

Q1, 2022

Martin Welschof, CEO:

“The exciting translational data presented on BI-1808 at AACR clearly show why we are so enthusiastic about our ongoing clinical studies in solid tumors. It is highly encouraging that we see similar biomarker correlations in patient samples as we observe in the preclinical setting.”

BioInvent at a glance

4

projects in
clinical development

10+

Licensing, supply and
collaboration agreements

86

employees
(full time equivalent)

1,281

SEKm
in liquid funds etc

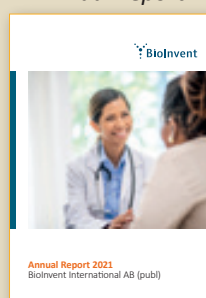
FINANCIAL INFORMATION

First quarter 2022

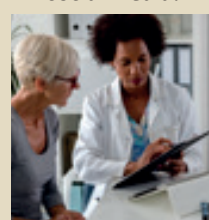
- Net sales SEK 16.7 (6.2) million.
- Loss after tax SEK -67.7 (-79.8) million.
- Loss after tax per share before and after dilution SEK -1.16 (-1.94).
- Cash flow from operating activities SEK -79.8 (-49.5) million.
- Liquid funds, current and long-term investments as of March 31, 2022: SEK 1,280.9 (1,577.1) million

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Q1 Highlights

EVENTS IN THE FIRST QUARTER

- (R) Orphan Drug Designation granted to BI-1206 for the treatment of follicular lymphoma.
- The preclinical and clinical data presented at AACR 2022 boost prospects for BI-1808.
- CTA approval received for BI-1607 which primarily will focus on treating breast cancer.
- BioInvent and Transgene presented preclinical data at AACR 2022 demonstrating BT-001's superiority to systemically administered anti-CTLA-4. The two companies published preclinical BT-001 proof-of-concept data in the Journal of ImmunoTherapy of Cancer (JITC).
- Marie Moores was appointed Chief Operating Officer.

EVENTS AFTER THE END OF THE PERIOD

- (R) Annual Report 2021 was published.

(R)= Regulatory event

The BioInvent colleagues Ingrid Teige, Head of Preclinical and Linda Mårtensson, Principal Scientist, had some busy days at the AACR (American Association for Cancer Research) Annual Meeting 2022 in New Orleans, Louisiana, US.

Exciting translational data were presented for BioInvent's anti-TNFR2 antibody BI-1808, showing similar biomarker correlations in patient samples as observed in the preclinical setting. The first data from the ongoing Phase 1/2a trial are expected mid-2022. The poster on BioInvent's second anti-FcγRIIB antibody BI-1607 reinforces BioInvent's evidence base that blocking the Fcγ receptor is a key strategy in controlling outcomes in cancer. The upcoming clinical Phase 1/2a study is expected to start during the second quarter 2022.

BioInvent's and its collaboration partner Transgene presented a poster demonstrating that the companies' jointly developed oncolytic virus drug candidate BT-001 has the potential to improve anti-tumor activity and provide greater therapeutic benefit than systemically administered anti-CTLA-4 antibodies. Initial Phase 1/2a data are expected during the second quarter 2022.





Martin Welsch
CEO

Continuing strong progress in our portfolio of clinical projects

BioInvent continued its strong clinical progress in the first quarter with our exciting pipeline of novel and first-in-class immuno-modulatory antibodies for cancer therapy. During the second quarter, a fourth drug candidate (BI-1607) is expected to enter clinical development, which then brings the total number of ongoing trials to five. This demonstrates the ability of our n-CoDeR/F.I.R.S.T platforms to produce novel, differentiating drug candidates.

EXCITING DATA PRESENTED AT AACR22 AACR data boost prospects for BI-1808

At the annual meeting of the American Association for Cancer Research in April 2022 (AACR22), we presented exciting translational data on the anti-TNFR2 drug candidate BI-1808, currently in Phase I development against solid tumors. Results from toxicological studies demonstrate a very good tolerability profile and there have been no safety concerns in the clinical trial to date. Furthermore, in vivo studies using experimental cancer models showed a clear relationship between dose, receptor occupancy and efficacy.

BI-1607 for the treatment of breast cancer

We presented two further important data sets at AACR, including the first data on BI-1607, an FcγRIIB-blocking antibody which differs from BI-1206 in that it has been engineered for reduced Fc-binding to FcγRs. These data

provide further evidence that our approach of targeting FcγRIIB with antibodies could be a key strategy in controlling outcomes in cancer. The BI-1607 clinical Phase 1/2a study is planned to enroll its first patient during the second quarter 2022.

BT-001 superior to systemically administered anti-CTLA-4

Together with our partner Transgene, we also had a poster presentation on preclinical studies of the novel oncolytic virus BT-001 showing the robust anti-tumoral activity, highlighting its potential to provide greater therapeutic benefit than systemically administered anti-CTLA-4 antibodies.

GOOD PROGRESS FOR BI-1206

The two Phase 1/2 trials with our lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, continue to make good progress. The first study combines BI-1206 with

rituximab for the treatment of non-Hodgkin lymphomas (including mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), and follicular lymphoma (FL), with the second in combination with anti-PD-1 therapy Keytruda® (pembrolizumab) in solid tumors.

BI-1206 GRANTED A SECOND ORPHAN DRUG DESIGNATION

The FDA has also granted BI-1206 Orphan Drug Designation (ODD) for the treatment of FL, the most common form of slow-growing Non-Hodgkin lymphoma. This is another important step forward in the development of BI-1206, which already had ODD from the FDA for the treatment of MCL.

STRENGTHENED LEADERSHIP

Our leadership team was further strengthened with the appointment of the experienced industry leader Marie Moores as Chief Operating Officer. Marie's regulatory and drug development experience is proving invaluable as we continue to develop and expand our pipeline. Her responsibility for day-to-day operations allows me, as CEO, to devote more of my time to the broader, long-term strategic development of BioInvent, including new partnerships and capital markets.

We have also held an internal kick-off where our new Scientific Advisory Board member, Alexander Eggermont

MD, PhD held a lecture on the future of immunotherapy, for all BioInvent employees. It was truly inspiring and motivating for our efforts. Prof. Eggermont is an internationally recognized expert in surgical oncology, immunotherapy, melanoma, sarcoma and cancer drug development.

In April, we published our Annual Report, where you can read more details on BioInvent's recent accomplishments and longer-term plans.

We are looking forward to some important developments in Q2 2022 and beyond. We expect to dose the first patient in our Phase 1 trial of BI-1607 in Q2. We also will give a first clinical update from the Phase 1 trial of BT-001. Both studies are in patients with solid tumors. In mid-2022 we anticipate the first clinical data from the Phase 1 trial of BI-1808.

Once again, I would like to thank all the employees of BioInvent for their continued dedication and hard work, which underpins this highly satisfactory progress. I am also grateful for the support and trust of our investors and partners. I look forward to providing you with further updates on our work through the rest of 2022.

Martin Welschhof, CEO



Pipeline with four clinical programs

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

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

Target: TNFR2 and CTLA-4

BI-1808 (TNFR2)	Solid tumors	Completed	Ongoing	Up-coming	Up-coming	MSD*
BT-001 (CTLA-4, GM-CSF)	Solid tumors	Completed	Ongoing	Up-coming	Up-coming	transgene
BI-1910 (TNFR2)	Solid tumors	Completed	Ongoing	Up-coming	Up-coming	

- Completed
- Ongoing
- Up-coming

* Clinical supply and collaboration agreement

Andres McAllister
Chief Medical Officer

Clinical programs

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

BI-1206

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

BI-1206 in NHL

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

BI-1206 in solid tumors

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

BI-1808

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

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

BT-001

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

BI-1206 in non-Hodgkin's lymphoma

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

Status: clinical phase 1/2a study with BI-1206 in combination with rituximab for the treatment of non-Hodgkin's lymphoma (NHL) (NCT03571568)

In December 2021, positive interim top-line data were presented showing increased response levels and sustained complete responses in the ongoing clinical Phase 1/2a study of BI-1206 in combination with rituximab for the treatment of non-Hodgkin's lymphoma (NHL).

The response rate for follicular lymphoma was particularly impressive: of nine evaluable patients, three developed a complete response, three developed a partial response and one patient had stable disease at the cut-off date, giving an objective response rate (ORR) of 67% and 78% disease control rate (DCR).

Overall, the study provided an ORR of 54%, with three complete responses and four partial responses in 13 patients evaluated for therapeutic benefit for the three indications (mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma) enrolled. The treatment stabilized disease in one additional patient, giving an overall DCR of 62% (8 out of 13 patients).

All three complete responses have been sustained for extended periods, with the longest complete response enduring beyond 36 months. In two patients, complete responses have lasted beyond 12 and 24 months after end of treatment. Previous rituximab treatments without BI-1206 had failed in these patients, prior to participation in the trial all patients had relapsed on earlier lines of rituximab-containing treatments.

Study design

The Phase 1/2a study is divided into two parts:

1) Phase 1, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase 2a dose (RP2D); and

2) Phase 2a, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma. Patients in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Those who show clinical benefit at week 6 continue onto maintenance therapy and receive BI-1206 and rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 1 year from first dose of BI-1206.

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

Orphan Drug Designation for the treatment of FL and MCL

In January 2022, BI-1206 was granted Orphan Drug Designation (ODD) by the U.S. Food and Drug Administration (FDA) for the treatment of follicular lymphoma (FL), the most common form of slow-growing Non-Hodgkin lymphoma. The FDA's Office of Orphan Drug Products grants orphan status to support the development of medicines for rare disorders that affect fewer than 200,000 people in the U.S. Since 2019, BI-1206 has ODD for mantle cell lymphoma.

Clinical development in China with BI-1206 in combination with rituximab and as single-agent

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

CASI is planning Phase 1 trials of BI-1206 as a single agent with the aim to evaluate the PK profile and in combination with rituximab in NHL (mantle cell lymphoma, marginal zone lymphoma and follicular lymphoma) to assess safety and tolerability, select the Recommended Phase 2 Dose and assess early signs of clinical efficacy as part of its development program for BI-1206 in China and associated markets. The studies are expected to start in H1 2022.

Out-licensing and partnering

Since October 2020, BioInvent has a licensing agreement in place with CASI Pharmaceuticals for the China region. Under the terms of the agreement, BioInvent and CASI will develop BI-1206 in both hematological and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent received USD 12 million upfront in combination of cash and equity investment and eligible to receive up to USD 83 million in milestone payments, plus tiered royalties.

BI-1206 in solid tumors

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

Status: clinical phase 1/2a study with BI-1206 in combination with pembrolizumab (NCT04219254)

Early observations are that BI-1206 in combination with pembrolizumab may stem and reverse metastatic disease progression in patients who have previously progressed on PD-1/PDL-1 therapies and other prior treatments. No major safety concerns have been noted and dose-escalation will continue. Next patient cohort will be dosed at 2 mg/kg.

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.

Study design

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

The Phase 2a part will study the BI-1206/Keytruda combination treatment in patients with advanced lung cancer, melanoma and other types of malignancies.

Positive early clinical data

As of the fourth quarter 2021, eleven patients in three dose cohorts have been treated with BI-1206 in combination with pembrolizumab. During the study period, a patient with stage IV sarcoma was able to stop all pain medication, the coughing disappeared, and the shortness of breath markedly improved. From the time of ending participation in the BI-1206 study, the patient did not receive any other anti-cancer treatment and showed on a scan performed in September 2021 that some metastatic lesions have disappeared, some are smaller, and others have not changed. No lesions have grown, and no new lesions are evident.

Another patient, with uveal melanoma, demonstrated a partial response and is still on treatment with the combination of BI-1206 and pembrolizumab. Metastatic uveal melanoma is a difficult-to-treat disease, with median overall survival of approximately 13.4 months, with only 8% of patients surviving after 2 years. (Uveal melanoma: epidemiology, etiology, and treatment of primary disease, Krantz et al, Clin Ophthalmology 31 Jan 2017.)

Out-licensing and partnering

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206 and Merck's anti-PD-1 therapy, Keytruda in a Phase 1/2a clinical trial for patients with solid tumors. Under the agreement, Merck supplies Keytruda which supports the evaluation of BI-1206 for the treatment of solid tumors in combination with one of the most successful immuno-oncology drugs.

BI-1808 i solida tumörer och CTCL

Läkemedelskandidaten BI-1808, riktad mot målstrukturen TNFR2, ingår i BioInvents program för utveckling av antikroppar riktade mot regulatoriska T-celler (Treg). TNFR2 är särskilt uppreglerad på Tregs i tumörmikromiljön och har visat sig vara viktig för tumörexansion och överlevnad och utgör därför ett nytt och lovande mål för immunterapi av cancer. Två olika typer av TNFR2-antikroppar utvecklas av BioInvent. Förutom BI-1808 har företaget även BI-1910 (en TNFR2-agonist) som är i preklinisk utveckling.

Status: Klinisk fas 1/2a-studie (NCT04752826)

Viktiga translationella data presenterades på AACR:s (American Association for Cancer Research) årsmöte i april 2022 (AACR22). In vivo-studier i experimentella modeller för cancer visar på ett tydligt samband mellan dos, bindning till receptorn (receptor occupancy, RO) och effekt. Mängden lösligt TNFR2 påverkades tydligt av behandlingen och korrelerade väl med RO, både i tumörmodellerna och de toxikologiska studierna. I likhet med i de prekliniska studierna har korrelationer mellan dos, RO och löslig TNFR2 tydligt observerats hos patienterna i den pågående kliniska fas 1/2a-studien.

I april 2021 godkände det amerikanska läkemedelverket FDA IND-ansökan (Investigational New Drug) avseende en klinisk fas 1/2a-studie med BI-1808. Studien genomförs för närvarande i Danmark, Ungern och Storbritannien.

Sedan januari 2021 inkluderas patienter i Europa till den första delen av den pågående fas 1/2a-studien som utvärderar säkerhet, tolerabilitet och potentiella signaler på effekt av BI-1808 som monoterapi och i kombination med Keytruda i patienter med äggstockscancer, icke-småcellig lungcancer och CTCL (kutant T-cellslymfom). Studien förväntas rekrytera totalt cirka 120 patienter.

De första fas 1-data förväntas i mitten av 2022.

Studiedesign

Den pågående fas 1-komponenten i studien är uppdelad i två delar:

Del A är en doseskaleringsstudie som utvärderar säkerheten och tolerabiliteten samt farmakokinetik/farmakodynamik för BI-1808 för att fastställa den rekommenderade dosen för fas 2 (RP2D). Del B kommer att undersöka säkerheten och tolerabiliteten av BI-1808 i kombination med Keytruda.

Utlicensiering och partnering

Den efterföljande fas 2a-delen av studien består av större patientgrupper för att studera potentiella signaler på effekt av BI-1808 dels separat ("single agent") dels i kombination med Keytruda, i lungcancer- och äggstockscancerpatienter. En annan kohort kommer att utvärdera BI-1808 som single agent för behandling av kutant (hud) T-cellslymfom (CTCL).

BioInvent har sedan augusti 2021 ett kliniskt prövnings-samarbete och leveransavtal med Merck, för att utvärdera kombinationen av BI-1808 och Mercks anti-PD-1-behandling Keytruda i en klinisk fas 1/2a-studie i patienter med avancerade solida tumörer. Genom avtalet förser Merck studien med Keytruda, vilket stödjer utvärderingen av BI-1808 i kombination med ett av de mest framgångsrika immunonkologiläkemedlen på marknaden.

BT-001 in solid tumors

BT-001 is an oncolytic virus developed with Transgene's Invir.IO™ platform, engineered to encode both a Treg-depleting human recombinant anti-CTLA-4 antibody generated by BioInvent's proprietary n-CoDeR/F.I.R.S.T platforms, and the human GM-CSF cytokine. The use of an oncolytic virus to deliver the anti-CTLA-4 locally and selectively in the tumor microenvironment allows high intratumoral concentrations, eliciting a stronger and more effective antitumor response. By reducing systemic exposure to a very low level, this local therapeutic activity furthermore allows to increase the safety and tolerability profile of the anti-CTLA-4 antibody.

Status: Clinical phase 1/2a study (NCT04725331)

In January 2022, BioInvent and Transgene published preclinical proof-of-concept data that demonstrate that their co-developed clinical stage product, based on Transgene's patented oncolytic vector and encoding BioInvent's proprietary anti-CTLA-4 antibody, has the potential to provide greater therapeutic benefit than systemically administered anti-CTLA-4 antibodies. Systemically administered anti-CTLA-4 antibodies, such as the approved ipilimumab, have demonstrated substantial efficacy but also clinically limiting toxicity. The JITC paper is titled 'Vectorized Treg-depleting α CTLA-4 elicits antigen cross-presentation and CD8+ T cell immunity to reject "cold" tumors' and can be accessed here: <https://jitc.bmj.com/content/jitc/10/1/e003488.full.pdf>.

Preclinical data on BT-001 were presented at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) in November 2021 and at the AACR (American Academy for Cancer Research) in April 2022.

Since March 2021, patients are enrolled to the ongoing Phase 1/2a open-label, multicenter, dose-escalation study evaluating BT-001 as a single agent and in combination with pembrolizumab. The study is currently enrolling patients at sites in France and Belgium. Initial Phase 1 data is expected H1 2022.

Study design

The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BT-001 alone and in combination with pembrolizumab. The ongoing Phase 1 component of the study is divided into two parts: Part A will evaluate intra-tumoral injections of BT-001 as single agent in up to 42 patients with advanced solid tumor disease. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab in several cohorts of up to 12 patients each.

The subsequent Phase 2a component of the study will evaluate the combination regimen in several patient cohorts with different tumor types. These expansion cohorts will offer the possibility of exploring the activity of this approach to treat other malignancies not traditionally addressed with this type of treatment.

Out-licensing and partnering

Since 2017, BioInvent and Transgene collaborate on the development of oncolytic virus (OV) drug candidates aimed at treating solid tumors, with the potential to be significantly more effective than the combination of a virus and an antibody as single agents. The clinical drug candidate BT-001 encode both a differentiated and proprietary anti-CTLA-4 antibody and the GM-CSF cytokine.

Transgene is contributing its proprietary oncolytic virus (OV) platform Invir.IO™, designed to directly and selectively destroy cancer cells by intracellular replication of the virus in the cancer cell (oncolysis). Oncolysis induces an immune response against tumors, while the "weaponized" virus allows the expression of genes carried by the viral genome, here an anti-CTLA-4 antibody, which will further boost immune response against the tumor.

The research and development costs, as well as revenue and royalties from drug candidates generated from the collaboration, are shared 50:50.

Ingrid Teige
Head of Preclinical

Preclinical programs

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

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

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

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

BI-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. Data suggests that the company's approach of targeting FcγRIIB with antibodies could potentially be extended to breast cancer treatments. In analogy with BI-1206 (BioInvent's clinical-stage FcγRIIB antibody), BI-1607 is intended to be used to enhance the efficacy and overcome resistance to existing cancer treatments. The BI-1607 clinical Phase 1/2a study is planned to enroll its first patient during the second quarter 2022.

BI-1910

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

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



Strategic collaborations

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

COLLABORATIONS WITH LEADING PHARMACEUTICAL COMPANIES

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

SIX CLINICAL PROJECTS OUTLICENSED

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

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

Program	Indication	Phase				Partner
		Phase 1	Phase 2	Phase 3	Market	
MT-2990 α-IL33 Mab	Endometriosis	██████████	██████████	██████████	██████████	Mitsubishi Tanabe
TAK-079 α-CD38	Myasthenia Gravis, CPIT	██████████	██████████	██████████	██████████	Takeda
Orticumab α-ApoB100	Psoriasis	██████████	██████████	██████████	██████████	Abcentra
TAK-169/MT-0169 α-CD38	Multiple Myeloma	██████████	██████████	██████████	██████████	Takeda & Molecular Templates
DS-1055 α-GARP MAb	Solid tumor	██████████	██████████	██████████	██████████	Daiichi-Sankyo
HMI-115 α-PRLR MAb	Alopecia, Endometriosis	██████████	██████████	██████████	██████████	Hope Medicine/Bayer

BioInvent’s external projects is a seal of excellence for the quality of the company’s research and development.

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 16.7 million (6.2). Revenues for the period were mainly derived from production of antibodies for clinical studies. Revenues for the corresponding period 2021 were mainly derived from production of antibodies for clinical studies.

The Company's total costs amounted to SEK 85.0 million (86.0). Operating costs are divided between external costs of SEK 57.1 million (62.2), personnel costs of SEK 24.4 million (20.3) and depreciation of SEK 3.5 million (3.5). In January 2021, BioInvent announced that it had restructured a clinical development agreement with Cancer Research UK (CRUK) for BI-1206. In exchange for a one-time payment of £2.5 million, the revised deal simplifies and reduces Bioinvent's obligations to CRUK. This cost is included in external costs for the first quarter 2021.

Research and development costs amounted to SEK 71.9 million (76.6). Sales and administrative costs amounted to SEK 13.1 million (9.4).

Profit/loss after tax amounted to SEK -67.7 million (-79.8). The net financial items amounted to SEK 0.5 million (0.2). Profit/loss per share before and after dilution amounted to SEK -1.16 (-1.94).

FINANCIAL POSITION AND CASH FLOW

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

As of March 31, 2022, the Group's liquid funds, current and long-term investments amounted to SEK 1,280.9 million (1,577.1). The cash flow from operating activities for the January-March period amounted to SEK -79.8 million (-49.5).

The shareholders' equity amounted to SEK 1,299.3 million (1,565.2) at the end of the period. The Company's share capital was SEK 11.7 million. The equity/assets ratio at the end of the period was 94 (96) percent. Shareholders' equity per share amounted to SEK 22.22 (26.77).

INVESTMENTS

Investments for the January-March period in tangible fixed assets amounted to SEK 2.8 million (2.0).

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, 2022, BioInvent had 86 (74) employees (full time equivalent). 77 (66) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

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

RISK FACTORS

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

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

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

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

	3 MONTHS 2022 JAN.-MAR.	3 MONTHS 2021 JAN.-MAR.	12 MONTHS 2021 JAN.-DEC.
Net sales	16,659	6,200	19,384
<i>Operating costs</i>			
Research and development costs	-71,870	-76,578	-258,337
Sales and administrative costs	-13,168	-9,470	-39,438
Other operating income and costs	91	-117	41
	-84,947	-86,165	-297,734
Operating profit/loss	-68,288	-79,965	-278,350
Profit/loss from financial investments	540	177	-94
Profit/loss before tax	-67,748	-79,788	-278,444
Tax	-	-	-
Profit/loss	-67,748	-79,788	-278,444
Other comprehensive income			
Items that have been or may be reclassified subsequently to profit or loss	-	-	-
Comprehensive income	-67,748	-79,788	-278,444
Other comprehensive income attributable to parent Company's shareholders	-67,748	-79,788	-278,444
Profit/loss per share, SEK			
Before dilution	-1.16	-1.94	-5.14
After dilution	-1.16	-1.94	-5.14

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

	2022 MAR. 31	2021 MAR. 31	2021 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	25,908	11,247	27,433
Tangible fixed assets - other	22,494	16,905	21,651
Financial fixed assets - long-term investments	274,120	-	282,208
Total fixed assets	322,522	28,152	331,292
Inventories	13,485	6,891	16,848
Current receivables	37,996	14,395	16,342
Current investments	236,948	-	172,074
Liquid funds	769,793	1,577,077	910,755
Total current assets	1,058,222	1,598,363	1,116,019
Total assets	1,380,744	1,626,515	1,447,311
SHAREHOLDERS' EQUITY			
Total shareholders' equity	1,299,287	1,565,223	1,366,987
LIABILITIES			
Lease liabilities	20,050	3,985	21,532
Total long term liabilities	20,050	3,985	21,532
Lease liabilities	6,731	6,183	6,835
Other liabilities	54,676	51,124	51,957
Total short term liabilities	61,407	57,307	58,792
Total shareholders' equity and liabilities	1,380,744	1,626,515	1,447,311

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

	2022 JAN.-MAR.	2021 JAN.-MAR.	2021 JAN.-DEC.
Shareholders' equity at beginning of period	1,366,987	743,499	743,499
Comprehensive income			
Profit/loss	-67,748	-79,788	-278,444
Comprehensive other income	-	-	-
Total comprehensive income	-67,748	-79,788	-278,444
Total, excluding transactions with equity holders of the Company	1,299,239	663,711	465,055
Transactions with equity holders of the Company			
Employee options program	48	718	1,138
Directed share issue	-	900,794	900,794
Shareholders' equity at end of period	1,299,287	1,565,223	1,366,987

The share capital as of March 31, 2022 consists of 58,471,096 shares and the share's ratio value was 0.20.

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

	2022	2021	2021
	JAN.-MAR.	JAN.-MAR.	JAN.-DEC.
Operating activities			
Operating profit/loss	-68,288	-79,965	-278,350
Depreciation	3,475	3,475	14,610
Adjustment for other non-cash items	48	718	1,138
Interest received and paid	-176	-72	-269
Cash flow from operating activities before changes in working capital	-64,941	-75,844	-262,871
Changes in working capital	-14,855	26,323	17,028
Cash flow from operating activities	-79,796	-49,521	-245,843
Investment activities			
Acquisition of tangible fixed assets	-2,794	-2,001	-13,260
Acquisition of financial investments	-56,786	-	-454,282
Cash flow from investment activities	-59,580	-2,001	-467,542
Cash flow from operating activities and investment activities	-139,376	-51,522	-713,385
Financing activities			
Directed share issue	-	900,794	900,794
Amortization of lease liability	-1,586	-1,465	-5,924
Cash flow from financing activities	-1,586	899,329	894,870
Change in liquid funds	-140,962	847,807	181,485
Opening liquid funds	910,755	729,270	729,270
Liquid funds at end of period	769,793	1,577,077	910,755
Liquid funds, specification:			
Cash and bank	769,793	1,577,077	910,755
	769,793	1,577,077	910,755

Key financial ratios for the Group

	2022	2021	2021
	MAR. 31	MAR. 31	DEC. 31
Shareholders' equity per share at end of period, SEK	22.22	26.77	23.38
Number of shares at end of period (thousand)	58,471	58,471	58,471
Equity/assets ratio, %	94.1	96.2	94.5
Number of employees at end of period	86	74	84

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

	3 MONTHS 2022 JAN.-MAR.	3 MONTHS 2021 JAN.-MAR.	12 MONTHS 2021 JAN.-DEC.
Net sales	16,659	6,200	19,384
<i>Operating costs</i>			
Research and development costs	-72,088	-76,504	-258,521
Sales and administrative costs	-13,187	-9,464	-39,454
Other operating income and costs	91	-117	41
	-85,184	-86,085	-297,934
Operating profit/loss	-68,525	-79,885	-278,550
Profit/loss from financial investments	716	249	420
Profit/loss after financial items	-67,809	-79,636	-278,130
Tax	-	-	-
Profit/loss	-67,809	-79,636	-278,130
Other comprehensive income	-	-	-
Comprehensive income	-67,809	-79,636	-278,130

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

	2022 MAR. 31	2021 MAR. 31	2021 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	22,494	16,905	21,651
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	274,120	-	282,208
Total fixed assets	297,301	17,592	304,546
Current assets			
Inventories	13,485	6,891	16,848
Current receivables	37,684	15,933	16,030
Current investments	236,948	-	172,074
Cash and bank	769,793	1,577,077	910,755
Total current assets	1,057,910	1,599,901	1,115,707
Total assets	1,355,211	1,617,493	1,420,253
SHAREHOLDERS' EQUITY			
Restricted equity	39,387	39,387	39,387
Non-restricted equity	1,260,499	1,526,334	1,328,260
Total shareholders' equity	1,299,886	1,565,721	1,367,647
LIABILITIES			
Short term liabilities	55,325	51,772	52,606
Total short term liabilities	55,325	51,772	52,606
Total shareholders' equity and liabilities	1,355,211	1,617,493	1,420,253

Lund, April 27, 2022

Martin Welschhof
CEO

Review report

INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on March 31, 2022 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 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, April 27, 2022
KPMG AB

Linda Bengtsson
Authorized Public Accountant

Information notes

NOTE 1 ACCOUNTING PRINCIPLES

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

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

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

For more detailed information about the Group's accounting principles regarding revenues, see Note 1 Accounting principles, page 64, in the Company's annual report 2022.

NOTE 2 NET REVENUE

SEK THOUSAND	2022	2021	2021
	JAN.-MAR.	JAN.-MAR.	JAN.-DEC.
Revenue by geographical region:			
Sweden	14,658	3,067	13,515
Europe	1,532	2,745	4,213
USA	469	388	1,656
Other countries	-	-	-
	16,659	6,200	19,384
Revenue consists of:			
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	-	-
Revenue from technology licenses	-	-	-
Revenue from external development projects	16,659	6,200	19,384
	16,659	6,200	19,384

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

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- (R) Annual Report 2021 was published.

(R)= Regulatory event

Other information

FINANCIAL CALENDAR

- Interim reports August 25, October 27, 2022.

CONTACT

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

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

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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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