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab.

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 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

Phase 1 study part B, i.e. BT-001 in combination with pembrolizumab, is planned to start in H2 2023.

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.

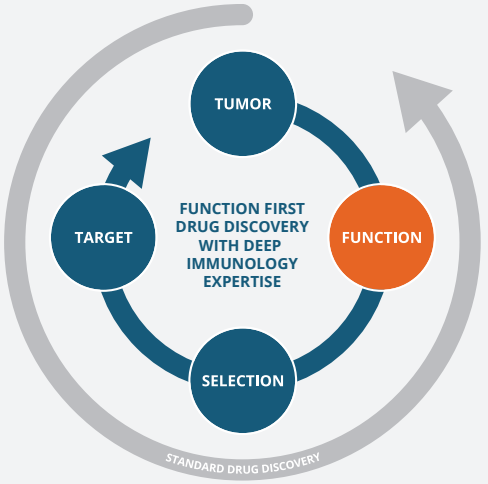
The strength of the company's technology platform with its development tool F.I.R.S.T™ and the n-CoDeR® antibody library is a strong driver in the discovery phase where the company currently is working on a number of promising candidates.

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.

Second quarter

Net sales amounted to SEK 13.1 million (270.9). Revenues for the period were mainly derived from production of antibodies for clinical trials, 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, and also production of antibodies for clinical studies. See also note 2.

The Company's total costs amounted to SEK 110.4 million (103.3). These are divided between external costs of SEK 74.0 million (72.6), personnel costs of SEK 32.3 million (27.1) and depreciation of SEK 4.1 million (3.6).

Research and development costs amounted to SEK 97.6 million (91.4). Sales and administrative costs amounted to SEK 12.8 million (11.9).

Profit/loss after tax amounted to SEK -88.3 million (167.4). The net financial items amounted to SEK 8.4 million (1.7). Profit/loss per share before and after dilution amounted to SEK -1.34 (2.86).

January - June

Net sales amounted to SEK 29.3 million (287.6). Revenues for the period were mainly derived from production of antibodies for clinical trials, 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, and also production of antibodies for clinical studies. See also note 2.

The Company's total costs amounted to SEK 207.3 million (188.4). These are divided between external costs of SEK 140.7 million (129.8), personnel costs of SEK 58.7 million (51.5) and depreciation of SEK 7.9 million (7.1).

Research and development costs amounted to SEK 182.1 million (163.3). Sales and administrative costs amounted to SEK 25.2 million (25.1).

Profit/loss after tax amounted to SEK -162.1 million (99.7). The net financial items amounted to SEK 15.6 million (2.2). Profit/loss per share before and after dilution amounted to SEK -2,47 (1.71).

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. 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 June 30, 2023.

As of June 30, 2023, the Group's liquid funds, current and long-term investments amounted to SEK 1,461.7 million (1,214.6). Amount as of June 30, 2022, does not include upfront fee from Exelixis SEK 255.8 million (USD 25 million) received in July 2022, and net capital from the directed share issue SEK 279.8 million, also received in July 2022. The cash flow from operating activities for the January-June period amounted to SEK -163.1 million (-142.3).

The shareholders' equity amounted to SEK 1,476.3 million (1,467.4) 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 92 (94) percent. Shareholders' equity per share amounted to SEK 22.44 (25.10).

INVESTMENTS

Investments for the January-June period in tangible fixed assets amounted to SEK 7.8 million (4.9).

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 June 30, 2023, BioInvent had 103 (89) employees (full time equivalent). 92 (80) 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.

Since Russia invaded Ukraine in February 2022 the macro-economic situation is characterized by great uncertainty and the course of events unpredictable. The market reactions on the development have been strongly negative, which is shown through significant price drops in the stock markets in the countries concerned, but also in other markets, including the Swedish market. In addition, the United States and Europe have imposed economic sanctions on Russia. In relation to BioInvent's operations,

in the form of ongoing clinical trials and the results of these, this has so far not been affected in any material way. However, it cannot be completely ruled out that the situation in the world will change, which may also have an impact on BioInvent's operations, primarily in the form of delays in the company's ongoing clinical trials and clinical trials that will soon be initiated. If such an impact on the operation is expected to arise, BioInvent will provide updates as necessary.

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

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

	3 MONTHS 2023 APR.-JUN.	3 MONTHS 2022 APR.-JUN.	6 MONTHS 2023 JAN.-JUN.	6 MONTHS 2022 JAN.-JUN.	12 MONTHS 2022 JAN.-DEC.
Net sales	13,095	270,907	29,345	287,566	326,126
Operating costs					
Research and development costs	-97,646	-91,400	-182,108	-163,270	-325,929
Sales and administrative costs	-12,778	-11,923	-25,200	-25,091	-50,750
Other operating income and costs	577	-1,802	267	-1,711	-368
	-109,847	**-105,125**	**-207,041**	**-190,072**	**-377,047**
Operating profit/loss	**-96,752**	**165,782**	**-177,696**	**97,494**	**-50,921**
Profit/loss from financial investments	8,405	1,666	15,617	2,206	8,418
Profit/loss before tax	**-88,347**	**167,448**	**-162,079**	**99,700**	**-42,503**
Tax	-	-	-	-	-
Profit/loss	**-88,347**	**167,448**	**-162,079**	**99,700**	**-42,503**
Other comprehensive income					
Items that have been or may be reclassified subsequently to profit or loss	-	-	-	-	-
Comprehensive income	**-88,347**	**167,448**	**-162,079**	**99,700**	**-42,503**
Other comprehensive income attributable to parent Company's shareholders	-88,347	167,448	-162,079	99,700	-42,503
Profit/loss per share, SEK					
Before dilution	-1.34	2.86	-2.47	1.71	-0.69
After dilution	-1.34	2.86	-2.47	1.71	-0.69

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

	2023 JUN. 30	2022 JUN. 30	2022 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	22,891	24,382	26,543
Tangible fixed assets - other	28,962	22,589	25,469
Financial fixed assets - long-term investments	360,485	236,539	576,140
Total fixed assets	**412,338**	**283,510**	**628,152**
Inventories	10,754	12,174	11,506
Current receivables	74,476	283,020	55,075
Current investments	530,599	386,813	502,434
Liquid funds	570,567	591,224	515,047
Total current assets	**1,186,396**	**1,273,231**	**1,084,062**
Total assets	**1,598,734**	**1,556,741**	**1,712,214**
SHAREHOLDERS' EQUITY			
Total shareholders' equity	**1,476,329**	**1,467,374**	**1,606,122**
LIABILITIES			
Lease liabilities	15,166	18,559	18,773
Total long term liabilities	**15,166**	**18,559**	**18,773**
Lease liabilities	7,966	6,626	8,190
Other liabilities	99,273	64,182	79,129
Total short term liabilities	**107,239**	**70,808**	**87,319**
Total shareholders' equity and liabilities	**1,598,734**	**1,556,741**	**1,712,214**

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

	2023 APR.-JUN.	2022 APR.-JUN.	2023 JAN.-JUN.	2022 JAN.-JUN.	2022 JAN.-DEC.
Shareholders' equity at beginning of period	**1,563,845**	**1,299,287**	**1,606,122**	**1,366,987**	**1,366,987**
Comprehensive income					
Profit/loss	-88,347	167,448	-162,079	99,700	-42,503
Comprehensive other income	-	-	-	-	-
Total comprehensive income	**-88,347**	**167,448**	**-162,079**	**99,700**	**-42,503**
Total, excluding transactions with equity holders of the Company	**1,475,498**	**1,466,735**	**1,444,043**	**1,466,687**	**1,324,484**
Transactions with equity holders of the Company					
Employee options program	831	639	1,327	687	1,789
Directed share issue			30,959		279,849
Shareholders' equity at end of period	**1,476,329**	**1,467,374**	**1,476,329**	**1,467,374**	**1,606,122**

The share capital as of June 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 APR.-JUN.	2022 APR.-JUN.	2023 JAN.-JUN.	2022 JAN.-JUN.	2022 JAN.-DEC.
Operating activities					
Operating profit/loss	-96,752	165,782	-177,696	97,494	-50,921
Depreciation	4,097	3,584	7,960	7,059	14,724
Adjustment for other non-cash items	831	639	1,327	687	1,789
Interest received and paid	2,674	-139	4,100	-315	-44
Cash flow from operating activities before changes in working capital	**-89,150**	**169,866**	**-164,309**	**104,925**	**-34,452**
Changes in working capital	5,017	-232,402	1,252	-247,257	-6,775
Cash flow from operating activities	**-84,133**	**-62,536**	**-163,057**	**-142,332**	**-41,227**
Investment activities					
Acquisition of tangible fixed assets	-4,676	-2,153	-7,801	-4,947	-12,377
Changes of financial investments	118,963	-112,284	197,270	-169,070	-616,471
Cash flow from investment activities	**114,287**	**-114,437**	**189,469**	**-174,017**	**-628,848**
Cash flow from operating activities and investment activities	**30,154**	**-176,973**	**26,412**	**-316,349**	**-670,075**
Financing activities					
Directed share issue			30,959		279,849
Amortization of lease liability	-1,921	-1,596	-3,830	-3,182	-6,362
Cash flow from financing activities	**-1,921**	**-1,596**	**27,129**	**-3,182**	**273,487**
Change in liquid funds	**28,233**	**-178,569**	**53,541**	**-319,531**	**-396,588**
Opening liquid funds	542,516	769,793	515,047	910,755	910,755
Accrued interest on investments classified as liquid funds	-182		1,979		880
Liquid funds at end of period	**570,567**	**591,224**	**570,567**	**591,224**	**515,047**
Liquid funds, specification:					
Cash and bank	570,567	591,224	570,567	591,224	515,047
	570,567	**591,224**	**570,567**	**591,224**	**515,047**

Key financial ratios for the Group

	2023 JUN. 30	2022 JUN. 30	2022 DEC. 31
Shareholders' equity per share at end of period, SEK	22.44	25.10	24.72
Number of shares at end of period (thousand)	65,804	58,471	64,968
Equity/assets ratio, %	92.3	94.3	93.8
Number of employees at end of period	103	89	94

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

	3 MONTHS 2023 APR.-JUN.	3 MONTHS 2022 APR.-JUN.	6 MONTHS 2023 JAN.-JUN.	6 MONTHS 2022 JAN.-JUN.	12 MONTHS 2022 JAN.-DEC.
Net sales	13,095	270,907	29,345	287,566	326,126
Operating costs					
Research and development costs	-97,794	-91,616	-182,405	-163,704	-326,368
Sales and administrative costs	-12,791	-11,942	-25,226	-25,129	-50,788
Other operating income and costs	577	-1,802	267	-1,711	-368
	-110,008	**-105,360**	**-207,364**	**-190,544**	**-377,524**
Operating profit/loss	**-96,913**	**165,547**	**-178,019**	**97,022**	**-51,398**
Profit/loss from financial investments	8,564	1,831	15,947	2,547	9,068
Profit/loss after financial items	**-88,349**	**167,378**	**-162,072**	**99,569**	**-42,330**
Tax	-	-	-	-	-
Profit/loss	**-88,349**	**167,378**	**-162,072**	**99,569**	**-42,330**
Other comprehensive income	**-**	**-**	**-**	**-**	**-**
Comprehensive income	**-88,349**	**167,378**	**-162,072**	**99,569**	**-42,330**

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

	2023 JUN. 30	2022 JUN. 30	2022 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	28,962	22,589	25,469
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	360,485	236,539	576,140
Total fixed assets	**390,134**	**259,815**	**602,296**
Current assets			
Inventories	10,754	12,174	11,506
Current receivables	75,036	282,708	55,450
Current investments	530,599	386,813	502,434
Cash and bank	570,567	591,224	515,047
Total current assets	**1,186,956**	**1,272,919**	**1,084,437**
Total assets	**1,577,090**	**1,532,734**	**1,686,733**
SHAREHOLDERS' EQUITY			
Restricted equity	40,854	39,387	40,687
Non-restricted equity	1,436,315	1,428,516	1,566,268
Total shareholders' equity	**1,477,169**	**1,467,903**	**1,606,955**
LIABILITIES			
Short term liabilities	99,921	64,831	79,778
Total short term liabilities	**99,921**	**64,831**	**79,778**
Total shareholders' equity and liabilities	**1,577,090**	**1,532,734**	**1,686,733**

Declaration by the Board

The board of directors and the CEO hereby ensure that this interim report for the period January 1, 2023 – June 30, 2023 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.

Lund, August 30, 2023

Leonard Kruimer Chairman of the Board	Vessela Alexieva Deputy Board member	Natalie Berner Board member	Kristoffer Bissessar Board member
Erik Esveld Board member	Thomas Hecht Board member	Nanna Lüneborg Board member	Vincent Ossipow Board member
Martin Pålsson Board member	Bernd Seizinger Board member	Martin Welschof CEO	

Review report

INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on June 30, 2023 and for the six-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, August 30, 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 APR.-JUN.	2022 APR.-JUN.	2023 JAN.-JUN.	2022 JAN.-JUN.	2022 JAN.-DEC.
Revenue by geographical region:					
Sweden	2,360	4,271	7,529	18,929	25,634
Europe	1,713	6,911	3,023	8,443	27,102
USA	9,022	259,725	18,793	260,194	273,390
Other countries	-	-	-	-	-
	13,095	**270,907**	**29,345**	**287,566**	**326,126**
Revenue consists of:					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	8,846	255,763	18,319	255,763	268,753
Revenue from technology licenses	-	5,221	-	5,221	5,221
Revenue from external development projects	4,249	9,923	11,026	26,582	52,152
	13,095	**270,907**	**29,345**	**287,566**	**326,126**

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

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- The dose-escalation part of the BI-1607 study was completed without any safety concerns. Exploratory work at intermediate dose levels is now being conducted to determine the best dose to move forward in subsequent studies.

(R)= Regulatory event

Other information

FINANCIAL CALENDAR

- Interim report Q3: October 26, 2023

CONTACT

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

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

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

FORWARD LOOKING INFORMATION

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

TRADEMARKS


BioInvent
VISIT OUR VIDEO & INTERVIEW ARCHIVE