

China licensing agreement further validates technology and strategy

“The exclusive licensing agreement with CASI Pharmaceuticals for BI-1206 in China is an important validation of BioInvent’s technology, expertise and business model. It provides further impetus to our lead drug candidate and reinforces our financial position with \$12 million upfront in cash and equity investment, plus potential future milestones and royalties.”

Martin Welschhof, CEO BioInvent

Financial information

Third quarter 2020

- Net sales SEK 16.3 (18.1) million.
- Loss after tax SEK -32.9 (-37.1) million.
- Loss after tax per share before and after dilution SEK -0.04 (-0.07).
- Cash flow from operating activities and investment activities SEK -33.1 (-25.0) million.

January – September 2020

- Net sales SEK 48.6 (68.4) million.
- Loss after tax SEK -104.9 (-97.7) million.
- Loss after tax per share before and after dilution SEK -0.16 (-0.22).
- Cash flow from operating activities and investment activities SEK -96.9 (-100.8) million. Liquid funds as of September 30, 2020: SEK 642.1 (183.9) million.

Events in the third quarter

- BioInvent’s agreement with Pfizer Inc. was further extended until the end of 2020 to permit the companies to further identify and characterize new targets and antibodies binding to these targets.
- The Extraordinary General Meeting on July 3 resolved to increase the Board of Directors with one member through new election of Dr. Thomas Hecht as a Board member. (R)
- 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. The repair rights issue followed the successfully completed directed share issues of approximately SEK 487 million before transaction costs. (R)

Events after the reporting period

- In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals, Inc (NASDAQ: CASI) for the Greater China region. The collaboration accelerates and expands BioInvent’s global development plans for BI-1206. BioInvent is to receive \$12 million upfront in combination of cash and equity investment and eligible to receive up to \$83 million in milestone payments, plus tiered royalties. The equity investment is subject to the approval of an Extraordinary Shareholders’ Meeting (EGM) to be held on 27 November 2020. (R)
- The Board of Directors has also proposed that the EGM approves 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 109,378,025 new shares (corresponding to 4,375,121 shares after the reverse share split). (R)
- BioInvent announced, in October 2020, regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL.
- In October 2020, BioInvent announced that it will receive 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)

(R)= Regulatory event

Comments from the CEO

BioInvent took a significant step forward with the signing of an exclusive licensing agreement with CASI Pharmaceuticals for the development and commercialization of our novel anti-FcγRIIB antibody, BI-1206, in mainland China, Taiwan, Hong Kong and Macau. It is an important validation of BioInvent's technology, expertise and business model and provides further impetus to our lead drug candidate.



This agreement will further accelerate the development and commercialization preparations for BI-1206, based on CASI's clinical and regulatory expertise and strong presence across this major market. Their established commercial infrastructure and medical marketing team, together with their wide access to a strong network of investigators across Greater China, make them an ideal partner to expand our global development footprint in this important region.

The agreement also further reinforces our financial position, as BioInvent receives \$12 million upfront as a combination of cash and equity investment. We are eligible for 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 of BI-1206.

In short this collaboration adds significant value to our overall BI-1206 program, through the leveraging of CASI's capabilities in this major market and the financial terms.

The clinical development of BI-1206 in both hematological cancers and solid tumors is progressing well. A Phase I/IIa trial of BI-1206 in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) in solid tumors is continuing as planned, as is the Phase I/IIa trial of BI-1206 in combination with rituximab for the treatment of non-Hodgkin lymphoma (NHL). With this exciting agreement with CASI now in place, we anticipate there could be further interest in similar partnerships for BI-1206 in other regional markets, or a license of the rest of the world.

Beyond BI-1206, BioInvent's pipeline is expanding further based on the productivity of our proprietary n-CoDeR®/F.I.R.S.T™ platforms and ability to generate antibodies to novel targets with potent anti-tumoral activity to address major unmet medical needs.

We have received regulatory authority approval of our clinical trial application in Denmark for a Phase I/IIa, first-in-human study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL. BI-1808 will be the first anti-TNFR2 antibody to enter clinical development, and we believe this is a very promising approach for cancer therapy. We expect to enroll the first patient before the end of the year and to submit an investigational new drug (IND) application in the U.S. in the coming weeks. Together with our partner Transgene, we also continue to expect to initiate a Phase I clinical trial with the multifunctional oncolytic virus BT-001 before the end of 2020.

We continue our value-creating collaborations with various partners and most recently announced receipt of a €2 million milestone payment under our collaboration with Daiichi Sankyo, related to the initiation of a global Phase I clinical trial with a GARP directed antibody.






This all adds up to further substantial progress for BioInvent, across the pipeline, and I look forward to continuing to keep you up to date with further developments through the rest of 2020 and beyond.

As previously informed, BioInvent has taken necessary precautions with regards to the corona virus. Although we see an increase of cases, which is of course terrible for all those affected and their families, we still remain on track with our clinical trials and results. As the situation is still evolving, timelines are still subject to potential changes and we will provide updates as necessary.

With financing in place, a new partnering collaboration and the strong support of our investors, BioInvent is well positioned to continue to deliver on the promise of our pipeline.

Martin Welschhof, 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.™ αTreg				
Target: Tumor-associated myeloid cells					
Solid cancer	F.I.R.S.™ αTAMs			Partner: 	

Business focus

BioInvent's current operational activities are focused on:

- Progressing and expanding the clinical development of its lead antibody BI-1206 for treatment of NHL, and in combination with pembrolizumab (KEYTRUDA®) in advanced solid cancers.
- Developing preclinical first-in-class antibodies targeting tumor associated myeloid cells in collaboration with Pfizer, potential other partners, or alone.
- Advancing three compounds into clinical programs:
 - BI-1808, the Company's most advanced anti-TNFR2 antibody, as a single agent and in combination with an anti-PD1 antibody. A clinical trial application was approved in October 2020.
 - BI-1607 (an anti-FcγRIIB antibody) in combination with a checkpoint inhibitor. A clinical trial application is expected to be submitted in Q2 2021.
 - Developing, in combination with Transgene, oncolytic viruses encoding either a proprietary anti-CTLA-4 antibody sequence, or antibody sequences targeting undisclosed targets for the treatment of solid tumors. BT-001, an anti-CTLA-4/oncolytic virus – a clinical trial application was submitted in Q1 2020.

Clinical programs

BI-1206 in non-Hodgkin lymphoma and chronic lymphocytic leukemia

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 liquid and solid cancers, with CASI responsible for commercialization in China and associated markets. BioInvent is to receive \$12 million upfront in combination of cash and equity investment and eligible to receive up to \$83 million in milestone payments, plus tiered royalties. The equity investment is subject to the approval of an EGM to be held on 27 November 2020.

In April 2020, BioInvent provided a preliminary insight into progress of its Phase I/IIa trial of BI-1206 in combination with rituximab for the treatment of Non-Hodgkin Lymphoma (NHL). In the Phase I part of the trial, three separate early signs of activity have been observed across different subtypes of NHL, even though the doses of BI-1206 are still suboptimal. In particular, a patient in the 70mg cohort has achieved a complete response. The patient is reported to be in "a very good general condition and without any signs of toxicity". In the 30mg cohort, one patient with follicular lymphoma (FL) remained on treatment for the full maintenance period of one year, and another patient with mantle cell lymphoma (MCL) showed complete depletion of circulating MCL cells. The dose escalation process continues as planned.

As reported earlier, target-mediated drug disposition has not yet been overcome, and thus, the optimal dose has not yet been reached. Notwithstanding, pharmacodynamic analysis at the current doses showed depletion of peripheral B cells, including circulating mantle cell lymphoma cells during the first week of therapy.

Early results from the Phase I open label study in indolent non-Hodgkin lymphoma are expected in H2 2020.

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.

In September 2018 BioInvent started a dose escalation, consecutive-cohort, open-label Phase I/IIa study of BI-1206. The study will recruit approximately 30 patients across sites in the EU and the U.S. The trial is evaluating BioInvent's proprietary antibody BI-1206 in combination with rituximab in patients with indolent relapsed or refractory Fc NHL. The targeted subindications are mantle cell lymphoma, follicular lymphoma, and marginal zone lymphoma. The study will explore BI-1206's safety and tolerability, and seek to determine a recommended Phase II dose (RP2D) when given in combination with rituximab. Expression of biomarkers will be assessed to explore a potential correlation with clinical activity.

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

BioInvent has previously published (ASH-2019) preclinical data demonstrating that BI-1206 had potent single-agent activity in a patient-derived xenograft model (PDX) obtained from a mantle cell lymphoma (MCL) patient, resistant to both ibrutinib and venetoclax. FcγRIIB was also shown to be highly expressed in 20/20 primary patient MCL samples examined. These data further corroborated the important role of FcγRIIB in establishing resistance to rituximab, and the ability of BI-1206 to overcome this resistance. Collectively, 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 from the FDA to proceed for an IND application 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.

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.

Background

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 (anti-TNFR2)

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 October 2020, regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL. We expect to enroll the first patient before the end of the year and to submit an investigational new drug (IND) application in the U.S. in the coming weeks.

The study will explore the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent and in combination with KEYTRUDA® in patients with ovarian cancer, non-small cell lung cancer and cutaneous T cell lymphoma. It will also investigate the expression of potential immunological markers that might be associated with clinical responses. It will be conducted at several sites across Europe and the U.S. and is expected to enroll approximately 120 patients.

The Phase I stage is divided into two sections. Part A is a dose escalation of BI-1808 to assess safety, tolerability, and pharmacokinetics & pharmacodynamics, and to determine the recommended dose as a single agent for Phase II trials. It will be followed by part B, which will explore the safety, tolerability and recommended dose of BI-1808 in combination with KEYTRUDA®. Phase IIa 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. A separate cohort will explore the activity as single agent in CTCL (Sézary syndrome and mycosis fungoides).

Exciting translational data was presented at AACR Virtual Annual Meeting II in June 2020. In vivo studies show that both ligand-blocking and agonistic 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.

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.

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. The purpose of the research extension is to permit the companies to further identify and characterize new targets and antibodies binding to these targets.

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. Under the terms of the 2016 agreement, potential selection and development of antibodies directed against these targets, as well as potential selection of further targets and development of antibodies directed at them, would allow BioInvent to be eligible for further milestone payments.

BioInvent is eligible for potential future development milestones in excess of \$500 million (assuming five antibodies are 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 during 2017, 2018, 2019 and 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.

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 March 2020 that the first clinical trial application for BT-001 was submitted and that the first-in-human trial is expected to start before the end of 2020 in Europe and the US.

Promising findings was presented at AACR Virtual Annual Meeting II in June 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 multiple mechanisms of action. It has been designed to combine the killing of cancer cells (oncolysis), and the production of the anti-CTLA4 antibody and GM-CSF directly in the tumor site, while also generating an immune response against tumor cells. It was shown that the anti-CTLA-4 antibody and GM-CSF accumulate in tumors with low systemic exposure. When new tumor cells were implanted in mice that had been cured after a first BT-001 treatment, a strong tumor-specific response and long-lasting immune memory were developed by these mice. 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 Vaccinia viruses, 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 an undisclosed target, which can 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.

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 16.3 million (18.1). Revenues for the period are mainly derived from production of antibodies for clinical studies. Revenues for the corresponding period 2019 were mainly derived from production of antibodies for clinical studies, revenues from research funding and also a \$0.3 million milestone payment from Pfizer Inc. in connection with selection of the first target discovered by BioInvent.

The Company's total costs amounted to SEK 48.8 million (55.2). Operating costs are divided between external costs of SEK 32.4 million (37.5), personnel costs of SEK 13.3 million (14.8) and depreciation of SEK 3.1 million (2.9).

Research and development costs amounted to SEK 41.3 million (48.4). Sales and administrative costs amounted to SEK 7.5 million (6.8).

Loss after tax amounted to SEK -32.9 million (-37.1). The net financial items amounted to SEK -0.1 million (-0.1). Loss per share before and after dilution amounted to SEK -0.04 (-0.07).

January - September

Net sales amounted to SEK 48.6 million (68.4). Revenues for the period are mainly derived 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 a \$0.3 million milestone payment from Pfizer Inc. in connection with selection of the first 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 154.0 million (169.8). Operating costs are divided between external costs of SEK 97.9 million (114.0), personnel costs of SEK 47.2 million (47.1) and depreciation of SEK 8.9 million (8.7).

Research and development costs amounted to SEK 131.3 million (148.3). Sales and administrative costs amounted to SEK 22.7 million (21.5).

Loss after tax amounted to SEK -104.9 million (-97.7). The net financial items amounted to SEK 0.0 million (-0.3). Loss per share before and after dilution amounted to SEK -0.16 (-0.22).

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.

After the share issues the share capital consists of 955,007,096 shares.

In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals for the Greater China region. Under the terms of the Agreement, as part of the upfront payment, CASI will also make a \$7 million investment (SEK 61,436,200) 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 27 October, 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 3.14 per share. The investment is subject to the approval of an Extraordinary Shareholders' Meeting in BioInvent to be held on 27 November 2020, announced by way of separate press release. If approved, it is expected that the new shares will be admitted to trade on or about 4 December 2020.

The Board of Directors has also proposed that the EGM approves their 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 109,378,025 new shares (corresponding to 4,375,121 shares after the reverse share split).

As of September 30, 2020, the Group's liquid funds amounted to SEK 642.1 million (183.9). The cash flow from operating activities and investment activities for the January-September period amounted to SEK -96.9 million (-100.8).

The shareholders' equity amounted to SEK 653.8 million (210.5) at the end of the period. The Company's share capital was SEK 76.4 million. The equity/assets ratio at the end of the period was 93 (77) percent. Shareholders' equity per share amounted to SEK 0.68 (0.42).

Investments

Investments for the January-September period in tangible fixed assets amounted to SEK 5.1 million (2.5).

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 September 30, 2020, BioInvent had 73 (73) employees. 66 (67) 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 the coronavirus, no other significant changes to the risks and uncertainty factors have occurred during the period.

BioInvent has taken necessary precautions with regards to the coronavirus. We may see a delay of the early results from the Phase I open label study with a combination of BI-1206 and rituximab for treatment of Non-Hodgkin Lymphoma (NHL). Management still expects the results of the study in H2 2020. For the time being, early clinical trial results for BI-1206 in combination with pembrolizumab and clinical trial initiations in other programs remain on track.

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

Upcoming financial reports

BioInvent will present the following financial reports:

- Financial statement 2020: February 25, 2021

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

	3 MONTHS 2020 July-Sep.	3 MONTHS 2019 July-Sep.	9 MONTHS 2020 Jan.-Sep.	9 MONTHS 2019 Jan.-Sep.	12 MONTHS 2019 Jan.-Dec.
Net sales	16,267	18,053	48,629	68,353	93,740
<i>Operating costs</i>					
Research and development costs	-41,297	-48,374	-131,344	-148,237	-207,896
Sales and administrative costs	-7,466	-6,863	-22,699	-21,516	-29,094
Other operating income and costs	-317	182	532	4,010	5,402
	<u>-49,080</u>	<u>-55,055</u>	<u>-153,511</u>	<u>-165,743</u>	<u>-231,588</u>
Operating loss	-32,813	-37,002	-104,882	-97,390	-137,848
Loss from financial investments	-63	-121	29	-302	-785
Loss before tax	-32,876	-37,123	-104,853	-97,692	-138,633
Tax	-	-	-	-	-
Loss	-32,876	-37,123	-104,853	-97,692	-138,633
Other comprehensive income					
<i>Items that have been or may be reclassified subsequently to profit or loss</i>	-	-	-	-	-
Comprehensive income	-32,876	-37,123	-104,853	-97,692	-138,633
Other comprehensive income attributable to parent Company's shareholders	-32,876	-37,123	-104,853	-97,692	-138,633
Loss per share, SEK					
Before dilution	-0.04	-0.07	-0.16	-0.22	-0.31
After dilution	-0.04	-0.07	-0.16	-0.22	-0.31

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

	2020 30 Sep.	2019 30 Sep.	2019 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	12,414	18,318	16,842
Tangible fixed assets - other	16,779	16,301	16,163
Total fixed assets	29,193	34,619	33,005
Current assets			
Inventories	4,206	10,793	5,380
Current receivables	28,042	44,485	33,751
Liquid funds	642,098	183,901	153,975
Total current assets	674,346	239,179	193,106
Total assets	703,539	273,798	226,111
Shareholders' equity and liabilities			
Shareholders' equity			
Total shareholders' equity	653,800	210,455	169,436
Liabilities			
Long term liabilities			
Lease liabilities	5,119	10,905	9,472
Short term liabilities			
Lease liabilities	6,057	6,057	6,057
Other liabilities	38,563	46,381	41,146
	44,620	52,438	47,203
Shareholders' equity and liabilities	703,539	273,798	226,111

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

	2020 July-Sep.	2019 July-Sep.	2020 Jan.-Sep.	2019 Jan.-Sep.	2019 Jan.-Dec.
Shareholders' equity at beginning of period	193,418	247,317	169,436	87,621	87,621
Comprehensive income					
Loss	-32,876	-37,123	-104,853	-97,692	-138,633
Comprehensive other income	-	-	-	-	-
Total comprehensive income	-32,876	-37,123	-104,853	-97,692	-138,633
Total, excluding transactions with equity holders of the Company	160,542	210,194	64,583	-10,071	-51,012
Transactions with equity holders of the Company					
Employee options program	96	261	-166	457	379
Directed share issues and rights issue	493,162		589,383		
Directed share issue, Board Share Program 2018				54	54
Rights issue and directed issue				220,015	220,015
Shareholders' equity at end of period	653,800	210,455	653,800	210,455	169,436

The share capital as of September 30, 2020 consists of 955,007,096 shares and the share's ratio value is 0.08. 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 million before issue expenses and approximately SEK 589 million after issue expenses.

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

	2020 July-Sep.	2019 July-Sep.	2020 Jan.-Sep.	2019 Jan.-Sep.	2019 Jan.-Dec.
Operating activities					
Operating loss	-32,813	-37,002	-104,882	-97,390	-137,848
Depreciation	3,073	2,930	8,896	8,660	11,612
Adjustment for other non-cash items	96	261	-166	457	379
Interest received and paid	-16	7	-202	-252	-414
Cash flow from operating activities before changes in working capital	-29,660	-33,804	-96,354	-88,525	-126,271
Changes in working capital	-1,695	9,398	4,532	-9,748	844
Cash flow from operating activities	-31,355	-24,406	-91,822	-98,273	-125,427
Investment activities					
Acquisition of tangible fixed assets	-1,696	-612	-5,085	-2,500	-3,839
Cash flow from investment activities	-1,696	-612	-5,085	-2,500	-3,839
Cash flow from operating activities and investment activities	-33,051	-25,018	-96,907	-100,773	-129,266
Financing activities					
Directed share issues and rights issue	494,326		589,383		
Directed issue, Board Share Program 2018				54	54
Rights issue and directed issue				220,015	220,015
Amortization of lease liability	-1,461	-1,424	-4,353	-4,246	-5,679
Cash flow from financing activities	492,865	-1,424	585,030	215,823	214,390
Change in liquid funds	459,814	-26,442	488,123	115,050	85,124
Opening liquid funds	182,284	210,343	153,975	68,851	68,851
Liquid funds at end of period	642,098	183,901	642,098	183,901	153,975
Liquid funds, specification:					
Current investments	-	-	-	-	-
Cash and bank	642,098	183,901	642,098	183,901	153,975
	642,098	183,901	642,098	183,901	153,975

Key financial ratios for the Group

	2020 30 Sep.	2019 30 Sep.	2019 31 Dec.
Shareholders' equity per share at end of period, SEK	0.68	0.42	0.34
Number of shares at end of period (thousand)	955,007	501,770	501,770
Equity/assets ratio, %	92.9	76.9	74.9
Number of employees at end of period	73	73	72

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

	3 MONTHS 2020 July-Sep.	3 MONTHS 2019 July-Sep.	9 MONTHS 2020 Jan.-Sep.	9 MONTHS 2019 Jan.-Sep.	12 MONTHS 2019 Jan.-Dec.
Net sales	16,267	18,053	48,629	68,353	93,740
<i>Operating costs</i>					
Research and development costs	-41,355	-48,431	-131,516	-148,408	-208,124
Sales and administrative costs	-7,471	-6,868	-22,714	-21,531	-29,114
Other operating income and costs	-317	182	532	4,010	5,402
	-49,143	-55,117	-153,698	-165,929	-231,836
Operating loss	-32,876	-37,064	-105,069	-97,576	-138,096
Profit from financial investments	16	-7	291	66	-312
Loss after financial items	-32,860	-37,071	-104,778	-97,510	-138,408
Tax	-	-	-	-	-
Loss	-32,860	-37,071	-104,778	-97,510	-138,408
<i>Other comprehensive income</i>	-	-	-	-	-
Comprehensive income	-32,860	-37,071	-104,778	-97,510	-138,408

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

	2020 30 Sep.	2019 30 Sep.	2019 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	0	0
Tangible fixed assets	16,779	16,301	16,163
Financial fixed assets	687	687	687
Total fixed assets	17,466	16,988	16,850
Current assets			
Inventories	4,206	10,793	5,380
Current receivables	29,579	46,023	35,289
Current investments	-	-	-
Cash and bank	642,098	183,901	153,975
Total current assets	675,883	240,717	194,644
Total assets	693,349	257,705	211,494
Shareholders' equity and liabilities			
Shareholders' equity			
Restricted equity	104,094	67,835	67,835
Non-restricted equity	550,044	142,840	101,864
Total shareholders' equity	654,138	210,675	169,699
Liabilities			
Current liabilities	39,211	47,030	41,795
Total shareholders' equity and liabilities	693,349	257,705	211,494

Lund, October 29, 2020

Martin Welschof
CEO

Review report

Introduction

We have reviewed the summarized interim financial information for BioInvent International AB (publ) on September 30, 2020 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 29, 2020
KPMG AB

Linda Bengtsson
Authorised 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 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 July-Sep.	2019 July-Sep.	2020 Jan.-Sep.	2019 Jan.-Sep.	2019 Jan.-Dec.
<i>Revenue by geographical region:</i>					
Sweden	244	5,019	2,517	21,004	23,990
Europe	12,966	104	27,952	273	1,091
USA	3,057	12,930	18,160	38,968	60,551
Other countries	-	-	-	8,108	8,108
	<u>16,267</u>	<u>18,053</u>	<u>48,629</u>	<u>68,353</u>	<u>93,740</u>
<i>Revenue consists of:</i>					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	8,562	6,698	19,515	21,834
Revenue from technology licenses	-	-	-	12,717	12,717
Revenue from external development projects	<u>16,267</u>	<u>9,491</u>	<u>41,931</u>	<u>36,121</u>	<u>59,189</u>
	<u>16,267</u>	<u>18,053</u>	<u>48,629</u>	<u>68,353</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. Each option entitles the holder to subscribe for 1.02 new share in BioInvent during the period from the day of release of the Company's year-end report for the financial year 2019 up to and including December 15, 2020. The subscription price per share shall be SEK 2.93. Subscription price and number of shares that each option entitles to are recalculated pursuant to rights issue carried out in 2020. The program includes currently 10 persons. During the course of the program, 1,422,832 options have been allotted. No further allotments are due. The program, including costs for potential social security charges, is hedged by 1,900,000 warrants held by BioInvent Finans AB.

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 1.02 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 3.09. 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 took place in February 2020.

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

Note 4 Events after the reporting period

In October 2020, BioInvent licensed the anti-FcγRIIB antibody BI-1206 to CASI Pharmaceuticals, Inc (NASDAQ: CASI) for the Greater China region. The collaboration accelerates and expands BioInvent's global development plans for BI-1206. BioInvent is to receive \$12 million upfront in combination of cash and equity investment and eligible to receive up to \$83 million in milestone payments, plus tiered royalties. The equity investment is subject to the approval of an Extraordinary Shareholders' Meeting (EGM) to be held on 27 November 2020. (R)

The Board of Directors has also proposed that the EGM approves 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 109,378,025 new shares (corresponding to 4,375,121 shares after the reverse share split). (R)

BioInvent announced, in October 2020, regulatory authority approval of a clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and CTCL.

In October 2020, BioInvent announced that it will receive 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)

(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.

BioInvent International AB (publ)

Co. reg. no. 556537-7263
Address: Sölvegatan 41, 223 70 Lund
Tel.: +46 (0)46 286 85 50

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 press release.