

# DIAXONHIT - Group 2014 annual results

# Further improvement of operating result and significant progress in line with the strategic plan

- 5.9% increase in sales of *in vitro* specialty diagnostic products
- Further significant reduction of operating loss by 21% compared to 2013
- Strengthened financial position with a 31% decrease in net cash used in operations and cash position increased by € 8.4 million, enabling continued growth and development of innovative products under the strategic plan in specialty diagnostics
- CE marking and launch of BJI InoPlex, a proprietary test for prosthetic infections
- An integrated group, with improved financial performance and fully positioned in specialty tests, the most dynamic sector in the diagnostics market

**Paris, France – March 26, 2015** – 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 25, 2015 to close the consolidated financial accounts for the year ending on December 31, 2014. These accounts were verified by the Supervisory Board<sup>1</sup>.

Consolidated in € M	2014	2013	Variation
Sales of in vitro diagnostic products	27.9	26.3	+5.9%
Other revenues	3.8	4.9	
TOTAL REVENUES	31.7	31.2	+1.6%
Cost of goods sold	(17.4)	(16.2)	
Research and Development expenses	(5.6)	(7.4)	
Marketing and Sales expenses (*)	(9.1)	(7.9)	
General and Administrative expenses	(4.9)	(6.5)	
OPERATING RESULT	(5.4)	(6.8)	+21%
NET RESULT	(5.5)	(6.0)	+8.5%
Cash and cash equivalents at December 31	14.1	5.7	+8.4 M€

(\*) Includes amortization of intangible assets derived from Purchase Price Allocation

DIAXONHIT 2014 sales of diagnostic products increased by 5.9% compared to 2013, despite a stable global diagnostics market in Europe. This performance underlines the strength of DIAXONHIT positioning in specialty *in-vitro* diagnostics, leading to a 1.6% increase of total consolidated revenues at  $\in$  31.7 million, more than offsetting the end of the collaboration with Allergan in 2014.

Operating profitability improved notably with an operating result of  $\in$  -5.4 million, a 21% increase compared to 2013. Net result also increased by 8.5% to  $\in$  -5.5 million. This performance reflects a thorough management of expenses that helped further strengthen sales and marketing investments to support the launch of Allomap and BJI Inoplex in Europe.

With  $\in$  14.1 million in cash and cash equivalents following the successful issuance of convertible bonds with warrants to US investors, and a lower cash burn during the second semester of 2014, DIAXONHIT will maintain in 2015 its investments in marketing and R&D in order to further strengthen its position in specialty *in-vitro* diagnostics.



#### Revenues : sales growth offsets the end of the Allergan collaboration

2014 sales of *in-vitro* diagnostic products reached  $\in$  27.9 million, up 5.9% compared to 2013. This increase more than offsets lower revenues in relation with the end of the Allergan collaboration which R&D fees decreased by 34% in 2014, before the end of the program in December 2014.

Thus, despite lower R&D revenues, DIAXONHIT's consolidated revenues at December 31, 2014 totaled € 31.7 million, a slight increase compared to 2013.

#### Improvement of operating result

Operating result totaled  $\in$  -5.4 million, up 21% compared to 2013 ( $\in$  -6.8 million). This significant improvement reflects both the impact of synergies following the acquisition of InGen BioSciences ("IBS") and the rationalization of expenses, as part of the acquisition and preparing for the end of the R&D collaboration with Allergan in December 2014. It was achieved despite an increase of almost  $\in$  0.7 million in the accrual for retirement benefits, which amount more than doubled this year because of a change in calculation method and the sharp decline of discount rates.

The consolidation of DIAXONHIT's scientific teams on a single site, and the discontinuation of certain activities reduced R&D spending from  $\in$  7.4 million to  $\in$  5.6 million.

In a context of increased focus on commercial activities, sales and marketing expenses increased by 15% in 2014 to € 9.1 million. This growth is mainly due to the reorganization and strengthening of marketing activities undertaken to launch AlloMap and to prepare for the launch of BJI InoPlex.

General and administrative expenses decreased to  $\notin$  4.9 million against  $\notin$  6.5 million in 2013. This reduction is mainly due to the implementation of the synergies resulting from the acquisition of IBS.

Marketing and sales assets derived from IBS purchase price allocation are being amortized over 10 years, for a total of  $\notin$  1,286 K at December 31, 2014. They are included in marketing and sales 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  $\notin$  308 K at December 31, 2014.

## Reduction of net loss

Despite increased financial expenses related to the sharp rise of the US dollar in 2014 as well as higher interest payments on loans and newly issued convertible bonds, and extraordinary expenses related to the reorganization undertaken as part of the end of the Allergan collaboration, the net loss decreased to  $\notin$  5.5 million, an improvement of 8.5% compared to 2013. Excluding amortization of goodwill, the net loss would have been  $\notin$  5.2 million, and  $\notin$  3.9 million when further excluding amortization of marketing and sales assets derived from IBS purchase price allocation.

#### Strengthened financial position

On January 1, 2014, DIAXONHIT had  $\in$  5.7 million in cash and cash equivalents. After financings for a net total of  $\in$  11.8 million, primarily related to the successful issuance of convertible bonds with warrants to US investors for  $\in$  10 million, an operating cash consumption of  $\in$  3.4 million against  $\in$  4.9 million in 2013, which included an increase in net working capital of  $\in$  0.8 million against  $\in$  1.5 million in 2013, investments for a total of  $\in$  0.3 million, and a positive impact of currency exchange rate variations for  $\in$  0.3 million, the Group's cash and cash equivalents stands at  $\in$  14.1 million at December 31, 2014.



#### R&D Developments

#### • CE marking of BJI Inoplex proprietary test

Late 2014 as expected, DIAXONHIT obtained CE marking of BJI InoPlex, the first blood test to aid in the diagnosis of prosthetic bone and joint infections. With excellent specificity of 82.2% and sensitivity of 75.9% for all types of staphylococci, this simple and quick test will enable to better tailor patient treatment. This final regulatory step paves the way for commercialization by DIAXONHIT in 2015.

#### • Launch of the final validation study of DX15, proprietary test in thyroid cancer

Having successfully completed the first two phases of DX15 development, DIAXONHIT initiated in October 2014 the final validation study of this test for the diagnosis of thyroid cancer by identifying the malignant or benign status of a thyroid nodule when cytology is indeterminate. As a result it could reduce the number of unnecessary thyroid ablations. The European multicenter clinical study will include nearly 1,000 patients, of which 180 have already been recruited. The results are expected late 2016. CE marking and launch of DX15 could then take place in 2017.

#### Development of a companion diagnostic for a therapeutic vaccine against AIDS

In 2014, DIAXONHIT obtained a  $\in$  1.7 million funding from Bpifrance, as part of a project for the development of a therapeutic vaccine to treat AIDS patients and diagnostic tests for personalized care. DIAXONHIT was chosen for its competence to develop diagnostic tests in the field of infectious diseases and for the recognition of its expertise in proteomics.

#### Commercial developments

## • Launch of BJI Inoplex

The launch of BJI Inoplex began in Q1 2015, following its CE marking in December 2014. It will be distributed directly by DIAXONHIT in France and through distributors in Europe.

#### • European launch of AlloMap test

CareDx, DIAXONHIT's US partner, successfully tested the first blood sample of a German patient with AlloMap in a commercial setting.

To accompany commercialization of the AlloMap test in Europe, a centralized laboratory is being set up in the Strasbourg University Hospitals. Its location is a key asset to allow rapid handling of blood samples received from heart transplant centers across Europe. AlloMap is the only blood test that provides a non-invasive solution for monitoring heart transplants to clinicians and patients. DIAXONHIT also initiated the process required to obtain reimbursement of the test.

#### Renewal of the partnership with One Lambda

In November 2014, DIAXONHIT renewed for several years its exclusive partnership for the commercialization in France of diagnostic tests for transplantation manufactured by One Lambda, a subsidiary of Thermo Fisher. DIAXONHIT is the leading provider of diagnostic products to laboratories that are responsible for carrying out all tests related to transplantation in France, and the group maintains a strong position in this dynamic sector.

### **Perspectives**

« In 2014, the combined effects of our solid growth, continued control of our expenses and significant progress on the clinical and commercial fronts, allowed us to pursue DIAXONHIT's mutation. Today DIAXONHIT is an integrated group, with improved financial performance and fully positioned in specialty tests, the most dynamic sector in the diagnostics market. In 2015, building on our patented technologies and our strengthened marketing activities, we will continue to innovate, specifically through the development of new tests, and grow sales both with distribution and with our own products such as BJI Inoplex. Innovations, achieving financial balance and external growth opportunities are now our main goals through a strengthened financial position. » 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 2014 management report.

#### **Upcoming financial events**

Shareholders Annual General Meeting : June 25, 2015 H1 2015 revenues : July 21, 2015

#### 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, 2014	12 months ended December 31, 2013
Sales of in vitro diagnostic products Research and Development revenues	27,890 2,726	26,326 4,174
Other products	672	248
Research & Development grants	428	468
Total revenues	31,716	31,216
Cost of goods sold	(17,419)	(16,217)
Research and Development expenses	(5,642)	(7,346)
Marketing and Sales expenses	(9,099)	(7,932)
including amortization of intangible assets derived from the PPA	(1,286)	(1,340)
General and Administrative expenses	(4,935)	(6,495)
Total operating expenses	(19,676)	(21,774)
Operating result	(5,379)	(6,775)
Financial expenses	(340)	(74)
Financial income	92	114
Currency exchange gain (loss) - net	(423)	(124)
Financial income (loss)	(671)	(85)
Extraordinary expenses	(262)	(262)
Extraordinary income	158	241
Extraordinary income (loss)	(103)	(21)
Income (loss) before tax and amortization of goodwill	(6,154)	(6,881)
Tax benefit (expenses)	980	1,137
Amortization of goodwill	(308)	(250)
Net result	(5,483)	(5,994)
Net result, Group	(5,487)	(5,994)
Net result, minority	4	-
Weighted average number of shares outstanding	61,993,653	56,922,318
Net result per share	(0.09)	(0.11)
Net result per share (diluted)	(0.09)	(0.11)



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# DIAXONHIT S.A. CONSOLIDATED BALANCE SHEET

(in thousands of euros)

ASSETS	December 31, 2014	December 31, 2013
Goodwill, net	2,450	2,757
Intangible assets, net	11,998	13,382
Property and equipment, net	1,190	1,048
Other long term assets	274	280
Deferred tax assets, long-term	74	-
Deferred expenses, long-term	289	-
Total long-term assets	s 16,274	17,467
Inventory	2,008	1,480
Trade accounts receivable (net)	4,755	5,797
Other receivables, short-term	3,242	2,978
Deferred tax assets, short-term	85	-
Deferred expenses, short-term	8	-
Marketable securities	11,145	2,546
Cash and cash equivalents	2,981	3,147
Total short-term assets		15,947
TOTAL ASSETS	40,497	33,414
LIABILITIES	December 31, 2014	December 31, 2013
Share capital	1,088	934
Additional paid-in capital	109,930	104,531
Acquisition premium	9,795	9,795
Accumulated deficit	(102,162)	(96,663)
Other	1,264	968
Minority interest	12	-
Shareholders' equity	19,927	19,565
Convertible bonds	6,992	-
Redeemable advances	1,029	999
Other equity		999
Accrual for risks	s 1,482	800
Long-term debt less current portion	902	1,399
Long-term capital lease obligations less current portion	278	124
Long-term portion of deferred income		
Total long-term liabilities	s 1 179	1 523
Current portion of long-term debt	494	510
Current portion of capital lease obligations	198	138
Accounts payable	5,741	5,480
Social and tax liabilities	3,151	3,339
Other current liabilities	26	
Deferred revenues, short-term	277	1,060
Total short-term liabilities		10,526
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## DIAXONHIT S.A. CONSOLIDATED CASH FLOW STATEMENT

(in thousands of euros)

(in thousands of euros)	12 months ended December 31, 2014	12 months ended December 31, 2013
OPERATIONS		
Net result	(5,483)	(5,994)
Less :		
Depreciation and amortization of property & equipment	612	634
Depreciation of intangible assets	1,406	1,481
Amortization of goodwill	308	250
Financial expenses	61	-
Capital gain or loss	(64)	39
Accrual for risks, net	664	231
Deferred tax	(82)	-
Other	-	(4)
Change in working capital requirements :	(808)	(1,537)
Inventory	(528)	341
Accounts receivable	1,042	(1,689)
Research tax credit receivable	97	2
Other current receivables	(446)	674
Other long-term receivables	(289)	-
Accounts payable	262	(391)
Social and tax liabilities	(188)	48
Other current liabilities	26	(18)
Deferred revenues	(783)	(504)
Net cash used in operations	(3,385)	(4,901)
INVESTING ACTIVITIES		
Purchase of tangibles and intangibles	(658)	(574)
Disposals of tangibles and intangibles	378	168
Other financial assets	25	193
Net cash used in investing activities	(255)	(213)
FINANCING ACTIVITIES		
Issuance of shares (net of fees)	5,551	1,602
Issuance of convertible bonds	10,044	-
Reimbursement of convertible bonds	(3,114)	-
Receipt of redeemable advances	100	-
Repayment of redeemable advances	(70)	156
Reimbursement of loans	(514)	(401)
Reimbursement of capital leases	(217)	(230)
Treasury shares	(6)	-
Dividends paid to minority	(3)	-
Net cash provided by (used in) financing activities	11,770	1,127
Net increase (decrease) in cash and cash equivalents	8,130	(3,987)
Effects of currency exchange rate variations on cash	302	(121)
Cash and cash equivalents, beginning of period	5,694	9,802
Cash and cash equivalents, end of period	14,126	5,694

