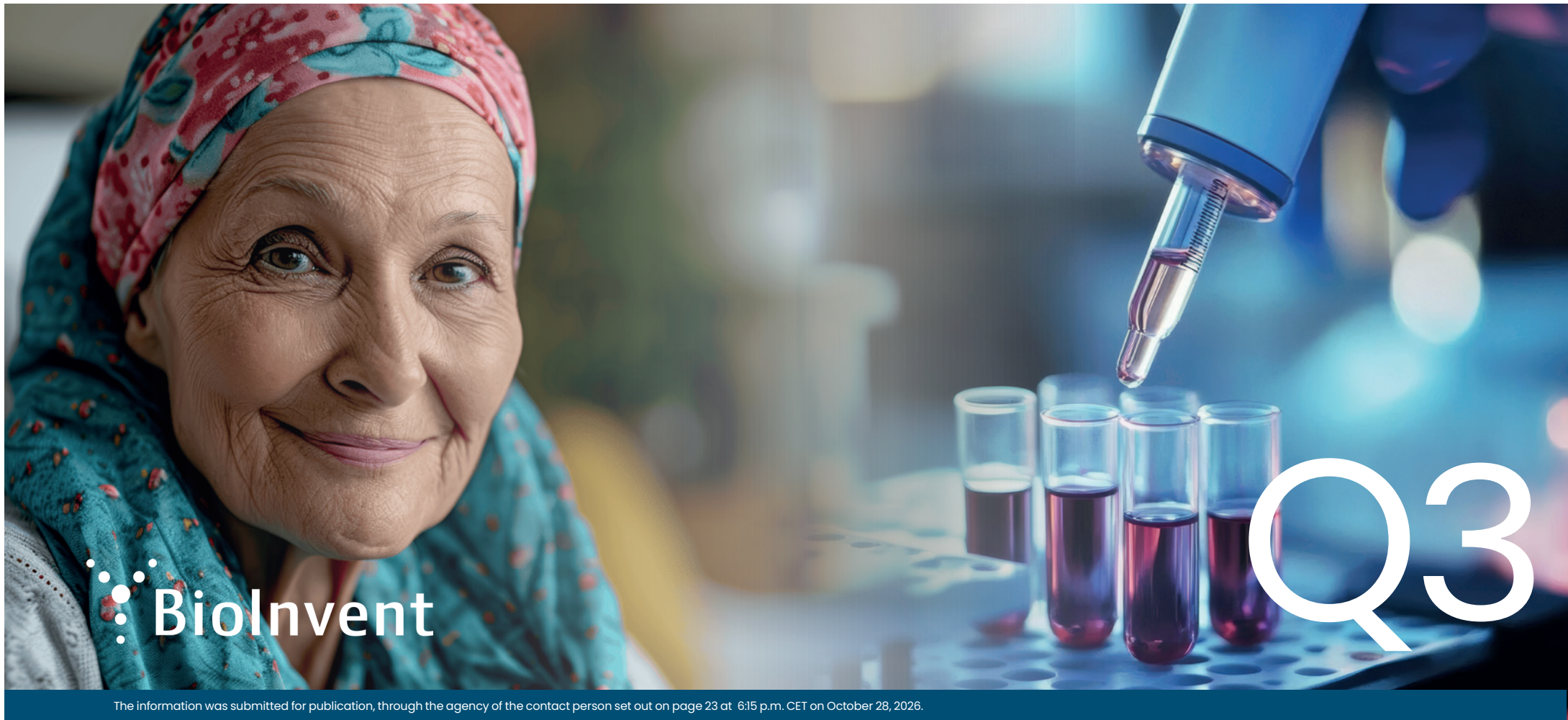


BioInvent International AB (publ)

Interim Report January 1 – September 30, 2026



Highlights in the third quarter 2026

EVENTS IN THE THIRD QUARTER

- BI-1808 received FDA Fast Track Designation for the treatment of ovarian cancer
- BioInvent's BI-1808 abstract from Modest to Meaningful in platinum-resistant ovarian cancer accepted for poster presentation at ESMO 2026
- BioInvent published two scientific papers in peer-reviewed journals. One in Cancer Research: "Ligand-Blocking and Agonist Antibodies Targeting TNFR2 Employ Distinct Modes of Action to Induce Antitumor Immunity" and one in JECRC: Tailored FcγR Blockade with BI-1206 and BI-1607 Enhances Cancer Antibody Therapies and Overcomes Resistance in Preclinical Models

EVENTS AFTER THE END OF THE PERIOD

- (R) The Board of Directors has decided to carry out a rights issue of approximately SEK 430 million (gross, before issue costs), of which SEK 350 million is covered by subscription commitments and guarantee undertakings, subject to approval at an Extraordinary General Meeting
- (R) Streamlining of the organization to support prioritized clinical programs
- (R) BI-1808 and KEYTRUDA® induce durable responses in heavily pretreated platinum-resistant ovarian cancer. The poster was granted Best Poster Award, Investigational Immunotherapy at ESMO 2026
- (R) The company announced that its CFO will retire in 2027
- First-in-Human BI-1808 Data Published in Clinical Cancer Research

(R) = Regulatory event

All figures in SEK million unless otherwise stated	THIRD QUARTER		JANUARY–SEPTEMBER	
	2026	2025	2026	2025
Net sales	10.8	3.3	37.0	223.5
Profit/loss after tax	-118.9	-129.2	-361.0	-207.1
Profit/loss after tax per share before and after dilution, SEK	-1.81	-1.96	-5.49	-3.15
Cash flow from operating activities	-113.5	-104.0	-358.3	-157.2
Liquid funds and current investments at the end of the period	224.6	690.5	224.6	690.5

Note to the reader. 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.



BI-1808 Development Defines Next Steps

Encouraging clinical progress in ovarian cancer and a planned financing to support the next phase of development

The rights issue announced today is intended to provide BioInvent with the financial resources to advance its prioritized clinical programs, with a particular focus on BI-1808 in platinum-resistant ovarian cancer. Building on the encouraging and durable responses observed to date, we plan to initiate a randomized Phase 2a study in Q1 2027 to further evaluate BI-1808 in combination with Keytruda and paclitaxel, with first data expected in the second half of 2027.

In parallel, we are sharpening our strategic focus and adapting our organization to concentrate resources on our most promising clinical opportunities. We have also engaged an experienced international business development adviser to support partnering discussions across our pipeline.

Together, these initiatives are intended to strengthen BioInvent's position as we advance towards important clinical milestones and seek to unlock the potential of our programs for patients and shareholders.

At ESMO 2026, we presented updated data showing that BI-1808 combined with pembrolizumab continues to deliver durable responses in heavily pretreated platinum-resistant ovarian cancer. With 34 evaluable patients, the 24% response rate presented at ASCO remains the same, and the com-

bination is safe and well tolerated. Building on these results, we plan to start a randomized Part C in Q1 2027, adding BI-1808 to the newly established pembrolizumab and paclitaxel backbone. The poster was granted "Best poster award", Investigational Immunotherapy. This award recognizes researchers, clinicians, and scientists who present standout poster abstracts demonstrating high scientific relevance, innovative research design, or impactful clinical data in oncology.

Winning the award highlights the quality of both the underlying data and the clear, structured presentation of complex medical research.

In early August, the FDA granted Fast Track Designation to BI-1808 for the treatment of ovarian cancer. In October, Clinical Cancer Research published Phase 1 data showing that the mechanism we characterized in preclinical models translates to treated patients, with dose-dependent regulatory T-cell (Treg) depletion at every dose level.

These steps build on the results we presented earlier this year: a 24% objective response rate for BI-1808 plus pembrolizumab in recurrent ovarian cancer at ASCO, and an 83% objective response rate for the BI-1206 triplet in relapsed/refractory NHL at EHA. Both programs are moving beyond

single read-outs toward the evidence base needed to support pivotal trial design.

For BI-1206, our anti-FcγRIIB antibody, Phase 2a work continues toward first solid tumor data and a potential pivotal trial in non-Hodgkin's lymphoma (NHL).

BI-1808 (ANTI-TNFR2)

Encouraging ESMO data in 34 patients

The updated analysis (cutoff September 14, 2026) includes 34 evaluable patients, up from 25 at ASCO, with a median of four prior lines of therapy. Eight patients responded (one complete and seven partial responses), for an objective response rate of 24%, including patients with high-grade serous and clear cell histology and patients with active liver metastases. The disease control rate was 53%, with several patients in stable disease beyond 10 months, and six patients remained on treatment at cutoff. Duration of response was not met at cutoff (median follow-up 11.6 months), suggesting that responses are durable.

Median progression-free survival was 4.1 months by RECIST and 10.3 months by iRECIST, a criterion designed to capture delayed responses. For context, KEYNOTE-100 reported 2.1 months by RECIST for pembrolizumab alone (an indirect comparison).

Treatment-related discontinuations occurred in fewer than 5% of the 81 solid



Martin Welschhof, CEO

tumor patients treated with the combination to date, and biomarker data were consistent with the mechanism, including Treg reduction and induction of cytokines and chemokines linked to myeloid reprogramming and tertiary lymphoid structure formation.

Following the KEYNOTE-B96 results, which established pembrolizumab plus weekly paclitaxel, with or without bevacizumab, as a new standard of care in this setting, Part C will randomize 20 patients to each of three arms: BI-1808 at 1000 mg, BI-1808 at 500 mg, or control, each with pembrolizumab and paclitaxel. Part C is expected to start in Q1 2027, with first data in H2 2027.

Randomized triplet study to start in Q1 2027

Part C will evaluate a randomized triplet of BI-1808, pembrolizumab and weekly paclitaxel, with or without bevacizumab, in patients with platinum-resistant ovarian cancer. New preclinical studies show that BI-1808 combines with paclitaxel, alone and with anti-PD-1 therapy, and that adding BI-1808 increases intratumoral immune activation and improves survival in experimental models compared with paclitaxel with or without anti-PD-1 therapy. Enrollment to the BI-1808 plus pembrolizumab combination cohort is complete.

Fast Track Designation now covers ovarian cancer and two CTCL subtypes

The ovarian cancer designation reflects the significant unmet medical need in this difficult-to-treat disease. BI-1808 also holds Fast Track Designation for relapsed or refractory mycosis fungoides and Sézary

syndrome, which are forms of cutaneous T-cell lymphoma (CTCL).

Phase 1 monotherapy results published: no maximum tolerated dose

In October, we announced publication of the first-in-human Phase 1 results for BI-1808 in Clinical Cancer Research. The study treated 24 patients with advanced solid tumors across five dose cohorts. It did not identify a maximum tolerated dose, with no dose-limiting toxicities and no deaths, and all treatment-related adverse events were Grade 1 or 2. Tumor regression occurred in 2 of 21 evaluable patients, including a partial response lasting more than two years in a patient with GIST. Treg depletion was dose dependent at all dose levels and sustained at 1000 mg every three weeks, the recommended Phase 2 dose. A complementary paper in Cancer Research describes how ligand-blocking and agonist antibodies targeting TNFR2 use distinct modes of action to induce antitumor immunity.

BI-1206 (ANTI-FCγRIIB)

BI-1206 data in NHL Phase 2a triplet data are maturing, no clinical data in 1L NSCLC yet

The most recent clinical data for BI-1206 come from the Phase 2a triplet with rituximab and acalabrutinib in relapsed/refractory NHL. At the May 6, 2026 cutoff, the triplet achieved an 83% objective response rate among 23 evaluable patients, with 11 complete responses and 8 partial responses. Phase 2a triplet data are maturing to be ready for a potential pivotal trial, pending partnering.

In our recent publication in Journal of Experimental & Clinical Cancer Research (JECCR), preclinical models showed that tailored FcγR blockade with BI-1206 and BI-1607 (currently paused) enhances cancer antibody therapies and overcomes resistance. The Phase 2a study of BI-1206 plus pembrolizumab in first-line non-small cell lung cancer (NSCLC) and uveal melanoma continues, with first data expected in H1 2027 (previously H2 2026), due to ongoing patient follow-up.

FINANCING AND ORGANIZATION

To secure funding for our clinical programs, the Board has decided to carry out a rights issue of approximately SEK 430 million (gross, before issue costs), of which SEK 350 million is covered by subscription commitments and guarantee undertakings, subject to approval at an Extraordinary General Meeting on December 1.

As part of adapting to our project needs and financial situation, we will reduce the organization with up to 20 positions. The reduction is designed to preserve our core capabilities and keep the focus on advancing primarily BI-1808 and secondly BI-1206.

STEFAN ERICSSON TO RETIRE AS CFO IN JANUARY 2027

On October 12, we announced that Stefan Ericsson, our Chief Financial Officer, will retire when he turns 64 in January 2027. He has been with BioInvent since 1998 and will remain in his current role until his departure in January 2027 and a successor has taken office. We thank Stefan for nearly 30 years of outstanding service.

MILESTONES AHEAD

We expect the following key events:

H1 2027:

- Start of the BI-1808 Phase 2a randomized triplet study (60 patients) in ovarian cancer (Part C)
- First read-out from the Phase 2a study of BI-1206 in combination with Keytruda® for treatment-naïve NSCLC patients and uveal melanoma patients

H2 2027:

- First Phase 2a data from BI-1808 triplet study (+Keytruda® + paclitaxel +/- bevacizumab) in ovarian cancer
- Potential start of Phase 2b BI-1206 in combination with Keytruda®, pending partnering

OUR FOCUS

Our clinical portfolio remains focused on two targets, TNFR2 and FcγRIIB, but with a current priority on BI-1808 in cancers where patients have few effective options. With the planned rights issue and a leaner organization, we aim to secure the resources to advance BI-1808 into randomized and potentially pivotal studies, while continuing to develop BI-1206 together with a partner. Thank you to all the patients, investigators, employees and shareholders who support this work.

Sincerely,

Martin Welschhof
Chief Executive Officer

Sharp focus to maximize clinical and commercial success

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 FcγRIIB, but with a current priority on BI-1808 in cancers where patients have few effective options.

A supply agreement with MSD supports the combination study with pembrolizumab of our BI-1808 and BI-1206 solid tumor programs and the triplet study of BI-1206 in NHL is conducted under a supply agreement for acalabrutinib with AstraZeneca.

BI-1808

BI-1808 is a first-in-class monoclonal antibody targeting TNFR2, a novel immuno-modulatory target with potential for therapeutic efficacy across many tumor types. It selectively focuses on TNFR2, a target

which is overexpressed on immune cells of the tumor microenvironment and is now known to promote cancer progression.

BI-1808 is associated with several crucial activities such as depletion of Tregs, expansion of effector T-cells, and reprogramming of myeloid cells, and potential direct killing of tumoral T-cells in the case of T-cell lymphomas. Its strong safety and tolerability features allow single agent administration as well as combinations for high clinical impact.

BI-1206

BI-1206 is a first-in-class, high-affinity monoclonal antibody targeting FcγRIIB (CD32B), the only inhibitory Fcγ receptor and a key resistance mechanism to several antibody-based cancer therapies.

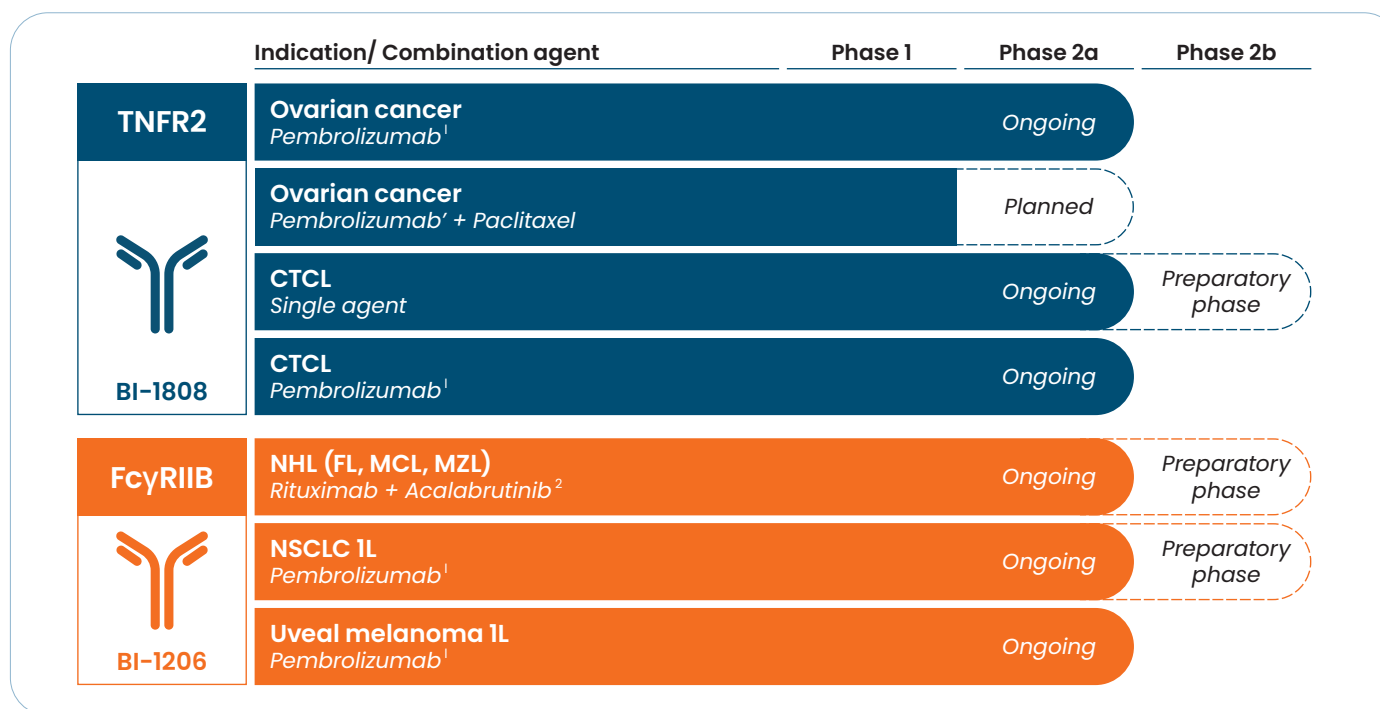
FcγRIIB is overexpressed in multiple forms of non-Hodgkin's lymphoma (NHL) and is associated with poor prognosis in difficult-to-treat subtypes such as mantle cell lymphoma. By blocking FcγRIIB, BI-1206 is designed to restore and enhance the activity of rituximab and other anti-CD20 antibodies, overcoming a well-recognized barrier to effective treatment.

BioInvent's preclinical data has demonstrated the ability of BI-1206 to address an important mechanism of resistance to PD-1 inhibition, providing a way to enhance anti-tumor immune responses in patients with solid tumors.

CTCL: Cutaneous T-cell Lymphoma
NHL: Non-Hodgkin's Lymphoma
FL: Follicular Lymphoma
MCL: Mantle Cell Lymphoma
MZL: Marginal Zone Lymphoma
1L: First-line treatment
NSCLC: Non-small cell lung cancer

Notes

1. Supply agreement with MSD
2. Supply agreement with AstraZeneca





BI-1808 for the treatment of ovarian cancer

BI-1808 is a first-in-class antibody targeting TNFR2 and is part of BioInvent's program against tumor-associated regulatory T cells (Tregs). The antibody blocks TNFR2 signaling and is designed to deplete immunosuppressive Tregs in the tumor and modulate the myeloid compartment, which is intended to promote activation and expansion of tumor-reactive CD8+ T cells. BI-1808 is being developed for solid tumors and T-cell lymphoma and is being evaluated in an ongoing Phase 1/2a study, in which the combination with pembrolizumab has shown clinical efficacy and good tolerability in ovarian cancer.

STATUS

BI-1808: ovarian cancer data presented at ESMO 2026

Enrollment in the ovarian cancer cohort of Part B of the BI-1808 Phase 1/2a study (NCT04752826, KEYNOTE-D20) has been completed. The cohort evaluates BI-1808 in combination with pembrolizumab (KEYTRUDA®) in heavily pretreated patients with platinum-resistant recurrent ovarian cancer. Updated data vs ASCO 2026 were presented in a poster at the ESMO Congress 2026 on October 24.

At September 14, 2026 data cutoff, 8 of 34 evaluable patients had an objective response (1 complete and 7 partial responses; objective response rate 24%). The

disease control rate was 53%, with several patients in stable disease for more than 10 months, and 6 patients remained on treatment. Preliminary median progression-free survival was 4.1 months per RECIST 1.1, compared with 2.1 months reported for pembrolizumab alone in KEYNOTE-100 (an indirect comparison), and 10.3 months per iRECIST, which captures delayed responses. Responses were seen in both high-grade serous and clear cell histology, including in patients with liver metastases.

The combination was well tolerated, with fewer than 5% treatment-related discontinuations among the 81 patients with solid tumors treated to date. Translational data showed Treg depletion and CD8+ T-cell activation, as well as signs of myeloid reprogramming and tertiary lymphoid structure formation.

Based on these results, BioInvent plans to start Part C, a randomized evaluation of two BI-1808 dose levels (1000 mg and 500 mg) versus control, each combined with pembrolizumab and weekly paclitaxel with or without bevacizumab.

STUDY DESIGN

This Phase 1/2a trial (NCT04752826) is designed to assess the safety and tolerability of BI-1808 as a single agent (Part A), in combination with pembrolizumab (Part B) and in a triple combination with pembrolizumab and paclitaxel (Part C). The study

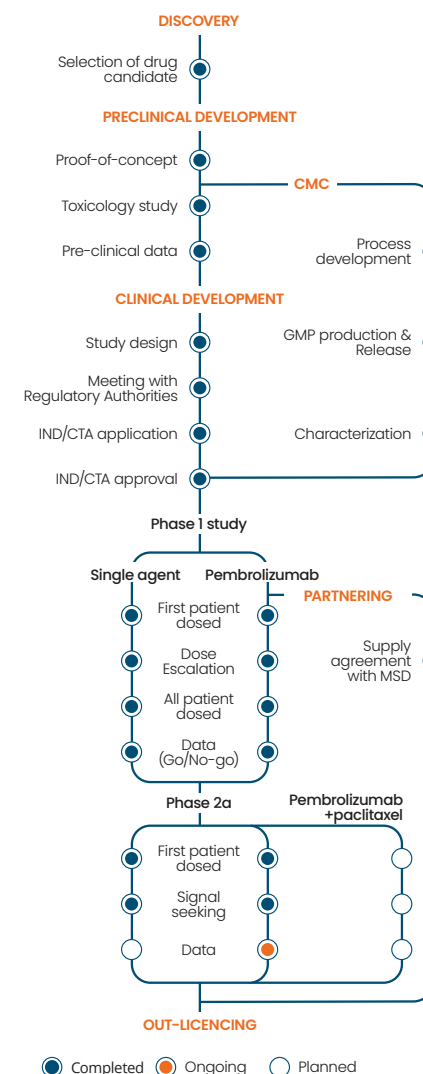
aims to characterize safety, pharmacokinetics and pharmacodynamics, and assess preliminary antitumor activity by ORR, DoR (duration of response), and progression-free survival (PFS), as measured by RECIST v1.1 and iRECIST.

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

Part C (BI-1808 + standard-of care) of the Phase 1/2a trial is expected to start in Q1 2027, with first data expected in the second half of 2027.





BI-1808 for the treatment of CTCL

BioInvent's anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate in clinical development for cutaneous T-cell lymphoma (CTCL) and solid tumors. In the ongoing CTCL cohort of the Phase 1/2a study, BI-1808 has shown single-agent activity, as well as promising signs of efficacy and a favorable safety profile in combination with pembrolizumab. BI-1808 has been granted FDA Fast Track Designation for relapsed or refractory mycosis fungoides and Sézary syndrome, FDA Orphan Drug Designation for T-cell lymphoma, and EMA Orphan Drug Designation for CTCL.

STATUS

Efficacy in clinical Phase 1/2a study in CTCL

In June 2026, 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) 2026 Congress in Stockholm, Sweden in a poster titled "Targeting TNFR2 with BI-1808 with or without pembrolizumab: Immune activation and promising responses in advanced cutaneous T-cell lymphomas (CTCLs)".

Low Rate of Severe Side Effects Allows Patients to Remain on Treatment Long-Term

BI-1808 was very well tolerated as a single agent. Only one patient (4%) discontinued due to an adverse event. The combination with pembrolizumab was generally well tolerated in this heavily pretreated population.

BI-1808 Single Agent Cohort

Of 15 patients evaluable, BI-1808 achieved an ORR of 40%, with 5 confirmed partial responses across both MF and SS subtypes, and one Sézary syndrome patient achieving a complete response that remains ongoing at approximately two years. Eight additional patients achieved stable disease as best response, corresponding to a disease control rate (DCR) of 93%. Two patients with peripheral T-cell lymphoma (PTCL), an aggressive type of lymphoma, were also evaluable, with one achieving a partial response and one stable disease.

Combination with Pembrolizumab

Of 8 evaluable patients in the combination arm, 4 achieved a partial response at first assessment and 2 achieved stable disease, resulting in an ORR of 50% and a DCR of 75%. The lower DCR of 75% in the combination arm compared to 93% in the

monotherapy arm is consistent with the smaller, more heavily pretreated patient population evaluated to date.

Translational data from the study provides important mechanistic support for BI-1808's activity.

STUDY DESIGN

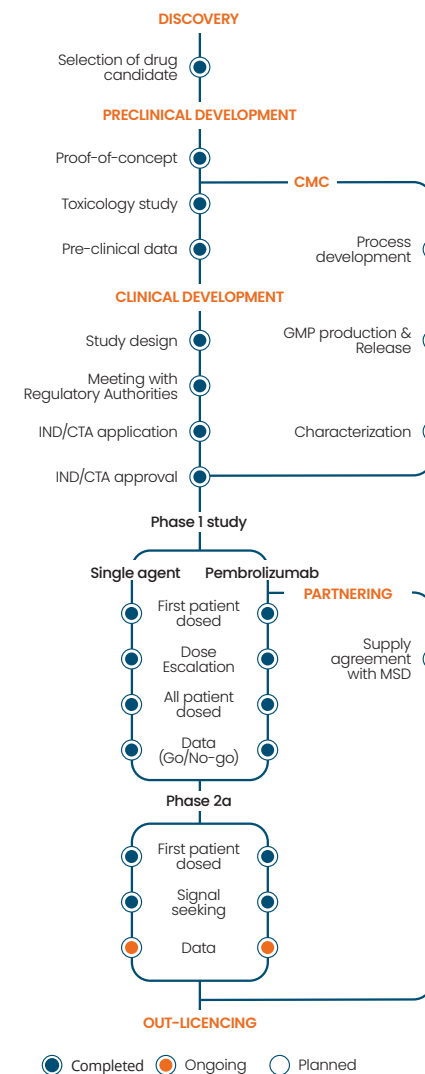
The aim of Phase 2a (NCT04752826) is to further assess the safety and tolerability of BI-1808 as a single agent (Part A) and in combination with pembrolizumab (Part B), characterize its pharmacokinetics and pharmacodynamics, and assess preliminary antitumor activity by ORR, DoR (duration of response), and progression-free survival (PFS), the modified Severity-Weighted Assessment Tool (mSWAT) for 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

Complete Phase 2a dose optimization monotherapy data is expected H1 2027.





BI-1206 for the treatment of NHL (FL, MCL, MZL)

BI-1206 is a first-in-class antibody targeting FcγRIIB, which is overexpressed in several forms of non-Hodgkin lymphoma (NHL) and has been associated with poor prognosis in difficult-to-treat forms, such as mantle cell lymphoma (MCL). By blocking FcγRIIB on tumor cells, BI-1206 is expected to restore and enhance the activity of rituximab in the treatment of several forms of NHL. BI-1206 has been granted Orphan Drug Designation by the FDA for the treatment of follicular lymphoma (FL), the most common form of indolent non-Hodgkin lymphoma, and for MCL.

STATUS

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

As of data cut-off May 6, 2026, the triplet of BI-1206 + rituximab + acalabrutinib delivered an 83% objective response rate (ORR) in the total population (n=23 evaluable), with 11 complete responses (CR) and 8 partial responses (PR). In the follicular lymphoma (FL) subset (n=16), ORR was 81% and complete response rate (CRR) was 44%. All remaining patients exhibited stable disease as best response, giving a disease control rate (DCR) of 100%.

The regimen showed a very favorable tolerability profile, with treatment-related

serious adverse events observed in only 4 (14%) patients and discontinuation due to a drug-related adverse event in 1 patient. Grade 3+ treatment-related adverse events observed in only 31% of patients, versus 54–84% for comparator regimens.

STUDY DESIGN

The triple combination arm in the ongoing Phase 2a part of the study (NCT03571568) combines the subcutaneous formulation of BI-1206 with rituximab and acalabrutinib in subjects with indolent B-cell non-Hodgkin's lymphoma (NHL) who have relapsed or are refractory to rituximab. Patient enrolment (approximately 30 patients) has been completed in Spain, Germany, USA, and Brazil. BioInvent has a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) providing Calquence® (acalabrutinib) for the combination arm.

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 development and 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.

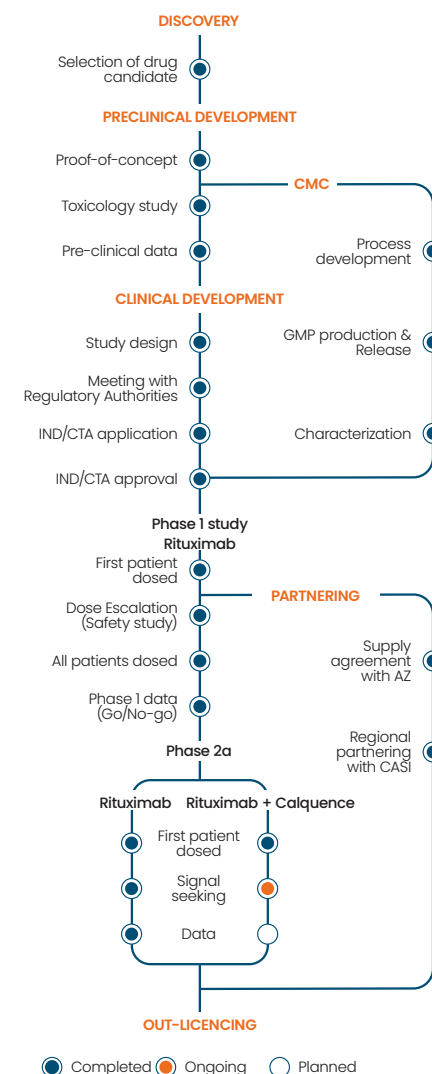
OUT-LICENSING AND PARTNERING

BioInvent has a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) providing Calquence® (acalabrutinib) for the triple combination arm.

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

Phase 2a triplet data for BI-1206 in combination with rituximab and acalabrutinib are maturing to be ready for initiation of a potential pivotal trial in H1 2027E, pending partnering.





BI-1206 for the treatment of NSCLC and uveal melanoma

BI-1206 is a first-in-class antibody targeting FcγRIIB. Based on clinical Phase 1 data in patients with solid tumors, in which BI-1206 enhanced the effect of anti-PD-1 therapy, MSD and BioInvent agreed to study the combination of BI-1206 and pembrolizumab (KEYTRUDA®) at an earlier stage of disease. The ongoing Phase 2a study is being conducted in patients who have not previously received any treatment for their disease (treatment-naïve), with non-small cell lung cancer (NSCLC) or uveal melanoma.

STATUS

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

The ongoing Phase 2a clinical trial is 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 previously presented, 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-PD-1/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.

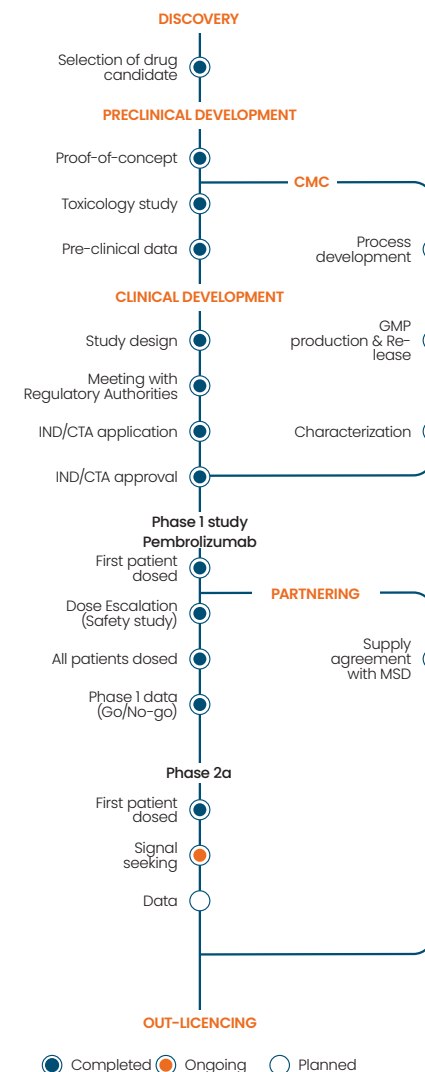
The trial is designed in two parts. In the first part, or signal-seeking phase, up to 30 NSCLC and 12 uveal melanoma patients will receive BI-1206 and pembrolizumab every 21 days for up to 2 years. The study may then proceed to a dose optimization phase, designed to refine the dosing strategy to maximize 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 then 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 and uveal melanoma are expected in H1 2027.



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.

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 6–10 and 12 for details.

BioInvent has supply and collaboration agreements with MSD to support the development of the clinical trial programs for the anti-TNFR2 antibody BI-1808 and the anti-FcγRIIB antibody BI-1206, and also for 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.

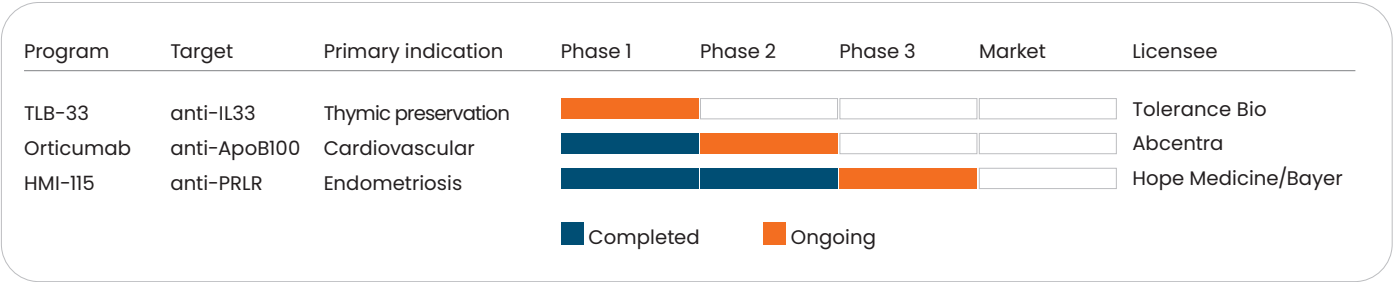
ROYALTY TRANSACTION WITH XOMA

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. 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.

THREE CLINICAL PROJECTS OUTLICENSED

BioInvent currently has three 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 co-developed with Transgene

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. BT-001 is a drug candidate being developed in collaboration with the French biotech company Transgene.

STATUS

Clinical phase 1/2a study (NCT04725331) concluded

BioInvent and Transgene have jointly presented 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 was 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 was divided into two parts. In part A, patients with metastatic/advanced tumors received single agent, intra-tumoral administrations of BT-001. Part B explored 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 continue the evaluation of BT-001 via an investigator-initiated trial in an early-stage setting.

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 10.8 million (3.3). Revenues for the period were mainly derived from production of antibodies for clinical studies.

Revenues for the corresponding period 2025 were mainly derived from production of antibodies for clinical studies. See also note 2.

The Company's total costs amounted to SEK 131.0 million (137.2). These are divided between external costs of SEK 94.3 million (95.7), personnel costs of SEK 32.5 million (36.7) and depreciation of SEK 4.2 million (4.8).

Research and development costs amounted to SEK 115.0 million (119.5). Sales and administrative costs amounted to SEK 16.0 million (17.7).

Profit/loss after tax amounted to SEK -118.9 million (-129.2). The net financial items amounted to SEK 1.6 million (4.5). Profit/loss per share before and after dilution amounted to SEK -1.81 (-1.96).

January–September

Net sales amounted to SEK 37.0 million (223.5). Revenues for the period were mainly derived from a EUR 1.0 million (SEK 11.3 million) milestone payment under the collaboration with Bayer/Hope Medicine related to the initiation of a Phase 3 clinical trial, and revenue from production of antibodies for clinical studies.

Revenues for the corresponding period 2025 were mainly derived from USD 20 million (SEK 191.0 million) that BioInvent received when XOMA Royalty acquired the rights to future royalty and milestone interests for mezaglitamab (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. See also note 2.

The Company's total costs amounted to SEK 403.8 million (445.5). These are divided between external costs of SEK 280.9 million (314.5), personnel costs of SEK 109.6 million (116.0) and depreciation of SEK 13.3 million (15.0).

Research and development costs amounted to SEK 353.8 million (392.0). Sales and administrative costs amounted to SEK 50.0 million (53.5).

Profit/loss after tax amounted to SEK -361.0 million (-207.1). The net financial items amounted to SEK 6.4 million (15.4). Profit/loss per share before and after dilution amounted to SEK -5.49 (-3.15).

FINANCIAL POSITION AND CASH FLOW

On October 28, 2026, BioInvent announced that the Board of Directors had, subject to approval by an extraordinary general meeting, resolved to carry out a new issue of shares of approximately SEK 430 million with preferential rights for the Company's existing shareholders. The rights issue is carried out to strengthen the Company's financial position and fund the continued clinical development of the Company's priority programs, principally its solid tumor opportunities for BI-1808 and BI-1206.

The Company has received subscription commitments from the three largest shareholders, Redmile, Van Herk and Forbion, as well as other existing shareholders, including HealthInvest, amounting to approximately SEK 80 million, and shareholding members of the Board of Directors and Management intend to enter into subscription commitments following the publication of the interim report January – September 2026 amounting to approximately SEK 0.6 million in total, including pro rata subscription commitments from CEO Martin Welschof and Chairman Leonard Kruimer. Additionally, due to restrictions on

participation of US persons in the Rights Issue, members Kate Hermans, Bernd Seizinger and Scott Zinober of the Board of Directors have declared their intention to purchase shares on the market during the subscription period in the rights issue corresponding to approximately SEK 0.7 million in total. The Company has also received guarantee undertakings up to approximately SEK 270 million. Accordingly, the rights issue is covered by subscription commitments and guarantee undertakings up to approximately SEK 350 million, corresponding to approximately 81 percent of the rights issue.

Based on the Company's cash position as of September 30, 2026, and the current business plan, successful completion of the part of the rights issue covered by subscription commitments and guarantee undertakings is expected to extend the Company's cash runway to the end of 2027. Any additional net proceeds in addition to the amount covered by the subscription commitments and guarantee undertakings, up to full subscription in the rights issue, are intended primarily to strengthen the Company's liquidity reserve and provide additional financial flexibility in the implementation of the Company's priority clinical programs.

The share capital consists of 65,804,362 shares as of September 30, 2026.

As of September 30, 2026, the Group's liquid funds and current investments amounted to SEK 224.6 million (690.5). The cash flow from operating activities for the January–September period amounted to SEK –358.3 million (–157.2). The shareholders' equity amounted to SEK 200.9 million (683.0) 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 65 (87) percent. Shareholders' equity per share amounted to SEK 3.05 (10.38).

INVESTMENTS

Investments for the January–September period in tangible fixed assets amounted to SEK 1.4 million (6.0).

PARENT COMPANY

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

ORGANIZATION

As of September 30, 2026, BioInvent had 107 (124) employees (full time equivalent). 92 (110) of these work in research and development.

DISCLOSURE OF RELATED PARTY TRANSACTIONS

For description of benefits to senior executives, see page 56 in the Company's annual report 2025. 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 39, in the Company's annual report 2025.

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

	3 MONTHS 2026 JULY-SEP.	3 MONTHS 2025 JULY-SEP.	9 MONTHS 2026 JAN.-SEP.	9 MONTHS 2025 JAN.-SEP.	12 MONTHS 2025 JAN.-DEC.
Net sales	10,793	3,321	36,966	223,479	226,495
<i>Operating costs</i>					
Research and development costs	-115,031	-119,458	-353,765	-391,972	-504,218
Sales and administrative costs	-15,936	-17,716	-50,056	-53,545	-73,668
Other operating income and costs	-259	247	-382	-234	-293
	-131,226	-136,927	-404,203	-445,751	-578,179
Operating profit/loss	-120,433	-133,606	-367,237	-222,272	-351,684
Profit/loss from financial investments	1,596	4,457	6,425	15,429	19,223
Profit/loss before tax	-118,837	-129,149	-360,812	-206,843	-332,461
Tax	-75	-74	-231	-213	-397
Profit/loss after tax	-118,912	-129,223	-361,043	-207,056	-332,858
Other comprehensive income					
Items that have been or may be reclassified subsequently to profit or loss					
Translation differences for the period	28	-5	82	-45	-65
Comprehensive income	-118,884	-129,228	-360,961	-207,101	-332,923
Profit/loss attributable to parent Company's shareholders	-118,912	-129,223	-361,043	-207,056	-332,858
Comprehensive income attributable to parent Company's shareholders	-118,884	-129,228	-360,961	-207,101	-332,923
Profit/loss per share, SEK					
Before dilution	-1.81	-1.96	-5.49	-3.15	-5.06
After dilution	-1.81	-1.96	-5.49	-3.15	-5.06

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

	2026 SEP. 30	2025 SEP. 30	2025 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets - leases	21,343	11,585	9,639
Tangible fixed assets - other	17,733	25,399	23,870
Financial fixed assets - long-term investments	-	-	-
Total fixed assets	39,076	36,984	33,509
Inventories	9,739	9,419	12,292
Current receivables	34,679	48,962	32,653
Current investments	-	207,181	236,579
Liquid funds	224,562	483,274	356,169
Total current assets	268,980	748,836	637,693
Total assets	308,056	785,820	671,202
SHAREHOLDERS' EQUITY			
Total shareholders' equity	200,937	683,016	557,615
LIABILITIES			
Lease liabilities	10,908	1,593	1,157
Total long term liabilities	10,908	1,593	1,157
Lease liabilities	8,418	9,093	7,370
Other liabilities	87,793	92,118	105,060
Total short term liabilities	96,211	101,211	112,430
Total shareholders' equity and liabilities	308,056	785,820	671,202

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

	2026 JULY-SEP.	2025 JULY-SEP.	2026 JAN.-SEP.	2025 JAN.-SEP.	2025 JAN.-DEC.
Shareholders' equity at beginning of period	317,335	810,744	557,615	885,815	885,815
Comprehensive income					
Profit/loss	-118,912	-129,223	-361,043	-207,056	-332,858
Other comprehensive income	28	-5	82	-45	-65
Total comprehensive income	-118,884	-129,228	-360,961	-207,101	-332,923
Total, excluding transactions with equity holders of the Company	198,451	681,516	196,654	678,714	552,892
Transactions with equity holders of the Company					
Employee options program	2,486	1,500	4,283	4,302	4,723
Shareholders' equity at end of period	200,937	683,016	200,937	683,016	557,615

The share capital as of September 30, 2026 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)

	2026 JULY-SEP.	2025 JULY-SEP.	2026 JAN.-SEP.	2025 JAN.-SEP.	2025 JAN.-DEC.
Operating activities					
Operating profit/loss	-120,433	-133,606	-367,237	-222,272	-351,684
Depreciation	4,152	4,812	13,266	15,019	19,871
Adjustment for other non-cash items	2,486	1,500	4,283	4,302	4,723
Interest received and paid	1,522	3,541	7,373	22,392	29,878
Income taxes paid	-66	-	-514	-164	-177
	-112,339	-123,753	-342,829	-180,723	-297,389
Changes in working capital	-1,210	19,770	-15,484	23,518	49,634
Cash flow from operating activities	-113,549	-103,983	-358,313	-157,205	-247,755
Investment activities					
Acquisition of tangible fixed assets	-153	-1,834	-1,434	-5,981	-7,260
Changes of financial investments	34,238	183,561	236,001	216,389	187,387
Cash flow from investment activities	34,085	181,727	234,567	210,408	180,127
Cash flow from operating activities and investment activities	-79,464	77,744	-123,746	53,203	-67,628
Financing activities					
Amortization of lease liability	-2,148	-2,258	-6,602	-6,728	-8,985
Cash flow from financing activities	-2,148	-2,258	-6,602	-6,728	-8,985
Change in liquid funds	-81,612	75,486	-130,348	46,475	-76,613
Opening liquid funds	306,480	404,053	356,169	434,826	434,826
Accrued interest on investments classified as liquid funds	-306	3,735	-1,259	1,973	-2,044
Liquid funds at end of period	224,562	483,274	224,562	483,274	356,169
Liquid funds, specification:					
Cash and bank	99,757	86,633	99,757	86,633	97,106
Current investments, equivalent to liquid funds	124,805	396,641	124,805	396,641	259,063
	224,562	483,274	224,562	483,274	356,169

Key financial ratios for the Group

	2026 SEP. 30	2025 SEP. 30	2025 DEC. 31
Shareholders' equity per share at end of period, SEK	3.05	10.38	8.47
Number of shares at end of period (thousand)	65,804	65,804	65,804
Equity/assets ratio, %	65.2	86.9	83.1
Number of employees at end of period	107	124	109

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

	3 MONTHS 2026 JULY-SEP.	3 MONTHS 2025 JULY-SEP.	9 MONTHS 2026 JAN.-SEP.	9 MONTHS 2025 JAN.-SEP.	12 MONTHS 2025 JAN.-DEC.
Net sales	10,793	3,321	36,966	223,479	226,495
<i>Operating costs</i>					
Research and development costs	-115,453	-118,793	-354,707	-392,551	-504,957
Sales and administrative costs	-16,168	-17,879	-50,785	-53,928	-74,223
Other operating income and costs	-211	247	-193	-234	-461
	-131,832	-136,425	-405,685	-446,713	-579,641
Operating profit/loss	-121,039	-133,104	-368,719	-223,234	-353,146
Profit/loss from financial investments	1,782	4,547	6,822	15,743	19,612
Profit/loss after financial items	-119,257	-128,557	-361,897	-207,491	-333,534
Tax	-33	-32	-97	-117	-205
Profit/loss	-119,290	-128,589	-361,994	-207,608	-333,739
Other comprehensive income	-	-	-	-	-
Comprehensive income	-119,290	-128,589	-361,994	-207,608	-333,739

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

	2026 SEP. 30	2025 SEP. 30	2025 DEC. 31
ASSETS			
Intangible fixed assets	0	0	0
Tangible fixed assets	17,733	25,399	23,870
Financial fixed assets – Shares in subsidiaries	1,008	1,008	1,008
Financial fixed assets – long-term investments	–	–	–
Total fixed assets	18,741	26,407	24,878
Current assets			
Inventories	9,739	9,419	12,292
Current receivables	38,648	50,610	34,426
Current investments	–	207,181	236,579
Cash and bank	224,359	482,844	355,752
Total current assets	272,746	750,054	639,049
Total assets	291,487	776,461	663,927
SHAREHOLDERS' EQUITY			
Restricted equity	40,854	40,854	40,854
Non-restricted equity	159,348	642,769	517,059
Total shareholders' equity	200,202	683,623	557,913
LIABILITIES			
Short term liabilities	91,285	92,838	106,014
Total short term liabilities	91,285	92,838	106,014
Total shareholders' equity and liabilities	291,487	776,461	663,927

Lund, October 28, 2026

Martin Welschof
CEO

Review report

*To the Board of Directors of BioInvent International AB (publ.)
Corp. id. 556537-7263*

INTRODUCTION

We have reviewed the condensed interim financial information (interim report) of BioInvent International AB (publ.) as of 30 September 2026 and the nine-month period then ended. The Board of Directors and the Managing Director 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 International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information 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 International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

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 in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Malmö, October 28, 2026

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 2026 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	2026 JULY-SEP.	2025 JULY-SEP.	2026 JAN.-SEP.	2025 JAN.-SEP.	2025 JAN.-DEC.
Revenue by geographical region:					
Sweden	56	2,036	673	12,241	13,723
Europe	167	134	12,299	968	1,238
USA	10,476	1,151	22,933	209,958	210,952
Other countries	94	-	1,061	312	582
	10,793	3,321	36,966	223,479	226,495
Revenue consists of:					
Revenue from collaboration agreements associated with outlicensing of proprietary projects	-	-	-	-	-
Revenue from technology licenses	89	-	11,365	200,941	200,941
Revenue from external development projects	10,704	3,321	25,601	22,538	25,554
	10,793	3,321	36,966	223,479	226,495

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

In January-September 2026, BioInvent had two customers where revenues exceeded ten percent of total revenues. Revenues for these customers amounted to SEK 21.9 million (59%) and SEK 11.3 million (31%) of total revenues of SEK 37.0 million.

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 the 2025 financial year, BioInvent had one customer where revenues exceeded ten percent of total revenues. Revenues for the customer amounted to SEK 200.9 million (89%) of total revenues of SEK 226.5 million.

NOTE 3 EVENTS AFTER THE PERIOD

- (R) The Board of Directors has decided to carry out a rights issue of approximately SEK 430 million (gross, before issue costs), of which SEK 350 million is covered by subscription commitments and guarantee undertakings, subject to approval at an Extraordinary General Meeting
- (R) Streamlining of the organization to support prioritized clinical programs
- (R) BI-1808 and KEYTRUDA® induce durable responses in heavily pretreated platinum-resistant ovarian cancer. The poster was granted Best Poster Award, Investigational Immunotherapy at ESMO 2026
- (R) The company announced that its CFO will retire in 2027
- First-in-Human BI-1808 Data Published in Clinical Cancer Research

(R) = Regulatory event

Other information

EXTRA GENERAL MEETING

The Extra General Meeting will be held on December 1, 2026, at 4 p.m. at the Alfa house (room Focus), Scheelevägen 15, Lund. Notice to attend will be announced in Post- och Inrikes Tidningar and on the Company website.

FINANCIAL CALENDAR

- Year-end report 2026: March 4, 2027
- Interim report January–March 2027: April 29
- Interim report January–June 2027: August 26
- Interim report January–September 2027: October 28

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

n-CoDeR® and F.I.R.S.T™ are trademarks belonging to BioInvent International AB.

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

Q&A with CMO Andres McAllister on BI-1808 ESMO data



The response rate came in at 24 percent, three times the 8 percent for pembrolizumab alone. What does a difference like that mean clinically?

"Platinum-resistant ovarian cancer is a setting where patients have few options and where checkpoint inhibitors alone have mostly disappointed. At 8 percent, roughly one patient in twelve responds. At 24 percent it's closer to one in four. For a patient, that is the difference between a drug that rarely shrinks the tumor and one that does so with some regularity. We also see this in a population that is heavily pretreated, so the bar is high."

"I'd add two cautions. This is a single-arm study compared against a historical benchmark, so we are careful about drawing hard conclusions. Response rate is also only one measure, and what matters in the end is duration of benefit. But a tripling of the response rate, achieved without chemotherapy and with very few treatment

discontinuations due to side effects, is a signal worth taking seriously."

You have worked on this mechanism for years. With Part B now complete, what stands out most to you in the data?

"What stands out is how well the clinical picture matches the biology we have been describing. TNFR2 is highly expressed on regulatory T cells in the tumor, and BI-1808 is designed to deplete them and to reprogram myeloid cells, which should make a PD-1 inhibitor work better. When we see responses in a setting where PD-1 blockade has historically done little, and we see the biomarker changes you would expect, such as a shift in the balance between CD8 T cells and Tregs in tumor biopsies, that is a coherent story."

"The second thing is that the activity holds across both high-grade serous and clear cell subtypes, which are quite different diseases. And the safety profile has stayed clean across a large body of patients, which matters a great deal when you want to build on top of the combination."

One of the responders had already progressed on pembrolizumab in an earlier line. What does it tell you that the combination worked where the checkpoint inhibitor alone had not?

"This is exactly the kind of case you hope to see if the mechanism is real. If a tumor has already shown it can escape PD-1 block-

ade alone, and adding a Treg-depleting, myeloid-reprogramming antibody produces a response, it suggests that BI-1808 is contributing something the checkpoint inhibitor was not providing, rather than simply riding along with it. It supports the idea that Treg-mediated suppression is one of the things holding these tumors back."

Why add chemotherapy in Part C after a chemotherapy-free Part B, and how did KEYNOTE-B96 shape that decision?

"Part B was designed to answer a clean question: does BI-1808 add something to pembrolizumab on its own? It does appear to, and that was important to establish without the confounding effect of chemotherapy."

"KEYNOTE-B96 changed the landscape, though. It showed that pembrolizumab with weekly paclitaxel is a meaningful step forward in platinum-resistant ovarian cancer, and it is becoming the reference regimen. So the relevant question for patients and physicians is no longer only how we compare with pembrolizumab alone, but whether we can improve on the new standard. Chemotherapy can also help release tumor antigens and prime the immune system, which fits well with what BI-1808 does. Part C is therefore a randomized comparison, with BI-1808 at two dose levels, against pembrolizumab plus weekly paclitaxel with or without bevacizumab,

which is how the regimen is used in practice."

"We think the chemotherapy-free combination remains valuable for patients who cannot tolerate chemotherapy, and Part C addresses the larger group where the standard of care now sits."

Which upcoming readouts or decisions around BI-1808 do you see as the most important over the next 12 to 18 months?

"First, the full Part B dataset, which we expect before the end of this year. That will tell us whether the 24 percent holds as the numbers grow and give us more mature durability data, including by subtype."

"Second, the start of Part C, which we expect to begin enrolling in the first quarter of 2027, with initial data in the second half of 2027. That is the most important readout, because it is randomized and it will also help us choose the dose."

– Third, the regulatory and partnering side. The FDA's Fast Track designation for ovarian cancer gives us closer dialogue with the agency about what a registrational path could look like, and the data from Part C will shape those discussions. Alongside this, we continue to develop BI-1808 in T-cell lymphoma, where it has orphan drug designation, so there are several ways this program can move forward.