

DIAXONHIT – 2015 mid-year results

- 6% growth of *in vitro* diagnostic products sales
- Improved operating result at constant euro-dollar exchange rate
- €1.7 M impact on cost of goods sold related to the stronger dollar, partially compensated by a €1.1 M gain in currency exchange
- Strong financial situation with €11.6 M in cash and cash equivalents, enabling the company to maintain investments in R&D and commercial development

Paris, France – September 24, 2015 - DIAXONHIT (Alternext: ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, announced its financial results for the 6 months ended June 30, 2015.

€ M	H1 2015	H1 2014
IVD products sales	15,3	14,5
Other revenues	0,7	1,7
TOTAL REVENUES	16,0	16,2
COGS	(11,0)	(9,0)
R&D expenses	(1,6)	(2,8)
Marketing and sales expenses ⁽¹⁾	(4,5)	(4,2)
G&A expenses	(2,3)	(2,1)
OPERATING RESULT	(3,4)	(1,9)
Financial result	1,0	(0,3)
NET RESULT	(2,3)	(1,9)
Consolidated cash & cash equivalents at June 30	11,6	14,7

(1) Includes amortization of intangible assets derived from InGen's Purchase Price Allocation

“Again, the 6% increase of our sales highlights, in a globally declining French market, the strength of DIAXONHIT’s positioning in specialty in vitro diagnostics and reinforces our innovation strategy with the current launches of AlloMap and BJI InoPlex.” Commented Loïc Maurel, President of DIAXONHIT’s Management Board. “H1 2015 profitability was affected by the strengthening of the US dollar against the euro despite foreign exchange instruments set up by our Group, as purchase costs of our distribution products increased over the period. At constant exchange rates, our results would have improved, in line with the trend initiated in 2014. Given this situation and with a strong cash position at € 11.6 million, we will continue to adapt and accelerate the diversification of our product sourcing as well as the development of our sales in dollars with a test dedicated to the US market in thyroid cancer.”

Comments on H1 2015 results

During the first semester of 2015, sales of DIAXONHIT's diagnostic products were up 6% compared to the first half of 2014. In a French diagnostics market down about 5%, the relevance of DIAXONHIT's positioning in specialty *in vitro* diagnostics enabled this growth. Supplemented mainly by a milestone payment of USD 500,000 received from Allergan, total revenues are maintained at € 16.0 million, offsetting the end of the partnership with Allergan in December 2014.

In accordance with Company's expectations, operating expenses decreased overall by € 0.6 million compared to the first half of 2014 :

- R&D expenses were reduced, in connection with the end of the partnership with Allergan;
- Marketing and selling expenses rose in line with efforts to launch BJI InoPlex and AlloMap;
- Administrative costs increased slightly, mainly due to an accounting reclassification of expenses from selling to administration and the implementation of a new management tool.

Operating profitability is nevertheless affected by the significant strengthening of the US dollar against the euro, which resulted in an increase of the purchase cost of distribution products by approximately € 1.7 million. Operating profit thus declined by € 1.5 million to € -3.4 million. However, this decline was offset by financial gains generated by instruments put in place by the Company to reduce the effects of currency fluctuations. As a result, net income stood at - € 2.3 million, down only € 0.3 million compared to the first half of 2014.

Using the average exchange rate for the first half of 2014, the purchase cost of distribution products would have been lower by approximately € 1.7 million during the first semester of 2015, which would have resulted in an operating profit of - € 1.6 million, an improvement of 14% compared to the same period of 2014. This reflects the continuous efforts to control operational expenses.

With a strong cash position of € 11.6 million, DIAXONHIT intends to maintain its investments in marketing and R&D in order to further develop and launch commercially its proprietary products that represent the future of the group.

Significant events: continued deployment of the strategic plan

- ***CE Mark and launch of our proprietary BJI Inoplex[®] test***

In December 2014, DIAXONHIT obtained the CE marking of BJI InoPlex, the first blood test to aid in the diagnosis of bone and joint prosthetic infections. With a very good performance, this simple and quick test will allow to better tailor patients care.

The launch of BJI Inoplex began during the first half of 2015. To ensure its marketing, DIAXONHIT operates directly in France and is currently setting up a distribution network for the rest of Europe.

In late August 2015, BJI InoPlex was included in the new Repository of provisional codes for innovative procedures (RIHN) under the permanent system put in place by the French Ministry of Health to support innovative medical biology. This registration enables the test to be supported financially through special budgets dedicated to innovation.

- ***European commercialization of the AlloMap test and confirmation of its clinical utility***

AlloMap is the only blood test that provides clinicians and patients with a non-invasive solution for regular monitoring of heart transplants.

To support the ramp up of the commercialization of the AlloMap test in Europe, a centralized laboratory was set up in the Strasbourg University Hospitals. Its location is key to enable rapid handling of blood samples received from heart centers across Europe. The laboratory is currently under accreditation for performing the test.

In parallel, the results of a European clinical study confirmed the usefulness and performance of AlloMap test. The CARGO II study results, which evaluated the use of AlloMap on 594 heart transplant patients, confirmed a performance similar to that previously published in the United States. The results of this study reinforce the attractiveness of the test for European clinicians and should facilitate the processes put in place by DIAXONHIT for reimbursement of the test in different countries.

- **Thyroid cancer tests : Dx15 and Dx17 for the US**

Late 2014, after having successfully completed the first two development phases of DX15, DIAXONHIT initiated the final validation study of this test for the diagnosis of thyroid cancer through identification of the benign or malignant nature of a thyroid nodule when cytological examination is undetermined. The utility of the test is to reduce the number of unnecessary thyroid ablations.

This multicentre European clinical study will include approximately 1,000 patients, of which 540 have already been recruited from 16 clinical centers, 9 in France and 7 located in Spain and Italy. New centers are currently being opened to meet the inclusion schedule. The results are expected in late 2016, leading to CE marking and launch of DX15 in 2017.

In parallel, and to accelerate the introduction of a thyroid test in the United States, DIAXONHIT initiated the development Dx17, a modified version of DX15 best suited for this market and benefiting from all the developments already made on DX15 .

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

In synergy with the development of InnaVirVax's VAC-3S AIDS vaccine, DIAXONHIT is currently developing two diagnostic tests, a predictive test and a companion test, drawing on its expertise in the field of infectious diseases and allowing patients personalized care.

Following the announcement of very encouraging Phase I results for the VAC-3S vaccine, the potential market of DIAXONHIT's two tests could be significantly strengthened if the ability of the vaccine to limit the development of the virus in HIV infected patients without recourse to existing antiretroviral treatments is confirmed. A Phase IIa clinical trial is underway for the vaccine.

The first prototype of the disease evolution predictive test should be finalized by June 2016.

- **Previously developed therapeutic assets**

Developped by DIAXONHIT's R&D team before refocusing on specialty *in-vitro* diagnostics, several therapeutic assets have been monetized by the company in the areas of oncology and ophthalmology.

DIAXONHIT received a milestone payment of \$ 500,000 from Allergan, subsequently to the filing of an IND application with the US Federal Drug Administration (FDA) for molecules developed within the previous collaboration between both companies. If their development is successful, DIAXONHIT will be eligible to receive further milestone payments as well as royalties if the molecules are marketed.

In addition, DIAXONHIT granted an exclusive worldwide license on a series of candidate molecules to Felicitex Therapeutics, Inc., a US biotechnology company specialized in the discovery and development of treatments against cancer, focused on dormant cancer cells. Felicitex made an upfront payment and will pay an annual license fee to DIAXONHIT. Felicitex will also make milestone payments if the product covered by the license agreement reaches specific development milestones, and royalties if the product is marketed.

Upcoming financial events :

2015 revenues: january 2016

2015 annual results : march 2016

About DIAXONHIT

DIAXONHIT (NYSE 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: <http://www.diaxonhit.com>

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

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Contacts

DIAXONHIT

Hervé Duchesne de Lamotte, CFO, +33 (0)1 53 94 52 49, herve.delamotte@diaxonhit.com

NewCap

Julien Perez, Investor Relations & Financial Communication, +33 (0)1 44 71 98 52, jperez@newcap.fr
Annie-Florence Loyer, Media Relations, +33 (0)1 44 71 00 12, afloyer@newcap.fr



DIAXONHIT S.A.

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

	6 months ending June 30, 2015 (1)	6 months ending June 30, 2014 (1)	12 months December 31, 2014
Sales of <i>in vitro</i> diagnostic products	15 343	14 537	27 890
Research and Development revenues	464	1 429	2 726
Research & Development grants	176	186	428
Other products	58	27	672
Total revenues	16 041	16 179	31 716
Cost of goods sold	(10 958)	(8 990)	(17 419)
Research and Development expenses	(1 587)	(2 803)	(5 642)
Marketing and Sales expenses	(4 518)	(4 188)	(9 099)
<i>Including amortization of intangibles assets derived from PPA</i>	<i>(643)</i>	<i>(643)</i>	<i>(1 286)</i>
General and Administrative expenses	(2 345)	(2 077)	(4 935)
Total operating expenses	(9 068)	(9 068)	(19 676)
Loss from operations	(3 367)	(1 879)	(5 379)
Interest expense	(197)	(53)	(340)
Interest income	58	41	92
Currency exchange gain (loss) - net	1 109	(259)	(423)
Financial income (loss)	970	(271)	(671)
Extraordinary expense	(31)	(229)	(262)
Extraordinary income	72	105	158
Extraordinary income (loss)	41	(124)	(103)
Income (loss) before tax	(2 355)	(2 274)	(6 154)
Tax benefit	241	488	980
Depreciation of goodwill	(154)	(154)	(308)
Net income (loss)	(2 368)	(1 940)	(5 483)
<i>Net result, Group</i>	<i>(2 271)</i>	<i>(1 940)</i>	<i>(5 487)</i>
<i>Net result, minority shareholders</i>	<i>3</i>	<i></i>	<i>4</i>
Weighted average number of shares outstanding	69 570 755	60 139 691	61 993 653
<i>Net loss per share</i>	<i>(0,03)</i>	<i>(0,03)</i>	<i>(0,09)</i>
<i>Net loss per share (diluted)</i>	<i>(0,03)</i>	<i>(0,03)</i>	<i>(0,09)</i>

(1) Unaudited

DIAXONHIT S.A.

CONSOLIDATED BALANCE SHEET (in thousands of euros)

ASSETS	June 30, 2015 (1)	December 31, 2014
Goodwill, net	2 296	2 450
Intangible assets, net	11 284	11 998
Property and equipment, net	1 127	1 190
Long term deferred tax assets	74	74
Long term deferred charges	206	289
Other long term assets	240	274
Total long-term assets	15 227	16 274
Inventory	2 411	2 008
Accounts and grants receivable (net)	6 343	4 755
Other short term receivables	3 589	3 242
Short term deferred tax assets	8	8
Short term deferred charges	89	85
Cash and cash equivalents	11 614	14 126
Total short-term assets	24 055	24 223
TOTAL ASSETS	39 281	40 497
LIABILITIES AND SHAREHOLDERS' EQUITY		
Share capital	1 127	1 088
Additional paid-in capital	110 940	109 930
Acquisition premium	9 795	9 795
Accumulated deficit	(104 433)	(102 162)
Other	1 287	1 264
Minority interests	9	12
Shareholders' equity	18 725	19 927
Convertible bonds	6 289	6 992
Conditional advances	984	1 029
Other equity	7 273	8 021
Contingencies and loss provisions	1 289	1 482
Long-term debt less current portion	735	902
Long-term capital lease obligations less current portion	279	278
Long-term portion of deferred income	-	-
Total long-term liabilities	1 014	1 179
Current portion of long-term debt	405	494
Current portion of capital lease obligations	234	198
Accounts payable	7 645	5 741
Tax and social security liabilities	2 428	3 151
Other accrued liabilities	42	26
Deferred income short-term	226	277
Total short-term liabilities	10 980	9 888
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	39 281	40 497

(1) Unaudited



DIAXONHIT S.A.

CONSOLIDATED CASH FLOW STATEMENT

<i>(in thousands of euros)</i>	6 months ending June 30, 2015 ⁽¹⁾	6 months ending June 30, 2014 ⁽¹⁾	Year ending Dec 31, 2014
OPERATIONS			
Net loss	(2 268)	(1 940)	(5 483)
Less revenues and charges with no impact on cash or not related to activity :			
Depreciation and amortization net of reversals	1 006	1 089	2 990
Financial expenses	192	-	61
Capital gains or losses	(15)	(34)	(64)
Deferred taxes	-	(87)	(82)
Other	-	(3)	-
Change in working capital requirements :	(1 197)	(2 043)	(808)
Inventory	(404)	60	(528)
Research tax credit receivable	(97)	(389)	97
Operating receivables	(1 841)	(930)	306
Operating debt	1 196	(862)	100
Deferred revenues	(51)	79	(783)
Net cash used in operations	(2 281)	(3 019)	(3 385)
INVESTING ACTIVITIES			
Purchase of property, equipment and intangibles	(151)	(899)	(658)
Sale of property, equipment and intangibles	103	291	378
Sale (purchase) of other financial assets	33	(14)	25
Net cash used in investing activities	(15)	(621)	(255)
FINANCING ACTIVITIES			
Issuance of shares (net of fees)	1 084	2 420	5 551
Convertible bond issued	-	10 044	10 044
Convertible bond reimbursed	(801)	-	(3 114)
Redeemable advances received	-	65	100
Redeemable advances repaid	(45)	-	(70)
Reimbursement of loans	(256)	(258)	(514)
Reimbursement of capital leases	(124)	382	(217)
Financial expenses paid	(93)	-	-
Own share	3	(12)	(6)
Dividends paid to minority shareholders	(4)	-	(3)
Net cash provided by (used in) financing activities	(237)	12 642	11 770
Net increase (decrease) in cash and cash equivalents	(2 533)	9 002	8 130
Effects of currency exchange rate on cash	21	(34)	302
Cash and cash equivalents, beginning of period	14 126	5 694	5 694
Cash and cash equivalents, end of period	14 662	14 662	14 126

(1) Unaudited