

Press release 17 May 2017

### BioInvent Interim Report 1 January – 31 March 2017

# BioInvent engages international drug development experts

#### January - March 2017

- Net sales amounted to SEK 13 (29) million.
- Earnings after tax SEK -22 (0.3) million.
- Earnings after tax per share before and after dilution: SEK -0.07 (0.00) SEK.
- Liquid funds as of 31 March 2017 amounted to SEK 216 (41) million. Cash flow from operating activities and investment activities amounted to SEK -10 (1.5) million.

#### Important events in the first quarter and after the reporting period

- In January 2017, BioInvent's partner ThromboGenics, announced the enrollment of the first patients in a phase II clinical trial with THR-317 for the treatment of diabetic macular edema.
- In April 2017 BioInvent announced that the European Patent Office, EPO, has communicated its intention to grant the company a patent relating to the immuno-oncology antibody BI-1206. The patent covers the use of the company's drug candidate BI-1206, and similar CD32b antibodies, in combination with a CD19, CD20 or CD40 antibody in the treatment of cancer or inflammatory diseases in certain groups of patients.

#### Comments from the CEO

"In order to ensure continued effective and professional development of BioInvent's pharmaceutical project, the company has strengthened its collaboration with leading immuno-oncology and drug development authorities in a Scientific Advisory Board, which held its first meeting in London on 14 May. Five reputable authorities will under the leadership of Martin Glennie, Professor at the University of Southampton, assist us in the development of in particular our preclinical drug projects. The high-level science in the Company's projects has been an important factor in attracting these experts. A presentation of the members is available at www.bioinvent.com.

Confirmation that our projects have significant commercial potential came at the end of last year when we signed a collaboration agreement relating to tumour-associated myeloid cells with Pfizer. The partnership is now operational and we are looking forward to being part of the development of new drugs for several cancer diseases where there is a significant need for improved treatment.

The clinical trials involving drug candidates BI-1206 and TB-403 continued during the quarter. As previously announced, we expect to be able to present the first safety and dose results from the BI-1206 study in the first half of 2018. During the trials, independent safety committees continuously evaluate the safety profile of the antibodies.

BioInvent received in April 2017 a €0.5 million milestone payment under the collaboration with Mitsubishi Tanabe Pharma in connection with the approval of starting a Phase I study of an antibody identified from BioInvent's n-CoDeR<sup>®</sup> antibody library. We can also report that contract manufacturing of antibodies at our production facility in Lund continues to contribute to our financial sustainability," said Michael Oredsson, CEO of BioInvent.

#### Contact

Any questions regarding this report will be answered by Michael Oredsson, CEO, phone +46 (0)46 286 85 67, mobile +46 (0)707 18 89 30. The report is also available at www.bioinvent.com

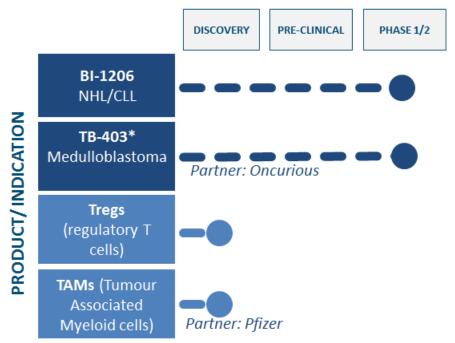
#### **Business focus**

BioInvent is generating value for shareholders by employing its antibody and cancer biology expertise to identify antibodies with novel mechanisms-of-action and novel oncology targets. The Company employs this approach to generate therapeutic immuno-modulating antibodies that can be developed for a broad range of cancer indications. The Company plans to bring these antibodies to the clinic through its own resources and together with partners.

To achieve these goals the Company is currently:

- Progressing clinical development of our lead antibody BI-1206 for treatment of haematological cancers.
- Advancing our innovative pre-clinical Treg immuno-oncology programmes identifying antibodies to novel targets and with novel functions as well as antibodies that address validated targets such as OX40 and 4-1BB.
- Developing a pre-clinical portfolio of first-in-class antibodies targeting tumour-associated myeloid cells in collaboration with Pfizer.
- Collaborating with Oncurious on the development of TB-403, a potential treatment for paediatric brain cancers.
- Generating further revenues through antibody contract manufacturing and technology deals.

#### **Clinical and Pre-Clinical Pipeline**



\*THR-317 (Indication: Diabetic Macular Edema, Partner: ThromboGenics) is based on the same antibody as TB-403, and this antibody targets the PIGF protein. BioInvent has a 40% equity stake provided it chooses to contribute half of the development costs.

#### **Clinical Projects**

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

BioInvent's lead drug candidate BI-1206 is a fully human antibody targeting CD32b, an immunosuppressive protein that is expressed in some patients with B-cell cancers. Research has shown that the expression of CD32b could lead to the development of resistance to rituximab, the current standard of care treatment of non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukaemia (CLL). As a result, BI-1206 is being developed as a drug candidate in combination with rituximab, in B-cell cancers.

The first clinical study (Phase I/II) with BI-1206 is currently ongoing in patients with NHL and CLL who are resistant to rituximab. The initial safety and dose readouts from this study are expected in the first

half of 2018. The study is financed and executed by Cancer Research UK (CRUK), Cancer Research Technology (CRT) and Leukaemia & Lymphoma Research (LLR).

### TB-403 in paediatric brain tumours - development in collaboration with Oncurious, subsidiary of ThromboGenics

TB-403 is a humanised antibody directed against the PIGF protein, which is believed to inhibit its signaling via the Nrp-1 receptor. PIGF is expressed in patients with medulloblastoma, Ewing's sarcoma, neuroblastoma and alveolar rhabdomyosarcoma.

TB-403 is currently in a Phase I/II study for the treatment of patients with medulloblastoma in cooperation with a US based pediatric oncology network, Neuroblastoma and Medulloblastoma Translational Research Consortium. The study is ongoing and the first dosage level with three patients has been finished.

TB-403 has recently received Orphan Drug Designation for medulloblastoma from the European Medicines Agency.

BioInvent has a 40% equity stake in TB-403, developed in conjunction with Oncurious. This is the result of a collaboration agreement signed in 2004 with Oncurious' parent company ThromboGenics. Under the terms of the agreement BioInvent pays 50% of development costs of TB-403.

#### THR-317 in diabetic macular edema - development in collaboration with ThromboGenics

ThromboGenics also allows for BioInvent to have a 40% equity stake in THR-317, an ophthalmologic formulation of TB-403, provided it chooses to contribute half of the development costs. As earlier communicated, BioInvent is currently evaluating how to ensure that the value of this project is optimized. The product is currently in a Phase II clinical study for the treatment of patients with diabetic macular edema. The study will evaluate the safety and efficacy of two dose levels of THR-317 and plans to include a total of 50 patients.

#### **Pre-clinical projects**

BioInvent's preclinical research is focused on developing novel immuno-modulatory antibodies to significantly improve on the efficacy of currently available checkpoint inhibitor therapies. These novel antibodies may also activate anti-cancer immunity in currently non-responding patients and cancer types.

BioInvent is developing antibodies that can overcome the effects of two key cells that suppress the immune system in the tumour micro-environment. These are:

- cancer-associated regulatory T cells (Tregs) and
- tumour-associated myeloid-derived suppressor cells.

Developing antibodies that act on regulatory T cells (Tregs) via either novel or validated targets Tregs can substantially inhibit various immune responses enabling tumour cells to escape detection. BioInvent is currently developing antibodies specific for currently undetermined Treg targets and functions as well as for known targets such as OX-40 and 4-1BB.

BioInvent currently works at expanding the pool of antibodies and targets that have been shown associated with Treg specificity and Treg depleting activity.

BioInvent is working in cooperation with Cancer Research Technology and the University of Southampton in the UK to develop new immunotherapeutic cancer drugs based on antibodies that target OX-40 and 4-1BB, two known co-receptors that help activate T cells, to produce long-lasting anti-tumour immune responses.

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

In December 2016, BioInvent announced that it has entered into a cancer immunotherapy research collaboration and license agreement with Pfizer Inc. to develop antibodies targeting tumour-associated myeloid cells. BioInvent will leverage its expertise to identify novel oncology targets and therapeutic antibodies that inhibit cancer growth either by reversing the immunosuppressive activity of tumour-associated myeloid cells or by reducing the number of tumour-associated myeloid cells in the tumour.

Under the terms of the agreement BioInvent could be eligible for potential future development milestones in excess of \$0.5 billion (assuming five antibodies are developed through to commercialisation). The Company could also receive up to double digit royalties related to product sales. In return Pfizer will have the right to develop and commercialise any antibodies generated from this agreement.

Pfizer has paid BioInvent an upfront payment of \$3 million and is committed to paying \$1 million in research funding during 2017. Pfizer has also made a \$6 million equity investment in new shares of BioInvent.

#### Manufacturing and technology revenues

The Company currently has several antibody manufacturing agreements with major pharma and biotech companies. Given its production capacity and expertise, BioInvent is actively seeking to secure more manufacturing contracts.

The Company has also several licensing agreements and, in some cases, research collaborations with several external partners including Bayer Pharma, Daiichi Sankyo, Mitsubishi Tanabe Pharma and Xoma. The structure and terms of these agreements and partnerships vary, but they all have in common that BioInvent receives license fees, research financing, milestone payments and royalties on the sale of commercial products. Of these external drug development programmes, five projects are currently in Phase I and one is in the preclinical phase.

BioInvent received in April 2017 a €0.5 million milestone payment under the collaboration with Mitsubishi Tanabe Pharma in connection with the approval of starting a Phase I study of an antibody identified from BioInvent's n-CoDeR<sup>®</sup> antibody library.

#### Revenues and result

Net sales amounted to SEK 13 million (29). Revenues for the period are derived from production of antibodies for clinical studies and as well revenues from research funding. BioInvent announced in February 2016 that a EUR 2 million milestone payment had been received under the collaboration with Daiichi Sankyo pertaining to the progression of a Phase I clinical trial.

The Company's total costs amounted to SEK 35 million (30). Operating costs are divided between external costs of SEK 21 million (19), personnel costs of SEK 14 million (11) and depreciation of SEK 0.3 million (0.2). Research and development costs amounted to SEK 25 million (22).

Profit/loss after tax amounted to SEK -22 million (0.3). The net financial items amounted to SEK 0.0 million (0.1). Earnings per share before and after dilution amounted to SEK -0.07 (0.00).

#### Financial position and cash flow

As of 31 March 2017, the Group's liquid funds amounted to SEK 216 million (41). The cash flow from operating activities and investment activities for the January - March period amounted to SEK -10 million (1.5).

The shareholders' equity amounted to SEK 208 million (30) at the end of the period. The Company's share capital at the end of the period was SEK 24 million. The equity/assets ratio at the end of the period was 87 (51) per cent. Shareholders' equity per share amounted to SEK 0.68 (0.18). The Group had no interest-bearing liabilities.

#### **Investments**

Investments in tangible fixed assets amounted to SEK 3.6 million (1.1).

#### Parent company

All operations of the Group are conducted by the Parent Company. The Group's and the Parent Company's financial statements coincide in every material way.

#### **Organisation**

As of 31 March 2017, BioInvent had 54 (43) employees. 48 (37) of these work in research and development.

#### **Option programmes**

Employee Options Programme 2013/2017

The 2013 Annual General Meeting voted in favour of establishing a new, long-term employee incentive programme involving the allotment of a maximum of 900,000 employee options free of charge to all Group employees.

The employees will receive options based on their performance in the 2013, 2014 or 2015 financial years and allotment will take place in connection with the publication of the year-end financial statement for the subsequent year. Each employee option will entitle the holder to acquire 1.207 new share in BioInvent for a subscription price of SEK 2.92 during the period from the date of publication of

the Company's year-end financial statement for the 2016 financial year up to and including 1 December 2017. Subscription price and number of shares that each employee option entitles to are converted pursuant to rights issues carried out. Allotment of 100,747 employee options took place in February 2014, 74,516 employee options took place in February 2015 and 50,250 employee options in February 2016.

To guarantee BioInvent's commitment and cover the costs associated with Employee Incentive programme 2013/2017, the 2013 Annual General Meeting resolved to issue a maximum of 1,182,780 warrants to BioInvent Finans AB.

If all allotted employee options relating to Employee Incentive Programme 2013/2017 are exercised for subscription of new shares and the additional warrants ensuring BioInvent's costs in relation to the allotted employee options, the Company's share capital will increase by SEK 28,617 equivalent to about 0.1 percent of shares and votes in the Company after full exercise.

#### Subscription Warrants Programme 2016/2019

The 2016 Annual General Meeting resolved to adopt an incentive programme for the company's employees in the form of a subscription warrants programme. Under the programme 957,571 subscription warrants have been transferred with a maximum dilution effect of approximately 0.3 percent.

The programme includes all employees except the CEO and other senior executives comprised by the retention bonus programme implemented in 2015. The subscription warrants are transferred at market value and each employee may be allotted a maximum of 50,000 subscription warrants. 855,000 subscription warrants were transferred in the second quarter 2016 and 102,571 subscription warrants were transferred by the end of December 2016. Subscription of shares by exercise of subscription warrants shall take place during the period from and including 1 July 2019 up to and including 1 December 2019. The subscription price per share shall be SEK 2.81. As part of the incentive programme, participants who remain in their employment with the company as per 1 June 2019 receive a stay-on bonus corresponding to two times the amount paid for the acquired subscription warrants, however no more than SEK 60,000.

#### Disclosure of related party transactions

For description of benefits to senior executives, see page 41 in the company's annual report 2016. The Company has, in accordance with the decision of the Annual General Meeting 2016 decided to implement a retention bonus programme which for a three-year period may amount to a maximum of 100 per cent of the fixed salary for a year. 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, commercialisation and partners, competition and fast technological development, biotechnology and patent risk, 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.

No significant changes to the risks and uncertainty factors occurred during the period. For a more detailed description of risk factors, see section "Risks and Risk Management", page 26, in the company's annual report 2016.

#### **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 2017 has had no material impact on the financial statements. The financial statements of the Parent company coincide in every material way with the consolidated financial statements.

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

Upcoming financial reports
BioInvent will present the following financial reports:

• Interim reports 26 July, 26 October 2017

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

	3 MONTHS 2017	3 MONTHS 2016	12 MONTHS 2016
	JanMarch	JanMarch	JanDec.
Net sales	12,973	29,379	71,284
Operating costs			
Research and development costs Sales and administrative costs	-24,698 -10,458	-22,200 -7,506	-99,477 -35,715
Other operating revenues and costs	<u>-159</u>	505	1,049
	-35,315	-29,201	-134,143
Operating profit/loss	-22,342	178	-62,859
Profit/loss from financial investments	5	149	272
Profit/loss before tax	-22,337	327	-62,587
Tax	-	-	-
Profit/loss	-22,337	327	-62,587
Other comprehensive income Items that have been or may be reclassified			
subsequently to profit or loss			
Changes in actual value current investments	-	-	-
Comprehensive income	-22,337	327	-62,587
Other comprehensive income			
attributable to parent company's shareholders	-22,337	327	-62,587
Earnings per share, SEK			
Before dilution	-0.07	0.00	-0.25
After dilution	-0.07	0.00	-0.25

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

-	2017 31 March	2016 31 March	2016 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	0	0
Tangible fixed assets	8,873	2.240	5,648
Total fixed assets	8,873	2,240	5,648
Current assets			
Inventories	225	2,188	1,918
Current receivables	13,246	12,218	42,618
Liquid funds	216,031	41,442	226,114
Total current assets	229,502	55,848	270,650
Total assets	238,375	58,088	276,298
Shareholders' equity and liabilities			
Shareholders' equity	208,076	29,742	230,437
Current liabilities	30,299	28,346	45,861
Shareholders' equity and liabilities	238.375	58.088	276,298

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

	2017 JanMarch	2016 JanMarch	2016 JanDec.
Shareholders' equity at beginning of period	230,437	29,454	29,454
Comprehensive income			
Profit/loss	-22,337	327	-62,587
Comprehensive other income	-	-	-
Total comprehensive income Total, excluding transactions with equity	-22,337	327	-62,587
holders of the Company	208,100	29,781	-33,133
Transaktioner med bolagets ägare			
Personaloptionsprogram	-24	-39	58
Överlåtelse av teckningsoptioner			587
Företrädesemission och riktad nyemission			209,541
Riktad nyemission	202.272	00 740	53,384
Eget kapital vid periodens utgång	208,076	29,742	230,437

The share capital as of 31 March 2017 consists of 304,695,213 shares and the share's ratio value is 0.08. The rights issue and the directed new share issue carried out in April 2016 raised SEK 209,541 thousand after issue expenses of SEK 24,074 thousand. The directed new share issue carried out in December 2016 raised SEK 53,384 thousand after issue expenses of SEK 2,868 thousand.

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

-	2017	2016	2016
- a a a	JanMarch	JanMarch	JanDec.
Operating activities	00.040	470	60.050
Operating profit/loss Depreciation	-22,342 338	178 174	-62,859 996
Adjustment for other non-cash items	-24	-39	58
Interest received and paid	-6	-2	34
Cash flow from operating activities			
before changes in working capital	-22,034	311	-61,771
Changes in working capital	<u>15,514</u>	2,249	-10,278
Cash flow from operating activities	-6,520	2,560	-72,049
Investment activities			
Acquisition of tangible fixed assets  Cash flow from investment activities	<u>-3,563</u> <b>-3,563</b>	<u>-1,091</u> <b>-1,091</b>	<u>-5,322</u> <b>-5,322</b>
Cash now from investment activities	-3,363	-1,091	-5,322
Cash flow from operating activities and			
investment activities	-10,083	1,469	-77,371
Financing activities			
Transfer of subscription warrants			587
Rights issue and directed new share issue			209,541
Directed new share issue			53,384 <b>263,512</b>
Cash flow from financing activities	-	-	203,312
Change in liquid funds	-10,083	1,469	186,141
Opening liquid funds	226,114	<u>39,973</u>	39,973
Liquid funds at end of period	216,031	41,442	226,114
Liquid funds, specification:			
Cash and bank	216,031	41,442	226,114
	216,031	41,442	226,114

#### **Key financial ratios for the Group**

	2017	2016	2016
	31 March	31 March	31 Dec.
Shareholders' equity per share at end of period, SEK Number of shares at end of period (thousand)	0.68	0.18	0.76
	304,695	162,919	304,695
Equity/assets ratio, % Number of employees at end of period	87.3	51.2	83.4
	52	43	51

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

	3 MONTHS 2017	3 MONTHS 2016	12 MONTHS 2016
	JanMarch	JanMarch	JanDec.
Net sales	12,973	29,379	71,284
Operating costs			
Research and development costs	-24,698	-22,200	-99,477
Sales and administrative costs	-10,458	-7,506	-35,715
Other operating revenues and costs	<u>-159</u>	505	1,049
	-35,315	-29,201	-134,143
Operating profit/loss	-22,342	178	-62,859
Profit/loss from financial investments	5	149	272
Profit/loss after financial items	-22,337	327	-62,587
Tax	-	-	-
Profit/loss	-22,337	327	-62,587
Other comprehensive income			
Changes in actual value current investments	-	-	-
Comprehensive income	-22,337	327	-62,587

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

	2017	2016	2016
	31 March	31 March	31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	0	0
Tangible fixed assets	8,873	2,240	5,648
Financial fixed assets	687	100	687
Total fixed assets	9,560	2,340	6,335
Current assets			
Inventories	225	2,188	1,918
Current receivables	13,246	12,218	42,618
Cash and bank	216,031	41,442	226,114
Total current assets	229,502	55,848	<b>270,650</b>
Total Current assets	229,302	33,040	270,030
Total assets	239,062	58,188	276,985
Shareholders' equity and liabilities			
Shareholders' equity			
Restricted equity	52,069	40,726	52,069
Non-restricted equitys	156,045	-10,946	178,406
Total shareholders' equity	208,114	29,780	230,475
1.1.100			
Liabilities			
Current liabilities	30,948	28,408	46,510
Total shareholders' equity and liabilities	239,062	58,188	276,985

Lund, 17 May 2017

Michael Oredsson President and CEO

#### **Review report**

#### Introduction

We have reviewed the summarised interim financial information for BioInvent International AB (publ) on 31 March 2017 and for the three month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

#### Scope of review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing, ISA, and other generally accepted auditing practices. The procedures

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

#### Conclusion

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

Malmö, 17 May 2017 KPMG AB

Eva Melzig Authorised Public Accountant

#### **BioInvent International AB (publ)**

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#### Forward looking information

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

This information is information that BioInvent International AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out above, at 11.00 a.m. CET, on 17 May, 2017.