



BioInvent Interim Report

1 January – 31 March 2013

❑ Important events in the first quarter and after the end of the reporting period

- ❑ Positive results were reported in the phase I study of BI-505 in patients with multiple myeloma. The candidate drug was well tolerated and indicated therapeutic effect.
- ❑ The first patient was dosed in April in an initial phase II study of BI-505.
- ❑ Preclinical data for BI-505 were published in the April issue of the scientific journal *Cancer Cell*, showing clear anti-myeloma effects.
- ❑ CEO Svein Mathisen resigned, Cristina Glad has been appointed as acting CEO and recruitment of new CEO and President is ongoing.

❑ Key financial points

- ❑ Net revenues for January – March 2013 amounted to SEK 12 (15) million.
- ❑ Earnings for January – March 2013: SEK -14 (-37) million. Earnings per share SEK -0.19 (-0.55).
- ❑ Liquid funds as of 31 March 2013: SEK 77 (138) million. Cash flow of current operations and investment activities for January – March 2013: SEK -23 (-36) million

BioInvent is a research-based pharmaceutical company focused on discovery and development of innovative antibody-based drugs against cancer. The Company also develops antibody-based drugs in collaboration with partners who finance the development of the new drug, and provide BioInvent the right to milestone payments and royalties on sales.

Comments from the CEO

The phase I study of BI-505 met our goals and we are now proceeding with an initial small phase II study in patients in the early stages of multiple myeloma, known as asymptomatic multiple myeloma. At the same time, we are strengthening the documentation for BI-505. The phase I study was presented at an international meeting on multiple myeloma in Kyoto, Japan, along with preclinical data indicating an enhanced anti-tumour effect when combining BI-505 with approved drugs, compared with using them in monotherapy. Preclinical *proof-of-concept* data supporting our BI-505 clinical development program was published in the April 2013 issue of the prestigious oncology journal *Cancer Cell*.

Published data also illustrate the potential of our unique F.I.R.S.T.[™] and n-CoDeR[®] platforms. In addition to simultaneous identification of target structures and the therapeutic antibodies directed against them, these can reveal previously unknown functions of known target structures and thus demonstrate their therapeutic use in new indications.

Today we have five successful partnerships with major pharmaceutical companies that are developing antibody-based drugs using our n-CoDeR[®] library platform. The contribution of these external drug programs to our pharmaceutical portfolio currently consists of five projects in preclinical phase and more than ten research phase projects. Some of these projects are expected to advance to clinical development this year.

Success in these external drug projects coupled with opportunities for new collaborations based on both n-CoDeR[®] and F.I.R.S.T.[™] provide great opportunities to increase revenues without taking any financial risk, since the partner company covers all development costs.

During the period, new preclinical research was published in Cell, which shows the potential of TB-403 (anti-PIGF) to improve treatment of medulloblastoma, the most common type of brain tumor in children. The potential for development in this area is currently investigated in together with our partner ThromboGenics.

Cristina Glad

Review of the project portfolio

Multiple myeloma (BI-505)

Project status

The initial results from the phase I study of BI-505 on patients in advanced stages of the malignant disease multiple myeloma were reported in January. The preliminary analysis showed a good safety profile for BI-505. In those dosage groups to which extended therapy was offered, 24% of these severely ill patients demonstrated stable disease for at least two months, indicating a beneficial effect of BI-505. Optimal dose was determined according to the study protocol and will be used in the next clinical trial.

The dose-escalating phase I study included a total of 35 patients with recurrent or refractory disease following at least two prior treatments with other drugs. The primary purpose of the study was to evaluate safety and tolerability among patients with advanced disease. The study also assessed pharmacokinetics and pharmacodynamics, such as relevant biomarkers for tumour response, to determine the appropriate dose of the antibody to pave the way for further clinical development. Groups of patients were treated with increasing intravenous doses of BI-505 (0.0004 - 20 mg/kg for a total of eleven dose levels) every other week for a four-week period. Treatment was subsequently extended among patients belonging to dose level six or higher for as long as the disease was stable. The study was conducted at seven clinics in Europe and the US.

Results from the phase I study were presented at the International Myeloma Workshop 2013 in Kyoto, Japan, after the end of the period (April). New preclinical data were also presented on the same occasion showing significantly enhanced antitumour activity compared with monotherapy when combining the approved drugs Velcade® or Revlimid® with BI- 505.

The April issue of the prestigious journal Cancer Cell presented data showing preclinical *proof-of-concept* both for BI-505, and for BioInvent's function-based F.I.R.S.T.™ platform with which the antibody was developed. The article presents data showing the potent action of BI-505 in several preclinical multiple myeloma models.

The first patient was dosed in April in an initial phase II study of BI-505. The study is carried out in patients with asymptomatic multiple myeloma ("smouldering multiple myeloma"). Patients with asymptomatic myeloma have no clinical symptoms; the disease can only be seen in laboratory tests. The study includes up to 10 patients and evaluates how BI-505 affects disease activity in these patients. Secondary objectives include safety, pharmacokinetics and evaluation of biomarkers.

Background

Candidate drug BI-505 is a human antibody that specifically binds to the ICAM-1 adhesion protein (also known as CD54). Expression of ICAM -1 is elevated in tumour cells, which makes it a suitable target for a candidate drug. BI-505 exerts its antitumour activity by inducing cell death of myeloma cells and by involving the patient's immune cells, known as macrophages, to attack myeloma cells. Macrophages are abundant in the bone marrow of myeloma patients, where they are thought to contribute to disease progression and development of resistance to currently available drugs. The ability of BI-505 to engage these disease-associated, disease-driving, immune cells to kill myeloma cells is therefore a very interesting mechanism of action. BI-505 has a new mechanism contributing to the effective killing of myeloma cells. In several animal models, BI-505 proved to be very effective at killing tumours and more effective than existing drugs. The number of newly diagnosed patients with multiple myeloma worldwide is estimated at more than 40,000 per year.

BI-505 has received Orphan Drug Designation in both Europe and the US for the indication multiple myeloma. This provides BI-505 with market exclusivity for treatment of multiple myeloma with an antibody against ICAM-1 for up to 10 years after marketing approval is granted.

BI-505 has the potential to be developed both as monotherapy for early stages of the disease and as combination therapy for recurrent disease or when the patient no longer responds to first-line therapy

for multiple myeloma. BioInvent intends to find a development partner for BI-505 and to take a final strategic decision on continued product development in cooperation with that partner.

Metastatic cancer (ADC-1013)

Background

ADC-1013 is a so-called agonistic (activating) immunostimulatory antibody developed for local administration into tumour tissue (intratumoural administration). The antibody is directed against the CD40 antigen, which is expressed on several types of immune system cells and stimulation of this protein activates the body's own defence mechanisms against cancer. CD40 is also expressed on several types of tumours, including lymphoma. ADC-1013 and a mouse-specific surrogate antibody have been studied in several different tumour models and consistently shown very promising effects. For example, it has been shown that local administration causes systemic immune activation, resulting in eradication of metastases. In addition, long-lasting immunity against the cancer is also created, thereby protecting against new metastases even after discontinuation of treatment. It has also been shown that the effect can be achieved at lower doses than when administering the antibody systemically, and that the risk of side effects is lower at the same doses. The product is FIND[®]-optimised from an origin antibody selected from BioInvent's n-CoDeR[®] antibody library. Development of ADC-1013 to date has been carried out by Alligator Bioscience, a Swedish Lund-based biotech company.

Project status

BioInvent obtained the right to co-develop the product candidate ADC-1013 with Alligator Bioscience through an option agreement. The parties will share future costs and revenues from the project equally. Development of the production process for ADC-1013 has begun. The next stage of development after up-scaling and production involves toxicological studies, which are expected to be carried out in 2013. Clinical investigation of ADC-1013 in cancer patients is expected to begin in the first half of 2014. Clinical investigation of ADC-1013 in cancer patients is expected to begin in the first half of next year.

Hematologic cancer (BI-1206)

Background

BI-1206 is a so-called antagonistic (blocking) antibody aimed at the immunosuppressive target protein Fc gamma receptor IIB, CD32b. CD32b is overexpressed on tumour cells in patients with lymphoma, especially in patients who respond poorly to currently available drugs. Data show that CD32b is directly involved in the development of tumour cell resistance to the current state-of-the-art treatment - Rituximab (Mabthera[®], Rituxan[®], Roche), an antibody directed against target protein CD20. Combined treatment with BI-1206 and rituximab has shown significantly enhanced antitumour effects in clinically relevant animal models of patients' tumour cells, compared with monotherapy with rituximab. Combination therapy therefore has the potential to significantly improve treatment of patients with non-Hodgkin's lymphoma. BI-1206 has also shown a strong ability to kill lymphoma cells on its own in preclinical models using tumour cells taken directly from patients. Moreover, other groups have shown that animals lacking CD32b (CD32b knockout mice) respond better to antibody treatment and are better able to kill tumour cells in a lung cancer model compared with animals that have the CD32b protein. These results show that BI-1206 also has the potential to be used as monotherapy and that by shutting off the immunosuppressive effect of CD32b and creating a more immunostimulatory environment, it can enhance the therapeutic effect of several previously approved antibody-based drugs other than rituximab.

BI-1206 will initially be developed for non-Hodgkin's lymphoma lymphoma (including chronic lymphocytic leukaemia), the most common type of hematologic cancer. Preclinical studies are also planned for assessment of the potential of this antibody to be effective for other types of hematologic cancer, for solid tumours and in combination with antibodies other than rituximab. The product will be developed in cooperation with a leading research group in Southampton, UK.

BioInvent believes that market for treatment with BI-1206 combined with other antibodies is significant. In 2012, Rituxan alone had sales of USD 7.1 billion, the majority for hematologic cancer, which makes it the second most sold antibody-based drug worldwide. In various studies, up to half of all cancer patients who responded to an initial course of Rituxan proved to be resistant to the drug on recurrence of the disease.

Project status

Development of the production process for BI-1206 has begun. The next stage of development after up-scaling and production involves toxicological studies, which are expected to begin in early 2014.

Review of technology platform and external collaborations

BioInvent's F.I.R.S.T[™] platform identifies antibodies directly based on their ability to kill primary cancer cells through differentially expressed, cancer cell-associated surface receptors. The Company is using this platform to look for new drug candidates for the treatment of various haematological cancers. The various advantages of the platform over other technology platforms in antibody development has been presented at scientific conferences. F.I.R.S.T[™] represents a further development of, and an important complement to, the company's n-CoDeR[®] platform. Its application coincides well with the Company's focus on developing cancer therapies in the field of hematologic oncology.

BioInvent is working with leading Swedish and international academic teams with the objective of developing antibodies based on new therapeutic concepts for the treatment of serious haematological and solid cancers. The research in this collaboration with Cancer Research Technology (CRT) and Queen Mary's University Hospital, for identification of novel antibody therapeutics within oncology focuses on function-modulating antibodies against so-called tumour-associated macrophages (TAM), a type of macrophage with oncogenic, tumour driving properties.

The Company is already conducting research and development of antibody-based drugs in cooperation with other external partners, such as Bayer HealthCare, Daiichi Sankyo, Mitsubishi Pharma and Servier. The structure of the various collaborations may vary, but common to them all is that BioInvent receives license fees and research financing, as well as milestone payments and royalties on sales of commercial products. These external drug programmes currently contribute five projects in preclinical phase and more than ten research phase projects to our pharmaceutical portfolio. Some of these projects are expected to advance into clinical development this year.

Revenues and result

Net revenues for the January – March period amounted to SEK 12 million (15). Revenues for the period are derived from partners developing therapeutic antibodies from the n-CoDeR[®] antibody library.

The Company's total costs for the January – March period amounted to SEK 26 million (58). Operating costs are divided between external costs of SEK 13 million (37), personnel costs of SEK 12 million (20) and depreciation of SEK 0.7 million (1.4). The decrease in external costs is due to a more extensive clinical programme was carried out during 2012.

Research and development costs for January – March amounted to SEK 20 million (50). During the period financial support from the EU's framework programme was reported for early research projects. The subsidy amounted to SEK 0.7 million (6.0) and has been reported in the income statement under "Other operating revenues and costs".

The loss for January – March amounted to SEK -14 million (-37). The net financial items, January – March, amounted to SEK -0.2 million (0.7). Loss per share, January – March, amounted to SEK -0.19 (-0.55).

Financial position and cash flow

As of 31 March 2013, the Group's liquid funds amounted to SEK 77 million (138). The cash flow from current operations and investment activities for January – March amounted to SEK -23 million (-36). Payment of reserves from 2012 for the remaining costs of the TB-402 project and for restructuring costs affected working capital during the first quarter 2013 and will also affect operating capital during the second and third quarters of 2013.

The shareholders' equity amounted to SEK 33 million (102) at the end of the period. The Company's share capital at the end of the period was SEK 37 million. The equity/assets ratio at the end of the period was 37 (63) per cent. Shareholders' equity per share amounted to SEK 0.45 (1.51). The Group had no interest-bearing liabilities.

Investments

No investments were made in tangible assets (-) and intangible assets during the period (-).

Continued operations

The Group's liquid funds at 31 March 2013 together with anticipated revenues are estimated to be sufficient to finance the planned activities for the next twelve months. Moreover, the company considers to turn to capital markets for further fund raising.

Organisation

As of 31 March 2013, BioInvent had 48 (86) employees. 40 (71) of these work in research and development.

Employee incentive programme

The annual general meeting on 24 March 2011 resolved on a complement to the previous employee incentive programme. The options programme 2011/2015 comprise newly employed members of management and key-employees who do not participate in the previous programme. The programme shall comprise maximum 350,000 employee options and to issue 459,970 warrants for the subsidiary BioInvent Finans AB, free of charge, to secure the company's commitment under the incentive programme and to cover the company's associated social security contributions. BioInvent Finans AB has subscribed all the warrants. Each employee option entitles after conversion due to the rights issue in the spring of 2012 the holder to subscribe to 1.004 new shares at a subscription price of SEK 30.24. A basic allocation of 37,500 employee options took place in June 2011. Extra allotment of 6,667 employee options took place in February 2012 and in February 2013 with 3,938 employee options.

Fully exercised the employee incentive programme 2011/2015 represent a dilution of about 0.6 per cent of the shares.

Riskfactors

The Company's operations are associated with risks related to factors such as drug development, competition, collaboration with partners, technology development, patents, capital requirements, currency and interest rates. The aforementioned 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 14, in the company's annual report 2012.

Accounting principles

This interim report was prepared in accordance with IAS 34, Interim Financial Reporting, and applicable sections of the Swedish Annual Accounts Act. The accounting principles applied here are essentially the same as those applied in the preparation of the most recent annual report. Changes in IFRS standards entered into force in 2013 has had no impact on the financial statements.

Upcoming financial reports

BioInvent will present the following financial reports:
Interim reports 25 July, 24 October 2013

Contact

Any questions regarding this report will be answered by:

BioInvent International AB (publ.)

Cristina Glad, CEO, phone.+46 (0)46 286 85 51, mobile +46 (0)708 16 85 70

The Trout Group

Christine Yang, Vice President, phone +1 646 378 2929, cyang@troutgroup.com

The report is also available at www.bioinvent.com

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

	3 MONTHS 2013 Jan.-March	3 MONTHS 2012 Jan.-March	12 MONTHS 2012 Jan.-Dec.
Net sales	11,638	14,509	42,946
<i>Operating costs</i>			
Research and development costs	-19,726	-50,177	-207,278
Sales and administrative costs	-6,319	-8,165	-39,241
Other operating revenues and costs	393	6,271	12,480
	-25,652	-52,071	-234,039
Operating profit/loss	-14,014	-37,562	-191,093
Profit/loss from financial investments	-245	732	3,248
Profit/loss after financial items	-14,259	-36,830	-187,845
Tax	-	-	-
Profit/loss	-14,259	-36,830	-187,845
Other comprehensive income			
<i>Items that have been or may be reclassified subsequently to profit or loss</i>			
Changes in actual value current investments	-10	-73	-13
Comprehensive income for the year	-14,269	-36,903	-187,858
Other comprehensive income for the year attributable to parent company's shareholders	-14,269	-36,903	-187,858
Earnings per share, SEK			
Before dilution	-0.19	-0.55	-2.61
After dilution	-0.19	-0.55	-2.61

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

	2013 31 March	2012 31 March	2012 31 Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	1,552	0
Tangible fixed assets	6,054	9,935	6,776
Current assets			
Inventories	123	252	249
Current receivables	6,099	12,054	9,457
Liquid funds	77,124	138,042	100,061
Total assets	89,400	161,835	116,543
Shareholders' equity and liabilities			
Shareholders' equity	33,367	101,632	47,624
Current liabilities	56,033	60,203	68,919
Total shareholders' equity and liabilities	89,400	161,835	116,543

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

	2013 Jan.-March	2012 Jan.-March	2012 Jan.-Dec.
Opening balance	47,624	137,952	137,952
Effect of employee incentive programme	12	583	995
Rights issue			96,535
Comprehensive income	-14,269	-36,903	-187,858
Closing balance	33,367	101,632	47,624
Shareholders' equity pertaining to the parent company's shareholders	33,367	101,632	47,624

The share capital as of 31 March 2013 consists of 73,925,782 shares and the share's ratio value is 0.5.

The rights issue carried out in April 2012 raised SEK 96,535 thousands after issue expenses, which amounted to SEK 8,305 thousands.

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

	2013 Jan.-March	2012 Jan.-March	2012 Jan.-Dec.
Current operations			
Operating profit/loss	-14,014	-37,562	-191,093
Depreciation	722	1,370	6,138
Adjustment for other non-cash items	12	583	995
Interest received and paid	460	1,260	3,918
Cash flow from current operations before changes in working capital	-12,820	-34,349	-180,042
Changes in working capital	-10,117	-1,574	9,661
Cash flow from current operations	-22,937	-35,923	-170,381
Investment activities			
Acquisition of tangible fixed assets	-	-	-58
Cash flow from investment activities	-	-	-58
Cash flow from current operations and investment activities	-22,937	-35,923	-170,439
Financing activities			
Rights issue	-	-	96,535
Cash flow from financing activities	-	-	96,535
Change in liquid funds	-22,937	-35,923	-73,904
Opening liquid funds	100,061	173,965	173,965
Liquid funds at end of period	77,124	138,042	100,061
Liquid funds, specification:			
Current investments	38,126	106,776	79,336
Cash and bank	38,998	31,266	20,725
	77,124	138,042	100,061

Key financial ratios for the Group

	2013 31 March	2012 31 March	2012 31 Dec.
Shareholders' equity per share at end of period, SEK	0.45	1.51	0.64
Number of shares at end of period (thousands)	73,926	67,205	73,926
Equity/assets ratio, %	37.3	62.8	40.9
Number of employees at end of period	48	86	50

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

	3 MONTHS 2013 Jan.-March	3 MONTHS 2012 Jan.-March	12 MONTHS 2012 Jan.-Dec.
Net sales	11,638	14,509	42,946
<i>Operating costs</i>			
Research and development costs	-19,726	-50,177	-207,278
Sales and administrative costs	-6,319	-8,165	-39,241
Other operating revenues and costs	393	6,271	12,480
	-25,652	-52,071	-234,039
Operating profit/loss	-14,014	-37,562	-191,093
Profit/loss from financial investments	-245	732	3,248
Profit/loss after financial items	-14,259	-36,830	-187,845
Tax	-	-	-
Profit/loss	-14,259	-36,830	-187,845
Other comprehensive income			
<i>Items that have been or may be reclassified subsequently to profit or loss</i>			
Changes in actual value current investments	-10	-73	-13
Comprehensive income for the year	-14,269	-36,903	-187,858

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

	2013 Jan.-March	2012 Jan.-March	2012 Jan.-Dec.
Assets			
Fixed assets			
Intangible fixed assets	0	1,552	0
Tangible fixed assets	6,054	9,935	6,776
Financial fixed assets	100	100	100
Current assets			
Inventories	123	252	249
Current receivables	6,099	12,054	9,457
Current investments	38,126	106,826	79,326
Cash and bank	38,998	31,266	20,725
Total assets	89,500	161,985	116,633
Shareholders' equity and liabilities			
Shareholders' equity	33,395	101,660	47,652
Current liabilities	56,105	60,325	68,981
Total shareholders' equity and liabilities	89,500	161,985	116,633

Lund, 25 April 2013

Cristina Glad, CEO

Review report

Introduction

We have reviewed the summarised interim financial information for BioInvent International AB (publ) on 31 March 2013 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 Standard on Review Engagements SÖG 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.

Lund, 25 April 2013

KPMG AB

Alf Svensson
Authorised Public Accountant

BioInvent International AB (publ)

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

Forward looking information

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

Information disclosed in this press release is provided herein pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 8.30 a.m. CET, on 25 April, 2013.