

# Net loss of 26.1M€ for the year 2018

# Cash position of 11.6M€ as of 31 December 2018, plus 5.7M€ of 2018 tax credit

**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 2018 and provides an update on its activities. The Board who met on April 29th, 2018, reviewed and approved the consolidated financial statement for the year closing on 31 December 2018 Audit procedures on consolidated financial statements were performed. The audited financial report is available on the Company's website.

# I. Key events of year 2018

#### Clinical studies

Amyotrophic Lateral Sclerosis (ALS)

In April 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicine Agency (EMA) adopted a negative opinion for the marketing authorization of masitinib in the treatment of adult patients with amyotrophic lateral sclerosis (ALS).

The grounds for this negative opinion were:

- The CHMP considered, based on a Good Clinical Practice inspection carried out on two of the main clinical investigation centers of the study, that the reliability of the data was not robust enough to support registration.
- The CHMP did not recognize the clinical relevance of the distinction made by AB Science between patients with "normal" progression (accounting for 85% of patients in the study) and for whom an improvement on the primary endpoint ALSFRS-R score has been demonstrated, and those with "rapid" progression (accounting for 15% of patients in the study).
- The CHMP considered that the primary analysis of the ALSFRS-R score for patients who stopped the study prematurely, based on the LOCF method (last observation carried forward), could introduce a bias in the analysis of the results.

The marketing authorization application was filed in September 2016 based on the interim results from study AB10015. The final safety data were generated in February 2018 and could not be inspected during the evaluation. New data cannot be presented as part of a reexamination procedure.

AB Science is therefore evaluating the possibility to resubmit the application based on the final results from study AB10015. As part of the resubmission, AB Science intends to submit:

- Final safety data
- New sensitivity analyses on the primary analysis of the ALSFRS-R score for patients who stopped the study prematurely, applying recommended methods as per EMA guidelines in order to corroborate the results based on the LOCF method (last observation carried forward)
- New preclinical data reinforcing the mechanism of action of masitinib, which is an important consideration in the context of an application based on a single pivotal trial

Moreover, a second study is needed to confirm the results of this first pivotal study, even in case of positive opinion by the CHMP. The design of this study has been validated by EMA through a *scientific advice* procedure. AB Science will initiate this confirmatory study once the ANSM clinical hold is lifted.

#### Other clinical studies

The phase 3 study evaluating masitinib in the treatment of primary progressive or relapse-free secondary progressive multiple sclerosis is still ongoing. The Independent Data Safety Monitoring Committee (IDMC) did not report any safety concern with masitinib in the study population. The recruitment is completed and final results of the study are expected in 2019.

The phase 3 study (AB12003) evaluating masitinib in the treatment of metastatic castrate resistant prostate cancer (mCRPC) is still ongoing following the blinded interim analysis of study data. According to the study protocol, an interim analysis performed by the IDMC was pre-planned once 50% of the events had been reached. Based on results from this interim analysis, the IDMC has recommended the continuation of study AB12003 in a pre-specified sub-population of patients that were identified based on a specific biological biomarker, and which is estimated to account for about two-thirds of the eligible population. A total of 468 patients are to be enrolled in this sub-population, while enrolment of patients with an absence of this biomarker will be stopped. Based on the rules set for the interim analysis, this recommendation from the IDMC means that the probability of success of study AB12003 is above 80% in the selected sub-population, assuming that the patients remaining to be enrolled behave similarly to those analyzed at the interim analysis. AB Science expects study AB12003 to be completed in 2020

The phase 3 study evaluating masitinib in patients with confirmed mild to moderate Alzheimer's disease has completed recruitment with 721 enrolled patients. The Independent Data Safety Monitoring Committee (IDMC) has, on each occasion, recommended the continuation of this phase 3 study based on the analysis of the safety data, and once based on the result of an efficacy futility test. Final analysis is expected in 2019.

#### Restructuring of the AB Science clinical development department in 2018

As a consequence of the ANSM decision to put AB Science studies on clinical hold in France, AB Science has completed reorganization of its clinical development activity to ensure compliance with good clinical practices

The main achievements of this restructuring are:

- New organization of the clinical development activity, with the recruitment of 9 professionals each having a minimum of 15 years of experience in the pharmaceutical industry
- Implementation of a new Quality Management System (QMS), the original system having been identified as the root cause of the findings reported during previous inspections
- Reassessment of all masitinib safety data, with a full analysis of masitinib safety data performed in 2018

An ANSM inspection was conducted in 2018 to ensure that the conditions required to lift the clinical hold have been met. AB Science will disclose the agency decision once available.

#### Other events

Other transactions of securities

#### During 2018:

- As a result of the exercise of share subscription warrants, 39,314 shares of nominal value of 0.01 euros were issued in the first half of 2018, resulting in an increase in equity of 393.14 euros.

- 7,527 preference shares of nominal value of 0.01 euros were issued.

#### Other information

AB Science confirms its eligibility for the PEA-SMEs in accordance with decree n°2014-283 of 4 March 2014 for the implementation of Article 70 of 2014 Finance Law n°2013-1278 of 29 December 2013, setting the PEA-PME eligibility for companies: less than 5 000 employees on one hand, a turnover lower than 1,500 million euros or total assets of less than 2,000 million, on the other hand.

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

No event after the closing likely to have an impact on the financial position of the Company has occurred since closing.

#### III. 2018 and 2017 consolidated financial statements

Global Profit and Loss Account – 31.12.2018 (IFRS):

(in thousands of euros)	31.12.2018	31.12.2017
Net Revenues	1 701	1 739
Operating loss	(28 944)	(28 404)
Net loss	(26 061)	(27 122)
Global loss of Period	(25 907)	(27 056)
Net income per share – in euros	(0,69)	(0,75)
Diluted income per share - in euros	(0,69)	(0,75)

# **Operating Results**

#### Operating income

(in thousands of euros)	31.12.2018	31.12.2017
Net Revenues	1 701	1 739
Other operating revenues	0	0
Total operating income	1 701	1 739

As of December 31<sup>st</sup> 2018, operating income, consisting exclusively of sales related to the drug in veterinary medicine, amounted to 1,701 K€ against 1,739 K€ last year. This represents a decrease of 2.2 %.

### Operating expenses

(in thousands of euros)	31.12.2018	31.12.2017
Cost of goods sold	248	121
Marketing costs	1 082	1 019
Administrative costs	2 388	2 269
R&D costs	26 926	26 734
Other operating expenses	0	0
Total operating expenses	30 645	30 143

As of 31 December 2018, operating expenses amounted to 30,645 K€, against 30,143 K€ last year, an increase of 1.67%.

As of 31 December 2018, cost of goods sold amounted to 248 K€, against 121 K€ last year, an increase of 127 K€.

As of 31 December 2018, marketing costs amounted to 1,082 K $\in$ , against 1,019 K $\in$  last year, an increase of 6.2%.

As of 31 December 2018, administrative expenses increased by 5.2%, from 2,269 K€ last year to 2,388 K€.

Research and development expenses increased by 0.71%, from 26,734 K€ as of 31 December 2017, to 26,926 K€ as of 31 December 2018.

# Operating profit/loss

The operating loss as of 31 December 2018 amounted to 28,944 K€, against 28,404 K€ as of 31 December 2017, which represents an increase of the operating loss by 540 K€ (2%) for the reasons indicated above.

#### Financial income/loss

The financial result as of 31 December 2018 is an income of 2,887 K€, against an income of 1,288 K€ last year.

This 2,887 K€ profit results from:

- ✓ Financial income: 2,963 K€. Financial income is mainly related to:
  - Cash remuneration: 9 K€
  - Currency effects: 90 K€
  - The booking of the variation in the fair value of financial liabilities: 2 863 K€. This variation generates a non-recurring profit with no cash impact.
- ✓ Financial loss: 76 K€. Financial loss is mainly related to:
  - Currency effects : 53 K€
  - Others Financial loss: 23 K€

#### *Net profit/loss*

The net loss amounted, as of 31 December 2018, to 26,061 K€ against 27,122 K€ at 31 December 2017, a decrease of 3.9%, for the reasons mentioned above.

#### IV. Consolidated balance sheet information

#### Assets

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 decreased by 8.4% as of 31 December 2018, from 1,677 K€ as of 31 December 2017 to 1.536 K€ as of 31 December 2018.

Inventories amounted to 153 K€ as of 31 December 2018 as compared to 159 K€ as of 31 December 2017.

Trade receivable decreased from 449 K€ at the end of 2017 to 236 K€ as of 31 December 2018.

The financial assets correspond mainly to cash instruments, the term of which is beyond 3 months. As of 31 December 2018, no financial asset has a term which is beyond 3 months.

Other current assets of the Company decreased by 482 K $\in$  (8,764 K $\in$  as of 31 December 2018, against 9,246 K $\in$  as of 31 December 2017).

Cash amounts to 11,560 K€ as of 31 December 2018, compared to 38,789 K€ as of 31 December 2017.

The total cash and financial current assets amount to 11,560 K€ as of 31 December 2018 compared to 38,789 K€ as of 31 December 2017. This cash amount does not include the 5,650 K€ corresponding to 2018 research tax credit reimbursement in 2019.

#### Liabilities

Funding used by the Company comes mainly from issue of bond loan agreements, issue of new shares with the equity line facilities and various public aids (research tax credits, reimbursable advances and subsidies).

The table hereafter shows the change in the Company's equity between 31 December 2017 and 31 December 2018.

(in thousands of euros) - IFRS norms	Company Equity
Equity as of 31 December 2017	10 735
Capital increases and additional paid-in capital net of issuance costs	61
Total profit/loss over the period	(25 907)
Conversion options	0
Payments in shares	149
Equity as of 31 December 2018	(14 962)

As of 31 December 2018, the Company's net negative equity amounts to 14,962 K€.

Current liabilities amount to 19,200 K€ as of 31 December 2018, compared to 18,713 K€ at the end of 2017, which represents an increase of 2.6%.

This increase (487 K $\in$ ) is explained in particular by:

- increase in current accruals (145 K€) related to employment-related legal disputes
- increase in other current liabilities (784 K€)
- decrease in trade payable (447 K€)

Non-current liabilities (18,253 K€) mainly include conditional advances for an amount of 9,331 K€ and financial instruments for 8,193 K€. They amount to 18,253 K€ as of 31 December 2018 against 21,152 K€ as of 31 December 2017, a decrease of 2,899 K€ due to financial instruments fair value variation.

#### V. Foreseeable evolution of the Group's situation and future prospects

In 2018, AB Science continued and reinforced the transformation plan started in 2017 in order to ensure that clinical studies are carried out in compliance with good clinical practices and intends to maintain this process of continuous improvement.

In 2019, AB Science continues to allocate most of its resources to the development of masitinib, the most advanced molecule of the Company.

The expected masitinib clinical milestones for 2019 are:

- Final analysis for phase 3 study in severe asthma uncontrolled by oral corticosteroids
- Final analysis for phase 3 study in progressive forms of Multiple Sclerosis
- Final analysis for phase 3 study in Alzheimer's disease
- Interim analysis for phase 3 study in pancreatic cancer

These results on studies that include a large sample of patients will increase the visibility on the portfolio and will lead to the identification of the indications with the greatest potential for the company.

Additionally, two confirmatory studies will be launched:

- Launch of a confirmatory phase 3 study in ALS
- Launch of a confirmatory phase 3 in systemic indolent mastocytosis

The Company also continued to invest in drug discovery activities in order to fuel its portfolio of molecules. The Company anticipates, subject to the availability of financial resources, to begin the regulatory preclinical studies of new molecules from its own research program.

Finally, AB Science intends to launch a phase 1/2 study in refractory acute myeloid leukemia with a new molecule developed by AB Science (AB8939).

#### Next 2019 financial appointments

Financial communication on 1st semester 2019: September 30, 2019 General Shareholders' Meeting: June 28, 2019

# Find our complete 2018 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 class of targeted proteins whose action are key in signaling pathways within cells. Our programs target only diseases with high unmet medical needs, often lethal with short term survival or rare or refractory to previous line of treatment.

AB Science has developed a proprietary portfolio of molecules and the Company's lead compound, masitinib, has already been registered for veterinary medicine and is developed in human medicine in oncology, neurological diseases, and inflammatory diseases. The company is headquartered in Paris, France, and listed on Euronext Paris (ticker: AB).

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

#### Forward-looking Statements - AB Science

This press release contains forward-looking statements. These statements are not historical facts. These statements include projections and estimates as well as the assumptions on which they are based, statements based on projects, objectives, intentions and expectations regarding financial results, events, operations, future services, product development and their potential or future performance.

These forward-looking statements can often be identified by the words "expect", "anticipate", "believe", "intend", "estimate" or "plan" as well as other similar terms. While AB Science believes these forward-looking statements are reasonable, investors are cautioned that these forward-looking statements are subject to numerous risks and uncertainties that are difficult to predict and generally beyond the control of AB Science and which may imply that results and actual events significantly differ from those expressed, induced or anticipated in the forward-looking information and statements. These risks and uncertainties include the uncertainties related to product development of the Company which may not be successful or to the marketing authorizations granted by competent authorities or, more generally, any factors that may affect marketing capacity of the products developed by AB Science, as well as those developed or identified in the public documents filed by AB Science with the Autorité des Marchés Financiers (AMF), including those listed in the Chapter 4 "Risk Factors" of AB Science reference document filed with the AMF on November 22, 2016, under the number R. 16-078. AB Science disclaims any obligation or undertaking to update the forward-looking information and statements, subject to the applicable regulations, in particular articles 223-1 et seq. of the AMF General Regulations.

For additional information, please contact:

#### **AB Science**

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# FINANCIAL STATEMENTS AS OF 31 DECEMBER 2018

Assets (in thousands of euros)	31/12/2018	31/12/2017
Intangible assets	1 572	1 739
Tangible assets	153	171
Non-current financial assets	54	47
Other non-current assets	0	0
Deferred tax assets	0	0
Non-current assets	1 779	1 957
Inventories	153	159
Trade receivable	236	449
Current financial assets	0	0
Other current assets	8 764	9 246
Cash and cash equivalent	11 560	38 789
Current assets	20 712	48 642
TOTAL ASSETS	22 491	50 600

Liabilities (in thousands of euros)	31/12/2018	31/12/2017
Share capital	411	410
Additional paid-in capital	193 271	193 284
Translation reserve	(63)	(55)
Other reserves and results	(208 580)	(182 903)
Total equity attributable to equity holders of the Company	(14 962)	10 735
Non-controlling interests		
Total equity	(14 962)	10 735
Non-current provisions	718	771
Non-current financial liabilities	17 535	20 381
Other non-current liabilities	0	0
Deferred tax liabilities	0	0
Non-current liabilities	18 253	21 152
Current provisions	145	0
Trade payable	15 036	15 483
Current financial liabilities	11	5
Tax liabilities / Tax payable	0	0
Other current liabilities	4 008	3 224
Current liabilities	19 200	18 713
TOTAL EQUITY AND LIABILITIES	22 491	50 600

# STATEMENT OF COMPREHENSIVE INCOME 31 DECEMBER 2018

(in thousands of euros)	31/12/2018	31/12/2017
Revenue	1 701	1 739
Other operating revenues	0	0
Total revenues	1 701	1 739
Cost of sales	(248)	(121)
Marketing expenses	(1 082)	$(1\ 019)$
Administrative expenses	(2 388)	$(2\ 269)$
Research and development expenses	(26 926)	(26734)
Other operating expenses	-	-
Operating income (loss)	(28 944)	(28 404)
Financial income	2 963	1 336
Financial expenses	(76)	(47)
Financial income (loss)	2 887	1 288
Income tax expense	(4)	(6)
Net income (loss)	(26 061)	(27 122)
Other comprehensive income		
Items that will not be reclassified subsequently to net income:		
- Actuarial gains	161	37
Items that should be reclassified subsequently to net income:		
- Translation differences – Foreign operations	(7)	29
Other comprehensive income for the period net of tax	154	66
Total comprehensive income for the period	(25 907)	(27 056)
Net income for the period attributable to:		
- Attributable to non-controlling interests	-	_
- Attributable to equity holders of the parent Company	(26 061)	(27 122)
Comprehensive income for the period attributable to:		
- Attributable to non-controlling interests	-	_
- Attributable to equity holders of the parent Company	(25 907)	$(27\ 056)$
Basic earnings per share - in euros	(0,69)	(0,75)
Diluted earnings per share - in euros	(0,69)	(0,75)

# CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands of euros)	31/12/2018	31/12/2017
Net income (loss)	(26 061)	(27 122)
- Adjustment for amortization and charges to provisions	923	338
- Adjustment for income (loss) from asset sales	0	0
- Non-cash income and expenses linked to share-based payments	149	125
- Other non-cash income and expenses	(2 857)	(1 313)
- Adjustment for income tax expense	0	0
- Adjustment for change in deferred tax	0	0
- Impact of change in working capital requirement generated by operating		
activities	1 038	5 080
- Income from interest on financial assets	15	(4)
- Cash flow from operations before tax and interest	(26 792)	(22 896)
- Income Tax (paid) / received	0	0
Net cash flow from operating activities	(26 792)	(22 896)
Acquisitions of fixed assets	(484)	(503)
Sales of tangible and intangible assets	0	0
Acquisitions of financial assets	0	0
Proceeds from the sale and financial assets	0	0
Changes in loans and advances	0	0
Interest received / (paid)	(6)	8
Other cash flow related to investing activities	0	0
Net cash flow from investing activites	(490)	(495)
Dividends paid		
Capital increase (decrease)	61	42 371
Issue of loans and receipt of conditional advances	0	0
Repayments of loans and conditional advances	0	0
Other cash flows from financing activities	0	0
Net cash flow from financing activites	61	42 371
Effect of exchange rate fluctuations	(7)	29
Effect of assets held for sale	0	0
Impact of changes in accounting principles	0	0
Net increase (decrease) in cash and cash equivalents – by cash flows	(27 229)	19 008
Control on the minutes of a section to the section of	20.700	10.700
Cash and cash equivalents – opening balance	38 789	19 780
Cash and cash equivalents – closing balance	11 560	38 789
Net increase / decrease in cash and cash equivalents – by change in	(27.220)	10 000
closing balances	(27 229)	19 008