AI-generated image showing how the immune system can attack a cancer tumor

Martin Welschof, CEO:

"The third quarter of 2025 marked continued momentum for BioInvent as we decided to focus on our most advanced programs BI-1206 and BI-1808. This strategic direction initiative is designed to accelerate the development of our most promising clinical assets and to focus on near to mid-term value creation."

All figures in SEK million unless otherwise stated	THIRD QUARTER 2025	THIRD QUARTER 2024	JAN. – SEP. 2025	JAN. – SEP. 2024
Net sales	3.3	12.8	223.5	23.3
Profit/loss after tax	-129.2	-97.2	-207.1	-312.5
Profit/loss after tax per share before and after dilution, SEK	-1.96	-1.48	-3.15	-4.75
Cash flow from operating activities	-104.0	-97.0	-157.2	-282.2
Liquid funds, current and long-term investments at the end of the period	690.5	979.2	690.5	979.2

EXPECTED KEY CATALYSTS

The company has a number of upcoming milestones. These include:

- **H2 2025:** Additional data for BI-1808 for the treatment of cutaneous T-cell lymphoma (CTCL)
- **H2 2025:** Additional data for BI-1206 triplet combination for the treatment of non-Hodgkin's lymphoma (NHL)
- **H2 2025:** Phase 2a data for BI-1808 in combination with Keytruda (pembrolizumab) for the treatment of solid tumors
- **H2 2026:** First read-out from the Phase 2a study of BI-1206 in combination with pembrolizumab for treatment-naïve NSCLC patients and uveal melanoma patients

The information was submitted for publication, through the agency of the contact person set out on page 23, at 8:00 a.m. CET on October 29, 2025.

Swedish version prevails. This Interim Report is published in Swedish and English. In the event of any discrepancy between the English version and the Swedish original, the Swedish version shall prevail.

Highlights Q3, 2025

EVENTS IN THE THIRD QUARTER

- Strategic changes in portfolio to accelerate lead clinical programs and enhance value creation
- (R) Changes to the Board; Vincent Ossipow stepped down

EVENTS AFTER THE END OF THE PERIOD

- Phase 2a trial with BI-1206 in combination with pembrolizumab started in advanced or metastatic NSCLC and uveal melanoma
- Phase 1 clinical data for BI-1910, a TNFR2 Agonist for the treatment of solid tumors, to be presented at SITC 2025
- Transgene and BioInvent presented translational data and updated clinical results on armed oncolytic virus BT-001 at ESMO 2025
-

(R)= Regulatory event

Doubling down on our most promising assets

The third quarter of 2025 marked continued momentum for BioInvent as we decided to focus on our most advanced programs BI-1206 and BI-1808, two first in class assets with activity in liquid and solid cancer with upcoming near to mid-term value-creating milestones.

During the quarter, we initiated a new Phase 2a study with BI-1206 in the first-line setting for advanced non-small cell lung cancer (NSCLC) and uveal melanoma that could significantly expand the reach of immunotherapy. The launch of this study marks a pivotal moment for us. It's the first time we're evaluating BI-1206 in treatment-naive patients, which allows us to better understand its full therapeutic potential. It also reflects our confidence in the drug candidate's ability to enhance checkpoint inhibitor efficacy.

The developments reflect the potential of our unique immuno-oncology therapies and our ability to execute across multiple fronts.

STRATEGIC FOCUS: ACCELERATING LEAD PROGRAMS

In August, we announced a strategic direction initiative designed to accelerate the development of our most promising clinical assets and to focus on near to mid-term value creation. Following a comprehensive review, we are concentrating our resources on advancing BI-1206 and BI-1808, both of which have demonstrated strong clinical signals and offer multiple upcoming catalysts.

As part of this focused strategy:

- Development of BI-1910 and BI-1607 has been paused.
- The oncolytic virus BT-001 will continue in an investigator-led trial in collaboration with Transgene.
- Research and preclinical operations are being aligned to fully support the lead programs, while retaining core capabilities to generate new clinical candidates.

This disciplined, opportunity-driven approach is intended to maximize therapeutic impact and shareholder value, while maintaining a strong foundation for future growth.

BI-1206: ENTERING THE FIRST-LINE SETTING IN SOLID TUMORS

We are pleased to announce the initiation of a Phase 2a clinical trial evaluating BI-1206, our FcγRIIB-blocking antibody, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab). This study is enrolling patients with advanced or metastatic NSCLC or uveal melanoma in the first-line setting, marking a significant step forward for BI-1206.

Martin Welschof, CEO

In Phase 1, BI-1206 demonstrated favorable safety and promising clinical activity in heavily pre-treated patients. Since these data were reported, we have upgraded BI-1206 to a subcutaneous injection, which releases the drug more slowly, potentially extending its effects while improving safety and convenience. The subcutaneous formulation of BI-1206, now in use, offers slower systemic entry and prolonged time on target, improving both safety and convenience.

This Phase 2a study builds on cumulative encouraging results and moves BI-1206 into treatment-naïve populations with a convenient subcutaneous injection. If successful, BI-1206 could become a key component in enhancing the activity of immune checkpoint inhibitors. We believe BI-1206 has the potential to deepen responses and expand immunotherapy benefits across multiple tumor types.

BI-1808: ADVANCING NOVEL TREATMENT IN CTCL

The Phase 2a trial for BI-1808, our first-in-class anti-TNFR2 antibody, in cutaneous T-cell lymphoma (CTCL) continues to enroll. This trial has demonstrated promising efficacy with 100 percent of evaluable patients achieving disease control and 45 percent demonstrating objective responses accompanied by strong immune activation and favorable safety (as reported at EHA 2025).

Underscoring the importance of this therapy, the US Food and Drug Administration (FDA) has granted BI-1808 Fast Track Designation for the treatment of adults with relapsed or refractory mycosis fungoides and Sézary syndrome, subtypes of CTCL, and ODD for the treatment of T cell Lymphoma. The FDA's Fast Track is designed to facilitate the development and expedite the review of drugs that treat serious conditions and address important unmet medical needs. The aim is to accelerate the development of urgently needed new drugs for patients.

These regulatory achievements and our continued focus on advancing BI-1808 will undoubtedly be key components for the future success of this novel therapy for T cell lymphomas.

LOOKING AHEAD

We continue to execute on our focused clinical strategy with BI-1206 and BI-1808. We are committed and well-funded to deliver meaningful milestones including:

- Additional data for BI-1206 triplet combination for the treatment of non-Hodgkin's lymphoma (NHL) already in H2 2025
- Additional data for BI-1808 for the treatment of cutaneous T-cell lymphoma (CTCL) already in H2 2025
- Phase 2a data for BI-1808 in combination with Keytruda (pembrolizumab) for the treatment of solid tumors in H2 2025
- First read-out from the Phase 2a study of BI-1206 in combination with pembrolizumab for treatment-naïve NSCLC patients and uveal melanoma patients in H2 2026

We are grateful to our patients, investigators, employees, and shareholders for their continued support and partnership.

Martin Welschof
CEO

EXPECTED KEY CLINICAL MILESTONES 2025/2026

BI-1808

Additional data for BI-1808 for the treatment of cutaneous T-cell lymphoma (CTCL).

H2 2025

BI-1206

Additional data for BI-1206 triplet combination for the treatment of non-Hodgkin's lymphoma (NHL).

H2 2025

BI-1808

Phase 2a data for BI-1808 in combination with Keytruda (pembrolizumab) for the treatment of solid tumors.

H2 2025

BI-1206

First read-out from the Phase 2a study of BI-1206 in combination with pembrolizumab for treatment-naïve NSCLC patients and uveal melanoma patients.

H2 2026

Sharp focus to maximize clinical and commercial success of lead programs

BioInvent is developing novel immuno-modulatory antibodies for cancer therapy. These innovative antibodies may significantly improve the efficacy of currently available checkpoint inhibitors and/or activate anti-cancer immunity in non-responding patients. Our clinical portfolio is currently focused on the immunological targets TNFR2 and FcyRIIB.

TNFR2

Program	Study arm	Discovery	Preclinical	Phase 1	Phase 2
BI-1808 in TCL/solid tumors	single agent				
	+ pembrolizumab[1]				

FcyRIIB

Program	Study arm	Discovery	Preclinical	Phase 1	Phase 2
BI-1206 in NHL	+ rituximab & acalabrutinib[2]				
	+ rituximab[3]				
BI-1206 in solid tumors	+ pembrolizumab[1]				

1) Supply agreement with MSD
2) Supply agreement with AZ
3) Licensed to CASI for China, Hong Kong, Macau and Taiwan

Completed Ongoing

BI-1808

BioInvent's anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate in clinical development for the treatment of solid tumors and for T-cell lymphoma. In the ongoing Phase 1/2a study, BI-1808 has shown single agent activity and excellent tolerability and signs of efficacy and favorable safety profile in combination with pembrolizumab.

STATUS

Efficacy in clinical Phase 1/2a study (NCT04752826) in CTCL

In June 2025, updated positive data from the ongoing Phase 2a dose expansion study of BI-1808 monotherapy in cutaneous T-cell lymphoma (CTCL) was announced. The data was presented at the European Hematology Association (EHA) 2025 congress. Data showed a 100% disease control rate in nine evaluable patients with CTCL. Forty-five percent of these patients achieved an objective response, with one patient achieving a complete response (CR), three achieving a partial response (PR), and five exhibiting stable disease (SD). Additionally, two patients with peripheral T-cell lymphoma (PTCL) were evaluable, of which one showed a PR, while the other showed SD.

Overall, BI-1808 monotherapy demonstrates promising clinical activity and robust immune engagement. Additionally, BI-1808 was well tolerated, with all treatment-related adverse events reported as mild or moderate (Grade 1-2). Notably, no Grade 3 or higher adverse events were observed. The safety and preliminary efficacy of BI-1808 monotherapy and in combination with KEYTRUDA® (pembrolizumab) are currently being evaluated in sub-cohorts in the ongoing Phase 2a part of the study in patients with T-cell lymphomas, including CTCL. These cohorts will form the basis for the selection of monotherapy or combination for the subsequent pivotal Phase 2 study. In April 2025, the U.S. Food and Drug Administration (FDA) granted BI-1808 Fast Track Designation for the treatment of CTCL and in March 2025, Orphan Drug Designation was received from the same agency for BI-1808 in T-cell lymphoma (TCL).

Efficacy in clinical Phase 1/2a study (NCT04752826) in solid tumors

Monotherapy data in solid tumors disclosed earlier in the year, show one complete response (CR), one PR and nine patients with SD (26 evaluable patients), presented at the American Society of Clinical Oncology conference (ASCO) in June 2024. The patient with PR is doing well and has completed study treatment. This patient continues the treatment outside of the study (per patient treatment). Early signs of efficacy and favorable safety profile in the Phase 1 dose escalation part studying BI-1808 in combination with pembrolizumab were also presented at ASCO. The Phase 2a combination arm of the study evaluating BI-1808 with pembrolizumab is ongoing.

STUDY DESIGN

During the first part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent (part A) and in combination with the anti-PD-1 therapy pembrolizumab (part B) are evaluated in patients with advanced solid tumors and T-cell lymphoma.

The dose escalation in Phase 1 Part B has been completed and the Phase 2a signal seeking cohorts are ongoing. These cohorts include ovarian cancer, all tumor types and T-cell lymphoma (including CTCL).

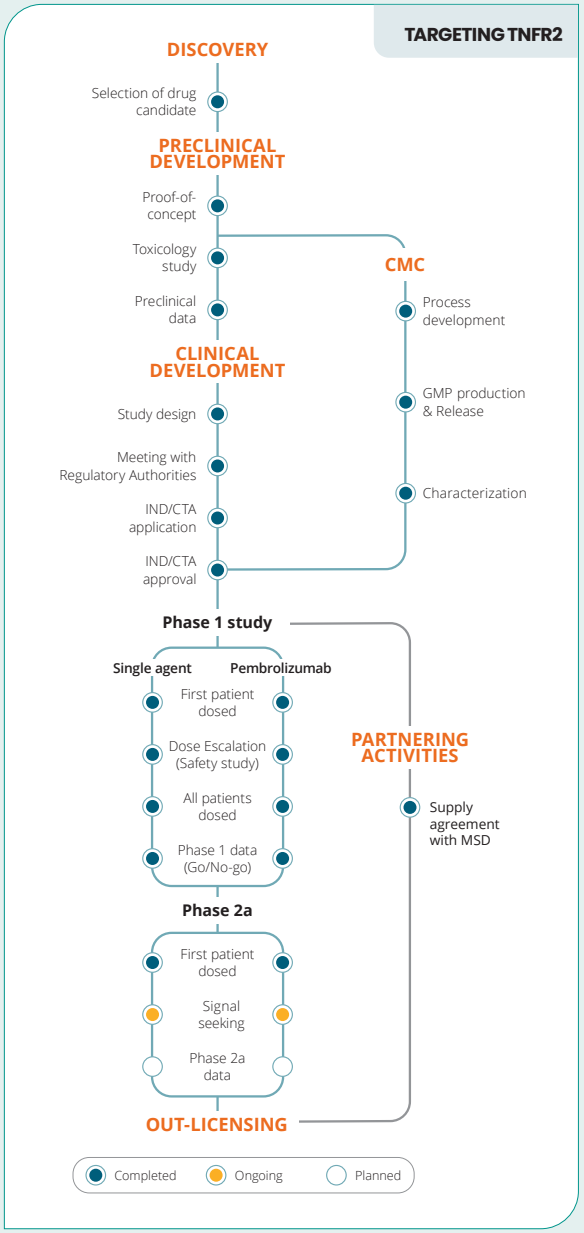
OUT-LICENSING AND PARTNERING

Since August 2021, BioInvent has a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BI-1808 and MSD's anti-PD-1 therapy, KEYTRUDA (pembrolizumab).

OUTLOOK

Additional TCL data from the Phase 2a single agent part is expected to be presented in H2 2025.

Data from the Phase 2a combination study with BI-1808 and pembrolizumab for the treatment of solid tumors is expected to be presented in H2 2025.



BI-1206 in non-Hodgkin's lymphoma

FcyRIIB 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 the receptor FcyRIIB on tumor cells, BI-1206 is expected to recover and enhance the activity of rituximab in the treatment of several forms of NHL. In February 2024, a clinical supply agreement was signed with AstraZeneca to evaluate BI-1206 in combination with rituximab and Calquence® (acalabrutinib). The combination of drugs could provide a new and important option for patients suffering from NHL and represents a substantial commercial opportunity.

STATUS

Triple combination arm of clinical Phase 1/2a study (NCT03571568) ongoing

In May 2025, updated data from the ongoing Phase 2a study of BI-1206 in combination with rituximab and Calquence® (acalabrutinib) for the treatment of non-Hodgkin's lymphoma (NHL) was presented. The data cover the first eight patients in the triple combination arm. All patients exhibited disease control at first assessment (DCR 100%), and results show an overall objective response rate of 63% with two patients achieving a complete response (CR) and three patients with partial responses (PR). Stable disease (SD) was observed in the three remaining patients. The combination was well tolerated in all patients treated at the cut-off-date.

Up to 30 patients are expected to be enrolled in Spain, Germany, the US, and Brazil.

Results in doublet arm of clinical Phase 1/2a study (NCT03571568)

Positive data have been generated in the study with BI-1206 in combination with rituximab for the treatment of relapsed/refractory (R/R) NHL.

All patients had received at least one previous line of rituximab-containing treatments. For the subgroup of patients with follicular lymphoma (FL), BI-1206 (IV and SC) dosing in combination with rituximab have so far yielded response rates of 59% ORR (*overall response rate*), 41% CRR (*complete response rate*) and 86% DCR (*disease control rate*). In the responding patients, the responses have been long-lasting, some of them have lasted several years after the end of treatment. The results show how BI-1206 can restore the efficacy of rituximab in the treatment of advanced NHL.

STUDY DESIGN

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

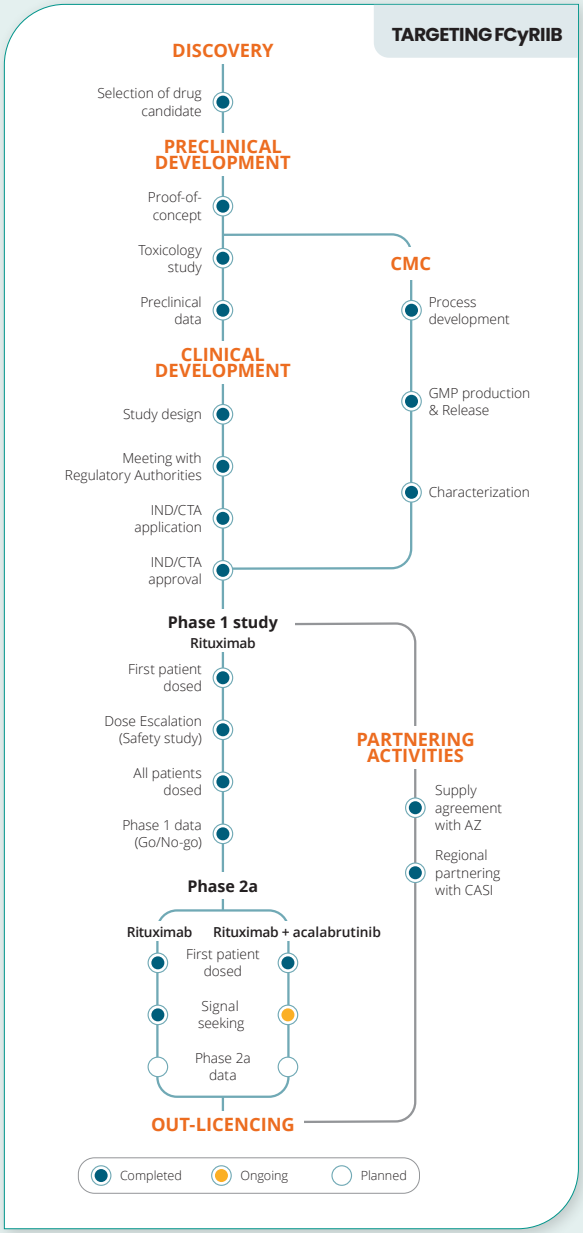
Phase 1: dose escalation with the aim of selecting the dose of BI-1206 to be further studied in Phase 2a; and

Phase 2a: signal seeking with a safety run-in, and a dose optimization to select the recommended dose of BI-1206 in combination with rituximab and acalabrutinib.

CLINICAL DEVELOPMENT IN CHINA

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

CASI is performing trials of BI-1206 in combination with rituximab in patients with NHL, to assess safety and tolerability, to further



evaluate the pharmacokinetic profile, select the dose for Phase 2 and assess early signs of clinical efficacy as part of its development program for BI-1206 in China and associated markets.

In March 2024, CASI reported interim data from its ongoing Phase 1 dose-escalation study, reinforcing previously reported positive efficacy data from BioInvent. The presented results include one complete response (CR), one partial response (PR) out of eight evaluable patients. A manageable safety profile was observed across all patients.

ODD FOR THE TREATMENT OF FL AND MCL

BI-1206 has been granted Orphan Drug Designation (ODD) by FDA for the treatment of follicular lymphoma (FL), the most common form of slow-growing NHL as well as for the more difficult-to-treat form mantle cell lymphoma (MCL).

OUT-LICENSING AND PARTNERING

In February 2024, a clinical supply agreement was signed with AstraZeneca to evaluate BI-1206 in combination with rituximab and Calquence (acalabrutinib). The ongoing trial of BI-1206 in combination with rituximab in NHL has been expanded to include acalabrutinib.

In January 2023, BioInvent was selected as partner of Blood Cancer United (formerly The Leukemia & Lymphoma Society)'s Therapy Acceleration Program® (TAP), aimed at advancing the company's program to treat blood cancers. The partnership gives access to the unique scientific, clinical and drug development expertise of Blood Cancer United and entailed a strategic capital equity investment from them of USD 3 million.

OUTLOOK

Further Phase 2a triplet data for BI-1206 in combination with rituximab and acalabrutinib are expected already in H2 2025.

BI-1206 in solid tumors

The ongoing clinical program addresses the ability of BI-1206 to target an important mechanism of resistance to PD-1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors. Phase 1 data in solid tumors verify preclinical findings that BI-1206 significantly enhances the effect of anti-PD-1. Based on this evidence, MSD and BioInvent agreed to further investigate the synergies between BI-1206 and pembrolizumab in earlier lines of treatment. The ongoing Phase 2a study of BI-1206 in combination with pembrolizumab is performed in treatment-naïve patients with NSCLC and uveal melanoma.

STATUS

Clinical Phase 1/2a study with BI-1206 in combination with pembrolizumab (NCT04219254) ongoing

In October 2025, a Phase 2a clinical trial was initiated evaluating BI-1206 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced or metastatic non-small cell lung cancer (NSCLC) and uveal melanoma in the first-line setting.

As presented at ASCO 2024, in Phase 1, BI-1206 was deemed to be safe and well-tolerated and demonstrated promising clinical activity in heavily pre-treated patients, with one complete response (CR), one long-lasting partial response (PR), and 11 patients with stable disease (SD) out of 36 evaluable patients. All patients had progressed after previous treatments with anti-PD1/L1 agents. The subcutaneous formulation provided slower systemic entry and prolonged time on target while improving safety and tolerability.

NSCLC is the most common type of lung cancer, accounting for about 85 percent of all lung cancer cases. While checkpoint inhibitors are widely accepted and can produce durable responses in NSCLC, the overall response rate remains low, rarely exceeding 25 percent.

A common resistance mechanism in cancer is the binding and degradation of therapeutic antibodies against PD-1 such as pembrolizumab by FcγRIIB expressing immune cells. Therefore, based on preclinical and early clinical data, the company believes that resistance or lack of response to anti-PD-1 treatment may be overcome by FcγRIIB blockade in particular in subjects who have never been exposed to anti PD-1 agents.

STUDY DESIGN

The ongoing Phase 2a trial (NCT04219254) will evaluate the safety and efficacy of BI-1206 in combination with pembrolizumab in patients with advanced or metastatic NSCLC and uveal melanoma. Patients will be enrolled at sites in Georgia, Germany, Poland, Rumania, Spain, Sweden and the US, with first data expected in H2 2026.

The trial will be conducted in two parts. In the first part, or signal-seeking phase, up to 30 NSCLC and 12 uveal melanoma patients will receive BI-1206 and pembrolizumab every 21 days for up to 2 years. Following the signal-seeking phase, the study will proceed to a dose optimization phase, designed to refine the dosing strategy to maximize both efficacy and tolerability of the combination. During dose optimization, patients will be randomized to receive a higher or a lower dose of BI-1206. A third cohort will receive pembrolizumab alone.

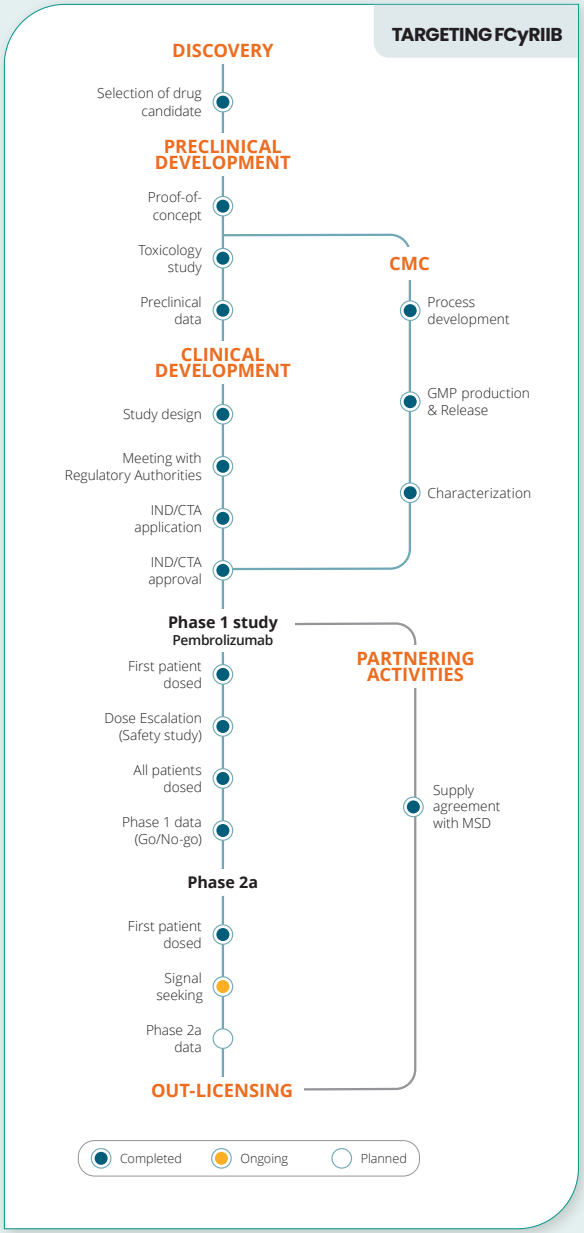
OUT-LICENSING AND PARTNERING

In December 2019 BioInvent entered into a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BioInvent's BI-1206 and MSD's anti-PD-1 therapy, KEYTRUDA (pembrolizumab) in a Phase 1/2a clinical trial for patients with solid tumors. Under the agreement, MSD supplies KEYTRUDA.

OUTLOOK

The first data from the Phase 2a study in first line NSCLC is expected in H2 2026.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.



Strategic collaborations

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

FOUR OUTLICENSED PROJECTS IN CLINICAL STUDIES

Program	Target	Primary indication	Phase 1	Phase 2	Phase 3	Market	Licensee
MT-2990	anti-IL33	Vasculitis (ANCA)					Mitsubishi Tanabe
Orticumab	anti-ApoB100	Cardiovascular					Abcentra
DS-1055	anti-GARP	Solid tumors					Daiichi-Sankyo
HMI-115	anti-PRLR	Endometriosis					Hope Medicine/Bayer

COLLABORATIONS WITH LEADING PHARMACEUTICAL COMPANIES

For its clinical programs, BioInvent has different kinds of collaborations with leading pharmaceutical companies such as CASI, MSD, AstraZeneca, and Transgene, see pages 5-9 and 11 for details.

BioInvent has five supply and collaboration agreements with MSD to support the expansion of the clinical trial programs for the anti-FcγRIIB antibodies BI-1206 and BI-1607, the anti-TNFR2 antibodies BI-1808 and BI-1910, and the oncolytic virus BT-001. The agreements with MSD give BioInvent the opportunity to explore the potential synergistic activity of its proprietary drug candidates in combination with pembrolizumab.

The agreement with AstraZeneca is a supply agreement to clinically evaluate Calquence® in combination with BI-1206 and rituximab.

As the external partners carefully review programs before establishing such agreements, these agreements provide further validation of the high quality of the programs.

STRATEGIC CLINICAL COLLABORATIONS

Since 2023, BioInvent has been a selected partner of Blood Cancer United's (former The Leukemia & Lymphoma Society) Therapy Acceleration Program® (TAP). The company has received a strategic equity investment of USD 3 million to support clinical advancement of BI-1206 in non-Hodgkin's Lymphoma and BI-1808 in cutaneous T-cell lymphoma. TAP is a strategic funding initiative to accelerate innovative blood cancer therapeutics worldwide.

ROYALTY TRANSACTION WITH XOMA

In May 2025, XOMA Royalty purchased the future mezagitamab (TAK-079) royalty and milestone interests held by BioInvent for a total transaction value of up to USD 30 million.

The future royalty and milestone economics interest in mezagitamab originated from a 2003 cross-licensing agreement covering XOMA Royalty's legacy bacterial protein expression technology and BioInvent's n-CoDeR® antibody library. Under the terms of XOMA Royalty's purchase of BioInvent's economic interest in mezagitamab, XOMA Royalty paid to BioInvent USD 20 million at closing and will pay an additional USD 10 million upon mezagitamab achieving a specific pre-defined regulatory milestone associated with receiving marketing approval in the IgA nephropathy indication from the U.S. Food and Drug Administration.

FOUR CLINICAL PROJECTS OUTLICENSED

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

BT-001

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

STATUS

Clinical phase 1/2a study (NCT04725331) ongoing

In October 2025, BioInvent and Transgene jointly presented a poster at the 2025 European Society for Medical Oncology (ESMO) Annual Meeting. The poster reported updated clinical results and positive antitumoral activity of BT-001 in patients with advanced refractory tumors. The data show that intra-tumoral (IT) BT-001 injection in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) intravenous (IV) anti-PD-1 therapy KEYTRUDA® (pembrolizumab), was well tolerated and showed positive local, abscopal, and sustained antitumoral activity in injected and non-injected lesions.

Long lasting partial responses (PRs) were observed in a patient with melanoma resistant to anti-PD-1/anti-CTLA-4 combination therapy and in a heavily pre-treated, PD-L1 negative leiomyosarcoma patient.

These immune-mediated tumor shrinkages are consistent with the mechanistic hypothesis that BT-001, in combination with pembrolizumab, turns "cold" tumors into immunologically active ones. The overall data support further development of BT-001 across a range of solid tumors to improve responses to cancer immunotherapies.

STUDY DESIGN

The Phase 1/2a study is a multicenter, open label, dose escalation trial evaluating BT-001 as a single agent and in combination with pembrolizumab (anti-PD-1 treatment).

The Phase 1 study is divided into two parts. In part A, patients with metastatic/advanced tumors received single agent, intra-tumoral administrations of BT-001. Part B is exploring intra-tumoral injections of BT-001 in combination with pembrolizumab.

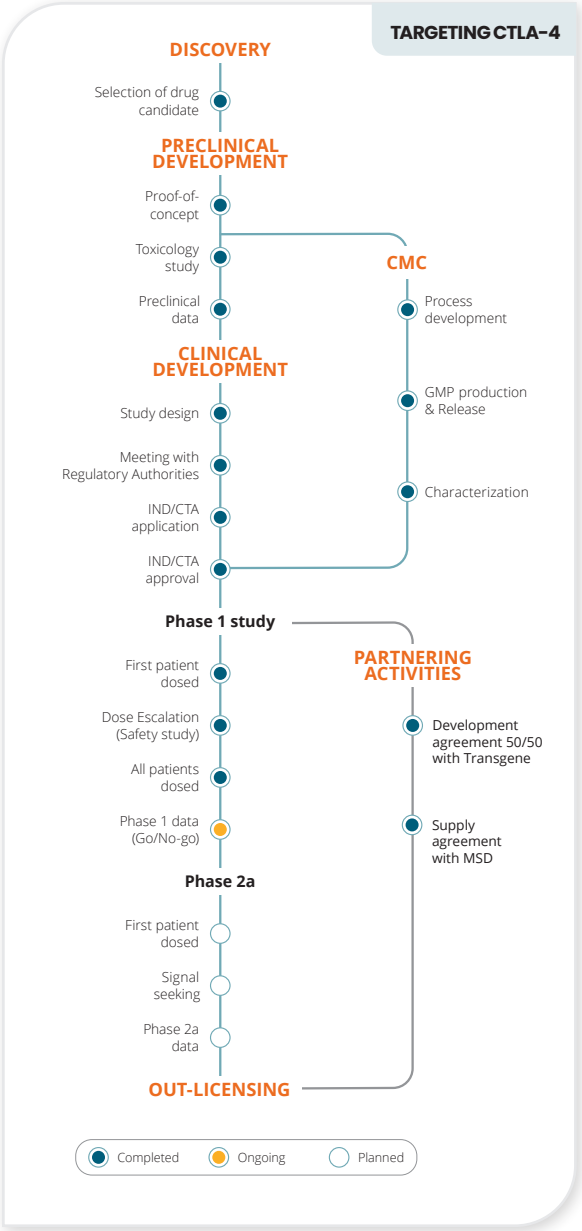
OUT-LICENSING AND PARTNERING

In June 2022, BioInvent and Transgene announced a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the oncolytic virus BT-001 in combination with MSD's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a Phase 1/2a clinical trial for the treatment of patients with solid tumors.

Since 2017, BioInvent and Transgene have been collaborating to develop the drug candidate BT-001, which encodes both a differentiated and proprietary CTLA-4 antibody and the cytokine GM-CSF. The research and development costs as well as revenue and royalties are shared 50:50.

OUTLOOK

BioInvent and its partner Transgene will continue the evaluation of BT-001 via an investigator initiated trial in an early-stage setting.



Discovery and preclinical development

BioInvent's discovery and 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.

Traditionally, drug discovery work is carried out according to a hypothesis in which first a receptor is found that is believed to be suitable for antibody drugs. The search then begins for antibodies that bind to this receptor. However, by combining new techniques looking simultaneously for both antibodies and the receptors they bind to, it is possible to find many more functioning antibodies than previously.

What BioInvent does is find antibodies against large amounts of different receptors on the cell and look at these antibodies' function directly. The strategy is to test how the antibodies work without any prior assumptions; for example, whether it can kill a tumor cell. Once we have identified which antibodies work, various tests are carried out to determine which receptor they bind to. By doing this, we have found antibodies that bind to cancer cells but not to normal cells in healthy individuals.

The process of looking for antibodies and targets simultaneously, rather than first finding a target and then looking for a suitable antibody is central in BioInvent's F.I.R.S.T™ platform. It is this strategy, combined with new techniques, that enables many more antibodies to be found than before. This method is important for the development of future antibody drugs that can be used to treat many different diseases.

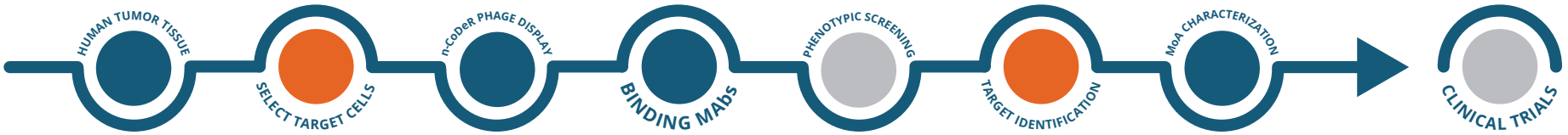
The Preclinical team at BioInvent is highly involved in all steps in a project – from idea to pulling out desired antibodies from our n-CoDeR library, functionally testing these in predictive cancer models, as well as in developing biomarkers for the clinic.

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

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

FUNCTION F.I.R.S.T DISCOVERY OF NEW ONCOLOGY TARGETS AND ANTIBODIES

Unique proprietary platform and deep immunology expertise yield both unique targets and high-quality antibodies.



Our approach contrasts with the more commonly used target-focused approach, where a target is picked on beforehand and consequently, functionality is restricted to this specified target. BioInvent applies a function-first approach, meaning it discovers the most functional antibodies to unknown targets, which can then be identified in a subsequent step. As such, BioInvent's approach discovers highly efficacious antibodies to targets that have not previously been pursued in cancer immunotherapy, as well as uniquely functional antibodies to validated targets. This is exemplified in, e.g., the company's BI-1808 first-in-class anti-TNFR2 antibody and the strongly Treg-depleting anti-CTLA-4 antibody that has been vectorized in the BT-001 program.

Financial information

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

Third quarter
Net sales amounted to SEK 3.3 million (12.8). Revenues for the period were mainly derived from production of antibodies for clinical studies.

Revenues for the corresponding period 2024 were mainly derived from production of antibodies for clinical studies. See also note 2.

The Company's total costs amounted to SEK 137.2 million (120.3). These are divided between external costs of SEK 95.7 million (85.6), personnel costs of SEK 36.7 million (29.9) and depreciation of SEK 4.8 million (4.8).

Research and development costs amounted to SEK 119.5 million (107.5). Sales and administrative costs amounted to SEK 17.7 million (12.8).

Profit/loss after tax amounted to SEK -129.2 million (-97.2). The net financial items amounted to SEK 4.5 million (9.9). Profit/loss per share before and after dilution amounted to SEK -1.96 (-1.48).

January – September
Net sales amounted to SEK 223.5 million (23.3). Revenues for the period were mainly derived from USD 20 million (SEK 191.0 million) BioInvent received when XOMA Royalty acquired the rights to future royalty and milestone interests for mezagitamab (TAK-079), prior to that a milestone payment of USD 1.0 million (SEK 9.9 million) was received in the collaboration, and revenue from production of antibodies for clinical studies.

Revenues for the corresponding period 2024 were mainly derived from production of antibodies for clinical studies and revenues from research services. See also note 2.

The Company's total costs amounted to SEK 445.5 million (369.0). These are divided between external costs of SEK 314.5 million (255.0), personnel costs of SEK 116.0 million (99.6) and depreciation of SEK 15.0 million (14.4).

Research and development costs amounted to SEK 392.0 million (328.4). Sales and administrative costs amounted to SEK 53.5 million (40.6).

Profit/loss after tax amounted to SEK -207.1 million (-312.5). The net financial items amounted to SEK 15.4 million (32.8). Profit/loss per share before and after dilution amounted to SEK -3.15 (-4.75).

FINANCIAL POSITION AND CASH FLOW
The share capital consists of 65,804,362 shares as of September 30, 2025.

As of September 30, 2025, the Group's liquid funds, current and long-term investments amounted to SEK 690.5 million (979.2). The cash flow from operating activities for the January-September period amounted to SEK -157.2 million (-282.2).

The shareholders' equity amounted to SEK 683.0 million (1,003.1) at the end of the period. The Company's share capital was SEK 13.2 million. The equity/assets ratio at the end of the period was 87 (92) percent. Shareholders' equity per share amounted to SEK 10.38 (15.24).

INVESTMENTS
Investments for the January- September period in tangible fixed assets amounted to SEK 6.0 million (9.2).

PARENT COMPANY
The main operations of the Group are conducted by the Parent Company. Except for financial leases, the Group's and the Parent Company's financial statements coincide in every material way.

ORGANIZATION
As of September 30, 2025, BioInvent had 124 (115) employees (full time equivalent). 110 (101) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS
For description of benefits to senior executives, see page 60 in the Company's annual report 2024. 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.

For a more detailed description of risk factors, see section "Risks and Risk Management", page 43, in the Company's annual report 2024.

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

	3 MONTHS 2025 JULY-SEP.	3 MONTHS 2024 JULY-SEP.	9 MONTHS 2025 JAN.-SEP.	9 MONTHS 2024 JAN.-SEP.	12 MONTHS 2024 JAN.-DEC.
Net sales	3,321	12,764	223,479	23,317	44,686
Operating costs					
Research and development costs	-119,458	-107,466	-391,972	-328,442	-457,733
Sales and administrative costs	-17,716	-12,819	-53,545	-40,602	-58,302
Other operating income and costs	247	375	-234	541	290
	-136,927	**-119,910**	**-445,751**	**-368,503**	**-515,745**
Operating profit/loss	**-133,606**	**-107,146**	**-222,272**	**-345,186**	**-471,059**
Profit/loss from financial investments	4,457	9,932	15,429	32,778	41,819
Profit/loss before tax	**-129,149**	**-97,214**	**-206,843**	**-312,408**	**-429,240**
Tax	-74	-28	-213	-87	-135
Profit/loss	**-129,223**	**-97,242**	**-207,056**	**-312,495**	**-429,375**
Other comprehensive income					
Items that have been or may be reclassified subsequently to profit or loss					
Translation differences for the period	-5	-	-45	-	-
Comprehensive income	**-129,228**	**-97,242**	**-207,101**	**-312,495**	**-429,375**
Profit/loss attributable to parent Company's shareholders	-129,223	-97,242	-207,056	-312,495	-429,375
Comprehensive income attributable to parent Company's shareholders	-129,228	-97,242	-207,101	-312,495	-429,375
Profit/loss per share, SEK					
Before dilution	-1.96	-1.48	-3.15	-4.75	-6.53
After dilution	-1.96	-1.48	-3.15	-4.75	-6.53

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

	2025 SEP. 30	2024 SEP. 30	2024 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	11,585	17,017	17,720
Tangible fixed assets - other	25,399	30,406	28,302
Financial fixed assets - long-term investments	-	29,065	-
Total fixed assets	**36,984**	**76,488**	**46,022**
Inventories	9,419	9,891	10,967
Current receivables	48,962	50,980	65,088
Current investments	207,181	232,752	432,333
Liquid funds	483,274	717,362	434,826
Total current assets	**748,836**	**1,010,985**	**943,214**
Total assets	**785,820**	**1,087,473**	**989,236**
SHAREHOLDERS' EQUITY			
Total shareholders' equity	**683,016**	**1,003,093**	**885,815**
LIABILITIES			
Lease liabilities	1,593	8,315	8,215
Total long term liabilities	**1,593**	**8,315**	**8,215**
Lease liabilities	9,093	8,709	9,198
Other liabilities	92,118	67,356	86,008
Total short term liabilities	**101,211**	**76,065**	**95,206**
Total shareholders' equity and liabilities	**785,820**	**1,087,473**	**989,236**

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

	2025 JULY-SEP.	2024 JULY-SEP.	2025 JAN.-SEP.	2024 JAN.-SEP.	2024 JAN.-DEC.
Shareholders' equity at beginning of period	**810,744**	**1,097,516**	**885,815**	**1,309,727**	**1,309,727**
Comprehensive income					
Profit/loss	-129,223	-97,242	-207,056	-312,495	-429,375
Other comprehensive income	-5	-	-45	-	-
Total comprehensive income	**-129,228**	**-97,242**	**-207,101**	**-312,495**	**-429,375**
Total, excluding transactions with equity holders of the Company	**681,516**	**1,000,274**	**678,714**	**997,232**	**880,352**
Transactions with equity holders of the Company					
Employee options program	1,500	2,819	4,302	5,861	5,463
Shareholders' equity at end of period	**683,016**	**1,003,093**	**683,016**	**1,003,093**	**885,815**

The share capital as of September 30, 2025 consists of 65,804,362 shares and the share's ratio value was 0.20.

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

	2025 JULY-SEP.	2024 JULY-SEP.	2025 JAN.-SEP.	2024 JAN.-SEP.	2024 JAN.-DEC.
Operating activities					
Operating profit/loss	-133,606	-107,146	-222,272	-345,186	-471,059
Depreciation	4,812	4,832	15,019	14,424	19,300
Adjustment for other non-cash items	1,500	2,819	4,302	5,861	5,463
Interest received and paid	3,541	19,957	22,392	38,887	58,369
Income taxes paid	-	-	-164	-114	-114
Cash flow from operating activities before changes in working capital	**-123,753**	**-79,538**	**-180,723**	**-286,128**	**-388,041**
Changes in working capital	19,770	-17,511	23,518	3,969	7,572
Cash flow from operating activities	**-103,983**	**-97,049**	**-157,205**	**-282,159**	**-380,469**
Investment activities					
Acquisition of tangible fixed assets	-1,834	-1,978	-5,981	-9,185	-10,034
Changes of financial investments	183,561	350,974	216,389	744,835	574,380
Cash flow from investment activities	**181,727**	**348,996**	**210,408**	**735,650**	**564,346**
Cash flow from operating activities and investment activities	**77,744**	**251,947**	**53,203**	**453,491**	**183,877**
Financing activities					
Amortization of lease liability	-2,258	-2,087	-6,728	-6,220	-8,455
Cash flow from financing activities	**-2,258**	**-2,087**	**-6,728**	**-6,220**	**-8,455**
Change in liquid funds	**75,486**	**249,860**	**46,475**	**447,271**	**175,422**
Opening liquid funds	404,053	470,255	434,826	259,548	259,548
Accrued interest on investments classified as liquid funds	3,735	-2,753	1,973	10,543	-144
Liquid funds at end of period	**483,274**	**717,362**	**483,274**	**717,362**	**434,826**
Liquid funds, specification:					
Cash and bank	86,633	37,692	86,633	37,692	75,564
Current investments, equivalent to liquid funds	396,641	679,670	396,641	679,670	359,262
	483,274	**717,362**	**483,274**	**717,362**	**434,826**

Key financial ratios for the Group

	2025 SEP. 30	2024 SEP. 30	2024 DEC. 31
Shareholders' equity per share at end of period, SEK	10.38	15.24	13.46
Number of shares at end of period (thousand)	65,804	65,804	65,804
Equity/assets ratio, %	86.9	92.2	89.5
Number of employees at end of period	124	115	114

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

	3 MONTHS 2025 JULY-SEP.	3 MONTHS 2024 JULY-SEP.	9 MONTHS 2025 JAN.-SEP.	9 MONTHS 2024 JAN.-SEP.	12 MONTHS 2024 JAN.-DEC.
Net sales	3,321	12,764	223,479	23,317	44,686
Operating costs					
Research and development costs	-118,793	-107,650	-392,551	-328,651	-458,125
Sales and administrative costs	-17,879	-12,834	-53,928	-40,620	-58,336
Other operating income and costs	247	375	-234	541	290
	-136,425	**-120,109**	**-446,713**	**-368,730**	**-516,171**
Operating profit/loss	**-133,104**	**-107,345**	**-223,234**	**-345,413**	**-471,485**
Profit/loss from financial investments	4,547	10,059	15,743	33,198	42,352
Profit/loss after financial items	**-128,557**	**-97,286**	**-207,491**	**-312,215**	**-429,133**
Tax	-32	-28	-117	-87	-135
Profit/loss	**-128,589**	**-97,314**	**-207,608**	**-312,302**	**-429,268**
Other comprehensive income	**-**	**-**	**-**	**-**	**-**
Comprehensive income	**-128,589**	**-97,314**	**-207,608**	**-312,302**	**-429,268**

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

	2025 SEP. 30	2024 SEP. 30	2024 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	25,399	30,406	28,302
Financial fixed assets - Shares in subsidiaries	1,008	687	687
Financial fixed assets - long-term investments	-	29,065	-
Total fixed assets	**26,407**	**60,158**	**28,989**
Current assets			
Inventories	9,419	9,891	10,967
Current receivables	50,610	52,135	66,470
Current investments	207,181	232,752	432,333
Cash and bank	482,844	717,362	434,826
Total current assets	**750,054**	**1,012,140**	**944,596**
Total assets	**776,461**	**1,072,298**	**973,585**
SHAREHOLDERS' EQUITY			
Restricted equity	40,854	40,854	40,854
Non-restricted equity	642,769	963,439	846,075
Total shareholders' equity	**683,623**	**1,004,293**	**886,929**
LIABILITIES			
Short term liabilities	92,838	68,005	86,656
Total short term liabilities	**92,838**	**68,005**	**86,656**
Total shareholders' equity and liabilities	**776,461**	**1,072,298**	**973,585**

Lund, October 29, 2025

Martin Welschof
CEO

Review report

INTRODUCTION
We have reviewed the summarized interim financial information (interim report) for BioInvent International AB (publ) on September 30, 2025 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 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, 2025

KPMG AB

Linda Bengtsson
Authorized Public Accountant
Auditor in charge

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 2025 has had no material impact on the financial statements.

Except for leases, the Group's and the Parent Company's financial statements coincide in every material way.

Disclosures according to IAS 34.16A appear in addition to the financial statements and their associated notes, also in other parts of the interim report.

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

NOTE 2 NET REVENUE

SEK THOUSAND	2025 JULY-SEP.	2024 JULY-SEP.	2025 JAN.-SEP.	2024 JAN.-SEP.	2024 JAN.-DEC.
Revenue by geographical region:					
Sweden	2,036	683	12,241	3,389	3,887
Europe	134	590	968	2,415	2,926
USA	1,151	11,299	209,958	16,844	36,822
Other countries	-	192	312	669	1,051
	3,321	**12,764**	**223,479**	**23,317**	**44,686**
Revenue consists of:					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	-	-	572	572
Revenue from technology licenses	-	-	200,941	-	-
Revenue from external development projects	3,321	12,764	22,538	22,745	44,114
	3,321	**12,764**	**223,479**	**23,317**	**44,686**

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

In January-September 2025, BioInvent had one customer where revenues exceeded ten percent of total revenues. Revenues for the customer amounted to SEK 200.9 million (90%) of total revenues of SEK 223.5 million.

In January-September 2024, BioInvent had two customers where revenues exceeded ten percent of total revenues. Revenues for these customers amounted to SEK 16.2 million (69%) and SEK 3.3 million (14%) of total revenues of SEK 23.3 million.

In the 2024 financial year, BioInvent had one customer where revenues exceeded ten percent of total revenues. Revenues for the customer amounted to SEK 36.0 million (81%) of total revenues of SEK 44.7 million.

NOTE 3 EVENTS AFTER THE REPORTING PERIOD

- Phase 2a trial started with BI-1206 in combination with pembrolizumab in advanced or metastatic NSCLC and uveal melanoma
- Phase 1 clinical data for BI-1910, a TNFR2 Agonist for the treatment of solid tumors, to be presented at SITC
- Transgene and BioInvent presented translational data and updated clinical results on armed oncolytic virus BT-001 at ESMO 2025

(R)= Regulatory event

Other information

ANNUAL GENERAL MEETING
The Annual General Meeting will be held on April 29, 2026, at 4 p.m. Elite Hotel Ideon, Scheelevägen 27, Lund. Notice to attend will be announced in Post- och Inrikes Tidningar and on the Company website.

FINANCIAL CALENDAR
- Year-end report: February 26, 2026
- Interim report Q1: April 29, 2026
- Interim report Q2: August 27, 2026
- Interim report Q3: October 29, 2026

CONTACT
Any questions regarding this report will be answered by
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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 outcome may deviate significantly from the scenarios described in this interim report.

TRADEMARKS
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Interview with Dr. Andres McAllister, BioInvent CMO

In this interview, originally published by Biostock, Dr. Andres McAllister, CMO at BioInvent, provides an in-depth description of BI-1206, one of the company's two most promising assets.

WHAT DOES THE START OF THIS PHASE IIA STUDY MEAN FOR BIOINVENT AND BI-1206?
"The launch of this study marks a pivotal moment for BioInvent. It's the first time we're evaluating BI-1206 in treatment-naive patients, which allows us to better understand its full therapeutic potential earlier in the disease course. It also reflects our confidence in the molecule's ability to enhance checkpoint inhibitor efficacy."

WHY IS IT IMPORTANT TO STUDY TREATMENT-NAIVE PATIENTS THIS TIME?
"In phase I, we saw promising responses in heavily pre-treated patients, that included several lines of treatment with immunotherapeutic agents. However, treatment-naive patients offer a better clinical situation to characterize the therapeutic potential. Their immune system has not been altered by prior therapies, which gives us a clearer view of how BI-1206 interacts with pembrolizumab and the tumor microenvironment."

WHAT LESSONS FROM PHASE I HELPED SHAPE THIS NEW TRIAL?
"Phase I taught us that BI-1206 is well tolerated and showed signs of robust and durable responses, even in patients who had failed previous immunotherapies. These insights helped us refine the dosing strategy and the transition to subcutaneous administration, which may improve target engagement and convenience for patients and clinicians."

HOW DOES BI-1206 ACTUALLY HELP OVERCOME RESISTANCE TO DRUGS LIKE KEYTRUDA?
"BI-1206 targets FcγRIIB, a receptor that dampens immune activation and contributes to resistance against anti-PD-1 therapies like Keytruda. FcγRIIB is the only inhibitory Fc receptor (all other Fc receptors activate the immune system), and it is also the most highly expressed in the tumor microenvironment. By blocking FcγRIIB, BI-1206 reactivates immune cells and enhances the anti-tumor response, potentially converting non-responders into responders, and prolonging and deepening the quality of the responses."

WHY WERE NSCLC AND UVEAL MELANOMA SELECTED AS THE FOCUS FOR THIS TRIAL?
"NSCLC represents a major unmet need, with variable responses to PD-1 inhibitors depending on PD-L1 expression. It also represents an ideal opportunity to test the activity of BI-1206 and Keytruda, without chemotherapy or any other agents, and yet in the frontline treatment. This makes it a very clean experimental situation because patients will receive the standard of care for their disease, with the addition of BI-1206. Uveal melanoma has very limited treatment options and poor response rates to current immunotherapies. Both indications offer a strong rationale for testing BI-1206's ability to boost checkpoint blockade. If the responses are as we expect, this will drive major inflexion points for the value of BI-1206."

HOW DOES THE TWO-PART STUDY DESIGN STRENGTHEN YOUR CHANCES OF SUCCESS?
"The study begins with a signal-seeking phase to identify early signs of efficacy in up to 30 NSCLC and 12 uveal melanoma patients. This is followed by a dose optimization phase. It's a flexible design that allows us to adapt based on initial findings and maximize the likelihood of meaningful clinical benefit. During the second part (dose optimization) two cohorts will receive BI-1206 and pembrolizumab, and one cohort will receive pembrolizumab alone. This will help us establish the magnitude of BI-1206's contribution to the response."

WHAT WILL YOU BE LOOKING FOR AS EARLY INDICATORS OF SUCCESS?
"We'll be monitoring objective response rates, duration of response, and biomarker changes—particularly in PD-L1 expression and immune cell activation. Stable disease and partial responses in early cohorts would be encouraging signs."

HOW HAS THE COLLABORATION WITH MSD CONTRIBUTED TO THE PROGRAM'S PROGRESS?
"MSD's support has been instrumental. Providing Keytruda for our studies and their shared commitment to exploring combination strategies has enabled our development strategy and has added credibility to the program. They are an ideal partner!"

WHEN DO YOU EXPECT THE FIRST RESULTS?
"We anticipate initial readouts from the signal-seeking phase in the second half of 2026. These will guide the dose optimization and help us determine the next steps for broader clinical development."

LOOKING AHEAD, WHAT ROLE COULD BI-1206 PLAY IN CANCER IMMUNOTHERAPY?
"If successful, BI-1206 could become a key component in overcoming resistance and enhancing the activity of immune checkpoint inhibitors. We now know that the activity of these agents is strongly influenced by Fc receptors, and among them, a key determinant is the inhibitory FcγRIIB. In that context, our initial data in lung cancer will very likely reflect the situation in other tumor types. Thus, we believe BI-1206 has the potential to expand the reach of immunotherapy to patients who currently do not benefit, and to deepen responses in those who do in many different indications."

"The fact that it is administered through a simple and quick subcutaneous administration adds to the value, in particular considering that the subcutaneous formulation of Keytruda has recently been approved. We are envisioning the moment when lung and other cancer types will be treated with convenient and effective treatments, and this will be one important milestone towards that end."