

DIAXONHIT - Group 2015 annual results

Further progress of commercial activity Initial sales of proprietary products

- 4% increase in sales of *in vitro* specialty diagnostic products
- Further reduction of operating expenses by 13% compared to 2014
- Negative impact of €3.3 million on cost of goods sold linked to a strengthened dollar, compensated by currency exchange gains of €2.0 million.
- Initial sales of BJI InoPlex for prosthetic infections and AlloMap for heart transplant monitoring
- Plan to increase profitability through commercialization of new products
- Implementation of new cost cutting plan

Paris, France – March 24, 2016 – The Management Board of Diaxonhit (Alternext: ALEHT, FR0004054427), the leading French provider of specialty *in vitro* diagnostic solutions for transplantation, infectious diseases and cancer, met on March 22, 2016 to close the consolidated financial accounts for the year ending on December 31, 2015. These accounts were verified by the Supervisory Board¹.

Consolidated in € M	2015	2014
Sales of <i>in vitro</i> diagnostic products	28.9	27.9
Other revenues	1.3	3.8
TOTAL REVENUES	30.2	31.7
Cost of goods sold	(21.1)	(17.4)
Research and Development expenses (*)	(4.0)	(5.6)
Marketing and Sales expenses (*)	(8.6)	(9.1)
General and Administrative expenses	(4.6)	(4.9)
OPERATING RESULT	(8.0)	(5.4)
Financial income (loss)	1.7	(5.6)
NET RESULT	(5.9)	(5.5)
Cash and cash equivalents at December 31	11.7	14.1

(*) Includes amortization of intangible assets derived from Purchase Price Allocation for a total of €1.4 million

DIAXONHIT 2015 sales of diagnostic products increased by 4% compared to 2014, despite a global diagnostics market down 2% in France. This performance offsets the 80% decline of R & D revenues following the end of the Allergan collaboration in December 2014.

Operating expenses continued to decline by 13% compared to 2014. However, the sharp rise of the dollar that occurred in 2015 resulted in a € 3.3 million increase in the cost of goods sold, and consequently a decline in operating income. However, this decline was offset in large part by foreign exchange gains of € 2.0 million from US dollar forward contracts, limiting the decline in net income to € 0.4 million. Excluding foreign exchange effects, operating profit would have improved by 12% compared to 2014.

The Group cash position stands at € 11.7 million at December 31, 2015.

2015 Annual results

In-vitro diagnostic products sales growth

2014 sales of *in-vitro* diagnostic products reached € 28.9 million, up 4% compared to 2014. This increase partially offsets lower R&D fees in connection with the Allergan collaboration that ended in December 2014 and resulted in an 80% drop in R&D revenues at € 0.6 million, corresponding to milestone payments related to DIAXONHIT's therapeutic assets.

Thus, DIAXONHIT's consolidated income at December 31, 2015 totaled € 29.5 million, and annual revenues stood at € 30.2 million compared to € 31.7 million in 2014.

Reduction of operating expenses and rising US dollar

The cost of goods sold was affected by the US dollar rising by about 20% against the euro between 2014 and 2015, with an increase of 21% to €21.1 million. The corresponding € 3.7 million increase is linked to the rising dollar for € 3.3 million and to the increase in turnover for € 0.4 million.

However, per the plan implemented by the Company, operating expenses were reduced by 13% compared to 2014.

- R&D Expenses fell by 30% to € 4.0 million as a result of the end of the Allergan collaboration and the end of the development program for BJI InoPlex that has just reached commercialization.
- Keeping our focus on commercial activities, marketing and sales expenses remained stable, the overall reduction of 6% to € 8.6 million primarily reflecting an adjustment in accruals for retirement.
- General and administrative expenses continued to decrease by 8% to € 4.6 million, following the implementation of synergies resulting from the acquisition of InGen BioSciences (IBS), which reached 100% of targets set for this acquisition.

Thus, despite a continued reduction of operating expenses, operating income was impacted by the decline of the euro and reached € -8.0 million, down compared to 2014. At constant exchange rates, it would have decreased by € 3.3 million to € -4.7 million, an improvement of 12% compared to 2014.

With respect to net result, this deterioration was offset in large part by foreign exchange gains of € 2.0 million derived from US dollar forward contracts entered into by the Company to reduce the effects of currency fluctuations. However, the favorable effect of these currency contracts which term is limited to 18 months, should subside in 2016. Given an exceptional result of € 134 K related to a supplemental Research Tax Credit receivable for prior years, net income amounted to € -5.9 million, down € 0.4 million compared to 2014

To note, marketing and sales assets derived from IBS purchase price allocation (PPA) are being amortized over 10 years, for a total of € 1,286 K at December 31, 2014. They are included in marketing and sales expenses. Similarly, with the start of BJI InoPlex's commercialization, an R&D PPA asset also derived from the acquisition of IBS, is now being amortized over 10 years, for € 68 K at December 31, 2015 that is included in R&D expenses. The remaining goodwill related to the acquisition of IBS is also being amortized over 10 years. It is deducted from the operating result and stands at € 308 K at December 31, 2015. Excluding amortization of goodwill, the net loss would have been € 5.6 million and € 4.2 million also excluding amortization of commercial and R&D PPA assets.

Strengthened financial position

On January 1, 2015, DIAXONHIT had € 14.1 million in cash and cash equivalents. After financings which offset interest payments as well as reimbursement of bonds, loans and capital leases, an operating cash consumption of € 2.4 million against € 3.4 million in 2014, the Group's cash and cash equivalents stand at € 11.7 million at December 31, 2015.

Operations

Commercial developments

- **Launch and reimbursement of BJI Inoplex**

The launch of BJI Inoplex, DIAXONHIT's proprietary test for the diagnosis of bone and joint prosthetic infections, began in S1 2015. During the second semester, a couple of Luminex instruments dedicated to performing the test were installed in two bone and joint infections Reference Centers, generating the first sales of the product in France.

In late August 2015, a new repository of innovative tests (RIHN) was set up by the French Ministry of Health to support innovative medical biology by financing the reimbursement of selected new tests. The innovative nature of BJI InoPlex was recognized, and the test was included in the quite exclusive RIHN list of about 250 tests.

Final reimbursement of the test by the French health insurance system, following its inclusion in the official nomenclature of medical biology acts (French CPT codes), should take place within three years following the submission of a plan for implementation of a registry study to assess the medical and economic utility of BJI InoPlex. This plan is currently being finalized and should soon be submitted with the support of the French Society for Microbiology. During these three years, BJI InoPlex will benefit from the RIHN reimbursement.

Outside of France, marketing agreements have been signed with four distributors covering 15 European countries, which led to initial orders at the end of 2015. The distributors are also setting up medical-marketing studies in Spain, Italy and Benelux to familiarize prescribers with BJI InoPlex.

On February 10, 2016, a first scientific paper was published in the Journal of Clinical Microbiology, confirming BJI InoPlex's performance in the medical and clinical environment of care for patients complaining of pain related to bone and joint prostheses. This publication will help support the marketing effort undertaken by the Company for promoting the test.

- **AlloMap test commercialization**

Since the beginning of 2016, a centralized laboratory, set up in the Strasburg University Hospitals (HUS), became operational in order to support European commercialization of AlloMap, the only blood test that provides a non-invasive solution for monitoring heart transplants to clinicians and patients, which is licensed to DIAXONHIT on an exclusive basis for Europe.

Future reimbursement of the test in France is based on achieving a medico-economic study (PRME), which goal is to assess the benefits of AlloMap compared with the current method of monitoring heart transplant patients using biopsies. This study, conducted by an independent group of biologists and heart surgeons under the lead of the Hospices Civils de Lyon (HCL), has been approved and is funded by the Ministry of Health. The cost of AlloMap is fully covered. HCL and HUS are currently finalizing the administrative documentation required to enable shipment of blood samples to be tested to the central laboratory in Strasburg. The study is expected to start in the second quarter 2016.

In the export market, in Spain and Italy, regional "Innovation" budgets can finance AlloMap testing, and thus generated the first sales.

In Germany, several tests were performed for patients covered by private insurance. For a comprehensive coverage of AlloMap by the German health insurance system, discussions

are underway with the authorities to assess the feasibility of a straight coverage on the basis of existing data, or coverage after a medico-economic utility study co-funded by the German Ministry of Health.

In parallel, CareDx, DIAXONHIT's US partner and developer of AlloMap, has been successfully pursuing the commercial development of the test in the United States. CareDx estimates that its annual turnover is expected to reach 28 to 30 M € in 2015, 80% of the tests being now reimbursed.

- ***New product ranges***

In parallel with the marketing of its own products, DIAXONHIT is currently accelerating the distribution of new products and new ranges in order to restore the margins of its commercial operations. Early 2016, it started marketing a new generation of HLA tests under NGS (Next Generation Sequencing). Furthermore, the Group aims at strengthening its range of molecular tests in the fast growing field of infectious diseases.

R&D Developments

- ***Final validation study of DX15, proprietary test in thyroid cancer***

Late 2014, DIAXONHIT initiated the CITHY final validation clinical study for DX15, a diagnostic test for thyroid cancer that identifies the malignant or benign character of a thyroid nodule when cytology is indeterminate. The objective of the test is to reduce the number of unnecessary thyroidectomies.

This clinical study, unique in Europe, allows for the first time a full characterization of the population of European patients diagnosed with a thyroid nodule as well as corresponding clinicians care practices.

To date, observations confirm both the potential and value of DX15. Moreover, given the variety of observed European practices, it was decided to extend patient recruitment until April 2016. Despite this change, DX15 CE mark is still expected for 2017, with market launch in 2018.

- ***Development of a companion diagnostic for a therapeutic vaccine against AIDS***

DIAXONHIT collaborates with a biotechnology company, InnaVirVax, as part of a consortium to develop VAC-3S, a therapeutic vaccine to treat AIDS patients, and a companion diagnostic to VAC-3S enabling personalized care of patients.

Mid-2015, InnaVirVax announced encouraging results of its phase 2a clinical study. VAC-3S immunotherapy was well tolerated and immune response consistent with expectations. In addition, administration of VAC-3S resulted in favorable immunovirological effects, and, in correlation with the immune response, a decrease of proviral DNA was observed. InnaVirVax indicated that, if this positive trend was confirmed in future studies, it could enable VAC-3S to contain HIV viral load while interrupting antiretroviral treatments. If VAC-3S were to confirm its potential, the market for the tests that DIAXONHIT currently develops would grow significantly.

Consequently, development of the VAC-3S companion test was accelerated to allow testing of the first clinical samples during the third quarter of 2016. The test prototype is currently being finalized on schedule.

Perspectives

"DIAXONHIT is now a fully integrated group positioned in specialty diagnostics, the most dynamic sector of the *in vitro* diagnostics market. While innovating through the development of new tests, and advancing our sales of third-party and proprietary products, such as BJI InoPlex, our main objective remains the achievement of break-even. Faced with a negative dollar impact on our business but with a solid cash position of 11.7 million euros, we are implementing a strong response with the deployment of a new commercial offer and implementation of a new plan of reduction of our operating costs, these two pathways contributing to achieving financial break-even. " concludes Loïc Maurel, President of the Management Board of DIAXONHIT.

(1) All financial statements were audited by the auditors and their report will be issued after review of the 2015 management report.

Upcoming financial events

Shareholders Annual General Meeting : June 16, 2016

H1 2016 revenues : July 21, 2016

About DIAXONHIT

Diaxonhit (Alternext, FR0004054427, ALEHT) is a French fully integrated leader in *in vitro* diagnostics, involved from research to commercialization of specialty diagnostic products in the fields of transplantation, infectious diseases and cancer. It is the leader for commercialization in France of HLA tests. With many partnerships and a strong presence in hospitals, Diaxonhit has an extensive commercialization network and a portfolio of proprietary products including Tetanus Quick Stick® and BJI Inoplex® in the field of infectious diseases. Each year, the Group invests in R&D more than 15% of its sales to develop new, innovative and proprietary diagnostic tests. Diaxonhit has more than 85 employees based in Paris and the Paris region. The Group is part of the Alternext BPI Innovation, PEA-PME 150 and Next Biotech indices.

For more information, please visit: www.diaxonhit.com

Symbol : ALEHT - ISIN Code: FR0004054427 - Reuters : ALEHT.PA - Bloomberg : ALEHT:FP

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DIAXONHIT S.A.

CONSOLIDATED INCOME STATEMENT
(in thousands of euros, except per share data)

	12 months ended December 31, 2015	12 months ended December 31, 2014
Sales of in vitro diagnostic products	28,901	27,890
Research and Development revenues	562	2,726
Other products	413	672
Research & Development grants	317	428
Total revenues	30,193	31,716
Cost of goods sold	(21,124)	(17,419)
Research and Development expenses	(3,965)	(5,642)
Marketing and Sales expenses	(8,583)	(9,099)
<i>including amortization of intangible assets derived from the PPA</i>	(1,286)	(1,286)
General and Administrative expenses	(4,555)	(4,935)
Total operating expenses	(17,103)	(19,676)
Operating result	(8,034)	(5,379)
Financial expenses	(388)	(340)
Financial income	72	92
Currency exchange gain (loss) - net	2,050	(423)
Financial income (loss)	1,734	(671)
Extraordinary expenses	(78)	(262)
Extraordinary income	211	158
Extraordinary income (loss)	134	(103)
Income (loss) before tax and amortization of goodwill	(6,167)	(6,154)
Tax benefit (expenses)	600	980
Amortization of goodwill	(308)	(308)
Net result	(5,874)	(5,483)
<i>Net result, Group</i>	(5,879)	(5,487)
<i>Net result, minority</i>	4	4
Weighted average number of shares outstanding	71,014,649	61,993,653
<i>Net result per share</i>	(0.08)	(0.09)
<i>Net result per share (diluted)</i>	(0.08)	(0.09)

DIAXONHIT S.A.
CONSOLIDATED BALANCE SHEET
(in thousands of euros)

ASSETS	December 31, 2015	December 31, 2014
Goodwill, net	2,142	2,450
Intangible assets, net	10,527	11,998
Property and equipment, net	1,211	1,190
Other long term assets	211	274
Deferred tax assets, long-term	74	74
Deferred expenses, long-term	139	289
Total long-term assets	14,304	16,274
Inventory	2,051	2,008
Trade accounts receivable (net)	4,248	4,755
Other receivables, short-term	3,362	3,242
Deferred tax assets, short-term	56	85
Deferred expenses, short-term	6	8
Marketable securities	7,100	11,145
Cash and cash equivalents	4,586	2,981
Total short-term assets	21,409	24,223
TOTAL ASSETS	35,713	40,497
LIABILITIES	December 31, 2014	December 31, 2014
Share capital	1,197	1,088
Additional paid-in capital	112,895	109,930
Acquisition premium	9,795	9,795
Accumulated deficit and other	(106,754)	(100,898)
Minority interest	11	12
Shareholders' equity	17,144	19,927
Convertible bonds	5,227	6,992
Redeemable advances	939	1,029
Other equity	6,166	8,021
Accrual for risks	1,278	1,482
Long-term debt less current portion	567	902
Long-term capital lease obligations less current portion	397	278
Long-term portion of deferred income	-	-
Total long-term liabilities	964	1,179
Current portion of long-term debt	334	494
Current portion of capital lease obligations	299	198
Accounts payable	6,844	5,741
Social and tax liabilities	2,463	3,151
Other current liabilities	62	26
Deferred revenues, short-term	159	277
Total short-term liabilities	10,161	9,888
TOTAL LIABILITIES	35,713	40,497

DIAXONHIT S.A.
CONSOLIDATED CASH FLOW STATEMENT
(in thousands of euros)

	Year ending Dec 31, 2015	Year ending Dec 31, 2014
OPERATIONS		
Net loss	(5,874)	(5,483)
Less revenues and charges with no impact on cash or not related to activity :		
Depreciation and amortization net of reversals	2,321	2,990
Financial expenses	339	61
Capital gains or losses	(9)	(64)
Deferred taxes	2	(82)
Other	(3)	-
Change in working capital requirements :	780	(808)
Inventory	(43)	(528)
Research tax credit receivable	439	97
Operating receivables	(19)	306
Operating debt	522	100
Deferred revenues	(118)	(783)
Net cash used in operations	(2,444)	(3,385)
INVESTING ACTIVITIES		
Purchase of property, equipment and intangibles	(155)	(658)
Sale of property, equipment and intangibles	45	378
Sale (purchase) of other financial assets	63	25
Net cash used in investing activities	(47)	(255)
FINANCING ACTIVITIES		
Issuance of shares (net of fees)	3,074	5,551
Convertible bond issued	-	10,044
Convertible bond reimbursed	(1,935)	(3,114)
Redeemable advances received	-	100
Redeemable advances repaid	(90)	(70)
Reimbursement of loans	(495)	(514)
Reimbursement of capital leases	(250)	(217)
Financial expenses paid	(266)	-
Own share	(7)	(6)
Dividends paid to minority shareholders	(4)	(3)
Net cash provided by (used in) financing activities	28	11,770
Net increase (decrease) in cash and cash equivalents	(2,465)	8,130
Effects of currency exchange rate on cash	25	302
Cash and cash equivalents, beginning of period	14,126	5,694
Cash and cash equivalents, end of period	11,686	14,126