

Promising early interim efficacy data on our lead drug candidate

“BioInvent has started 2021 with significant positive momentum We reported promising interim efficacy data from the ongoing Phase I/IIa trial of our lead drug candidate BI-1206. The company also closed a successful SEK 962 million financing round, expanding our institutional shareholder base. Furthermore, we announced the expansion of our clinical pipeline to include two further drug candidates for the treatment of solid tumors.”

Martin Welschof, CEO BioInvent

Financial information

Fourth quarter 2020

- Net sales SEK 98.7 (25.4) million.
- Profit/loss after tax SEK 28.5 (-40.9) million.
- Profit/loss after tax per share before and after dilution SEK 0.74 (-2.04).
- Cash flow from operating activities and investment activities SEK 27.6 (-28.5) million.

January – December 2020

- Net sales SEK 147.4 (93.7) million.
 - Loss after tax SEK -76.3 (-138.6) million.
 - Loss after tax per share before and after dilution SEK -2.66 (-7.64).
 - Cash flow from operating activities and investment activities SEK -69.3 (-129.3) million.
- Liquid funds as of December 31, 2020:
SEK 729.3 (154.0) million.

Events in the fourth quarter

- BI-1206 was out-licensed to CASI Pharmaceuticals for the Greater China region. The collaboration accelerates and expands BioInvent’s global development plans for BI-1206. BioInvent received \$12 million upfront in combination of cash and equity investment and is eligible to receive up to \$83 million in milestone payments, plus tiered royalties. The equity investment was approved at an EGM held on November 27, 2020. (R)
- BioInvent received a \$3 million milestone payment related to selection of antibodies under its collaboration with Pfizer. (R)
- Approval of a CTA was received in Denmark for the Phase I/IIa study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy KEYTRUDA® (pembrolizumab) for the treatment of solid tumors and cutaneous T-cell lymphoma (CTCL).
- BioInvent and Transgene received CTA approval for Phase I/IIa trial of oncolytic virus BT-001 in solid tumors.
- New preclinical data was presented on BI-1808 and BT-001 at the SITC 35th Anniversary Annual Meeting. New promising clinical and preclinical data on BI-1206 was also presented at the ASH Annual Meeting.
- BioInvent received a €2 million milestone payment under its collaboration with Daiichi Sankyo related to the initiation of a global Phase I clinical trial with a GARP directed antibody. (R)
- BioInvent and Cantargia signed a manufacturing agreement, which may generate revenue for BioInvent of up to SEK 30 million.
- BioInvent announced the appointment of Cecilia Hofvander as Senior Director Investor Relations, a new position at BioInvent starting mid-February 2021.
- The EGM held on November 27, 2020 approved the proposal on a reverse share split 1:25, a reduction of the share capital to adjust the share capital to the Company’s operations, and an updated authorization for the Board to decide on a new issue of shares comprising 4,375,121 shares (after the reverse share split). (R)

Events after the reporting period

- In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin’s lymphoma patients. Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin’s lymphoma patients who have relapsed after treatment with rituximab. Long-lasting complete responses observed in two patients beyond 12 months. (R)
- 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 subject to the approval of an EGM to be held on 23 March 2021. (R)

- 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. (R)
- BioInvent announced in January 2021, enrollment of the first patient in a Phase I/IIa study of BI-1808.
- In January 2021, BioInvent announced that An van Es Johansson should resign as a director of the board effective as of 15 February 2021, due to personal reasons. (R)

(R)= Regulatory event

Comments from the CEO

BioInvent has started 2021 with significant positive momentum. Promising interim efficacy data from the ongoing Phase I/IIa trial of our lead drug candidate BI-1206 was followed by a successful financing round, adding another specialized institutional owner to the company. Furthermore, we announced the expansion of our clinical pipeline to include two further drug candidates.



The data from the study of BI-1206, in combination with rituximab in patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL), are very encouraging. The responses in these severely ill patients suggest that BI-1206 may restore the response to rituximab in patients who have few treatment alternatives. Furthermore, the duration of complete response in two patients are particularly impressive and indicate that BI-1206 has the potential to significantly improve the lives of NHL patients who have progressed after previous lines of treatment.

We were proud to host a key opinion leader (KOL) event on these results with renowned lymphoma expert Professor Mats Jerkeman, MD, of Lund University. Based on these results, we will now move to identify the recommended dose for the Phase IIa part of the study. We also presented new data on BI-1206 at the ASH Annual Meeting in December and are excited to further evaluate its potential to bring much needed innovation to lymphoma patients.

This progress is reinforced by our partnership with CASI Pharmaceuticals for the development and commercialization of BI-1206 in mainland China, Taiwan, Hong Kong and Macau. Under this agreement for both liquid and solid cancers, BioInvent received \$12 million upfront in combination of cash and equity investment and is eligible to receive up to \$83 million in development and commercial milestone payments plus tiered royalties in the high-single to mid-double-digit range on net sales. CASI is a proven leader in China and their clinical development and regulatory expertise will be important in generating additional data on BI-1206.

We have simplified and reduced our obligations to CRUK related to BI-1206 by restructuring our clinical development agreement with CRUK (Cancer Research UK) for BI-1206, in exchange for a one-time payment. This provides us with further flexibility to carry out development and partnering activities with BI-1206.

Our innovative pipeline is expanding beyond BI-1206. We now have three products in clinical development, underlining the ability of our n-CoDeR®/F.I.R.S.T™ platforms to produce novel, differentiating drug candidates.

In January, we enrolled the first patient in a Phase I/IIa, first-in-human study of BI-1808, a first-in-class anti-TNFR2 antibody, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL. This is based on a solid preclinical data set for BI-1808, including the new data presented at the 35th Annual Meeting of SITC in November.

We have now received CTA approval to start a Phase I/IIa clinical trial of the novel oncolytic vaccinia virus BT-001 in solid tumors, through our collaboration with Transgene. BT-001 combines multiple mechanisms of action and has outstanding potential in a wide range of indications due to its combination of multiple anti-cancer properties. We also presented new data on BT-001 at SITC.

On February 23, we further reinforced our financial position with a directed share issue that raised approximately SEK 962 million before transaction costs. These proceeds intend to fund the continued transformation of BioInvent and expansion of our clinical programs. Assuming continued generation of positive data, we plan to in particular use the funds to prepare a pivotal clinical trial of BI-1206 for the treatment of NHL, with the aim of receiving an accelerated regulatory pathway. We also expect to expand the clinical programs of BI-1206 in combination with Keytruda® and BI-1808 as monotherapy and in combination with Keytruda®.

Our partner Pfizer has selected antibodies, directed at a previously selected target, under our agreement covering developing antibodies from the F.I.R.S.T™ drug discovery platform targeting tumor-associated myeloid cells. This is an impressive example of the productivity of our platform and further strengthens our financial position by \$3 million. We may now move forward to develop other antibodies internally or with other partners.






We also generated important revenue from a €2 million milestone payment under a collaboration with Daiichi Sankyo and we signed a new manufacturing agreement with Cantargia, under which BioInvent may generate revenue of up to SEK 30 million.

As previously communicated, BioInvent has taken all the necessary precautions with regards to managing the impact of Covid-19. Although we still observe viral spread throughout the community, which is of course terrible for all those affected and their families, 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. We will provide updates as necessary.

The company has made significant progress in delivering on our strategy in 2020 and this has set us up for a number of important milestones as we progress our portfolio through clinical development. 2021 promises to be a very exciting year for BioInvent.

Martin Welschof, CEO

Pipeline

Indication	Program	Discovery	Preclinical	Phase I	Phase II
Target: FcγRIIB					
NHL (MCL, MZL, iFL)	BI-1206/rituximab			Partner: 	
Solid cancer	BI-1206/pembrolizumab			Partner:  	
Solid cancer	BI-1607				
Target: Treg					
Solid cancer	BT-001 (αCTLA-4-GM-CSF-W)			Partner: 	
Solid cancer	BI-1808 (αTNFR2)				
Solid cancer	BI-1910 (αTNFR2)				
Solid cancer	F.I.R.S.T™ αTreg				
Target: Tumor-associated myeloid cells					
Solid cancer	F.I.R.S.T™ αTAMs			Partner: 	

Business focus

BioInvent's current operational activities are focused on:

- Progressing the clinical development of its lead Phase I/II first-in-class anti-FcγRIIB antibody BI-1206 in combination with rituximab for the treatment of NHL, *early results from the Phase I open label study were presented in January 2021*, and for the treatment of advanced solid tumors in combination with Keytruda® (pembrolizumab). *Early results from the Phase I open label study are expected in H2 2021.*
- Progressing the clinical development of BI-1808 (anti-TNFR2 antibody), as monotherapy and in combination with Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL. *The first patient in a Phase I/IIa study was enrolled in January 2021.*
- Developing BT-001 (oncolytic vaccinia virus expressing an anti-CTLA-4 antibody), in partnership with Transgene, for the treatment of solid cancers. *A clinical trial application (CTA) was approved in December 2020.*
- Advancing BI-1607 (anti-FcγRIIB antibody) into clinical development for the treatment of solid cancers. *A clinical trial application is expected to be submitted in H2 2021.*

- Continuing development of the Company's prioritized preclinical projects with the aim to generate additional clinical programs, e.g. BI-1910 (anti-TNFR2 antibody).

Clinical programs

BI-1206 in non-Hodgkin lymphoma

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Of the 9 patients who completed the induction cycle 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 12 and 24 months later. Another patient who had a blastoid form of MCL had achieved a partial response, and a complete depletion of peripheral tumor cells.

In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals for Greater China region. The collaboration accelerates and expands BioInvent's global development plans for BI-1206. 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 \$12 million upfront in combination of cash and equity investment and eligible to receive up to \$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 £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.

Background

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.

The Phase I/IIa study consists of two parts: i) Phase I, with dose escalation cohorts using a 3+3 dose-escalation design and selection of the recommended Phase IIa dose (RP2D); and ii) Phase IIa, an expansion cohort at the RP2D, enriched with patients with mantle cell lymphoma (MCL). Subjects in each phase receive 1 cycle (4 doses) of induction therapy with BI-1206 in combination with rituximab. Subjects 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.

In January 2019 the U.S. Food and Drug Administration granted orphan designation for BI-1206 for the treatment of mantle cell lymphoma.

These data further corroborated the important role of FcγRIIB in establishing resistance to rituximab, and indicate the ability of BI-1206 to overcome this resistance. Together with a high expression in mantle cell lymphoma patient cells, these data indicate the high potential of BI-1206 to address a significant unmet need in the treatment of MCL and other B-cell malignancies such as follicular lymphoma.

BI-1206 in combination with pembrolizumab in solid tumors

In July 2019 BioInvent received authorization to proceed from the FDA for a Phase I/IIa clinical trial of BI-1206 in combination with Keytruda® (pembrolizumab) for the treatment of solid tumors. The first patient was enrolled in June 2020.

Background

The objective of this trial is to explore the safety and tolerability profile of the combination of BI-1206 with Keytruda®, to characterize the pharmacokinetic/pharmacodynamic (PK/PD) profile and to determine the recommended dose of BI-1206 when combined with Keytruda®. It will be conducted in several sites across the US and Europe and will assess potential signs of antitumoral activity, as well

as exploring the expression of potential immunological markers that might be associated, and eventually predict clinical responses.

The Phase I/IIa trial is divided into part A, a dose escalation of BI-1206 in combination with the standard dose of Keytruda[®], and part B, which will explore the activity of the combination treatment in patients with advanced lung cancer, melanoma and other types of malignancies. Patients will be refractory to or have progressed on previous treatments with anti-PD1/PDL1 targeting agents. Early results from the Phase I open label study is expected in H2 2021.

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with Merck, to evaluate the combination of BioInvent's BI-1206, one of its proprietary anti-FcγRIIB antibodies and Merck's anti-PD-1 therapy, Keytruda[®] (pembrolizumab) in a Phase I/IIa clinical trial for patients with solid tumors. The agreement helps BioInvent to expand BI-1206 clinical development to solid tumors in combination with one of the most successful immuno-oncology drugs.

The 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. The Phase I/IIa clinical trial will evaluate the drug combination in patients with advanced solid tumors, who have been previously treated with anti-PD1 or anti-PD-L1 antibodies, and is a multicenter, dose-finding, consecutive-cohort, open-label trial. The Phase I/IIa trial is planned to be carried out in the U.S. and the EU.

BI-1808 and BI-1910 (anti-TNFR2 antibodies) for the treatment of solid tumors and CTCL

Two different types of TNFR2 targeting antibodies are being developed by BioInvent – BI-1808 in clinical development (a ligand blocker), and BI-1910 (an agonist) in preclinical development.

BioInvent announced, in [December 2020](#), regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808 for the treatment of solid tumors and CTCL. The first patient was enrolled in January 2021.

Background

BioInvent has identified tumor necrosis factor receptor 2 (TNFR2), a member of the so-called TNFR superfamily (TNFRS) as a target within the Treg program. 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[®] library and unique F.I.R.S.T[™] discovery tool, of which BI-1808 and BI-1910 are the lead development candidates.

The Phase I stage 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 dose as a single agent for Phase II trials. Part B will explore the safety, tolerability and recommended dose of BI-1808 in combination with Keytruda[®]. The Phase IIa stage will consist of expansion cohorts to assess signs of efficacy of BI-1808 as single agent, and in combination with Keytruda[®] in lung cancer and ovarian cancer patients. Another cohort will explore the activity as single agent in CTCL. The trial will be conducted at several sites across Europe and the U.S. and is expected to enroll approximately 120 patients.

Exciting preclinical data was presented at AACR Annual Meeting II in June 2020. In vivo studies show that both ligand-blocking (BI-1808 surrogate) and agonistic (BI-1910 surrogate) antibodies regress large established tumors and synergize with anti-PD-1 therapy. Further mode-of-action dissection demonstrate that while the ligand-blocking antibody depleted intratumoral Tregs, the agonist increased intratumoral CD8+ T effector cells. Both antibodies expanded tumor-specific CD8+ T cells and induced long-lasting T cell memory.

New translational data was presented on BI-1808 at the SITC 35th Annual Meeting in November 2020. The data showed that BI-1808 had an expected pharmacokinetic profile and was well tolerated in a toxicology study in doses up to 200 mg/kg.

BT-001 - Partnership with Transgene – developing next generation oncolytic viruses expressing an anti-CTLA-4 antibody to treat solid tumors

BioInvent and Transgene announced in December 2020 that regulatory approval had been received in Belgium for a clinical trial application for a Phase I/IIa study of BT-001 in solid tumors.

Promising findings was presented both at AACR Annual Meeting II in June 2020 and at the SITC 35th Annual Meeting in November 2020. Cure rates exceeding 70% were seen in multiple mouse models,

demonstrating the powerful therapeutic effect of BT-001 when used as a single agent, providing a solid basis for BT-001's upcoming clinical development. BT-001 has been designed to combine the killing of cancer cells (oncolysis mediated by the virus), with the production of the anti-CTLA-4 antibody and GM-CSF directly in the tumor site to enhance the generation of an efficacious immune response against tumor cells. It was shown that while the anti-CTLA-4 antibody and GM-CSF accumulate in tumors, the systemic exposure is very low. It was shown that a strong tumor-specific response and long-lasting immune memory were developed by BT-001 surrogate treated mice, which prevented establishment of re-implanted tumor cells in mice that had been cured. These data indicate that BT-001 has the potential to make a significant difference in the treatment of solid tumors.

Background

BioInvent and Transgene collaborate to co-develop oncolytic virus (OV) candidates encoding a validated anti-CTLA-4 antibody sequence – potentially with additional transgenes – 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.

Transgene is contributing both engineering expertise, as well as 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 immune modulatory anti-CTLA-4 antibody, which will further boost immune response against the tumor. BioInvent is providing its cancer biology and antibody expertise to the collaboration, as well as anti-CTLA-4 antibody sequences generated through its proprietary n-CoDeR®/F.I.R.S.T™ platforms.

In March 2019 BioInvent and Transgene announced an extension of their collaboration to co-develop multifunctional oncolytic viruses encoding antibodies targeting undisclosed targets, which could be used in the treatment of a broad range of solid tumors.

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

Preclinical programs

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

Strategic collaboration with Pfizer - developing antibodies that act on tumor-associated myeloid cells

In partnership with Pfizer Inc. since December 2016, BioInvent works to identify novel oncology targets and therapeutic antibodies that may either reverse the immunosuppressive activity of tumor-associated myeloid cells or reduce the number of tumor-associated myeloid cells in the tumor. In July 2020 BioInvent announced that the research term under its collaboration and license agreement with Pfizer had been further extended until the end of 2020.

In December 2020 BioInvent announced that Pfizer had selected antibodies directed at a previously selected target. The selection of these antibodies triggered a payment from Pfizer to BioInvent of \$3 million.

Background

BioInvent announced in July 2019 selection of the first target and in December 2019 the second target discovered by BioInvent's proprietary F.I.R.S.T™ technology platform under the collaboration with Pfizer Inc. The selection of targets triggered two payments from Pfizer to BioInvent of \$0.3 million.

BioInvent is eligible for potential future development milestones in excess of \$100 million if one antibody is developed through to commercialization. The Company could also receive up to double digit royalties related to product sales. In exchange, Pfizer will have the right to develop and commercialize any antibodies generated from this agreement.

BioInvent received an upfront payment of \$3 million when the agreement was signed in December 2016, and research funding has been received for the period 2017-2020. Pfizer also made a \$6 million equity investment in new shares of BioInvent when the agreement was signed.

Developing antibodies that act on regulatory T cells (Tregs) via novel or validated targets

Tregs can substantially inhibit various immune responses, enabling tumor cells to escape detection. BioInvent is utilizing its F.I.R.S.T™ platform to identify and characterize monoclonal antibodies to cancer-associated Treg targets in a function-first, target-agnostic, manner. The company is also pursuing differentiated antibodies to known targets through novel mechanisms and pathways.

FINANCIAL INFORMATION

Revenues and result

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

Fourth quarter

Net sales amounted to SEK 98.7 million (25.4). Revenues for the period were mainly derived from upfront payment of \$5 million in connection with licensing of BI-1206 to CASI Pharmaceuticals for the Greater China region, a \$3 million milestone payment related to selection of antibodies under the collaboration with Pfizer, a €2 million milestone payment under the collaboration with Daiichi Sankyo related to the initiation of a Phase I clinical trial, and also revenues from production of antibodies for clinical studies.

Revenues for the corresponding period 2019 were mainly derived from production of antibodies for clinical studies, and also a \$0.3 million milestone payment from Pfizer Inc. in connection with selection of the second target discovered by BioInvent.

The Company's total costs amounted to SEK 69.5 million (67.2). Operating costs are divided between external costs of SEK 46.0 million (44.7), personnel costs of SEK 20.4 million (19.5) and depreciation of SEK 3.1 million (3.0).

Research and development costs amounted to SEK 60.1 million (59.6). Sales and administrative costs amounted to SEK 9.5 million (7.6).

Profit/loss after tax amounted to SEK 28.5 million (-40.9). The net financial items amounted to SEK -0.9 million (-0.5). Profit/loss per share before and after dilution amounted to SEK 0.74 (-2.04). Loss per share in 2019 has been adjusted as if the reverse split in 2020 had been completed January 1, 2019.

January - December

Net sales amounted to SEK 147.4 million (93.7). Revenues for the period were mainly derived from upfront payment of \$5 million in connection with licensing of BI-1206 to CASI Pharmaceuticals for the Greater China region, a \$3 million milestone payment related to selection of antibodies under the collaboration with Pfizer, a €2 million milestone payment under the collaboration with Daiichi Sankyo related to the initiation of a Phase I clinical trial, and also revenues from production of antibodies for clinical studies and revenues from research funding.

Revenues for the corresponding period 2019 were mainly derived from production of antibodies for clinical studies, revenues from research funding and also two \$0.3 million milestone payment from Pfizer Inc. in connection with selection of the first and second target discovered by BioInvent, a €0.75 million milestone payment received from Mitsubishi Tanabe Pharma Corporation in connection with enrollment of the first patient in a Phase II clinical trial and a \$0.5 million milestone payment from XOMA Corporation related to the acceptance by FDA of an IND application.

The Company's total costs amounted to SEK 223.6 million (237.0). Operating costs are divided between external costs of SEK 144.0 million (158.7), personnel costs of SEK 67.6 million (66.7) and depreciation of SEK 12.0 million (11.6).

Research and development costs amounted to SEK 191.4 million (207.9). Sales and administrative costs amounted to SEK 32.2 million (29.1).

Loss after tax amounted to SEK -76.3 million (-138.6). The net financial items amounted to SEK -0.9 million (-0.8). Loss per share before and after dilution amounted to SEK -2.66 (-7,64). Loss per share in 2019 has been adjusted as if the reverse split in 2020 had been completed January 1, 2019.

Financial position and cash flow

In June and July 2020, BioInvent successfully completed a directed share issue of approximately SEK 487 million before transaction costs. Investors included new investors such as HBM Healthcare Investments Ltd., Swedbank Robur Medica and Invus Public Equities, L.P. as well as existing shareholders Van Herk Investments B.V., Omega Funds, The Fourth Swedish National Pension Fund and Handelsbanken Healthcare Fund. In July 2020, BioInvent's Board of Directors resolved on a repair rights issue of a maximum of approximately SEK 139 million. It was completed in August and was heavily oversubscribed.

In October 2020, BioInvent licensed BI-1206 to CASI Pharmaceuticals for the Greater China region. Under the terms of the Agreement, as part of the upfront payment, CASI has made a \$7 million investment (SEK 61.4 million) in 29,395,311 new shares in BioInvent at a subscription price of SEK 2.09 per share, which corresponds to 130 % of the average volume weighted price for the share during the ten trading days prior to October 27, 2020, and 14,697,655 new warrants (at no separate option premium), each warrant with a right to subscribe for an equal number of new shares in BioInvent within a period of five years and at a subscription price of SEK 78.50 per share. The equity investment was approved at an EGM held on November 27, 2020.

The EGM held on November 27, 2020 approved the proposal on a reverse share split 1:25, a reduction of the share capital to adjust the share capital to the Company's operations (the reduction was registered by the Swedish Companies Registration Office on February 11, 2021), and an updated authorization for the Board to decide on a new issue of shares comprising 109,378,025 new shares (corresponding to 4,375,121 shares after the reverse share split).

After the share issues in 2020 and the reverse share split, the share capital consists of 39,376,096 shares.

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 subject to the approval of an EGM to be held on 23 March 2021.

As of December 31, 2020, the Group's liquid funds amounted to SEK 729.3 million (154.0). The cash flow from operating activities and investment activities for the January-December period amounted to SEK -69.3 million (-129.3).

The shareholders' equity amounted to SEK 743.5 million (169.4) at the end of the period. The Company's share capital was SEK 78.8 million. The equity/assets ratio at the end of the period was 93 (75) percent. Shareholders' equity per share amounted to SEK 18.88 (8.44). Shareholders' equity per share in 2019 has been adjusted as if the reverse split in 2020 had been completed January 1, 2019.

Investments

Investments for the January-December period in tangible fixed assets amounted to SEK 6.7 million (3.8).

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.

Organisation

As of December 31, 2020, BioInvent had 72 (72) employees. 65 (66) of these work in research and development.

Disclosure of related party transactions

For description of benefits to senior executives, see page 49 in the Company's annual report 2019. 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.

Except for potential effects of Covid-19, no other significant changes to the risks and uncertainty factors have occurred during the period.

BioInvent has taken necessary precautions with regards to Covid-19. For the time being, and even though the virus continues to spread throughout the communities, early clinical trial results for BI-1206 in combination with pembrolizumab and other clinical programs remain on track. As the situation is still evolving, timelines may be impacted in geographic areas most severely affected. We will provide updates as necessary.

For a more detailed description of risk factors, see section "Risks and Risk Management", page 33, in the Company's annual report 2019.

Annual General Meeting and upcoming financial reports

The Annual General Meeting will be held on April 29, 2021. With a view to comply with the recommendations of the Public Health Agency of Sweden to limit social contacts as far as possible, the Board of Directors has resolved that shareholders in BioInvent shall be able to exercise its voting rights at the AGM by post, in accordance with the temporary rules which the Swedish Parliament has enacted. Notice to attend will be announced in the Swedish press in Post- och Inrikes Tidningar and on the Company's website.

The Board of Directors and the CEO do not propose the payment of any dividend for the 2020 business year.

BioInvent will present the following financial reports:

- Annual report expected to be available on the website 8 April 2021.
- Interim reports April 28, August 26, October 28, 2021

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

	3 MONTHS 2020 Oct.-Dec.	3 MONTHS 2019 Oct.-Dec.	12 MONTHS 2020 Jan.-Dec.	12 MONTHS 2019 Jan.-Dec.
Net sales	98,743	25,387	147,372	93,740
<i>Operating costs</i>				
Research and development costs	-60,077	-59,659	-191,421	-207,896
Sales and administrative costs	-9,456	-7,578	-32,155	-29,094
Other operating income and costs	198	1,392	730	5,402
	<u>-69,335</u>	<u>-65,845</u>	<u>-222,846</u>	<u>-231,588</u>
Operating profit/loss	29,408	-40,458	-75,474	-137,848
Profit/loss from financial investments	-888	-483	-859	-785
Profit/loss before tax	28,520	-40,941	-76,333	-138,633
Tax	-	-	-	-
Profit/loss	28,520	-40,941	-76,333	-138,633
Other comprehensive income <i>Items that have been or may be reclassified subsequently to profit or loss</i>	-	-	-	-
Comprehensive income	28,520	-40,941	-76,333	-138,633
Other comprehensive income attributable to parent Company's shareholders	28,520	-40,941	-76,333	-138,633
Profit/loss per share, SEK				
Before dilution	0.74	-2.04	-2.66	-7.64
After dilution	0.74	-2.04	-2.66	-7.64

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

	2020 31 Dec.	2019 31 Dec.
Assets		
Fixed assets		
Intangible fixed assets	0	0
Tangible fixed assets - leases	12,834	16,842
Tangible fixed assets - other	16,762	16,163
Total fixed assets	29,596	33,005
Current assets		
Inventories	4,079	5,380
Current receivables	39,695	33,751
Liquid funds	729,270	153,975
Total current assets	773,044	193,106
Total assets	802,640	226,111
Shareholders' equity and liabilities		
Shareholders' equity		
Total shareholders' equity	743,499	169,436
Liabilities		
Long term liabilities		
Lease liabilities	5,632	9,472
Short term liabilities		
Lease liabilities	5,972	6,057
Other liabilities	<u>47,537</u>	<u>41,146</u>
	53,509	47,203
Shareholders' equity and liabilities	802,640	226,111

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

	2020 Oct.-Dec.	2019 Oct.-Dec.	2020 Jan.-Dec.	2019 Jan.-Dec.
Shareholders' equity at beginning of period	653,800	210,455	169,436	87,621
Comprehensive income				
Profit/loss	28,520	-40,941	-76,333	-138,633
Comprehensive other income	-	-	-	-
Total comprehensive income	28,520	-40,941	-76,333	-138,633
Total, excluding transactions with equity holders of the Company	682,320	169,514	93,103	-51,012
Transactions with equity holders of the Company				
Employee options program	125	-78	-41	379
Directed share issues and rights issue			589,383	
Directed share issue	61,054		61,054	
Directed share issue, Board Share Program 2018				54
Rights issue and directed issue				220,015
Shareholders' equity at end of period	743,499	169,436	743,499	169,436

The share capital as of December 31, 2020 consists of 39,376,096 shares and the share's ratio value was 2.00. The directed share issues were completed in July 2020 and the repair rights issue was completed in August 2020. These amounted to in total approximately SEK 625.5 million before issue expenses and approximately SEK 589.2 million after issue expenses. The directed new share issue carried out in December 2020 raised approximately SEK 61.4 million before issue expenses and approximately SEK 61.1 million after issue expenses.

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

	2020 Oct.-Dec.	2019 Oct.-Dec.	2020 Jan.-Dec.	2019 Jan.-Dec.
Operating activities				
Operating profit/loss	29,408	-40,458	-75,474	-137,848
Depreciation	3,108	2,952	12,004	11,612
Adjustment for other non-cash items	125	-78	-41	379
Interest received and paid	-105	-162	-307	-414
Cash flow from operating activities before changes in working capital	32,536	-37,746	-63,818	-126,271
Changes in working capital	-3,336	10,592	1,196	844
Cash flow from operating activities	29,200	-27,154	-62,622	-125,427
Investment activities				
Acquisition of tangible fixed assets	-1,615	-1,339	-6,700	-3,839
Cash flow from investment activities	-1,615	-1,339	-6,700	-3,839
Cash flow from operating activities and investment activities	27,585	-28,493	-69,322	-129,266
Financing activities				
Directed share issues and rights issue			589,383	
Directed share issue	61,054		61,054	
Directed issue, Board Share Program 2018				54
Rights issue and directed issue				220,015
Amortization of lease liability	-1,467	-1,433	-5,820	-5,679
Cash flow from financing activities	59,587	-1,433	644,617	214,390
Change in liquid funds	87,172	-29,926	575,295	85,124
Opening liquid funds	642,098	183,901	153,975	68,851
Liquid funds at end of period	729,270	153,975	729,270	153,975
Liquid funds, specification:				
Current investments	-	-	-	-
Cash and bank	729,270	153,975	729,270	153,975
	729,270	153,975	729,270	153,975

Key financial ratios for the Group

	2020 31 Dec.	2019 31 Dec.
Shareholders' equity per share at end of period, SEK	18.88	8.44
Number of shares at end of period (thousand)	39,376	20,071
Equity/assets ratio, %	92.6	74.9
Number of employees at end of period	72	72

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

	3 MONTHS 2020 Oct.-Dec.	3 MONTHS 2019 Oct.-Dec.	12 MONTHS 2020 Jan.-Dec.	12 MONTHS 2019 Jan.-Dec.
Net sales	98,743	25,387	147,372	93,740
<i>Operating costs</i>				
Research and development costs	-60,133	-59,716	-191,649	-208,124
Sales and administrative costs	-9,461	-7,583	-32,175	-29,114
Other operating income and costs	198	1,392	730	5,402
	-69,396	-65,907	-223,094	-231,836
Operating profit/loss	29,347	-40,520	-75,722	-138,096
Profit/loss from financial investments	-819	-378	-528	-312
Profit/loss after financial items	28,528	-40,898	-76,250	-138,408
Tax	-	-	-	-
Profit/loss	28,528	-40,898	-76,250	-138,408
<i>Other comprehensive income</i>	-	-	-	-
Comprehensive income	28,528	-40,898	-76,250	-138,408

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

	2020 31 Dec.	2019 31 Dec.
Assets		
Fixed assets		
Intangible fixed assets	0	0
Tangible fixed assets	16,762	16,163
Financial fixed assets	687	687
Total fixed assets	17,449	16,850
Current assets		
Inventories	4,079	5,380
Current receivables	41,233	35,289
Current investments	-	-
Cash and bank	729,270	153,975
Total current assets	774,582	194,644
Total assets	792,031	211,494
Shareholders' equity and liabilities		
Shareholders' equity		
Restricted equity	106,445	67,835
Non-restricted equity	637,400	101,864
Total shareholders' equity	743,845	169,699
Liabilities		
Current liabilities	48,186	41,795
Total shareholders' equity and liabilities	792,031	211,494

Lund, February 23, 2021, The Board of Directors

This report has not been reviewed by the company's auditors.

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 2020 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 45, in the Company's annual report 2019.

Note 2 Net revenue

SEK thousand	2020 Oct.-Dec.	2019 Oct.-Dec.	2020 Jan.-Dec.	2019 Jan.-Dec.
<i>Revenue by geographical region:</i>				
Sweden	230	2,905	2,747	23,990
Europe	6,317	900	34,269	1,091
USA	71,529	21,582	89,689	60,551
Japan	20,667	-	20,667	8,108
Other countries	-	-	-	-
	<u>98,743</u>	<u>25,387</u>	<u>147,372</u>	<u>93,740</u>
<i>Revenue consists of:</i>				
Revenue from collaboration agreements associated with outlicensing of proprietary projects	70,015	2,282	76,713	21,834
Revenue from technology licenses	20,667	-	20,667	12,717
Revenue from external development projects	<u>8,061</u>	<u>23,105</u>	<u>49,992</u>	<u>59,189</u>
	<u>98,743</u>	<u>25,387</u>	<u>147,372</u>	<u>93,740</u>

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

Note 3 Share-related compensation

Option Program 2017/2020

The 2017 Annual General Meeting resolved to adopt a long-term incentive program in the form of an option program comprising management and other key persons. During the course of the program 1,422,832 options have been allotted. The last date to exercise was December 15, 2020. No subscription warrants were called for redemption.

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 be allotted 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 15 December 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 rights issue 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 AGM resolved on a directed issue of maximum of 5,040,000 warrants (corresponding to approximately 0.5 percent of the total number of shares and votes in the company) and approval of transfer of warrants. Allotment of 221,619 options took place in February 2020 and 1,008,141 options in February 2021.

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

Note 4 Events after the reporting period

In January 2021, BioInvent announced that Phase I/IIa data suggest that BI-1206 restores activity of rituximab in relapsed non-Hodgkin's lymphoma patients. Responses in 6 out of 9 patients evaluated provide exciting evidence that BI-1206 has the potential to restore activity of rituximab in non-Hodgkin's lymphoma patients who have relapsed after treatment with rituximab. Long-lasting complete responses observed in two patients beyond 12 months. (R)

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 subject to the approval of an EGM to be held on 23 March 2021. (R)

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. (R)

BioInvent announced in January 2021, enrollment of the first patient in a Phase I/IIa study of BI-1808.

In January 2021, BioInvent announced that An van Es Johansson should resign as a director of the board effective as of 15 February 2021, due to personal reasons. (R)

(R)= Regulatory event

Contact

Any questions regarding this report will be answered by Martin Welschhof, CEO, +46 (0)46 286 85 50, martin.welschhof@bioinvent.com. The report is also available at www.bioinvent.com.

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Forward looking information

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