

# BioInvent Q3

INTERIM REPORT JANUARY 1 - SEPTEMBER 30, 2021



## BioInvent's CEO:

**“The powerful combination of BioInvent’s R&D and in-house manufacturing provides invaluable support to our clinical development and facilitates the execution of our current clinical portfolio. The integration of functions, on top of world leading science, makes it possible for us to develop novel treatments for patients suffering from serious diseases. The solid balance sheet and strong, loyal shareholders support us in achieving our goals,”** said Martin Welschhof.

### Events in the quarter

- (R) BioInvent announced a second clinical trial collaboration and supply agreement with Merck to evaluate BI-1808 in combination with Keytruda® (pembrolizumab) in patients with advanced solid tumors.
- Emma Meurling joined Bioinvent as Human Resource (HR) Director.

### Events after the period

- BioInvent and Transgene announced that preclinical data for BT-001, a novel oncolytic virus delivering an anti-CTLA-4 antibody for the treatment of solid tumors, will be presented at SITC in November 2021.
- New data on the lead drug candidate BI-1206 Phase 1/2a study in non-Hodgkin's lymphoma (NHL) to be presented at the ASH (American Society of Hematology) conference December 11-14.
- New production agreement with CRUK to produce additional batch of anti-HER3 antibody.
- Prof. Eggermont new member of the BioInvent Scientific Advisory Board.

### Financial information

#### Third quarter 2021


- Net sales SEK 3.0 (16.3) million.
- Loss after tax SEK -62.6 (-32.9) million.
- Loss after tax per share before and after dilution SEK -1.07 (-1.00).
- Cash flow from operating activities -57.5 (-31.4) million.

#### January–September 2021

- Net sales SEK 14.5 (48.6) million.
- Loss after tax SEK -199.7 (-104.9) million.
- Loss after tax per share before and after dilution SEK -3.79 (-4.00).
- Cash flow from operating activities SEK -170.1 (-91.8) million.
- Liquid funds and long-term investments as of September 30, 2021: SEK 1,445.3 (642.1) million.

(R)= Regulatory event

*The information was submitted for publication, through the agency of the contact person set out on page 23, at 8:00 a.m. CEST on October 28, 2021.*



*"We are excited about the transformation of BioInvent into a diversified oncology company, with a broad portfolio of first-in-class cancer drug candidates driving a multitude of clinical milestones over the coming years."*

CEO Martin Welschhof comments the quarter

## Our clinical portfolio expanding and progressing as planned.

*We are very excited about the progress of our clinical portfolio during the quarter. The powerful combination of BioInvent's R&D and in-house manufacturing provides invaluable support to our clinical development and facilitates the execution of our current clinical portfolio. The integration of functions, on top of world leading science, makes it possible for us to develop novel treatments for patients suffering from serious diseases. The solid balance sheet and strong, loyal shareholders support us in achieving our goals.*

Today BioInvent has four ongoing clinical programs and expects to initiate a fifth before the end of this year. That is an unusually rich portfolio for a company of our size.

### **TWO ONGOING CLINICAL STUDIES EVALUATE BI-1206**

Two ongoing clinical studies evaluate BI-1206 (anti-FcγRIIB) in combination with other marketed antibody drugs. The Phase 1/2a trial of BI-1206 in combination with Rituxan® (rituximab) in non-Hodgkin's lymphoma (NHL) is progressing according to plan. New data will be presented at this year's ASH (American Society of Hematology) conference December 11-14. In connection with the ASH presentation, BioInvent will hold a live-streamed KOL event where we will also present the first data from the Phase 1/2a study of BI-1206 in combination with Keytruda® (pembrolizumab, anti-PD-1) for treating solid tumors.

### **EXTENDED COLLABORATION WITH MERCK AIMS TO TREAT PATIENTS WITH LUNG- OR OVARIAN CANCER**

In August, we entered into the second clinical trial collaboration and supply agreement with Merck. The purpose of the collaboration is to evaluate the combination of BI-1808 and

Keytruda in a Phase 1/2a clinical trial for patients with lung or ovarian cancer. Patient enrollment to the Phase 1 part of the trial is progressing well. These patients are suffering from lung cancer, ovarian cancer or from a rare form of blood cancer known as cutaneous T cell lymphoma (CTCL). We expect to provide updates on the progress of this study mid-2022.

### **EVALUATION OF BT-001 AS SINGLE AGENT AND IN COMBINATION WITH KEYTRUDA**

The fourth ongoing study evaluates BT-001 (oncolytic virus, Transgene collaboration) as a single agent and in combination with Keytruda for the treatment of solid tumors. Recruitment to the Phase 1/2a clinical study is progressing well. We expect to present data from this study in the first half of 2022.

The novel anti-FcγRIIB antibody program, BI-1607, is progressing as planned towards the clinic. We expect to submit a CTA (Clinical Trial Authorization) by the end of 2021.

The strong clinical progress is driven by the productivity of our technology platforms, the F.I.R.S.T™ functional screening technology and the n-CoDeR® antibody library.

### **STRONG FINANCIAL POSITION TO DELIVER ON BUSINESS DEVELOPMENT STRATEGY ...**

Our strong balance sheet and solid cash position support our development towards several key value creating milestones. As we progress, we continuously search and evaluate partnering opportunities for creating additional value and synergies. During the third quarter, we concluded a new production agreement with Cancer Research UK to produce an additional batch of an anti-HER3 antibody drug. This deepens our collaboration with CRUK and fully utilizes our manufacturing plant.

### **... AND AN EVEN STRONGER TEAM TO DO IT**

Our management and advisory teams have been further strengthened with two new appointments: Emma Meurling joined as the new Human Resource Director. She is an experienced human resources executive with former roles in companies such as Gambro, Tetra Pak and Polypeptide.

Prof. Alexander Eggermont MD., PhD joined our Scientific Advisory Board. Prof. Eggermont is a renowned immunotherapy scientist and was General Director of Institut Gustave Roussy in Paris. He currently holds roles as Chief Scientific Officer at the Princess Máxima Center for Pediatric Oncology and as Professor of Clinical & Translational Immunotherapy at the University Medical Center Utrecht, the Netherlands. His extensive knowledge and expertise in surgical oncology, immunotherapy and drug development will contribute valuable insights as BioInvent continues to expand its clinical pipeline of oncology drugs.

### **FURTHER UPCOMING PRESENTATIONS AND MEETINGS**

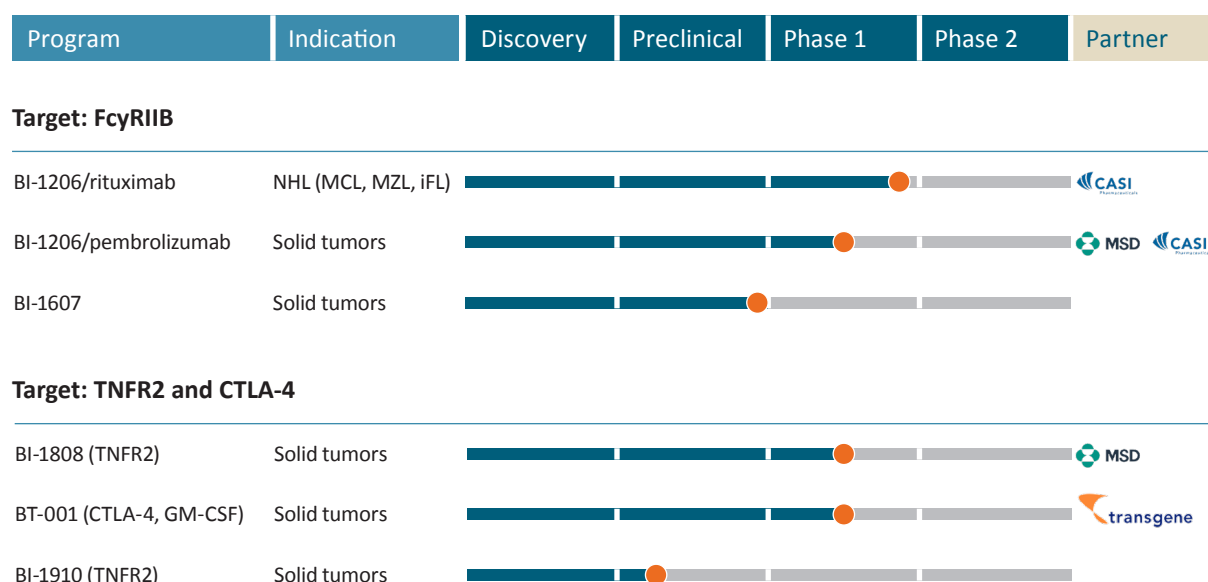
We are looking forward to further discussions with the scientific and investment communities in the coming period. Our Chief Scientific Officer Björn Frenhéus will present at the PEGS Europe Protein & Antibody Engineering Summit on November 2-4. His presentation is entitled "A First in Class Anti-TNFR2 Ab (BI-1808) for Single Agent and Anti-PD-1 Combination Immunotherapy of Cancer".

BioInvent management will also be available for meetings at the Investival LSX Conference, Redeye Life Science Day, Jefferies London Healthcare Conference and DNB Nordic Healthcare Conference.

We are excited about the transformation of BioInvent into a diversified oncology company, with a broad portfolio of first-in-class cancer drug candidates driving a multitude of clinical milestones over the coming years. We look forward to keeping you up to date on progress.

# Pipeline with four clinical programs.

*BioInvent is focused on developing novel immuno-modulatory antibodies for cancer therapy. BioInvent'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 BioInvent, 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 BioInvent and its partners are at the forefront.

BioInvent 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 BioInvent 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.

BioInvent 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 immune-mediated cancer rejection.

# Clinical programs

Andres McAllister  
VP Clinical Development



*"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."*



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.



# BI-1206 in non-Hodgkin's lymphoma.

Target: **FcγRIIB**

Status: **Phase 1**

Partner: **CASI Pharmaceuticals, Inc.**

## PROJECT STATUS AND OUTLOOK

### New clinical data to be presented at ASH

The Phase 1/2a trial of the novel anti-FcγRIIB antibody BI-1206, in combination with rituximab in non-Hodgkin's lymphoma (NHL), is progressing well. New data from this study will be presented at this year's ASH (American Society of Hematology) conference being held on December 11-14.

### 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.

### 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 de-

sign 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.

### Initiation of Phase 2 part expected H1, 2022

Since the administration of BI-1206 to patients has reached a higher dose level than expected, the determination of the recommended Phase 2 dose (RP2D) and progression to the expansion Phase 2a part of the study, is expected during H1 2022.

## 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 associ-

ated 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 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 (Merck), CASI Pharmaceuticals, Inc.**

### PROJECT STATUS AND OUTLOOK

#### Ongoing Phase 1/2a multicenter

BioInvent is conducting a Phase 1/2a 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.

#### 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 are expected to be presented mid-December 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.



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: **MSD (Merck)**

## PROJECT STATUS AND OUTLOOK

### Access to Keytruda secured

In early August 2021, a second clinical trial collaboration and supply agreement was signed with Merck, giving access to Keytruda® (pembrolizumab) for the continued clinical development of BI-1808. The agreement supports the strong rationale for combining anti-TNFR2 and pembrolizumab in the ongoing Phase 1/2a trial.

### Phase 1 data expected mid-2022

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 is conducted in Denmark, Hungary, the United Kingdom and Russia.

Since January 2021, patient enrollment is ongoing in Europe to the first part of the 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 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. The initial Phase 1 data are expected mid-2022.

### 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).

## OUT-LICENSING AND PARTNERING

As communicated in August 2021, BioInvent has entered into a second clinical trial collaboration and supply agreement with Merck. This time to evaluate the combination of BioInvent's BI-1808 and Merck's anti-PD-1 therapy, Keytruda

in a Phase 1/2a clinical trial in patients with advanced solid tumors. Under the agreement, Merck supplies Keytruda which supports the evaluation of BI-1808 in combination with one of the most successful immuno-oncology drugs on the market.



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

### Preclinical data to be presented at SITC

BioInvent and Transgene announced in early October that the companies will present additional preclinical data on BT-001 at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) in November 2021.

The poster "Vectorized Treg-depleting aCTLA-4 elicits antigen cross-presentation and CD8+ T cell immunity to reject "cold" tumors" will be presented on November 13.

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 (NCT04725331) is currently enrolling patients at sites in France and Belgium. 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 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 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

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.

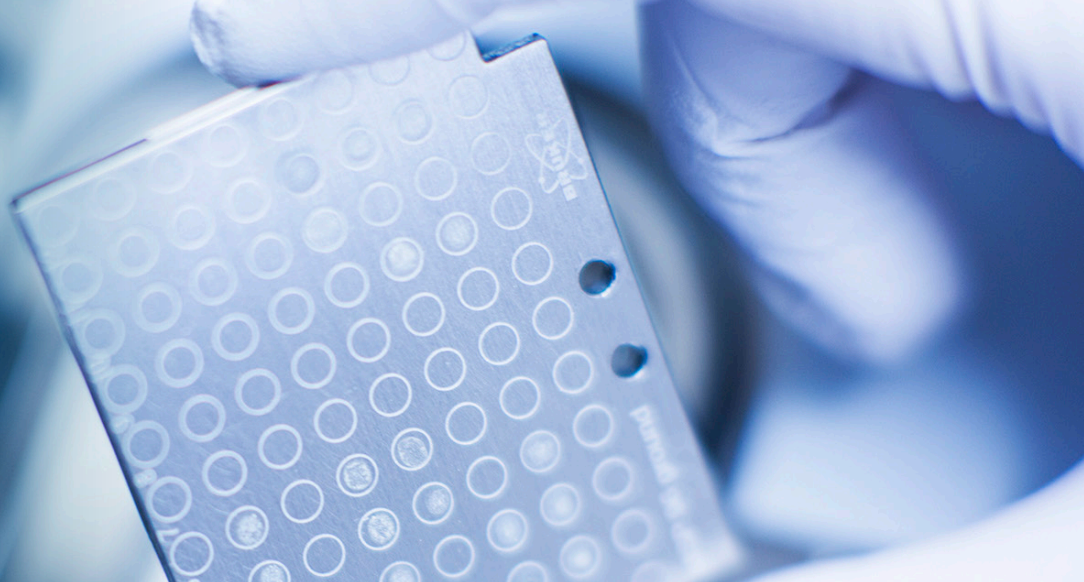
The research and development costs, as well as revenue and royalties from drug candidates generated from the collaboration, are shared 50:50.

# Preclinical programs

Ingrid Teige  
Head of Preclinical



*"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 and is key to sustain the creative and high-energy spirit at BioInvent."*



## BI-1607.

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

### PROJECT STATUS AND OUTLOOK

During the autumn, Syneos Health was selected as CRO (Contract Research Organization) for the planned phase 1/2a clinical study with BI-1607. Syneos Health is a global contract research organization based in Morrisville, North Carolina. Syneos has strong focus in supporting small and mid-sized biotechnology companies in early and late stages of development. The company has ranked consistently high in CRO reviews of CenterWatch and SCRS Eagle Awards. The submission of a BI-1607 clinical trial authorization (CTA) application is expected by the end of the year, and the clinical study is planned to start 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.

### Third quarter

Net sales amounted to SEK 3.0 million (16.3). 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.

The Company's total costs amounted to SEK 65.5 million (48.8). Operating costs are divided between external costs of SEK 44.6 million (32.4), personnel costs of SEK 17.0 million (13.3) and depreciation of SEK 3.9 million (3.1).

Research and development costs amounted to SEK 57.7 million (41.3). Sales and administrative costs amounted to SEK 7.8 million (7.5).

Loss after tax amounted to SEK -62.6 million (-32.9). The net financial items amounted to SEK -0.2 million (-0.1). Loss per share before and after dilution amounted to SEK -1.07 (-1.00). Loss per share in 2020 has been adjusted as if the reverse split in 2020 had been completed January 1, 2020.

### January - September

Net sales amounted to SEK 14.5 million (48.6). 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 215.4 million (154.0). Operating costs are divided between external costs of SEK 145.3 million (97.9), personnel costs of SEK 59.2 million (47.2) and depreciation of SEK 10.9 million (8.9). 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.

Research and development costs amounted to SEK 187.9 million (131.3). Sales and administrative costs amounted to SEK 27.5 million (22.7).

Loss after tax amounted to SEK -199.7 million (-104.9). The net financial items amounted to SEK -0.2 million (0.0). Loss per share before and after dilution amounted to SEK -3.79 (-4.00). 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 September 30, 2021, the Group's liquid funds and long-term investments amounted to SEK 1,445.3 million (642.1). The cash flow from operating activities for the January-September period amounted to SEK -170.1 million (-91.8).

The shareholders' equity amounted to SEK 1,445.5 million (653.8) 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 95 (93) percent. Shareholders' equity per share amounted to SEK 24.72 (17.12). Shareholders' equity per share in 2020 has been adjusted as if the reverse split in 2020 had been completed January 1, 2020.

In accordance with IFRS 16, right of use assets and leasing liabilities, in the statement of financial position per September 30, 2021, were increased by SEK 22.7 million, in comparison with December 31, 2020, as a result of the Group's agreement for premises with rent being extended.

## INVESTMENTS

Investments for the January-September period in tangible fixed assets amounted to SEK 10.3 million (5.1).

## 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 September 30, 2021, BioInvent had 85 (73) employees. 76 (66) 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 significant 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 JULY-SEP.	3 MONTHS 2020 JULY-SEP.	9 MONTHS 2021 JAN.-SEP.	9 MONTHS 2020 JAN.-SEP.	12 MONTHS 2020 JAN.-DEC.
Net sales	2,993	16,267	14,481	48,629	147,372
<i>Operating costs</i>					
Research and development costs	-57,642	-41,297	-187,889	-131,344	-191,421
Sales and administrative costs	-7,819	-7,466	-27,477	-22,699	-32,155
Other operating income and costs	38	-317	1,382	532	730
	<b>-65,423</b>	<b>-49,080</b>	<b>-213,984</b>	<b>-153,511</b>	<b>-222,846</b>
<b>Operating profit/loss</b>	<b>-62,430</b>	<b>-32,813</b>	<b>-199,503</b>	<b>-104,882</b>	<b>-75,474</b>
Profit/loss from financial investments	-175	-63	-181	29	-859
<b>Profit/loss before tax</b>	<b>-62,605</b>	<b>-32,876</b>	<b>-199,684</b>	<b>-104,853</b>	<b>-76,333</b>
Tax	-	-	-	-	-
<b>Profit/loss</b>	<b>-62,605</b>	<b>-32,876</b>	<b>-199,684</b>	<b>-104,853</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>-62,605</b>	<b>-32,876</b>	<b>-199,684</b>	<b>-104,853</b>	<b>-76,333</b>
Other comprehensive income attributable to parent Company's shareholders	-62,605	-32,876	-199,684	-104,853	-76,333
<b>Profit/loss per share, SEK</b>					
Before dilution	-1.07	-1.00	-3.79	-4.00	-2.66
After dilution	-1.07	-1.00	-3.79	-4.00	-2.66

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

	2021 SEP. 30	2020 SEP. 30	2020 DEC. 31
<b>ASSETS</b>			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	30,724	12,414	12,834
Tangible fixed assets - other	20,928	16,779	16,762
Financial fixed assets - long-term investments	188,802	-	-
<b>Total fixed assets</b>	<b>240,454</b>	<b>29,193</b>	<b>29,596</b>
Inventories	13,129	4,206	4,079
Current receivables	10,084	28,042	39,695
Liquid funds	1,256,516	642,098	729,270
<b>Total current assets</b>	<b>1,279,729</b>	<b>674,346</b>	<b>773,044</b>
<b>Total assets</b>	<b>1,520,183</b>	<b>703,539</b>	<b>802,640</b>
<b>SHAREHOLDERS' EQUITY</b>			
<b>Total shareholders' equity</b>	<b>1,445,495</b>	<b>653,800</b>	<b>743,499</b>
<b>LIABILITIES</b>			
Lease liabilities	23,004	5,119	5,632
<b>Total long term liabilities</b>	<b>23,004</b>	<b>5,119</b>	<b>5,632</b>
Lease liabilities	6,939	6,057	5,972
Other liabilities	44,745	38,563	47,537
<b>Total short term liabilities</b>	<b>51,684</b>	<b>44,620</b>	<b>53,509</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,520,183</b>	<b>703,539</b>	<b>802,640</b>

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

	2021 JULY-SEP.	2020 JULY-SEP.	2021 JAN.-SEP.	2020 JAN.-SEP.	2020 JAN.-DEC.
<b>Shareholders' equity at beginning of period</b>	<b>1,508,118</b>	<b>193,418</b>	<b>743,499</b>	<b>169,436</b>	<b>169,436</b>
<b>Comprehensive income</b>					
Profit/loss	-62,605	-32,876	-199,684	-104,853	-76,333
Comprehensive other income	-	-	-	-	-
<b>Total comprehensive income</b>	<b>-62,605</b>	<b>-32,876</b>	<b>-199,684</b>	<b>-104,853</b>	<b>-76,333</b>
<b>Total, excluding transactions with equity holders of the Company</b>	<b>1,445,513</b>	<b>160,542</b>	<b>543,815</b>	<b>64,583</b>	<b>93,103</b>
<b>Transactions with equity holders of the Company</b>					
Employee options program	-18	96	886	-166	-41
Directed share issues and rights issue		493,162		589,383	589,383
Directed share issue			900,794		61,054
<b>Shareholders' equity at end of period</b>	<b>1,445,495</b>	<b>653,800</b>	<b>1,445,495</b>	<b>653,800</b>	<b>743,499</b>

The share capital as of September 30, 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 JULY-SEP.	2020 JULY-SEP.	2021 JAN.-SEP.	2020 JAN.-SEP.	2020 JAN.-DEC.
<b>Operating activities</b>					
Operating profit/loss	-62,430	-32,813	-199,503	-104,882	-75,474
Depreciation	3,881	3,073	10,927	8,896	12,004
Adjustment for other non-cash items	-18	96	886	-166	-41
Interest received and paid	-18	-16	-154	-202	-307
<b>Cash flow from operating activities before changes in working capital</b>	<b>-58,585</b>	<b>-29,660</b>	<b>-187,844</b>	<b>-96,354</b>	<b>-63,818</b>
Changes in working capital	1,090	-1,695	17,739	4,532	1,196
<b>Cash flow from operating activities</b>	<b>-57,495</b>	<b>-31,355</b>	<b>-170,105</b>	<b>-91,822</b>	<b>-62,622</b>
<b>Investment activities</b>					
Acquisition of tangible fixed assets	-5,473	-1,696	-10,294	-5,085	-6,700
Acquisition of long-term securities	-188,802	-	-188,802	-	-
<b>Cash flow from investment activities</b>	<b>-194,275</b>	<b>-1,696</b>	<b>-199,096</b>	<b>-5,085</b>	<b>-6,700</b>
<b>Cash flow from operating activities and investment activities</b>	<b>-251,770</b>	<b>-33,051</b>	<b>-369,201</b>	<b>-96,907</b>	<b>-69,322</b>
<b>Financing activities</b>					
Directed share issues and rights issue		494,326		589,383	589,383
Directed share issue			900,794		61,054
Amortization of lease liability	-1,375	-1,461	-4,347	-4,353	-5,820
<b>Cash flow from financing activities</b>	<b>-1,375</b>	<b>492,865</b>	<b>896,447</b>	<b>585,030</b>	<b>644,617</b>
<b>Change in liquid funds</b>	<b>-253,145</b>	<b>459,814</b>	<b>527,246</b>	<b>488,123</b>	<b>575,295</b>
Opening liquid funds	1,509,661	182,284	729,270	153,975	153,975
<b>Liquid funds at end of period</b>	<b>1,256,516</b>	<b>642,098</b>	<b>1,256,516</b>	<b>642,098</b>	<b>729,270</b>
<b>Liquid funds, specification:</b>					
Current investments	6,000	-	6,000	-	-
Cash and bank	1,250,516	642,098	1,250,516	642,098	729,270
	<b>1,256,516</b>	<b>642,098</b>	<b>1,256,516</b>	<b>642,098</b>	<b>729,270</b>

## Key financial ratios for the Group

	2021 SEP. 30	2020 SEP. 30	2020 DEC. 31
Shareholders' equity per share at end of period, SEK	24.72	17.12	18.88
Number of shares at end of period (thousand)	58,471	38,200	39,376
Equity/assets ratio, %	95.1	92.9	92.6
Number of employees at end of period	85	73	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 JULY-SEP.	3 MONTHS 2020 JULY-SEP.	9 MONTHS 2021 JAN.-SEP.	9 MONTHS 2020 JAN.-SEP.	12 MONTHS 2020 JAN.-DEC.
Net sales	2,993	16,267	14,481	48,629	147,372
<i>Operating costs</i>					
Research and development costs	-57,606	-41,355	-187,778	-131,516	-191,649
Sales and administrative costs	-7,815	-7,471	-27,467	-22,714	-32,175
Other operating income and costs	38	-317	1,382	532	730
	<b>-65,383</b>	<b>-49,143</b>	<b>-213,863</b>	<b>-153,698</b>	<b>-223,094</b>
<b>Operating profit/loss</b>	<b>-62,390</b>	<b>-32,876</b>	<b>-199,382</b>	<b>-105,069</b>	<b>-75,722</b>
Profit/loss from financial investments	19	16	148	291	-528
<b>Profit/loss after financial items</b>	<b>-62,371</b>	<b>-32,860</b>	<b>-199,234</b>	<b>-104,778</b>	<b>-76,250</b>
Tax	-	-	-	-	-
<b>Profit/loss</b>	<b>-62,371</b>	<b>-32,860</b>	<b>-199,234</b>	<b>-104,778</b>	<b>-76,250</b>
<b>Other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Comprehensive income</b>	<b>-62,371</b>	<b>-32,860</b>	<b>-199,234</b>	<b>-104,778</b>	<b>-76,250</b>

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

	2021 SEP. 30	2020 SEP. 30	2020 DEC. 31
<b>ASSETS</b>			
Intangible fixed assets	0	0	0
Tangible fixed assets	20,928	16,779	16,762
Financial fixed assets - Shares in subsidiaries	687	687	687
Financial fixed assets - long-term investments	188,802	-	-
<b>Total fixed assets</b>	<b>210,417</b>	<b>17,466</b>	<b>17,449</b>
<b>Current assets</b>			
Inventories	13,129	4,206	4,079
Current receivables	11,622	29,579	41,233
Current investments	6,000	-	-
Cash and bank	1,250,516	642,098	729,270
<b>Total current assets</b>	<b>1,281,267</b>	<b>675,883</b>	<b>774,582</b>
<b>Total assets</b>	<b>1,491,684</b>	<b>693,349</b>	<b>792,031</b>
<b>SHAREHOLDERS' EQUITY</b>			
Restricted equity	39,387	104,094	106,445
Non-restricted equity	1,406,904	550,044	637,400
<b>Total shareholders' equity</b>	<b>1,446,291</b>	<b>654,138</b>	<b>743,845</b>
<b>LIABILITIES</b>			
Short term liabilities	45,393	39,211	48,186
<b>Total short term liabilities</b>	<b>45,393</b>	<b>39,211</b>	<b>48,186</b>
<b>Total shareholders' equity and liabilities</b>	<b>1,491,684</b>	<b>693,349</b>	<b>792,031</b>

Lund, October 28, 2021

Martin Welschhof  
Verkställande direktör

## Review report

### INTRODUCTION

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on September 30, 2021 and for the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### SCOPE OF REVIEW

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing, ISA, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a

level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

### CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the group's part according to IAS 34 and the Annual Accounts Act and for the parent Company's part according to the Annual Accounts Act.

Malmö, October 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 JULY-SEP.	2020 JULY-SEP.	2021 JAN.-SEP.	2020 JAN.-SEP.	2020 JAN.-DEC.
<b>Revenue by geographical region:</b>					
Sweden	2,595	244	9,409	2,517	2,747
Europe	353	12,966	3,843	27,952	34,269
USA	45	3,057	1,229	18,160	89,689
Japan	-	-	-	-	20,667
Other countries	-	-	-	-	-
	<b>2,993</b>	<b>16,267</b>	<b>14,481</b>	<b>48,629</b>	<b>147,372</b>
<b>Revenue consists of:</b>					
Revenue from collaboration agreements associated with out-licensing of proprietary projects	-	-	-	6,698	76,713
Revenue from technology licenses	-	-	-	-	20,667
Revenue from external development projects	2,993	16,267	14,481	41,931	49,992
	<b>2,993</b>	<b>16,267</b>	<b>14,481</b>	<b>48,629</b>	<b>147,372</b>

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

### NOTE 3 EVENTS AFTER THE PERIOD

- BioInvent and Transgene announced that preclinical data for BT-001, a novel oncolytic virus delivering an anti-CTLA-4 antibody for the treatment of solid tumors, will be presented at SITC in November 2021.
- New data on the lead drug candidate BI-1206 Phase 1/2a study in NHL to be presented at the ASH (American Society of Hematology) conference December 11-14.
- New production agreement with CRUK to produce additional batch of anti-HER3 antibody.
- Prof. Eggermont new member of the BioInvent Scientific Advisory Board

# 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

Financial statement 2021: February 23, 2022

Annual General Meeting 2022: April 28, 2022

## 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.