The image showcases a liquid with scattered DNA strands, symbolizing the potential of liquid biopsies in detecting early responses to immunotherapy.

Martin Welschof, CEO:

"During the first quarter of the year, we continued making excellent progress with our clinical pipeline targeting TNFR2 and FcyRIIB, building on the momentum we generated during a very successful 2023. Looking ahead in 2024, we are preparing for multiple data presentations for our six ongoing clinical programs."

	FIRST QUARTER	
	2024	2023
Net sales, SEK million	5.9	16.2
Profit/loss after tax, SEK million	-77.9	-73.7
Profit/loss after tax per share before and after dilution, SEK	-1.18	-1.12
Cash flow from operating activities, SEK million	-65.9	-78.9
Liquid funds, current and long-term investments at the end of the period, SEK million	1,219.2	1,546.4

BioInvent in numbers, March 31, 2024

- 6 projects in clinical development
- 10+ development agreements
- 109 employees (FTE)
- SEK 1,219 m in liquid funds & investments
- SEK 1,118 m in market cap

The information was submitted for publication, through the agency of the contact person set out on page 25, at 8:00 a.m. CEST on April 24, 2024. Note to reader: figures in parentheses refer to the outcome for the corresponding period in the preceding year.

Swedish version prevails. This Interim Report is published in Swedish and English. In the event of any discrepancy between the English version and the Swedish original, the Swedish version shall prevail.

Highlights Q1 2024

EVENTS IN THE FIRST QUARTER

- (R) CASI Pharmaceuticals reported positive interim Phase 1 data for BI-1206 in NHL in China
- Supply agreement signed with AstraZeneca to evaluate BI-1206 in combination with rituximab and Calquence® (acalabrutinib)
- BioInvent regained the rights to immuno-oncology targets from Exelixis

EVENTS AFTER THE END OF THE PERIOD

- New clinical trial collaboration and supply agreement signed with MSD to evaluate BI-1910, the company's second anti-TNFR2 antibody in combination with KEYTRUDA® (pembrolizumab)

(R)= Regulatory event

BioInvent continues advancing its promising portfolio of novel and first-in-class antibodies

During the first quarter of the year, we continued making excellent progress with our clinical pipeline targeting TNFR2 and FcγRIIB, building on the momentum we generated during a very successful 2023. Looking ahead in 2024, we are preparing for multiple data presentations for our six ongoing clinical programs.

First quarter highlights:

- Two clinical trial supply agreements
  - With AstraZeneca to evaluate BI-1206 and rituximab with CALQUENCE® (acalabrutinib) in the ongoing clinical study
  - Clinical collaboration and supply agreement with MSD to evaluate BI-1910 with KEYTRUDA® (pembrolizumab)
- Positive interim clinical Phase 1 data for BI-1206 from CASI Pharmaceuticals' program in China
- Active recruitment in six ongoing clinical study arms

ADDITION OF ACALABRUTINIB TO BI-1206 TREATMENT COMBINATION TO FURTHER IMPROVE CLINICAL OUTCOMES

In February we announced a clinical supply agreement with AstraZeneca who will provide their selective inhibitor acalabrutinib for use in combination with the novel anti-FcγRIIB antibody, BI-1206, and rituximab in our ongoing Phase 1/2a clinical study for the treatment of patients with non-Hodgkin's lymphoma (NHL).

Previously we announced impressive early efficacy data from the combination of BI-1206 with rituximab in the Phase 1 intravenous (IV) part of the study showing responses across the dose range of 30 to 100mg, including 4 long-lasting complete responses (CR). Based on the strong combination data we have seen, we believe a triplet combination of BI-1206, rituximab and acalabrutinib could further improve clinical outcomes and provide a new, chemotherapy-free treatment option for NHL patients. The Phase 2a IV dose expansion cohort which will include treatment with the triplet combination, is planned to start enrolling patients shortly with initial data expected already by the end of 2024.

In addition, in order to ensure we meet the needs of different groups and treating physicians we are simultaneously developing a subcutaneous (SC) formulation of BI-1206 to evaluate the optimal treatment modality for BI-1206. Data from the Phase 1 dose escalation segment evaluating BI-1206 SC should be available mid-2024.

CASI REPORTS POSITIVE INTERIM PHASE 1 DATA FOR BI-1206

In March, our partner CASI Pharmaceuticals (CASI) reported encouraging preliminary efficacy data for BI-1206 in combination with rituximab in patients with relapsed/refractory (R/R) indolent NHL in its ongoing development program in China. The Phase 1 dose escalation study showed impressive signs of clinical efficacy, with 4 partial responses and 1 complete response out of 8 evaluable patients.

These results and the CASI partnership provide validation for BI-1206 as a new treatment option for NHL and de-risk the program.

Martin Welschof, VD

NEW MSD AGREEMENT TO EVALUATE BI-1910 WITH KEYTRUDA

In April we entered into a new clinical trial collaboration and supply agreement with MSD to investigate the unique features of BI-1910 in combination with KEYTRUDA. The agreement underscores our ability to sign partnerships with leading players in the pharmaceutical industry in order to enhance the efficiency of conducting clinical studies. The Phase 1/2a study, which enrolled its first patient in December last year, is initially evaluating BI-1910 as a single agent in all solid cancer entities, and subsequently as a dose escalation phase in combination with pembrolizumab. Succeeding exploratory expansion cohorts are planned in hepatocellular carcinoma (HCC) and non-small cell lung cancer (NSCLC). The study is being conducted in the US and Europe and has an adaptive design to allow for ideal dose escalation.

BI-1910 is our second tumor necrosis factor receptor 2 (TNFR2) program to enter clinical development, after BI-1808 which is currently in Phase 2a. The BI-1910 study builds on our deep understanding of TNFR2 biology as we progress these two differentiated approaches to leverage the biology of TNFR2 to treat cancer. Initial data from the BI-1910 single agent arm is due by the end of this year.

BI-1808 continues to be evaluated both as a single agent and in combination with pembrolizumab. We expect readouts from both study arms this year, with data from the single-agent Phase 2a study expected by year-end and initial results from the Phase 1 dose escalation study combining BI-1808 and pembrolizumab anticipated by mid-year.

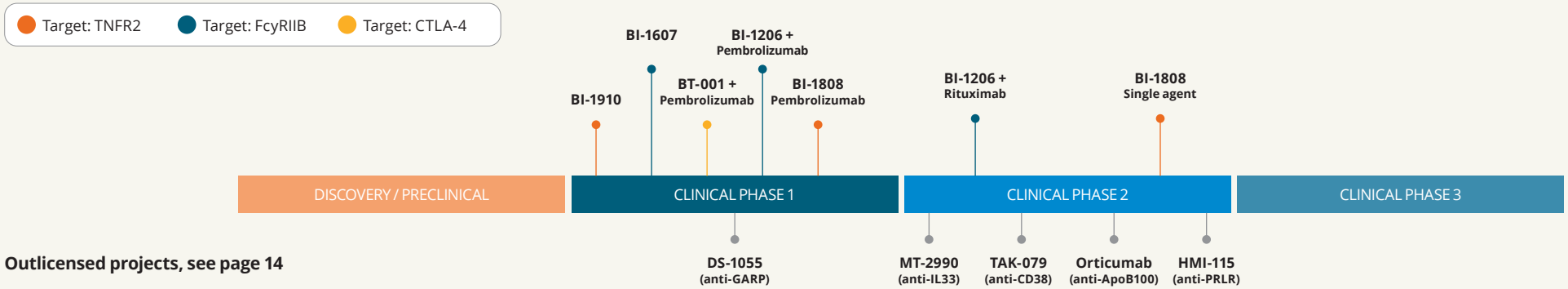
FINANCIALLY SOLID WITH SIGNIFICANT UPCOMING NEWS FLOW

BioInvent remains well-financed with sufficient funds to allow us to achieve the communicated upcoming inflection points in the coming year. A dynamic first quarter has provided a strong start to the year, and we have much to look forward to in the months ahead. I would like to thank our entire BioInvent team for their dedication and hard work, and our shareholders and partners for their continued support and belief in our endeavors. I look forward to updating you soon on our progress through the next quarter.

Martin Welschof, CEO
April, 2024

CLINICAL PROGRAMS

Proprietary development, see pages 5-12



Outlicensed projects, see page 14

Five drug candidates in six clinical studies

BioInvent is developing novel immuno-modulatory antibodies for cancer therapy. These innovative antibodies may significantly improve the efficacy of currently available checkpoint inhibitors and/or activate anti-cancer immunity in non-responding patients. Our clinical portfolio is currently focused on the immunological targets TNFR2, FcyRIIB, and CTLA-4.

TNFR2

Study number	Study arm	Primary indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
NCT04752826	BI-1808 single agent	Solid tumors/TCL					
	BI-1808 + pembrolizumab	Solid tumors/TCL					
NCT06205706	BI-1910 single agent	Solid tumors					
	BI-1910 + pembrolizumab	Solid tumors					

FcyRIIB

Study number	Study arm	Primary indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
NCT03571568	BI-1206 + rituximab	NHL					CASI
	BI-1206 + rituximab + acalabrutinib	NHL					
NCT04219254	BI-1206 + pembrolizumab	Solid tumors					CASI
NCT05555251	BI-1607	Solid tumors					

CTLA-4

Study number	Study arm	Primary indication	Discovery	Preclinical	Phase 1	Phase 2	Partner
NCT04725331	BT-001 + pembrolizumab	Solid tumors					transgene

Completed Ongoing Upcoming

NCT Number: The National Clinical Trial number is an identification that ClinicalTrials.gov assigns a study when it is registered.

BioInvent maximizes the chances of success and the patient populations we can treat, by choosing two drug candidates with different mechanisms of action against a novel target. Understanding the biology of the target is of the essence, and an area where the company excels.

BI-1808

BioInvent's anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate in clinical development for the treatment of solid tumors, and for blood cancer under the Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP). LLS TAP is aimed at supporting and accelerating the advancement of the most promising and innovative blood cancer therapies worldwide. BI-1808 is currently evaluated both as a single agent in Phase 2 and in combination with pembrolizumab in Phase 1.

STATUS

Clinical Phase 1/2a study (NCT04752826)

In December 2023, positive interim results from the Phase 1 part showcased early signs of efficacy and a strong safety profile. BI-1808 administered as single agent induced a robust partial response (PR) in a patient with a gastrointestinal tumor (GIST) who had received 12 previous lines of treatment. This patient is still receiving BI-1808 treatment, and a scan in early 2024 showed a 59% reduced tumor burden. Another patient, with lung cancer, also experienced a partial response but had to be taken off study due to an unrelated reason.

There are a further 7 cases of stable disease out of 21 evaluable patients and pharmacokinetic/ pharmacodynamic data has enabled identification of a wide dose range where complete target coverage can be achieved with a strong safety profile.

The ongoing Phase 1 Part B is exploring the safety and tolerability of BI-1808 in combination with pembrolizumab (KEYTRUDA).

SINGLE AGENT PHASE 2A ONGOING

The efficacy of BI-1808 as single agent is now 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 has enlarged 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 pembrolizumab is 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 pembrolizumab is evaluated in expansion cohorts in patients with the selected indications. The study is expected to enroll a total of approximately 180 patients.

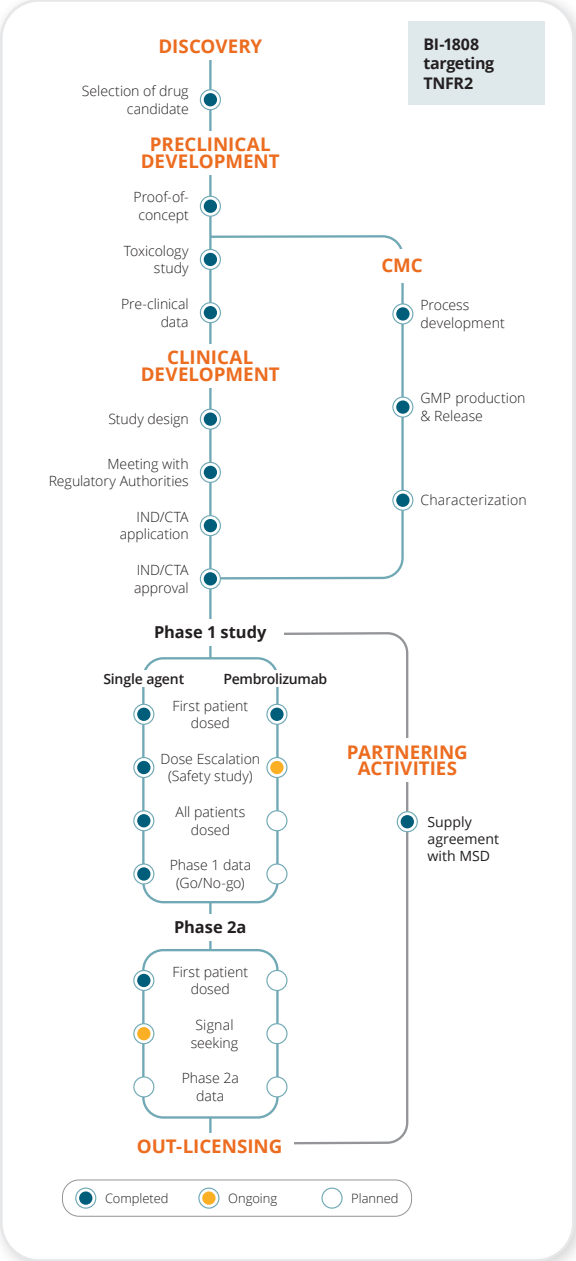
OUT-LICENSING AND PARTNERING

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 (pembrolizumab) 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

First data from the BI-1808 and pembrolizumab combination study are expected in mid-2024.

Initial data from Phase 2a study of single agent BI-1808 are expected by year-end 2024.



BI-1910

BI-1910 offers a differentiated, agonist approach to cancer treatment compared to BI-1808, BioInvent's first-in-class anti-TNFR2 antibody currently in a Phase 1/2a trial. Both monoclonal antibodies were chosen as potential best-in-class, from a large family of binders generated through BioInvent's proprietary F.I.R.S.T™ technology platform.

STATUS

Clinical Phase 1/2a study ongoing

The ongoing Phase 1/2a clinical trial, conducted in the US and Europe, is using an innovative, adaptive design for dose escalation. The first phase of the trial will enroll all solid cancer entities as single agent, followed by a dose escalation phase with BI-1910 in combination with pembrolizumab (KEYTRUDA). Subsequently, exploratory expansion cohorts are planned in hepatocellular carcinoma (HCC) and non-small cell lung cancer (NSCLC). The first patient was enrolled in December 2023.

STUDY DESIGN

During the first part of Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1910 as a single agent are evaluated in patients with advanced solid tumors. In the subsequent part of the Phase 1/2a study, BI-1910 as single-agent (Part A) and in combination (Part B) with the anti-PD-1 therapy pembrolizumab will be evaluated. The study is expected to enroll a total of approximately 180 patients.

LATEST DATA

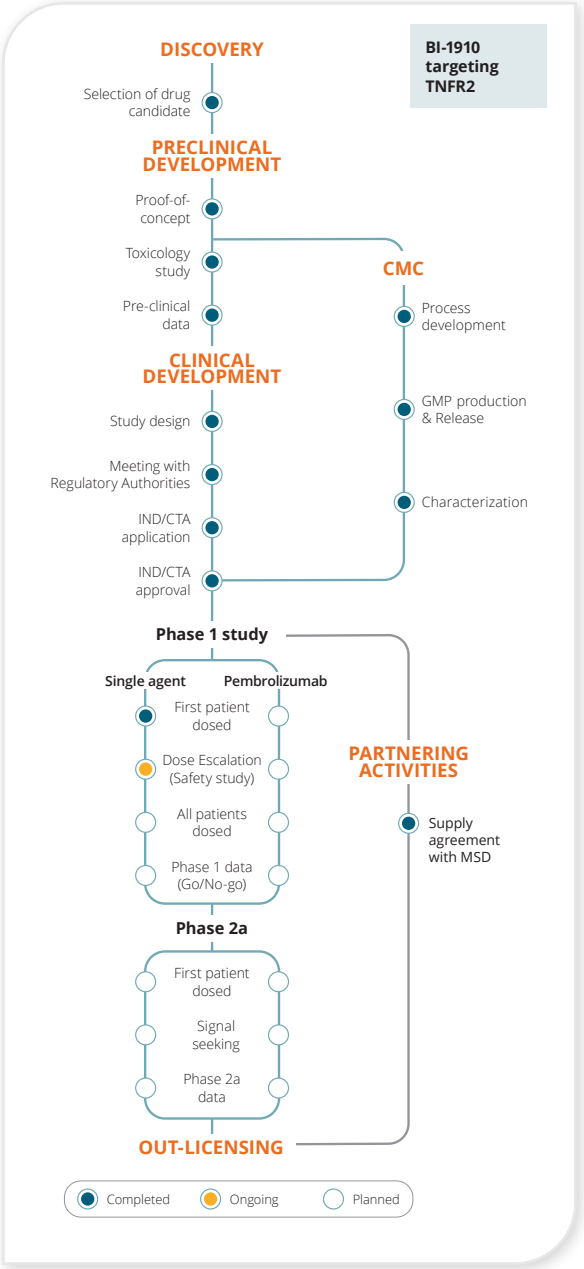
The presentation at SITC in November 2023, entitled "Preclinical development of an agonistic anti-TNFR2 antibody (BI-1910) for cancer immunotherapy," demonstrated that BI-1910 has broad anti-tumor activity, activating T cells and natural killer (NK) cells and showing antitumor activity independent of Fc gamma receptor (FcγR) expression.

OUT-LICENSING AND PARTNERING

In April 2024, BioInvent announced a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate BI-1910 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 BI-1910 in the ongoing Phase 1/2a clinical trial.

OUTLOOK

First data from the ongoing Phase 1/2a single agent study is expected by year-end 2024.



BI-1206 in non-Hodgkin's lymphoma

FcyRIIB is overexpressed in several forms of NHL and overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma. By blocking the receptor FcyRIIB on tumor cells, BI-1206 is expected to recover and enhance the activity of rituximab and acalabrutinib in the treatment of several forms of NHL. The combination of drugs could provide a new and important option for patients suffering from NHL and represents a substantial commercial opportunity.

STATUS

Clinical Phase 1/2a study (NCT03571568) ongoing

In March 2024, BioInvent's partner CASI Pharmaceuticals announced encouraging efficacy data for BI-1206 in combination with rituximab in patients with relapsed/refractory (R/R) indolent Non-Hodgkin's Lymphoma (iNHL) in the ongoing development program in China.

The Phase 1 dose-escalation study showed impressive signs of clinical efficacy, with 4 partial responses (PR) and 1 complete response (CR) out of 8 evaluable patients. Among the responders in the study being conducted in China, one patient with relapsed Marginal Zone Lymphoma (MZL) patient who achieved CR has maintained a durable complete remission for 20+ weeks (as of March 2024). The preliminary results demonstrated a manageable safety profile across all patients.

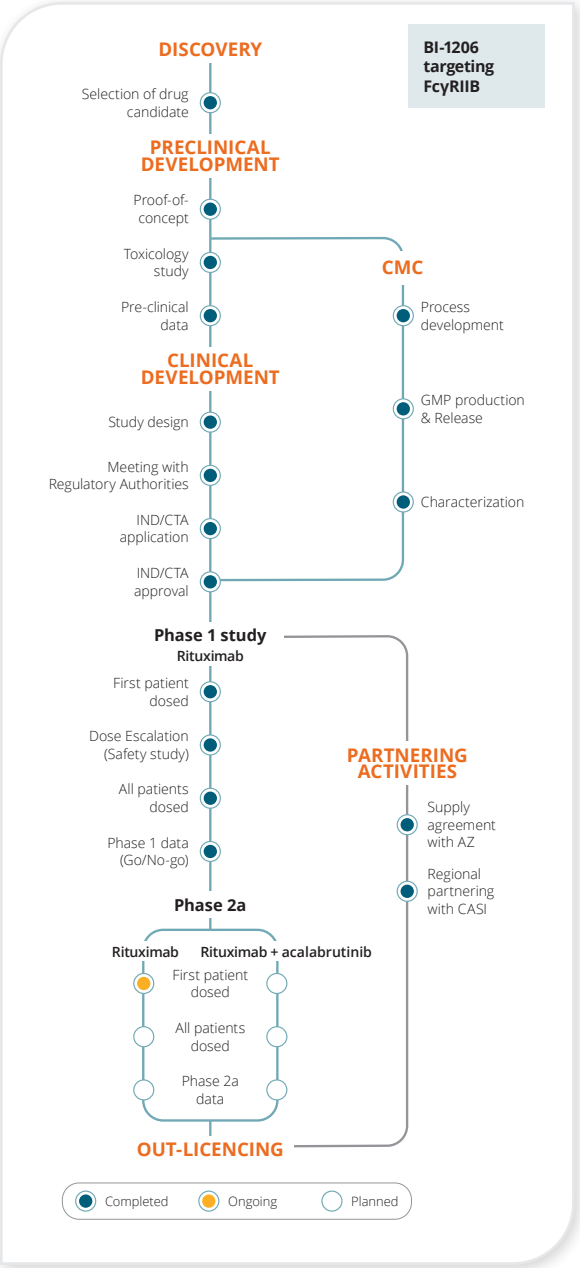
In February 2024, a clinical supply agreement was signed with AstraZeneca to evaluate BI-1206 in combination with rituximab and Calquence (acalabrutinib). The ongoing rituximab combination trial in NHL will be expanded to include the triplet arm.

A subcutaneous (SC) formulation is being developed in parallel to the intravenous (IV) and patient recruitment to the Phase 1 part with BI-1206 SC as well as to the Phase 2a expansion cohorts with BI-1206 IV is ongoing.

QUALITY OF RESPONSES PARTICULARLY IMPRESSIVE

All patients in BioInvent's 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 RITUXIMAB COMBINATION

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 dose to be studied further in the expansion phase; and

2) Phase 2a, an expansion cohort at the dose selected from Phase 1. Patients in each phase receive 1 cycle of induction therapy with 3 doses of BI-1206 in combination with 4 doses of 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 dose for Phase 2 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 (MCL).

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

Initial data from the Phase 1 study of BI-1206 SC in combination with rituximab in NHL are expected H1 2024. Initial Phase 2a triplet data for BI-1206 in combination with rituximab and acalabrutinib are expected by year-end 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.

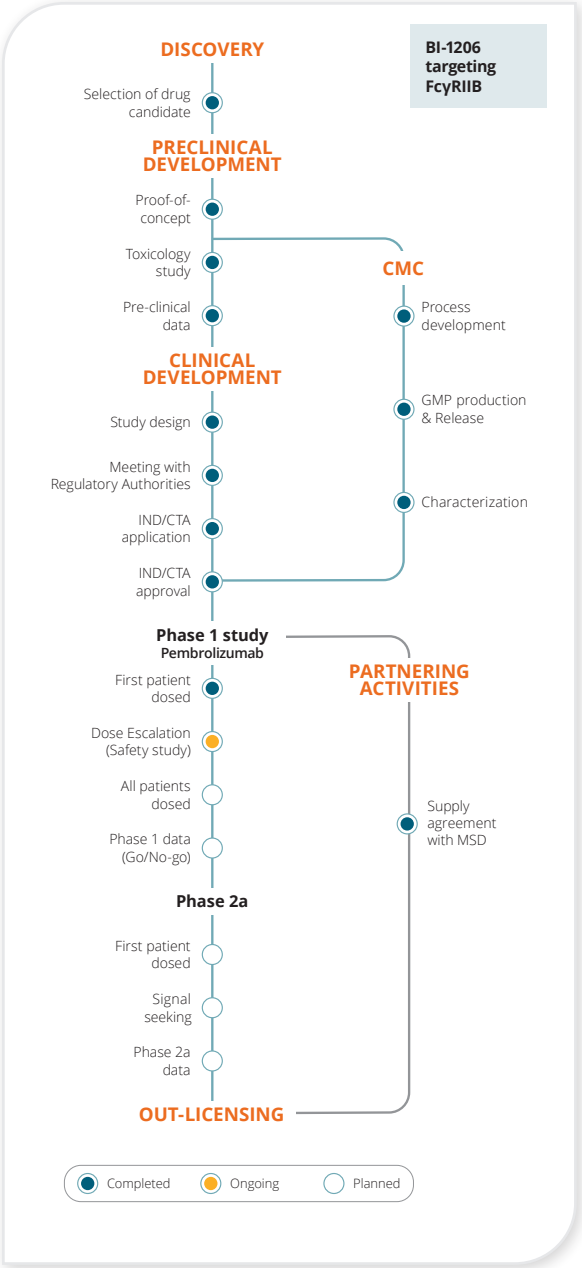
The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BI-1206 in combination with pembrolizumab. The Phase 1 part is a dose escalation study with the aim to determine the recommended Phase 2 dose (RP2D) of BI-1206 in combination with pembrolizumab. The Phase 2a part will study the BI-1206/ pembrolizumab 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 (pembrolizumab) 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 in combination with pembrolizumab is expected mid-2024.



BI-1607

Like BioInvent's lead anti-FcyRIIB antibody BI-1206, BI-1607 is intended to enhance efficacy and overcome resistance to existing cancer treatments. BI-1607 is an FcyRIIB-blocking antibody that differs from BI-1206 in that it has been engineered for reduced Fc-binding to FcyRs.

STATUS

Positive results from clinical Phase 1/2a study evaluating BI-1607 in combination with trastuzumab (NCT05555251)

The Phase 1 data, presented in December 2023 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, covered 18 patients treated at doses ranging from 75 mg up to 900 mg flat dose. Treatment was well tolerated, and no serious adverse events related to BI-1607 were observed. The best clinical response reported was stable disease (SD) in 6/11 evaluable patients, with disease control lasting up to 7 cycles (21 weeks).

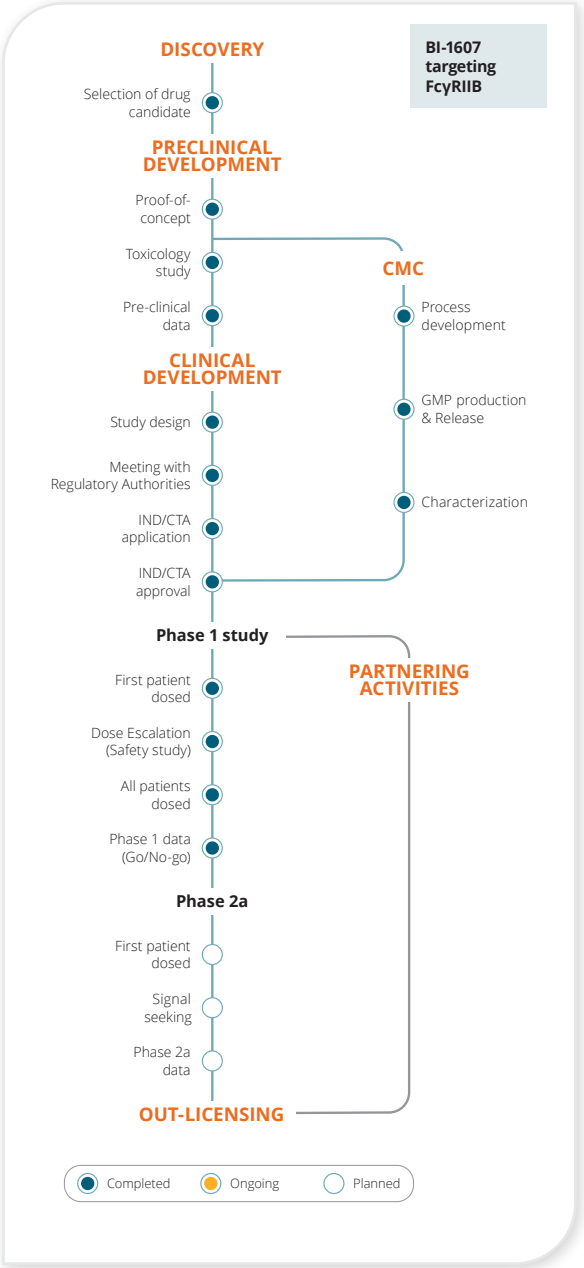
STUDY DESIGN

The first-in-human Phase 1 trial was a dose escalation study of BI-1607 in combination with trastuzumab in HER2+ advanced or metastatic solid tumors.

Pharmacokinetic and pharmacodynamic data allowed identification of a wide dose range, where complete target engagement throughout a 3-week dose interval can be achieved, and this will provide the basis for further investigation in a Phase 2a trial, which is planned to start 2024.

OUTLOOK

Discussions are ongoing to choose the most optimal combination regimen for BI-1607 in the continued development program.



BT-001

BT-001 is an oncolytic virus armed with BioInvent's anti-CTLA-4 antibody. When the virus is infecting the tumor cells it releases the anti-CTLA-4 locally in the tumor to decrease the risk for systemic side-effects. It is currently evaluated in a clinical Phase 1/2a study. BT-001 is a drug candidate being developed in collaboration with the French biotech company Transgene.

STATUS

Clinical phase 1/2a study (NCT04725331) ongoing

Data generated in Phase 1 part A, demonstrated that BT-001 as single agent is well tolerated with first signs of anti-tumor activity in a hard-to-treat population and confirmed the mechanism of action of BT-001.

Phase 1 part B clinical trial evaluating the combination of BT-001 and MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) is ongoing since October 2023. The ongoing Phase 1 Part B of the trial explores repeated intratumoral injections of BT-001 in combination with intravenous infusions of pembrolizumab. At least 12 patients with metastatic or advanced solid tumors, including melanoma, are planned to be enrolled. In accordance with our clinical trial and supply agreement, KEYTRUDA is being supplied by MSD (a tradename of Merck & Co., Inc., Rahway, NJ, USA). Trial endpoints include safety, evaluation of efficacy, and assessment of immune changes in the tumor microenvironment.

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).

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 pembrolizumab.

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.

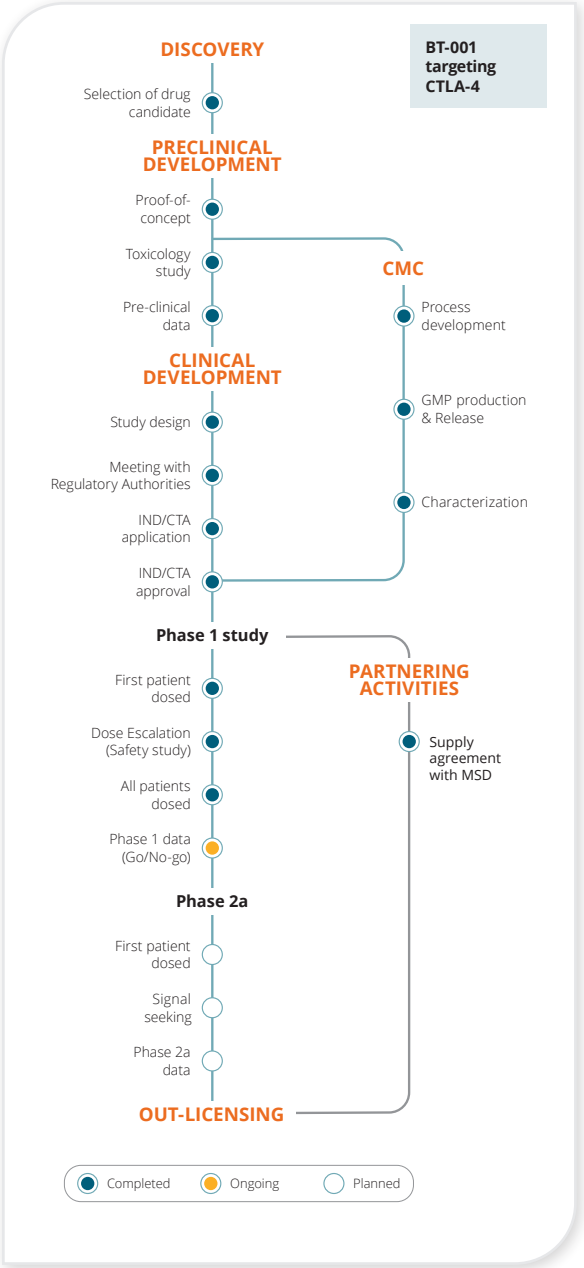
OUT-LICENSING AND PARTNERING

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.

Since 2017, BioInvent and Transgene have been collaborating to develop the drug candidate BT-001, which encodes both a differentiated and proprietary CTLA-4 antibody and the cytokine GM-CSF. The research and development costs as well as revenue and royalties are shared 50:50.

OUTLOOK

First results from Part B of the Phase 1 study, evaluating the combination of BT-001 and pembrolizumab are expected in H2 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.

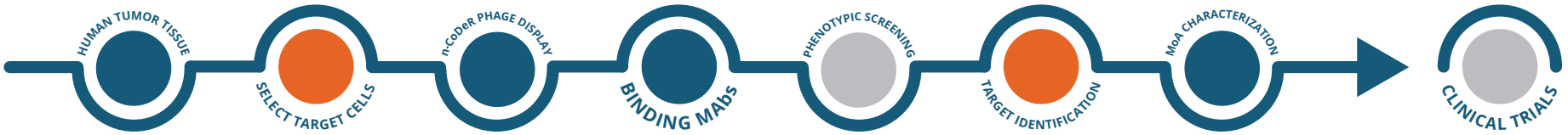
The Preclinical team at BioInvent is highly involved in all steps in a project – from idea to pulling out desired antibodies from our n-CoDeR library, functionally testing these in predictive cancer models, as well as in developing biomarkers for the clinic.

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 F.I.R.S.T DISCOVERY OF NEW ONCOLOGY TARGETS AND ANTIBODIES

Unique proprietary platform and deep immunology expertise yield both unique targets and high-quality antibodies.



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.

FIVE 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	Cardiovascular					Abcentra
DS-1055	anti-GARP	Solid tumor					Daiichi-Sankyo
HMI-115	anti-PRLR	Alopecia					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, AstraZeneca, and Transgene, see pages 6 to 10 for details.

BioInvent has four 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 antibodies BI-1808 ans BI-1910, 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.

The agreement with AstraZeneca is a supply agreement to clinically evaluate Calquence® in combination with BI-1206 and rituximab.

As the external partners carefully review programs before establishing such agreements, these agreements provide 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.

FIVE CLINICAL PROJECTS OUTLICENSED

BioInvent currently has five 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.

First quarter

Net sales amounted to SEK 5.9 million (16.2). Revenues for the period were mainly derived from production of antibodies for clinical studies and revenues from research services.

Revenues for the corresponding period 2023 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 95.7 million (96.9). These are divided between external costs of SEK 59.4 million (66.7), personnel costs of SEK 31.6 million (26.3) and depreciation of SEK 4.7 million (3.9).

Research and development costs amounted to SEK 82.4 million (84.5). Sales and administrative costs amounted to SEK 13.3 million (12.4).

Profit/loss after tax amounted to SEK -77.9 million (-73.7). The net financial items amounted to SEK 11.8 million (7.2). Profit/loss per share before and after dilution amounted to SEK -1.18 (-1.12).

FINANCIAL POSITION AND CASH FLOW

The share capital consists of 65,804,362 shares as of March 31, 2024.

As of March 31, 2024, the Group's liquid funds, current and long-term investments amounted to SEK 1,219.2 million (1,546.4). The cash flow from operating activities for the January-March period amounted to SEK -65.9 million (-78.9).

The shareholders' equity amounted to SEK 1,232.6 million (1,563.8) 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 93 (94) percent. Shareholders' equity per share amounted to SEK 18.73 (23.77).

INVESTMENTS

Investments for the January-March period in tangible fixed assets amounted to SEK 2.3 million (3.1).

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 March 31,2024, BioInvent had 109 (102) employees (full time equivalent). 97 (91) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 59 in the Company's annual report 2023. 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 42, in the Company's annual report 2023.

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

	3 MONTHS 2024 JAN.-MAR.	3 MONTHS 2023 JAN.-MAR.	12 MONTHS 2023 JAN.-DEC.
Net sales	5,942	16,250	71,461
Operating costs			
Research and development costs	-82,382	-84,462	-390,434
Sales and administrative costs	-13,304	-12,422	-51,606
Other operating income and costs	25	-310	637
	-95,661	**-97,194**	**-441,403**
Operating profit/loss	**-89,719**	**-80,944**	**-369,942**
Profit/loss from financial investments	11,804	7,212	39,842
Profit/loss before tax	**-77,915**	**-73,732**	**-330,100**
Tax	-31	-	-204
Profit/loss	**-77,946**	**-73,732**	**-330,304**
Other comprehensive income			
Items that have been or may be reclassified subsequently to profit or loss	-	-	-
Comprehensive income	**-77,946**	**-73,732**	**-330,304**
Other comprehensive income attributable to parent Company's shareholders	-77,946	-73,732	-330,304
Profit/loss per share, SEK			
Before dilution	-1.18	-1.12	-5.02
After dilution	-1.18	-1.12	-5.02

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

	2024 MAR. 31	2023 MAR. 31	2023 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	21,009	24,717	23,153
Tangible fixed assets - other	29,228	26,557	29,510
Financial fixed assets - long-term investments	155,053	527,905	214,252
Total fixed assets	**205,290**	**579,179**	**266,915**
Inventories	8,976	14,117	11,844
Current receivables	50,258	44,686	52,722
Current investments	594,962	475,956	809,151
Liquid funds	469,142	542,516	259,548
Total current assets	**1,123,338**	**1,077,275**	**1,133,265**
Total assets	**1,328,628**	**1,656,454**	**1,400,180**
SHAREHOLDERS' EQUITY			
Total shareholders' equity	**1,232,637**	**1,563,845**	**1,309,727**
LIABILITIES			
Lease liabilities	12,475	16,864	14,535
Total long term liabilities	**12,475**	**16,864**	**14,535**
Lease liabilities	8,709	8,190	8,709
Other liabilities	74,807	67,555	67,209
Total short term liabilities	**83,516**	**75,745**	**75,918**
Total shareholders' equity and liabilities	**1,328,628**	**1,656,454**	**1,400,180**

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

	2024 JAN.-MAR.	2023 JAN.-MAR.	2023 JAN.-DEC.
Shareholders' equity at beginning of period	**1,309,727**	**1,606,122**	**1,606,122**
Comprehensive income			
Profit/loss	-77,946	-73,732	-330,304
Comprehensive other income	-	-	-
Total comprehensive income	**-77,946**	**-73,732**	**-330,304**
Total, excluding transactions with equity holders of the Company	**1,231,781**	**1,532,390**	**1,275,818**
Transactions with equity holders of the Company			
Employee options program	856	496	2,950
Directed share issue		30,959	30,959
Shareholders' equity at end of period	**1,232,637**	**1,563,845**	**1,309,727**

The share capital as of March 31, 2024 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.

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

	2024 JAN.-MAR.	2023 JAN.-MAR.	2023 JAN.-DEC.
Operating activities			
Operating profit/loss	-89,719	-80,944	-369,942
Depreciation	4,711	3,863	16,755
Adjustment for other non-cash items	856	496	2,950
Interest received and paid	5,211	1,426	18,781
Income taxes paid	-57		-90
Cash flow from operating activities before changes in working capital	**-78,998**	**-75,159**	**-331,546**
Changes in working capital	13,097	-3,765	-10,145
Cash flow from operating activities	**-65,901**	**-78,924**	**-341,691**
Investment activities			
Acquisition of tangible fixed assets	-2,284	-3,125	-13,304
Changes of financial investments	272,522	78,307	72,985
Cash flow from investment activities	**270,238**	**75,182**	**59,681**
Cash flow from operating activities and investment activities	**204,337**	**-3,742**	**-282,010**
Financing activities			
Directed share issue		30,959	30,959
Amortization of lease liability	-2,060	-1,909	-7,820
Cash flow from financing activities	**-2,060**	**29,050**	**23,139**
Change in liquid funds	**202,277**	**25,308**	**-258,871**
Opening liquid funds	259,548	515,047	515,047
Accrued interest on investments classified as liquid funds	7,317	2,161	3,372
Liquid funds at end of period	**469,142**	**542,516**	**259,548**
Liquid funds, specification:			
Cash and bank	41,850	212,474	48,237
Current investments, equivalent to liquid funds	427,292	330,042	211,311
	469,142	**542,516**	**259,548**

Key financial ratios for the Group

	2024 MAR. 31	2023 MAR. 31	2023 DEC. 31
Shareholders' equity per share at end of period, SEK	18.73	23.77	19.90
Number of shares at end of period (thousand)	65,804	65,804	65,804
Equity/assets ratio, %	92.8	94.4	93.5
Number of employees at end of period	109	102	111

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

	3 MONTHS 2024 JAN.-MAR.	3 MONTHS 2023 JAN.-MAR.	12 MONTHS 2023 JAN.-DEC.
Net sales	5,942	16,250	71,461
Operating costs			
Research and development costs	-82,360	-84,611	-390,857
Sales and administrative costs	-13,302	-12,435	-51,643
Other operating income and costs	25	-310	637
	-95,637	**-97,356**	**-441,863**
Operating profit/loss	**-89,695**	**-81,106**	**-370,402**
Profit/loss from financial investments	11,957	7,383	40,476
Profit/loss after financial items	**-77,738**	**-73,723**	**-329,926**
Tax	-31	-	-204
Profit/loss	**-77,769**	**-73,723**	**-330,130**
Other comprehensive income	**-**	**-**	**-**
Comprehensive income	**-77,769**	**-73,723**	**-330,130**

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

	2024 MAR. 31	2023 MAR. 31	2023 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	29,228	26,557	29,510
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	155,053	527,905	214,252
Total fixed assets	**184,968**	**555,149**	**244,449**
Current assets			
Inventories	8,976	14,117	11,844
Current receivables	51,229	45,153	53,600
Current investments	594,962	475,956	809,151
Cash and bank	469,142	542,516	259,548
Total current assets	**1,124,309**	**1,077,742**	**1,134,143**
Total assets	**1,309,277**	**1,632,891**	**1,378,592**
SHAREHOLDERS' EQUITY			
Restricted equity	40,854	40,854	40,854
Non-restricted equity	1,192,967	1,523,833	1,269,880
Total shareholders' equity	**1,233,821**	**1,564,687**	**1,310,734**
LIABILITIES			
Short term liabilities	75,456	68,204	67,858
Total short term liabilities	**75,456**	**68,204**	**67,858**
Total shareholders' equity and liabilities	**1,309,277**	**1,632,891**	**1,378,592**

Lund, April 24, 2024

Martin Welschof
CEO

Review report

INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on March 31, 2024 and for the three-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 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, April 24, 2024

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 2024 has had no material impact on the financial statements. Except for financial leases, the Group's and the Parent Company's financial statements coincide in every material way.

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

NOTE 2 NET REVENUE

SEK THOUSAND	2024 JAN.-MAR.	2023 JAN.-MAR.	2023 JAN.-DEC.
Revenue by geographical region:			
Sweden	2,093	5,169	18,263
Europe	849	1,310	2,951
USA	2,690	9,771	47,393
Other countries	310	-	2,854
	5,942	**16,250**	**71,461**
Revenue consists of:			
Revenue from collaboration agreements associated with outlicensing of proprietary projects	572	6,777	44,303
Revenue from technology licenses	-	-	-
Revenue from external development projects	5,370	9,473	27,158
	5,942	**16,250**	**71,461**

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

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- New clinical trial collaboration and supply agreement signed with MSD to evaluate BI-1910, the company's second anti-TNFR2 antibody in combination with KEYTRUDA® (pembrolizumab)

(R)= Regulatory event

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 has been announced in Post- och Inrikes Tidningar and is available on the Company website.

FINANCIAL CALENDAR

- 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.

TRADEMARKS

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BioInvent
VISIT OUR VIDEO & INTERVIEW ARCHIVE