



# Filing to the European Medicines Agency of two conditional Marketing Authorization Applications in oncology

2012 Revenue of 1,340 K€, up 21%

# 2013 First quarter revenue of 571 K€, up 78%

**AB Science SA** (NYSE Euronext – FR0010557264 – AB), a pharmaceutical company specialized in research, development and marketing of protein kinase inhibitors (PKIs), reports today its annual financials as of 31 December 2012, as well as its revenue for the first quarter of 2013, and provides an update on its activities. The Board who met on April  $24^{th}$ , 2013, reviewed and approved the consolidated financial statement for the year closing on 31 December 2012. Audit procedures on consolidated financial statements were performed. The audited financial report is available on the Company's website.

Commenting on this announcement, Alain Moussy, Chairman and CEO of AB Science declared: "The acceptance by the European Medicines Agency to review our requests for conditional marketing authorization shows that the authorities consider masitinib as a potential candidate for registration in gastrointestinal stromal tumor (GIST) and in pancreatic cancer. Based on these results, the Company intends to actively pursue the development of masitinib in oncology where a major program of four phases 3 studies and twelve phase 2 studies is on-going, with the aim of demonstrating that masitinib increases survival for patients under treatment. The steady increase of masitinib sales in veterinary medicine reflects the increasing use of masitinib by the veterinarians because of its effectiveness in oncology."

#### I. Key events of year 2012:

## In human medicine

- Masitinib generated promising results in gastro-intestinal stromal tumor (GIST) cancer, a cancer of the digestive system that affects 15 new patients per one million inhabitants each year.
  - o In second-line of treatment, that is patients with resistance to Gleevec® which is the first-line treatment, AB Science announced on 1 February 2012 encouraging results from a phase II study with masitinib.
    - In this study, 44 patients with inoperable, locally advanced or metastatic GIST and showing disease progression while treated with Gleevec® (imatinib) (400 to 800 mg/day) received either masitinib (23 patients) at 12 mg/kg/day or Sutent® (21

patients) until progression. After a median follow-up of 14 months, median overall survival was not reached for masitinib (superior to 21.2 months) versus 15.2 months for Sutent® (p = 0.016). After 18 months, 79.9% of patients treated with masitinib were still alive, versus 21.6% for patients treated with Sutent®. The Hazard Ratio was 0.29 (95% CI [0.10; 0.85], meaning that the risk of death was decreased by 71% for the patients treated with masitinib versus the patients treated with Sutent®. These results have been presented orally during the American Society of Clinical Oncology (ASCO) 2012 Annual Meeting, (http://meetinglibrary.asco.org/content/96397-114).

- On the basis of these results, AB Science initiated a phase III study in GIST in secondline of treatment, in resistance to Gleevec®. This is a phase III, multicenter, randomized, open-label, controlled, two-parallel group study evaluating the efficacy and safety of masitinib as compared with sunitinib (Sutent®) in GIST patients after progression under imatinib (Gleevec®). The primary end-point is overall survival. The study is currently recruiting.
- AB Science filed a conditional Marketing Authorization Application (MAA) of masitinib in GIST resistant to Gleevec®. Filing has been accepted by the European Medicines Agency (EMA).
- AB Science announced the results from the phase III study evaluating the effect of masitinib in combination with Gemzar® (gemcitabine, Eli Lilly and Company) on overall survival (OS) in patients with pancreatic cancer. Masitinib in combination with Gemzar® significantly extended median OS by 6 and 2.7 months in two independent patient populations, representing 65% and 45% of the overall population; namely, patients with a genetic biomarker collected from simple blood sample indicative of aggressive disease progression, and patients with cancer pain. Pain intensity and the discovered genetic biomarker were shown to be of prognostic value for survival under Gemzar® alone and at the same time predictive of increased survival with masitinib in combination with Gemzar® for those patients identified as having a poor prognosis with Gemzar® alone.

AB Science also announced that the European Medicines Agency (EMA) has accepted to review a Marketing Authorization Application (MAA) for conditional approval of masitinib in combination with Gemzar® in the treatment of pancreatic cancer, following filing of this dossier.

Full data has been submitted for presentation at the American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium (24-26 January 2013, in San Francisco, California).

#### Other events

A bond loan agreement, convertible or repayable in ordinary shares, for the nominal amount of 10,000,500 euros (100 bonds with nominal amount of 10,005 euros), authorized by the Board of Directors on 2 March 2012, using the delegation given by the General Shareholder's Meeting on 23 May 2011, was subscribed and fully issued on 17 April 2012. The bonds bear 1.25% interest to be paid annually. They also bear 4.75% accrued interest to be paid only in case of repayment of the loan in cash. The bonds are convertible into shares at any time at the initiative of the bondholder, one bond giving right to a preset number of ordinary shares, determined as follows: "O/P", where O is the nominal value of the bonds and P is equal to 15.00 euros. The bonds are automatically repaid in shares, if after 31 December 2014, the

three-month moving average share price of the Company with a 1 euro cent nominal value is greater or equal to 20 euros. The bonds may be repaid by anticipation in cash at the option of AB Science under certain conditions. If not, they will be repayable in full on the seventh anniversary of the issue date at their nominal value, by 17 April 2019.

- AB Science set-up an equity financing facility (PACEO®) with Société Générale on 3 May 2012. Société Générale has subscribed warrants issued by AB Science (bons d'émission d'actions, or "BEA") that AB Science may exercise at its sole discretion, with the view to enabling the Company to carry out successive capital increases representing a maximum of 2,000,000 shares (approximately 6.3% of the current share capital). AB Science will decide to carry out share issues in accordance with its actual financing requirements over the next 3 years, in tranches of up to 400,000 shares (i.e. 1.3% of the current share capital). The issue price of the shares at the time of each capital increase will represent a 5% discount on the weighted average share price for the three trading days preceding the pricing date. When issued, the shares are not intended to be kept by Société Générale, which aims at selling them in the market.
- AB Science ended on 17 April 2012 the liquidity contract with SG Securities. 100,000 euros in cash were held on the liquidity account at the date of liquidity contract signature and 85,000 euros on 17 April 2012.
- Following the exercise of BSCPEs and BSAs (stock warrants), 110,300 shares of 0.01 euro nominal value were issued in 2012, resulting in a 1,003 euros capital increase.
- A bond loan agreement, convertible or repayable in ordinary shares, for the nominal amount of 7.539.400 euros (149 bonds with nominal amount of 50,600 euros), authorized by the Board of Directors on 23 May 2011, subscribed and fully issued on 19 August 2011, was converted into shares on 6 December 2012. 596,000 new shares have been issued.
- Since February 24th 2012, AB Science shares are eligible to "long-only" deferred settlement service (SRD) on NYSE-Euronext. Any potential investor has therefore the possibility to acquire AB Science shares through the SRD, while benefiting from leverage and differed payment.
- AB Science is listed on the SBF 120 since 24 December 2012.

## II. Recent events since the closing of the financial year

#### 2013 First quarter revenue

AB Science revenues in the first quarter of 2013 amounted to €571 thousand versus €321 thousand in the first quarter of 2012, up 78%.

These revenues derive from the commercial exploitation of masitinib in veterinary medicine in Europe and in the United States.

## 2013 First quarter other events

The company was subject to a tax audit for the research tax credit for 2010 and 2011.

A proposal for revision from the Public Finance Department was received in April 2013. The adjustment amounts to €646 thousand and mainly relates to the exclusion by the Tax Administration of employee profit-sharing in the tax base for the research tax credit calculation (€489 thousand). Due to this adjustment, a €226 thousand accrual was booked.

It should be noted that a judgment of the Administrative Court of Montreuil and a judgment of the Court of Appeal of Nantes made in 2012 considered the employee profit-sharing as part of salary and therefore eligible for research tax credit. In the absence of a decision of the State Council, the Company has maintained the accruals booked.

#### III. 2012 and 2011 consolidated financial statements

(in thousands of euros)	Dec 3	1 <sup>st</sup> , 2012	Dec 31 <sup>st</sup> , 2011
Revenues from Sales	1	340	1 104
Other operating revenues		0	0
Total operating income	1	340	1 104

Operating revenues as of 31 December 2012 amounted to €1,304 thousand, compared with €1,104 thousand in the previous year.

Sales as of 31 December 2012 amounted to €1,340 thousand, compared with €1,104 thousand as of 31 December 2011 – which represents a growth of 21.4% – and were entirely generated by the commercialization of a drug in veterinary medicine.

(in thousands of euros)	Dec 31 <sup>st</sup> , 2012	Dec 31 <sup>st</sup> , 2011
Cost of goods sold	238	301
Marketing costs	1 080	1 091
Administrative costs	1 909	1 843
R&D costs	8 725	7 586
Other operating expenses	0	0
Total operating expenses	11 953	10 820

Operating expenses as of 31 December 2012 amounted to €11,953 thousand, as compared with €10,820 thousand in the previous year, which is an increase of 10.5%.

The Company's marketing expenses amounted to €1,080 thousand as of 31 December 2012, as compared with €1,091 thousand in the previous year, which is a decrease of 1%.

Administrative expenses increased by 3.6%, up from €1,843 thousand as of 31 December 2011 to €1,909 thousand as of 31 December 2012.

Research and development expenses increased by 15%, up from €7,586 thousand as of 31 December 2011 to €8,725 thousand as of 31 December 2012.

This increase is explained mainly by the following factors:

- Decrease of the research tax credit by €344 thousand, from €3,154 thousand in 2011 to €2,810 thousand in 2012.
- Increase of other research and development expenses (+ €795 thousand) due to the continuation of the program of clinical studies.

#### Operating profit/loss

The operating loss as of 31 December 2012 amounted to €10,613 thousand, compared with €9,716 thousand as of 31 December 2011, which is an increase of the operating loss by €897 thousand (9.2%) for the reasons provided above.

## Financial profit/loss

The financial loss as of 31 December 2012 was €411 thousand, as compared with a €51 thousand income a year earlier.

Financial expenses, excluding currency effects and discounting effect, and after taking into account the cancellation of capitalized interest (€131 thousand) related to the bond loan converted in 2012, increased from €257 thousand as of 31 December 2011 to €570 thousand as of 31 December 2012. This increase results primarily from higher capitalized interest related to bond loans (€456 thousand as of 31 December 2012 against €178 thousand as of 31 December 2012) and to a lesser extent to the annual current interests (+€125 thousand since 31 December 2011).

Capitalized interests are calculated at the rate of 4.75% and are payable only in case of loan repayment in cash. The annual interests are calculated at the rate of 1.25% payable annually.

For the year 2012, interests earned from the investment of the obligations exceeded the interest payable annually.

#### Net profit/loss

The total net loss on 31 December 2012 amounts to €10,985 thousand, compared with €9,651 thousand on 31 December 2011, increasing by 13.8% for the reasons provided above.

#### IV. Consolidated balance sheet information

#### <u>Assets</u>

Given the expected sales perspectives, development costs were expensed. Fixed assets correspond essentially to the cost of registration of the Company's patents. Registration costs of the Company's patents booked as net fixed assets increased by 17.3% as of 31 December 2012, from €1,069 thousand as of 31 December 2011 to €1,254 thousand as of 31 December 2012.

Inventories amounted to €523 thousand as of 31 December 2011 as compared with €621 as of 31 December 2011. They are related to the inventory of raw materials and principal ingredient (€193 thousand), to the inventory of work-in-progress products (€186 thousand) and to the inventory of finished products (€144 thousand).

Trade receivable increased from €136 thousand at the end of 2011 to €149 thousand as of 31 December 2012. This increase was induced by the increase in sales.

Current financial assets increased by 36.8% between 31 December 2011 and 31 December 2012, i.e. from €8,558 thousand to €11,706 thousand. These financial assets correspond mainly to cash instruments, the term of which is beyond 3 months. This increase results from the investment of money raised through the collection of subsidies and conditional advances in January 2012, and also the release of the bond loan.

Other current assets of the Company amount to €3,837 thousand as of 31 December 2012, compared with €6,901 thousand as of 31 December 2011, i.e. a 44.4% decrease over the period.

This decrease is explained by the main following factors:

- Decrease in the research tax credit receivable (€2,810 thousand as of 31 December 2012, compared with €3,154 thousand as of 31 December 2011, i.e. a €344 thousand decrease)
- Decrease of conditional advances receivable (€1,956 thousand), advance received in January 2012
- Decrease of subsidies receivable (€974 thousand), subsidy received in January 2012

Cash remained stable between 31 December 2011 and 31 December 2012, amounting to €11,476 thousand as of 31 December 2012 and €11,808 thousand as of 31 December 2011.

The total cash and financial current assets amounted to €23,452 thousand as of 31 December 2012 compared with €20,366 thousand as of 31 December 2011.

#### Liabilities

Funding used by the Company comes mainly from capital increases and various public aids (research tax credits, reimbursable advances and subsidies), and issue of bond loan agreements.

The table hereafter shows the change in the Company's equity between 31 December 2011 and 31 December 2012.

(in thousands of euros) – IFRS norms	Company Equity
Equity as of 31 December 2011	7 731
Capital increases and additional paid-in capital net of issue costs	7 676
Total profit/loss over the period	(10 968)
Conversion options	361
Payments in shares	67
Own shares	31
Equity as of 31 December 2012	4 899

As of 31 December 2012, the Company's net equity stood at €4,899 thousand.

Over the last 2 years, the main variations, except for the annual profits/losses, derived from the capital increases in 2012 and 2011 respectively for €7,676 thousand and €1,315 thousand, and the booking of the equity component of the bond loan for €361 thousand.

Current liabilities amount to €9,710 thousand as of 31 December 2012 as compared with €9,359 thousand at the end of 2011, i.e. an increase of 3.8%.

This increase (€351 thousand) is explained in particular by the following factors:

- Increase in current accruals (€116 thousand) related to the adjustment of the tax accrual;
- increase in trade payable (€553 thousand);
- decrease in current financial liabilities (€632 thousand) related to the reimbursement of current financial liability of €1,000 thousand in February 2012;
- increase of other current liabilities (€314 thousand), mainly related to the increase of social debts.

Non-current liabilities include mainly a bond loan (€8,156 thousand), which has a maturity over 2 years, two bank debts for €1,473 thousand and conditional advances. They amount to €15,373 thousand as of 31 December 2012, compared with €12,372 thousand as of 31 December 2011, i.e. an increase of €3,001 thousand related notably to the issue of a bond loan convertible or reimbursable in ordinary shares in April 2012 (€10,000 thousand) and to the reclassification into equity of bonds subscribed in 2011 and converted into shares in December 2012 (€7.5 thousand).

## **Next financial appointments in 2013**

Financial communication on 1<sup>st</sup> semester 2013: 30 August 2013

General Shareholders' Meeting: 18 June 2013

#### Find our complete 2012 financial report on www.ab-science.com

#### **About AB Science**

Founded in 2001, AB Science is a pharmaceutical company specializing in the research, development and commercialization of protein kinase inhibitors (PKIs), a new class of targeted molecules whose action is to modify signaling pathways within cells. Through these PKIs, the Company targets diseases with high unmet medical needs (cancer, inflammatory diseases, and central nervous system diseases), in both human and veterinary medicines.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine in Europe and in the USA, and is pursuing 8 on-going phase 3 studies in human medicine in GIST, metastatic melanoma expressing JM mutation of c-Kit, multiple myeloma, mastocytosis, severe persistent asthma, rheumatoid arthritis, and progressive multiple sclerosis. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

Further information is available on AB Science website: www.ab-science.com.

This document contains prospective information. No guarantee can be given as for the realization of these forecasts, which are subject to those risks described in documents deposited by the Company to the Authority of the financial markets, including trends of the economic conjuncture, the financial markets and the markets on which AB Science is present.

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AB Science – Financial Communication & Media Relations investors@ab-science.com

# FINANCIAL STATEMENTS AS OF 31 DECEMBER 2012

Assets (in thousands of euros)	31/12/2012	31/12/2011
Intangible assets	1 266	1 103
Tangible assets	106	151
Non-current financial assets	649	159
Other non-current assets	0	25
Deferred tax assets	0	0
Non-current assets	2 020	1 438
Inventories	523	621
Trade receivable	149	136
Current financial assets	11 706	8 558
Other current assets	3 837	6 901
Cash and cash equivalents	11 746	11 808
Current assets	27 962	28 024
TOTAL ASSETS	29 982	29 462

Liabilities (in thousands of euros)	31/12/2012	31/12/2011
Share capital	323	316
Additional paid-in capital	75 493	67 823
Translation reserve	5	(12)
Other reserves and results	(70 922)	(60 397)
Total equity attributable to equity holders of the		
Company	4 899	7 731
Non-controlling interests		
Total equity	4 899	7 731
Non-current provisions	292	273
Non-current financial liabilities	14 373	11 532
Other non-current liabilities	0	0
Deferred tax liabilities	708	568
Non-current liabilities	15 373	12 372
Current provisions	818	702
Trade payable	5 786	5 233
Current financial liabilities	1 188	1 820
Tax liabilities / Tax payable	0	0
Other current liabilities	1 918	1 604
Current liabilities	9 710	9 359
TOTAL EQUITY AND LIABILITIES	29 982	29 462

# STATEMENT OF COMPREHENSIVE INCOME AS OF 31 DECEMBER 2012

(in thousands of euros)	31/12/2012	31/12/2011
Revenue	1 340	1 104
Other operating revenues	0	0
Total revenues	1 340	1 104
Cost of sales	(238)	(301)
Marketing expenses	(1 080)	(1 091)
Administrative expenses	(1 909)	(1 843)
Research and development expenses	(8 725)	(7 586)
Other operating expenses	-	-
Operating income (loss)	(10 613)	(9 716)
Financial income	490	378
Financial expenses	(901)	(327)
Financial income (loss)	(411)	51
Income tax expense	39	15
Net income (loss)	(10 985)	(9 651)
including:		
Attributable to non-controlling interests	-	-
Attributable to equity holders of the parent		
Company	(10 985)	(9 651)
Translation differences	17	(29)
Total Comprehensive income for the period	(10 968)	(9 680)
including:		
Attributable to non-controlling interests	-	-
Attributable to equity holders of the parent		
company	(10 968)	(9 680)
Basic earnings per share - in euros	(0,34)	(0,31)
Diluted earnings per share - in euros	(0,34)	(0,31)

# **CONSOLIDATED STATEMENT OF CASH FLOWS**

(in thousands of euros)	31/12/2012	31/12/2011
Net income (loss)	(10 985)	(9 651)
Adjustment for:	405	478
- Depreciation, amortization and charges to provisions	0	0
- Income (loss) from asset sale	67	97
- Non-cash income and expenses linked to share-based payments	166	5
- Other non-cash income and expenses	24	(16)
- Income tax expense	0	0
- Change in deferred tax	4 016	801
- Impact of change in working capital requirement generated by		
operating activities	160	(34)
- Income from interest on financial assets	(6 147)	(8 320)
Cash flow from operations before tax and interest	(64)	0
Income Tax (paid)/received	(6 211)	(8 320)
Net cash flow from operating activities	(324)	(433)
Acquisitions of fixed assets	0	0
Sales of tangible and intangible assets	(12 154)	(8 500)
Acquisitions of financial assets	8 500	17 000
Proceeds from the sale of financial assets	0	0
Changes in loans and advances	185	319
Interest received/(paid)	0	0
Other cash flow related to investing activities	(3 793)	8 386
Net cash flow from investing activities		
Dividends paid	291	1 315
Capital increase (decrease)	11 201	7 851
Issue of loans and receipt of conditional advances	(1 650)	(75)
Repayments of loans and conditional advances	85	0
Other cash flows from financing activities	9 926	9 091
Net cash flow from financing activities	17	(29)
Effect of exchange rate fluctuations	0	0
Effect of assets held for sale	0	0
Impact of changes in accounting principles	(61)	9 128
Net increase (decrease) in cash and cash equivalents – by cash flows		
Cash and cash equivalents – opening balance	11 808	2 679
Cash and cash equivalents – closing balance	11 746	11 808
Net increase / decrease in cash and cash equivalents – by change in		
closing balances	(61)	9 128