

INTERIM REPORT JANUARY 1 - MARCH 31, 2021

## Events in the quarter

### PROJECT UPDATES

- (R) BioInvent Phase 1/2a data suggest BI-1206 restores activity of rituximab in re-lapsed non-Hodgkin's lymphoma patients.
- BioInvent enrolled first patient in a Phase 1/2a trial of the first-in-class anti-TNFR2 antibody BI-1808 for the treatment of patients with solid tumors and CTCL.
- BioInvent and Transgene enrolled first patient in Phase 1/2a trial of novel oncolytic virus BT-001 in solid tumors.
- (R) BioInvent streamlined agreement with CRUK on anti-FcγRIIB antibody, BI-1206, ahead of Phase 1/2 data. In exchange for a one-off payment of GBP 2.5 million, the revised deal simplifies and reduces BioInvent's obligations to CRUK.
- BioInvent presented proof-of-concept data on anti-FcγRIIB antibody BI-1607 at AACR Annual Meeting 2021.

### FINANCING

- (R) BioInvent successfully carried out a directed share issue of approximately SEK 962 million (USD 116 million).

## Events after the period

- BioInvent received IND approval for Phase 1/2a trial of anti-TNFR2 antibody BI-1808.

## Financial information

### FIRST QUARTER 2021

- Net sales SEK 6.2 (16.7) million.
- Loss after tax SEK -79.8 (-32.6) million.
- Loss after tax per share before and after dilution SEK -1.94 (-1.63).
- Cash flow from operating activities and investment activities SEK -51.5 (-35.4) million. Liquid funds as of March 31, 2021: SEK 1,577.1 (117.1) million.

(R)= Regulatory event

The information was submitted for publication at 8:00 a.m. CEST on April 28, 2021.





CEO Martin Welschhof comments the quarter

## Strong clinical and financial progress underpin transformation.

*BioInvent continued to make strong clinical and financial progress in Q1 2021. Positive interim results from the Phase 1/2a study of BI-1206 in B-cell non-Hodgkin's lymphoma (NHL) are very encouraging. Our financial position was reinforced with a directed share issue, providing funding to continue the transformation of BioInvent with the expansion of our clinical programs and broadening our institutional shareholder base.*

### **BI-1206 STRATEGY FOCUSES ON THE FASTEST PATH TO MARKET IN COMBINATION WITH RITUXIMAB**

The data on BI-1206 clearly suggest that this novel anti-FcγRIIB antibody may restore the response to rituximab in patients who have few treatment alternatives, with clinical responses seen in six of nine patients who have completed the induction cycle. The long-lasting complete responses observed in two patients beyond 12 and 24 months are particularly impressive. Our clinical development strategy for BI-1206 focuses on the fastest path to market in combination with rituximab, including in China. Later in 2021, we will have an End of Phase 1 meeting with the U.S. Food and Drug Administration (FDA) to discuss the Phase 2 study design in the U.S., EU and China.

### **DIRECTED SHARE ISSUE ENABLES US TO ACCELERATE OUR CLINICAL DEVELOPMENT**

In the quarter, we raised SEK 962 million (USD 116 million) before transaction costs in a directed share issue, which enables us to accelerate and broaden our clinical development. We are now funded to achieve a number of important clinical efficacy milestones which have the potential to serve as a basis for partnership agreements. We are also strengthening our internal clinical team to ensure delivery.

### **DOUBLING THE SIZE OF OUR CLINICAL PIPELINE**

The initiation of two new studies in cancer patients, with BI-1808 and BT-001, has doubled the size of our clinical pipeline to four programs. We are assessing BI-1808 in a Phase 1/2a study as a single agent and in combination with the anti-PD-1

therapy Keytruda® (pembrolizumab), for the treatment of solid tumors and cutaneous T-cell lymphoma (CTCL). BI-1808 acts through the depletion of regulatory T-cells, releasing the brakes in the immune system.

BT-001 also acts by releasing the brakes of the immune system but through a different mechanism of action, as an oncolytic virus delivering an anti-CTLA-4 antibody, inducing anti-cancer immune activation both locally and in the rest of the body. In partnership with Transgene, we are investigating BT-001 in a Phase 1/2a study as a single agent and in combination with Keytruda in solid tumors. Enrolment and dosing are progressing in line with forecast.

### **PROOF-OF-CONCEPT DATA FOR BI-1607**

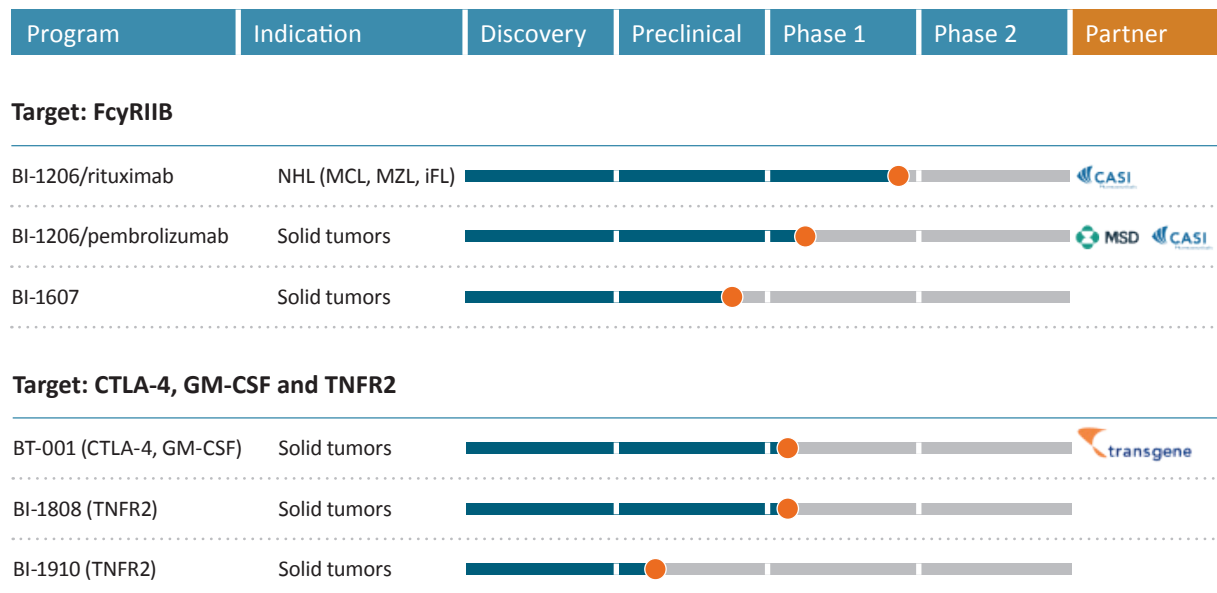
In April, we also presented preclinical proof-of-concept data for our novel, fully human FcγRIIB-blocking antibody BI-1607, at the American Association for Cancer Research (AACR) Annual Meeting 2021. We expect to file a clinical trial application for this drug candidate in H2 2021.

### **IMPORTANT MILESTONES COMING UP LATER THIS YEAR**

There are important milestones coming up for BioInvent in 2021. We expect BI-1206 to enter the dose expansion stage in the Phase 1/2a study in combination with rituximab, and to report first Phase 1 data on BI-1206 in combination with Keytruda. I look forward to continuing to update you on our exciting progress.

# Pipeline with four clinical programs.

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



## Discovery.

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

### TECHNOLOGY PLATFORMS

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

### TUMOR-ASSOCIATED MYELOID CELLS (TAM)

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

BiolInvent has so far received USD 6.6 million in milestone payments besides research funding for an R&D collaboration

with Pfizer 2017-2020 on the selection of TAM targets. Pfizer has selected its targets and BiolInvent is eligible for potential future development milestones in excess of USD 100 million if one antibody is developed through to commercialization, and up to double digit royalties on future sales.

### REGULATORY T CELLS (TREGS)

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

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



# Clinical programs

*BioInvent's team has put together one of the most exciting and unique cancer immunotherapy pipelines of any European biotech company. A solid scientific understanding, a sharp clinical development strategy and a robust capacity to execute plans have put the company in a very interesting track to develop innovative treatments capable of transforming the life of cancer patients. That's our goal!*

Andres McAllister  
Chief Medical Officer

## BI-1206 and rituximab

- Initially in development for relapsed or refractory indolent Non-Hodgkin's Lymphoma (iNHL) patients who are resistant to rituximab
- The iNHL market potential for BI-1206 in the US is approx. USD 200 million
- Possible label extension to all therapeutic areas where anti-CD20 mAbs are used

## BI-1206 and pembrolizumab

- Strong rationale for combination with pembro, as FcγRs have been shown to modulate the activity of immune checkpoint inhibitors
- Overexpression of FcγRIIb may increase resistance to anti-PD-1 therapy

## BT-001

- Designed for strong and sustained anti-tumor activity
- Designed for better safety vs current anti-CTLA-4 treatment
- Builds on 3 clinically validated targets (CTLA-4, aPD-1/PD-L1, oncolytic viruses), with expected enhanced efficacy and improved tolerability in a variety of tumor types

## BI-1808

- As a part of the Treg program, BioInvent identified and characterized a wide panel of TNFR2-specific antibodies, generated from its proprietary n-CoDeR® library and unique F.I.R.S.T™ discovery tool, of which BI-1808 is one of the leads
- TNFR2 is particularly upregulated on tumor-associated regulatory T cells (Tregs) and important for survival and growth



BI-1206 is a high-affinity monoclonal antibody that selectivity 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.



# BI-1206 in non-Hodgkin’s lymphoma.

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

## PROJECT STATUS AND OUTLOOK

### Positive data from Phase 1/2a study

In January 2021, positive data was presented from the ongoing clinical Phase 1/2a study (NCT03571568) of BI-1206 in combination with rituximab for the treatment of non-Hodgkin’s lymphoma (NHL). Data suggest that BI-1206 restores activity of rituximab in relapsed NHL patients.

Of the 9 patients who completed dosing in the first 4 cohorts, 6 patients showed either complete or partial responses, several of which are still ongoing. Two patients (at dose levels of 30 mg and 70 mg) achieved a complete response, which continued to be sustained after 12 and 24 months. Another patient who had an aggressive (blastoid) form of MCL had achieved a partial response, and a complete depletion of peripheral tumor cells.

### 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 (MCL). 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.

### Next milestone expected H2, 2021

The next milestone in the project is determination of the recommended Phase 2 dose (RP2D) and progression to the expansion Phase 2a part of the study, expected H2 2021.

## OUT-LICENSING AND PARTNERING

Since October 2020, BioInvent has a licensing agreement in place with CASI Pharmaceuticals for Greater 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.

In January 2021, BioInvent announced that it had restructured a clinical development agreement with CRUK for BI-1206. In exchange for a one-time payment of GBP 2.5 million, the revised deal simplifies and reduces BioInvent’s obligations to CRUK, which provides BioInvent with more flexibility to carry out development and partnering activities with BI-1206. The restructured agreement with CRUK releases BioInvent from obligations to pay development or commercial milestones to CRUK on BI-1206 and reduces the royalties due on net sales to low single digit levels.



BI-1206 is a high-affinity monoclonal antibody that 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 PD1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors.



# BI-1206 in solid tumors.

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

## PROJECT STATUS AND OUTLOOK

### Ongoing Phase 1/2a multicenter

A Phase 1/2a multicenter, dose-finding, open-label study of BI-1206 in combination with pembrolizumab (Keytruda®) in patients with advanced solid tumors, is ongoing since June 2020. Patients in the study will previously have received treatment with PD-1/PD-L1 immune checkpoint inhibitors. It is conducted at several sites across the US and Europe and will assess potential signs of antitumoral activity, as well as exploring the expression of potential immunological markers that might be associated, and eventually predict clinical responses.

### Evaluation of safety and tolerability

The overall objective of the Phase 1/2a study (NCT04219254) is to evaluate the safety and tolerability of BI-1206 in combination with Keytruda. The Phase 1 part is a dose escalation study with the aim to determine the recommended Phase 2 dose (RP2D) of BI-1206 in combination with Keytruda. Early results from the Phase 1 study is expected H2 2021.

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

## OUT-LICENSING AND PARTNERING

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with 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.





BT-001 is a best-in-class 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.

# BT-001 in solid tumors.

Target: **CTLA-4, GM-CSF**

Status: **Phase 1**

Partner: **Transgene**

## PROJECT STATUS AND OUTLOOK

### First patient enrolled

In March 2021, the first patient was enrolled to the ongoing Phase 1/2a open-label, multicenter, dose-escalation study evaluating BT-001 as a single agent and in combination with pembrolizumab. The study (NCT04725331) is currently enrolling patients at sites in France and Belgium. An IND submission will follow in the U.S. The first Phase 1 data is expected H1 2022.

### Evaluating the safety and tolerability

The overall objective of the Phase 1/2a study is to evaluate the safety and tolerability of BT-001 alone and in combination with pembrolizumab. The ongoing Phase 1 component of the

study is divided into two parts: Part A will evaluate intra-tumoral injections of BT-001 as single agent in up to 36 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 12 patients each.

### Exploring the activity in Phase 2a

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

## OUT-LICENSING AND 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 an 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 de-

stroy 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.



The anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate and is part of BioInvent's tumor-associated regulatory T cells (Treg)-targeting program. TNFR2 is particularly upregulated on Tregs of the TME and has been shown to be important for tumor expansion and survival, representing a new and promising target for cancer immunotherapies. Two different types of TNFR2 targeting antibodies are being developed by BioInvent. In addition to BI-1808, the company also has BI-1910 (a TNFR2 agonist) in preclinical development.



## BI-1808 in solid tumors and CTCL.

Target: **TNFR2**

Status: **Phase 1**

Partner: **Transgene**

### PROJECT STATUS AND OUTLOOK

#### First patient enrolled in January 2021

In January 2021, the first patient was enrolled to the ongoing Phase 1/2a study evaluating the safety, tolerability and potential signs of efficacy of BI-1808 as a single agent and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) in patients with ovarian cancer, non-small cell lung cancer and CTCL. The study (NCT04752826) is expected to enroll a total of approximately 120 patients.

In April 2021, the U.S. Food and Drug Administration (FDA) approved the Investigational New Drug (IND) for the BI-1808 Phase 1/2a clinical study. The study will be conducted in Denmark, Hungary, the United Kingdom and Russia and is already recruiting patients in Europe.

#### Dose escalation to determine the recommended single agent Phase 2 dose

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

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



# Preclinical programs

*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. Most of the research is performed in-house which gives the team a deep understanding of the mechanisms, characteristics, and potential behind all our candidate antibodies. The flexibility of the team and the close communication between the Preclinical, Translational and Core Research Teams and Clinical Development assures rapid adjustments to answer the most critical questions to advance our pipeline and is key to sustain the creative and high-energy spirit at BioInvent.*

Ingrid Teige  
Head of Preclinical





## BI-1607.

Target: **FcγRIIB**      Status: **Preclinical**

### PROJECT STATUS AND OUTLOOK

In March 2021, proof-of-concept data for BI-1607 was announced and the data was presented at the American Association for Cancer Research (AACR) Annual Meeting 2021 in April. The preclinical data show that BI-1607 increases the therapeutic efficacy of anti-CTLA-4 therapy in different tumor models and retains the efficacy of anti-CTLA-4 therapy at a lower dose of anti-CTLA-4. Furthermore, BI-1607 enhanced therapeutic efficacy and survival in a treatment resistant B16 model of anti-CTLA-4/anti-PD-1 combination therapy.

The submission of a BI-1607 clinical trial application (CTA) is expected during H2 2021, and it is planned to enter clinical development in 2022.

### BACKGROUND

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

## BI-1910.

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

### PROJECT STATUS AND OUTLOOK

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

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

### BACKGROUND

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



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

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

### **STRINGENT PORTFOLIO MANAGEMENT**

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

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

### **ATTRACTIVE SPACE IN THE PHARMACEUTICAL LANDSCAPE**

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

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

### **BIG PHARMA PARTNERS AND SOLID OWNERSHIP**

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

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



# Financial information

# Financial information

## REVENUES AND RESULT

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

### First quarter

Net sales amounted to SEK 6.2 million (16.7). Revenues for the period were mainly derived from production of antibodies for clinical studies. Revenues for the corresponding period 2020 were mainly derived from production of antibodies for clinical studies and revenues from research funding.

The Company's total costs amounted to SEK 86.0 million (50.2). Operating costs are divided between external costs of SEK 62.2 million (31.4), personnel costs of SEK 20.3 million (16.0) and depreciation of SEK 3.5 million (2.8). 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 GBP 2.5 million, the revised deal simplifies and reduces BioInvent's obligations to CRUK. This cost is included in external costs for the first quarter.

Research and development costs amounted to SEK 76.6 million (42.4). Sales and administrative costs amounted to SEK 9.4 million (7.8).

Loss after tax amounted to SEK -79.8 million (-32.6). The net financial items amounted to SEK 0.2 million (0.3). Loss per share before and after dilution amounted to SEK -1.94 (-1.63). Loss per share in 2020 has been adjusted as if the reverse split in 2020 had been completed January 1, 2020.

## FINANCIAL POSITION AND CASH FLOW

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

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

As of March 31, 2021, the Group's liquid funds amounted to SEK 1,577.1 million (117.1). The cash flow from operating activities and investment activities amounted to SEK -51.5 million (-35.4).

The shareholders' equity amounted to SEK 1,565.2 million (136.5) at the end of the period. The Company's share capital was SEK 11.7 million. The equity/assets ratio at the end of the period was 96 (70) percent. Shareholders' equity per share amounted to SEK 26.77 (6.80). Shareholders' equity per share in 2020 has been adjusted as if the reverse split in 2020 had been completed January 1, 2020.

## INVESTMENTS

Investments for the January-March period in tangible fixed assets amounted to SEK 2.0 million (1.0).

## 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, 2021, BioInvent had 74 (69) employees. 66 (63) of these work in research and development.

## DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 47 in the Company's annual report 2020. Otherwise there are no transactions with related parties, in accordance with IAS 24, to report.

## RISK FACTORS

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

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

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

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

	3 MONTHS 2021 JAN.-MARCH	3 MONTHS 2020 JAN.-MARCH	12 MONTHS 2020 JAN.-DEC.
Net sales	6,200	16,714	147,372
<i>Operating costs</i>			
Research and development costs	-76,578	-42,430	-191,421
Sales and administrative costs	-9,470	-7,799	-32,155
Other operating income and costs	-117	544	730
	<b>-86,165</b>	<b>-49,685</b>	<b>-222,846</b>
<b>Operating profit/loss</b>	<b>-79,965</b>	<b>-32,971</b>	<b>-75,474</b>
Profit/loss from financial investments	177	329	-859
<b>Profit/loss before tax</b>	<b>-79,788</b>	<b>-32,642</b>	<b>-76,333</b>
Tax	-	-	-
<b>Profit/loss</b>	<b>-79,788</b>	<b>-32,642</b>	<b>-76,333</b>
<b>Other comprehensive income</b>			
Items that have been or may be reclassified subsequently to profit or loss	-	-	-
<b>Comprehensive income</b>	<b>-79,788</b>	<b>-32,642</b>	<b>-76,333</b>
Other comprehensive income attributable to parent Company's shareholders	-79,788	-32,642	-76,333
<b>Profit/loss per share, SEK</b>			
Before dilution	-1.94	-1.63	-2.66
After dilution	-1.94	-1.63	-2.66



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

	2021 MARCH 31	2020 MARCH 31	2020 DEC. 31
<b>ASSETS</b>			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	11,247	15,366	12,834
Tangible fixed assets - other	16,905	15,828	16,762
<b>Total fixed assets</b>	<b>28,152</b>	<b>31,194</b>	<b>29,596</b>
Inventories	6,891	5,814	4,079
Current receivables	14,395	40,202	39,695
Liquid funds	1,577,077	117,127	729,270
<b>Total current assets</b>	<b>1,598,363</b>	<b>163,143</b>	<b>773,044</b>
<b>Total assets</b>	<b>1,626,515</b>	<b>194,337</b>	<b>802,640</b>
<b>SHAREHOLDERS' EQUITY</b>			
<b>Total shareholders' equity</b>	<b>1,565,223</b>	<b>136,456</b>	<b>743,499</b>
<b>LIABILITIES</b>			
Lease liabilities	3,985	8,030	5,632
<b>Total long term liabilities</b>	<b>3,985</b>	<b>8,030</b>	<b>5,632</b>
Lease liabilities	6,183	6,057	5,972
Other liabilities	51,124	43,794	47,537
<b>Total short term liabilities</b>	<b>57,307</b>	<b>49,851</b>	<b>53,509</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,626,515</b>	<b>194,337</b>	<b>802,640</b>

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

	2021 JAN.-MARCH	2020 JAN.-MARCH	2020 JAN.-DEC.
<b>Shareholders' equity at beginning of period</b>	<b>743,499</b>	<b>169,436</b>	<b>169,436</b>
<b>Comprehensive income</b>			
Profit/loss	-79,788	-32,642	-76,333
Comprehensive other income	-	-	-
<b>Total comprehensive income</b>	<b>-79,788</b>	<b>-32,642</b>	<b>-76,333</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>663,711</b>	<b>136,794</b>	<b>93,103</b>
<b>Transactions with equity holders of the Company</b>			
Employee options program	718	-338	-41
Directed share issues and rights issue			589,383
Directed share issue	900,794		61,054
<b>Shareholders' equity at end of period</b>	<b>1,565,223</b>	<b>136,456</b>	<b>743,499</b>

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

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

	2021 JAN.-MARCH	2020 JAN.-MARCH	2020 JAN.-DEC.
<b>Operating activities</b>			
Operating profit/loss	-79,965	-32,971	-75,474
Depreciation	3,475	2,827	12,004
Adjustment for other non-cash items	718	-338	-41
Interest received and paid	-72	-97	-307
<b>Cash flow from operating activities before changes in working capital</b>	<b>-75,844</b>	<b>-30,579</b>	<b>-63,818</b>
Changes in working capital	26,323	-3,811	1,196
<b>Cash flow from operating activities</b>	<b>-49,521</b>	<b>-34,390</b>	<b>-62,622</b>
<b>Investment activities</b>			
Acquisition of tangible fixed assets	-2,001	-1,016	-6,700
<b>Cash flow from investment activities</b>	<b>-2,001</b>	<b>-1,016</b>	<b>-6,700</b>
<b>Cash flow from operating activities and investment activities</b>	<b>-51,522</b>	<b>-35,406</b>	<b>-69,322</b>
<b>Financing activities</b>			
Directed share issues and rights issue			589,383
Directed share issue	900,794		61,054
Amortization of lease liability	-1,465	-1,442	-5,820
<b>Cash flow from financing activities</b>	<b>899,329</b>	<b>-1,442</b>	<b>644,617</b>
<b>Change in liquid funds</b>	<b>847,807</b>	<b>-36,848</b>	<b>575,295</b>
Opening liquid funds	729,270	153,975	153,975
<b>Liquid funds at end of period</b>	<b>1,577,077</b>	<b>117,127</b>	<b>729,270</b>
<b>Liquid funds, specification:</b>			
Current investments	-	-	-
Cash and bank	1,577,077	117,127	729,270
	<b>1,577,077</b>	<b>117,127</b>	<b>729,270</b>

## Key financial ratios for the Group

	2021 MARCH 31	2020 MARCH 31	2020 DEC. 31
Shareholders' equity per share at end of period, SEK	26.77	6.80	18.88
Number of shares at end of period (thousand)	58,471	20,071	39,376
Equity/assets ratio, %	96.2	70.2	92.6
Number of employees at end of period	74	69	72

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

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

	3 MONTHS 2021 JAN.-MARCH	3 MONTHS 2020 JAN.-MARCH	12 MONTHS 2020 JAN.-DEC.
Net sales	6,200	16,714	147,372
<i>Operating costs</i>			
Research and development costs	-76,504	-42,487	-191,649
Sales and administrative costs	-9,464	-7,804	-32,175
Other operating income and costs	-117	544	730
	<b>-86,085</b>	<b>-49,747</b>	<b>-223,094</b>
<b>Operating profit/loss</b>	<b>-79,885</b>	<b>-33,033</b>	<b>-75,722</b>
Profit/loss from financial investments	249	425	-528
<b>Profit/loss after financial items</b>	<b>-79,636</b>	<b>-32,608</b>	<b>-76,250</b>
Tax	-	-	-
<b>Profit/loss</b>	<b>-79,636</b>	<b>-32,608</b>	<b>-76,250</b>
<b>Other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Comprehensive income</b>	<b>-79,636</b>	<b>-32,608</b>	<b>-76,250</b>



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

	2021 MARCH 31	2020 MARCH 31	2020 DEC. 31
<b>ASSETS</b>			
Intangible fixed assets	0	0	0
Tangible fixed assets	16,905	15,828	16,762
Financial fixed assets	687	687	687
<b>Total fixed assets</b>	<b>17,592</b>	<b>16,515</b>	<b>17,449</b>
Inventories	6,891	5,814	4,079
Current receivables	15,933	41,740	41,233
Current investments	-	-	-
Cash and bank	1,577,077	117,127	729,270
<b>Total current assets</b>	<b>1,599,901</b>	<b>164,681</b>	<b>774,582</b>
<b>Total assets</b>	<b>1,617,493</b>	<b>181,196</b>	<b>792,031</b>
<b>SHAREHOLDERS' EQUITY</b>			
Restricted equity	39,387	67,835	106,445
Non-restricted equity	1,526,334	68,918	637,400
<b>Total shareholders' equity</b>	<b>1,565,721</b>	<b>136,753</b>	<b>743,845</b>
<b>LIABILITIES</b>			
Short term liabilities	51,772	44,443	48,186
<b>Total short term liabilities</b>	<b>51,772</b>	<b>44,443</b>	<b>48,186</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,617,493</b>	<b>181,196</b>	<b>792,031</b>

Lund, April 28, 2021

Martin Welschof  
CEO

## Review report

### INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on March 31, 2021 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 28, 2021  
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 2021 has had no material impact on the financial statements. The financial statements of the Parent Company coincide in every material way with the consolidated financial statements.

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

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

### NOTE 2 NET REVENUE

SEK THOUSAND	2021 JAN.-MARCH	2020 JAN.-MARCH	2020 JAN.-DEC.
<b>Revenue by geographical region:</b>			
Sweden	3,067	763	2,747
Europe	2,745	5,016	34,269
USA	388	10,935	89,689
Japan	-	-	20,667
Other countries	-	-	-
	<b>6,200</b>	<b>16,714</b>	<b>147,372</b>
<b>Revenue consists of:</b>			
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	6,698	76,713
Revenue from technology licenses	-	-	20,667
Revenue from external development projects	6,200	10,016	49,992
	<b>6,200</b>	<b>16,714</b>	<b>147,372</b>

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

### NOTE 3 SHARE-RELATED COMPENSATION

#### Option Program 2019/2025

The 2019 Annual General Meeting resolved to adopt a long-term incentive program in the form of an option program comprising the management group. The option program comprise a maximum of 3,971,000 stock options and the participants may vest options free of charge based on performance and continued employment. Each option entitles the holder to subscribe for 0.04 new share in BioInvent during the period from the day of release of the company's year-end report for the financial year 2022 up to and including December 15, 2025. The subscription price per share shall be SEK 77.25. Subscription price and number of shares that each option entitles to are recalculated pursuant to the rights issue and reverse share split carried out in 2020.

To enable the company's delivery of shares pursuant to the option program and to secure costs connected therewith, primarily social security charges, the 2019 AGM resolved on a directed issue of maximum of 5,040,000 warrants and approval of transfer of warrants. If fully exercised, Option Program 2019/2025 will represent a dilution of 0.3 percent of the shares in the Company. Vesting in 2019 amounted to 221,619 options and 1,008,141 in 2020. As of December 31, 2020, 3,680,086 stock options were outstanding, of which 2,450,326 can be vested in 2021 and 2022.

More information is available at [www.bioinvent.com](http://www.bioinvent.com) (Investors / Corporate Governance / Incentive Program)

### NOTE 4 EVENTS AFTER THE REPORTING PERIOD

- BioInvent received IND approval for Phase 1/2a trial of anti-TNFR2 antibody BI-1808

# Other information.

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## 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](mailto:cecilia.hofvander@bioinvent.com). The report is also available at [www.bioinvent.com](http://www.bioinvent.com).

### *BioInvent International AB (publ)*

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## FINANCIAL CALENDAR

Annual General Meeting: April 29, 2021

Quarter 2 report: August 26, 2021

Quarter 3 report: October 28, 2021

## 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.