## **PRESS RELEASE**



# Exonhit - Half-year 2011 results

# Significant achievements reached for EHT/AGN 0001 with Allergan, AclarusDx®, and EHT Dx14

## Key highlights since the beginning of 2011

- CE marking and introduction in France of the Company's first test, AclarusDx®
- Initiation of Phase II clinical development of EHT/AGN 0001 by Bristol-Myers Squibb
- Successful clinical validation of EHT Dx14 with a performance greater than 90%
- Successful completion of a TEPA capital increase for 1.5 million euros

## Outlook for the second half of 2011

- Initiation of a real life clinical study of AclarusDx® in France
- Initiation of a pilot study of AclarusDx® in the United-States
- Convertible bonds refinancing project

**Paris, France – September 13, 2011** – The Exonhit (Alternext: ALEHT) Supervisory Board met on September 12 to close the consolidated half-year accounts for the six-month period ended June 30, 2011. These accounts were subject to a limited review by the auditors.

Commenting on the half-year results, Loïc Maurel, M.D., President of the Management Board of ExonHit said: « During this semester Exonhit reached significant milestones, in line with our plan. AclarusDx® CE marking, announced in March, is followed by a progressive introduction of this test in memory centers and the set-up of the observational study required for its adoption. We also successfully validated the superior performance of our second diagnostic test, EHT Dx14 in breast cancer, which can now be introduced into the major cancer centers for clinical investigation. I am satisfied that we are able to execute our clear and ambitious strategy: to become a key player in Personalized Medicine ».

## **Key figures**

	June 30, 2011 (million EUR)	June 30, 2010 (million EUR)
Total revenues	2,4	5,5
R&D expenses	4,2	4,1
Marketing and sales expenses	0,9	0,7
G&A expenses	2,0	2,4
Operating result	(4,7)	(1,7)
Net result	(4,6)	(1,1)
Cash burn from operations	4,7	2,3
Consolidated cash & cash equivalents at June 30	20,6	29,5

## **Operating result**

Consolidated revenues for first half 2011 amounted to  $\leqslant$  2.4 million, a decrease of 56% compared to the  $\leqslant$  5.5 million achieved in first half 2010. These revenues are mainly derived from R&D activities within the Allergan partnership. In 2010, a non-recurrent revenue linked to the milestone payment of \$4 million ( $\sim$   $\leqslant$  3 million) from Allergan related to the out-licensing of AGN/EHT 0001 to Bristol-Myers Squibb, was specifically recorded. Excluding this non-recurrent revenue, R&D revenues received during the first half of 2011 remain unchanged compared to the same period in 2010.

Research and Development expenses remained stable at € 4.2 million during the first half of 2011 compared to € 4.1 million for the same period in 2010. This stability reflects a continuity of R&D programs between 2010 and 2011, in particular for the CE marking of AclarusDx® and the validation of EHT Dx14 in diagnostics, and R&D work performed under the Allergan collaboration.

Marketing and Sales expenses increased to € 0.9 million, compared to € 0.7 million in 2010, due to strengthened marketing efforts for the introduction of AclarusDx<sup>™</sup> in France.

General and Administrative costs decreased by 14% to € 2 million during the first semester of 2011.

As a result, Exonhit's operating expenses remained stable at € 7.1 million for the first half of 2011 compared to € 7.2 million for the first half of 2010.

Consequently, the Company posted an operating loss of € 4.7 million for first half 2011, compared to € 1.7 million for the same period in 2010.

The combined effect of interest income and expenses combined with currency exchange gains and losses led to a financial expense of  $\in$  0.6 million during the first semester of 2011, compared to an expense of  $\in$  0.1 million during the same period in 2010. The strength of the euro versus the US dollar during the first semester of 2011 generated a currency exchange loss, compared to a currency exchange gain related to a weak euro during the same period in 2010.

The R&D tax credit is estimated at  $\leq$  0.6 million for the first semester of 2011, compared to  $\leq$  0.7 million in 2010.

As a consequence, ExonHit recorded a consolidated net loss of  $\leq$  4.6 million in first half 2011, compared to  $\leq$  1.1 million for the first half of 2010.

## **Balance-Sheet**

At the end of the first semester of 2011, the cash position of the Company amounted to € 20.6 million, compared to € 25.6 million at the end of 2010. The cash of the Company is only invested in high quality funds with a reasonably guaranteed liquidity.

As of June 30, 2011, total shareholder's equity decreased to € 14.4 million, compared to € 19.2 million as at December 31, 2010, reflecting the consolidated net result recorded during the first half of 2011.

On November 8, 2011, the remaining convertible bonds issued by the company in 2006 mature. The total amount of  $\in$  7.8 million to be reimbursed on that date is equal to the total amount recorded under Convertible Bonds increased by a reimbursement premium of  $\in$  1.3 million that was recorded in 2010 under Accrued Liabilities.

As at June 30, 2011, Accrued Liabilities increased by € 0.3 million compared to December 31, 2010. This increase mainly reflects a new accrual for € 0.2 million corresponding to expenses related to the reorganization of Exonhit's US affiliate initiated within the strategic plan implemented since the beginning of 2011.

## **Financial Perspectives**

Since the beginning of the year, Exonhit systematically reviewed its human and financial resources in order to optimize their use and adapt its resources to the Company's strategy in Personalized Medicine.

## Reorganization

In order to strengthen the efficacy of its research and development programs, the Company optimized its organization. R&D activities undertaken in the United-States were transferred to Paris, France and the laboratory located in Gaithersburg, MD was closed in July 2011. As a result, Exonhit's US affiliate will essentially handle commercialization of AclarusDx® for clinical research (RUO), and bioinformatics. Beyond an operational optimization that maintains scientific excellence, this reorganization also reduces expenses related to the US affiliate

## TEPA financing

In July 2011, Exonhit renewed the TEPA financing undertaken in June 2010 in order to enable its shareholders to benefit from the ISF-TEPA tax incentive. As a result the Company successfully raised € 1.5 million by issuing 782,718 new common shares. These funds strengthen the financial resources available for the Company to pursue its strategy.

## Convertible bonds

On November 8, 2011, the remaining convertible bonds issued by the Company in 2006 mature and will be reimbursed. Exonhit maintains its project for refinancing this reimbursement in order to keep its cash position at the required level to maintain current strategic objectives.

## Supervisory and management board membership

On September 7, 2011, Exonhit announced the appointment of Isabelle Barber, Executive Vice-President, Diagnostics Division, as a member of its Management Board. This decision taken by the Supervisory Board of July 28th 2011 was effective immediately.

Exonhit also announces that Mr. Frédéric Desdouits, member of its Management Board, resigned from his position following a change in his professional situation incompatible with his mandate on Exonhit's Supervisory Board. This decision was effective on September 1, 2011.

## Objectives reached on all products since the beginning of the year

## AclarusDx® CE marking

AclarusDx® is a blood-based test designed to aid in the diagnosis of Alzheimer's disease (AD). This molecular signature associated with AD is to be used in association with standard methods of assessment to help clinicians in the diagnosis of AD. ExonHit received CE marking for this test in March 2011 and is now actively introducing AclarusDx® in expert memory centers in France, with support from well-recognized French Experts on an Advisory Board chaired by Professor Françoise Forette. In order to deliver the test for the French market and, later, other European markets.

Almac Diagnostics, to which the necessary technology was transferred, will be the Reference Laboratory for the test and the only laboratory with the ability to analyze blood samples with AclarusDx®.

## Successful clinical validation of EHT Dx14

EHT Dx14 a molecular signature for breast cancer diagnostic developed using ExonHit's hGWSA array, was licensed from Institut Gustave Roussy, one of the largest French cancer center, in May 2009. When assessing a suspicious cyst discovered during mammography, the EHT Dx14 test allows the accurate reading of samples obtained by fine-needle aspiration (FNA) in cases where standard analysis returns inconclusive results. Taking into account the frequency, in the global population, of patients for whom FNA remains inconclusive, the adjusted global performance of EHT Dx14 is 93.4%, with a specificity of 90.7% and a sensitivity of 96.1%. This performance above 90% in the population of patients for whom FNA was performed at Institut Gustave Roussy, confirms the ability of Exonhit's technology to identify biomarkers and generate diagnostic tests with excellent performance.

## Allergan Collaboration: initiation of phase II clinical trials of EHT/AGN 0001 by Bristol-Myers Squibb

EHT/AGN 0001, the lead compound synthesized within the Allergan collaboration, as well as EHT/AGN 0002 and associated compounds were licensed by Allergan to Bristol-Myers Squibb (BMS) in March 2010. During the first half of 2011, BMS initiated phase II clinical trials of EHT/AGN 0001 for the treatment of neuropathic pain. During clinical development and regulatory approval of this product, Exonhit is entitled to receive milestone payments totaling \$32 million if successful. During commercialization, the Company will also receive royalty payments.

#### Status of collaborations

The collaboration with Allergan is moving forward and continues to advance EHT/AGN 0003, Exonhit proprietary lead compounds added to the collaboration in 2010, and additional preclinical research in ophthalmology, neurodegeneration and pain.

The collaboration with bioMérieux, for the development of blood-based biomarkers of prostate cancer is also on-going. It will continue beyond October 9, 2011, the expiration date of the main collaboration agreement.

## To become a key player in Personalized Medicine

Implementation of Exonhit's strategy in Personalized Medicine includes four key milestones that can be summarized as follows:

## Demonstrate the potential of ExonHit's technology

Exonhit's proprietary GWSA technology already demonstrated its potential as a tool to develop therapeutic and diagnostic products. Within the collaboration with Allergan, the Company's technology led to the discovery and development of the EHT/AGN 0001 compound, currently in phase II clinical trial with BMS. Both diagnostic tests, AclarusDx® and EHT Dx14 were also developed using proprietary GWSA arrays.

## Develop and commercialize a diagnostic product

With AclarusDx® Exonhit demonstrated its ability to successfully develop a diagnostic product, obtain its regulatory approval with the CE marking, and introduce it in expert memory centers in France. The Company is currently implementing the necessary steps for successful adoption of

the product, including a real life observational clinical study of the test and its inclusion in several other AD studies in order to demonstrate clinical utility.

## · Collaborations for the development of biomarkers and companion diagnostics

Confirmation of Exonhit's technology value and its ability to develop new products requires implementation of new collaborations that will enrich the Company's pipeline with Personalized Medicine products. The Company is currently initiating an ambitious program of partnerships and collaborations.

## Commercialization of a first companion diagnostics

In order to confirm the Company status as a key player in Personalized Medicine, the ultimate step is the commercialization of a first companion diagnostics. Exonhit is already preparing the basis for such a program.

## Outlook for the second half of 2011

## Initiation of a real life clinical study of AclarusDx® in France

In close collaboration with key French specialists of AD, Exonhit is finalizing the implementation of a clinical study to collect real life data and to position AclarusDx® within current diagnostic algorithms. This study will include 600 patients recruited in approximately 40 memory centers, who are subject to cognitive impairment or memory loss. With a 12-month follow-up, the primary endpoint of the study will be the prevalence of positive AclarusDx® testing in patients diagnosed with AD. This study will also analyze combinations of AclarusDx® test results with one or several parameters collected during patients' visits in order to facilitate the diagnostic of AD.

## • Initiation of a pilot study of AclarusDx® in the United-States

For future commercialization of AclarusDx® in the United-States, the Company will initiate a pilot clinical study and recruit 160 US patients with memory impairment referred to a clinical reference center for further diagnostic evaluation. The primary end-point of the study will be the assessment of AclarusDx® performance in the study population. Collected clinical data will also be used to define clinical utility of the test in the United-States and position it within the diagnostic process. This study will be performed with Professor Jeff Cummings, a renowned US specialist of AD (Cleveland Clinic, Las Vegas) and member of the Company's Alzheimer advisory board.

## Continued efforts for EHT 0202 and EHT Dx14

Exonhit maintains its goals for EHT 0202, its lead compound for the treatment of AD. Phase IIa clinical study results are in favor of moving the product into phase IIb, and the Company is actively looking for alternative solutions to resume development of this product.

Exonhit is also moving forward with EHT Dx14 and is currently finalizing a scientific board with key specialists in breast cancer, including oncologists, radiologists and pathologists.

## **About Exonhit**

Exonhit (Alternext: ALEHT) is a biotech company, focused on personalized medicine, which develops targeted innovative therapeutic and diagnostic products, in oncology and Alzheimer's disease. Exonhit has a balanced investment strategy with internal development programs and strategic collaborations, in particular with Allergan.

Exonhit is headquartered in Paris, France and has U.S. offices in Gaithersburg, Maryland. The Company is listed on NYSE Alternext in Paris and is part of the NYSE Alternext OSEO innovation index. For more information, please visit http://www.exonhit.com.

#### **Disclaimer**

This press release contains elements that are not historical facts including, without limitation, certain statements on future expectations and other forward-looking statements. Such statements are based on management's current views and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those anticipated.

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Finally, this press release may be drafted in the French and English languages. In an event of differences between the texts, the French language version shall prevail.

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## **EXONHIT S.A.**

# **CONSOLIDATED INCOME STATEMENT**

(in thousands of euros, except per share data)

*unaudited	6 months June 30, 2011*	6 months June 30, 2010*	12 months December 31, 2010
Research and Development revenues Other products	2 430 5	5 412 62	8 077 94
Research and Development Grants	3		247
Total revenues	2 438	5 474	8 418
Research and Development expenses  Marketing and Sales expenses  General and Administrative expenses	(4 182) (850) (2 059)	(4 080) (703) (2 402)	(8 480) (1 334) (5 578)
Total operating expenses	(7 091)	(7 185)	(15 392)
Loss from operations	(4 653)	(1 711)	(6 974)
Interest expense	(117)	(1 371)	(2 230)
Interest income	107	153	271
Exchange gain (loss) - net	(555)	1 118	(144)
Income (loss) before tax	(5 217)	(1 812)	(9 077)
Tax benefit	617	722	1 329
Net income (loss)	(4 601)	(1 090)	(7 748)
Weighted average number of shares outstanding	33 325 287	32 838 630	33 082 489
Net loss per share Net loss per share (diluted)	(0,14) (0,14)	(0,03) (0,03)	(0,23) (0,23)

## **EXONHIT S.A.**

# **CONSOLIDATED BALANCE SHEET**

(in thousands of euros)

\*unaudited

ASSETS	June 30, 2011*	December 31, 2010
Intangible assets, net	53	142
Property and equipment, net	1 025	1 282
Other long term assets	374	347
Total long-term assets _	1 452	1 772
Accounts and grants receivable	1 145	1 173
Other short term assets	3 523	2 710
Cash and cash equivalents	20 571	25 607
Total short-term assets	25 239	29 490
TOTAL ASSETS	26 691	31 261
LIABILITIES AND SHAREHOLDERS' EQUITY		
Share capital	533	533
Additional paid-in capital	95 431	95 432
Accumulated deficit	(82 401)	(77 801)
Other _	810	1 027
Shareholders' equity _	14 374	19 191
Convertible bonds	6 522	6 522
Provisions for risks	1 826	1 534
Long-term debt less current portion	6	15
Long-term portion of deferred income	=	-
Total long-term liabilities		
Total long-term habilities _	6	15
Current portion of long-term debt	220	<b>15</b>
· ·		
Current portion of long-term debt Current portion of capital lease obligations Accounts payable	220	107
Current portion of long-term debt Current portion of capital lease obligations	220 17	107 66
Current portion of long-term debt Current portion of capital lease obligations Accounts payable	220 17 1 056	107 66 904
Current portion of long-term debt Current portion of capital lease obligations Accounts payable Accrued liabilities	220 17 1 056 1 608	107 66 904 1 736

# **EXONHIT S.A.**

# **CONSOLIDATED CASH FLOW STATEMENT**

(in thousands of euros)

*unaudited	6 months ending June 30, 2011*	6 months ending June 30, 2010*	Year ending Dec 31, 2010
OPERATING ACTIVITIES	·	•	
Net loss	(4 601)	(1 090)	(7 748)
Less:			
Depreciation and amortization of property & equipment	249	269	577
Depreciation of intangible assets	91	64	130
Allowance for bad debts	-	62	93
Retirement liability accrual and other	292	(52)	(64)
Other accruals/ Convertible bonds reimbursement premium	-	1 254	1 254
Capitalized interests on convertible bonds	113	113	-
Gain (loss) on sales			30
Increase (decrease) in cash from:			
Inventory	63	4	(16)
Accounts receivable	32	(215)	(154)
Research tax credit receivable	(617)	(722)	287
Prepaid expenses and other assets	(273)	(1 268)	(81)
RedPath's bridge loan	-	(827)	-
Accounts payable and accrued expenses	157	(317)	(410)
Accrued compensation	(118)	338	343
Deferred income, short term	(124)	168	75
Deferred income, long term	- -	(61)	(119)
Net cash used in operating activities	(4 735)	(2 279)	(5 803)
INVESTING ACTIVITIES			
Purchase of property and equipment	(113)	(15)	(220)
Payment of patent and acquisition of other intangibles	49	-	84
Net cash used in investing activities	(64)	(15)	(135)
FINANCING ACTIVITIES			
Issuance of shares (net of fees)	39	1 194	1 238
Capital increase receivables			
Proceeds from loan	(57)	(64)	(129)
Net cash provided by (used in) financing activities	(18)	1 130	1 109
Net increase (decrease) in cash and cash equivalents	(4 817)	(1 164)	(4 829)
Effects of exchange rate on cash	(220)	423	191
Cash and cash equivalents, beginning of period	25 607	30 245	30 245
Cash and cash equivalents, end of period	20 571	29 505	25 607