

# Analyst Report

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Aurgalys is contracted by Diaxonhit to provide equity research

# Aurgalys

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## Diaxonhit

ALTERNEXT PARIS: ALEHT [FR0004054427]

June 6<sup>th</sup>, 2016

### Estimated price:

€1.60

Share price (€)

0.42

(as of Jun. 6<sup>th</sup>, 2016)

High/Low (€)

0.55/0.36

(since Jan. 1<sup>st</sup>, 2016)

Market Cap. (€M)

32.5

(as of Jun. 6<sup>th</sup>, 2016)

Estimated Net Cash

3.2

(€M)

Estimated Market Cap.

123.9

(€M)

Number of shares (M)

77.4

Estimated price (€)

1.60

3-month average daily

177,000

volume

Free Float

84.7%

## Diaxonhit enrolls first patients in cost-utility analysis study for AlloMap

On May 25<sup>th</sup>, 2016, Diaxonhit inaugurated the European Center for AlloMap at the Strasbourg University Hospital. AlloMap is an innovative non-invasive blood test for heart transplant patient monitoring, which can replace heart biopsies. The company also announced the enrollment of the first patients of a French cost-utility analysis of the AlloMap test compared to traditional heart biopsies, whose positive results could support reimbursement of the test in France. This analysis could generate up to €1.5M of revenues for Diaxonhit over the duration of the study. Moreover, with the Strasbourg Center now operational, Diaxonhit will also be able to generate sales from the major markets of Europe, for which the company has an exclusive license. Our target price for Diaxonhit is €1.60/share.

### AlloMap, a non-invasive test that can replace heart biopsies

AlloMap is a non-invasive blood test intended for heart transplant rejection monitoring. Developed by the US company CareDx and both, FDA approved through a 510K and CE marked, AlloMap is an in vitro diagnostic test that can replace heart biopsies. The test is recommended by the ISHLT (International Society of Heart and Lung Transplants) for monitoring heart transplant patients, between 6 months and 5 years after they received the graft. Diaxonhit has the exclusive license for AlloMap in Europe.

The ECRI Institute identified two cost-analysis study comparing heart biopsies to AlloMap in the US (AlloMap's US price is \$3,600 per test). In a first 2005 study based on CareDx's CARGO clinical trial, per patient savings were \$3,741, \$4,193, and \$6,511 to hospitals, Medicare, and private insurers, respectively. A second study published in 2010, based on CareDx's IMAGE trial, showed similar costs for both monitoring methods. Therefore, in terms of

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**Euronext since Jan. 1<sup>st</sup>, 2016**

<b>Diaxonhit</b>	<b>-12.5%</b>
<b>Alys France*</b>	<b>-11.0%</b>
<b>Next Biotech</b>	<b>-9.5%</b>
<b>CAC Healthcare</b>	<b>-5.1%</b>
<b>CAC 40</b>	<b>-4.6%</b>
<b>Alternext Allshares</b>	<b>-0.1%</b>

\* Index of French smallcaps (less than €1B market capitalization at time of inclusion) in the healthcare and life sciences sector, listed on Euronext Paris.

See <http://www.aurgalys.com/aurgalys-indices>

costs, AlloMap testing is at least equivalent to biopsies, or cheaper. Moreover, the advantage of AlloMap resides in quality of life improvement for heart transplant patients. For instance, the ECRI Institute indicated that two studies showed that patients monitored with AlloMap were more satisfied with this method compared to those receiving biopsies.

### First patients included in French cost-utility analysis study

In 2015, the French Ministry of Health approved a €2.3 M cost-utility analysis study (CUPIDON study), to be conducted by the Hospices Civils de Lyon hospital. The aim of the CUPIDON study is to evaluate the costs associated with heart transplant monitoring with AlloMap, compared to routine heart biopsies performed in France. Table 1 summarizes the heart biopsy schedule as recommended by the ISHLT after a heart transplant. Although this schedule may vary from one hospital to another, the number of biopsies performed in the first year post-transplant is high. The first objective of the study is to demonstrate that the use of AlloMap (costing €2,000 pretax) in patients with low risks of rejection is more cost-effective than traditional heart biopsies, requiring full day of hospitalization, and whose costs can increase due to associated complications. The second objective is to compare the quality of life of heart transplant patients who often suffer from anxiety, discomfort and pain due to routine heart biopsies. In contrast, the AlloMap test only requires a blood sample. Diaxonhit announced that the first patients have been included in the study.

Table 1. Heart biopsy schedule

Time after transplant	Frequency
1 <sup>st</sup> month	Every week
2 <sup>nd</sup> month	Every 2 weeks
3 <sup>rd</sup> to 5 <sup>th</sup> month	Every 3 weeks
6 <sup>th</sup> to 12 <sup>th</sup> month	Every month
After 1 <sup>st</sup> year	Every 6 months

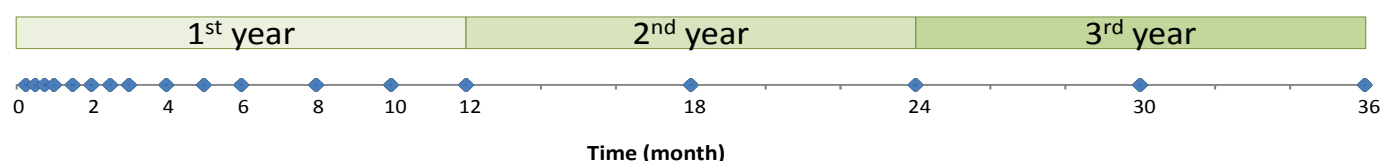
### Up to €1.5M of revenue for the duration of the study

The CUPIDON study is a two-arm, 216-patient study that will monitor heart transplant patients from 6 month to 36 months post-transplant. One hundred and eight patients will be monitored by heart biopsies while the other 108 will be followed-up with the AlloMap test. According to clinicaltrials.gov, the estimated completion date of the

study is 2021. We can therefore anticipate that patient recruitment would take two years, until mid-2018.

As indicated in Figure 1, we can estimate that over the 3-year monitoring period, one patient can receive as many as 8 AlloMap tests. This could represent up to 864 tests performed for this French trial alone, or up to €1.5 M of sales for Diaxonhit for the duration of the study, considering a price of €1,700 per test. As previously indicated, Diaxonhit has a license for the European territory and the company will focus its effort on the top 5 European countries in terms of population, which hold 70% of the heart transplant market. Diaxonhit also seeks to conduct similar studies in other territories such as Germany. This could contribute to the adoption of the AlloMap test in European clinical practice. Positive results in terms of cost-utility or improvement of patients' quality of life would also support reimbursement of the AlloMap test.

Figure 1. Example of biopsy schedule (Blue dots are biopsies performed within 3 years post-transplant)



## European center for AlloMap inaugurated at the Strasbourg University Hospitals

On May 25<sup>th</sup>, 2016, Diaxonhit inaugurated the AlloMap European test center at the Strasbourg University Hospitals. The location of the Strasbourg University Hospitals in the center of Europe will facilitate the processing of all samples from the continent. Clinicians will send blood samples collected from heart transplant patients to the AlloMap European Center, where the analyses will be conducted. Diaxonhit will provide CareDx's AlloMap tests, the equipment necessary for the analyses, and also preparation and shipping kits for blood samples.

## Upcoming News flow

- Q2/Q3-2016: First Prototype of DIAG-3S diagnostic test
- H1-2017: Dx15 validation study results

## Valuation

Our valuation of Diaxonhit is €120.7 M (enterprise value), unchanged since our last report on January 27<sup>th</sup>, 2016. Including an estimated net cash of €3.2 M, we value Diaxonhit at €1.60/share.

## Stock Performance

Diaxonhit was not spared by the market sell-off affecting biotech stocks at the beginning of this year. The Company's shares have lost 12.5% since January 1<sup>st</sup>, 2016, trading at €0.42 as of June 6<sup>th</sup>, 2016. As a comparison, the Alys France index lost 11.0% over the same period.

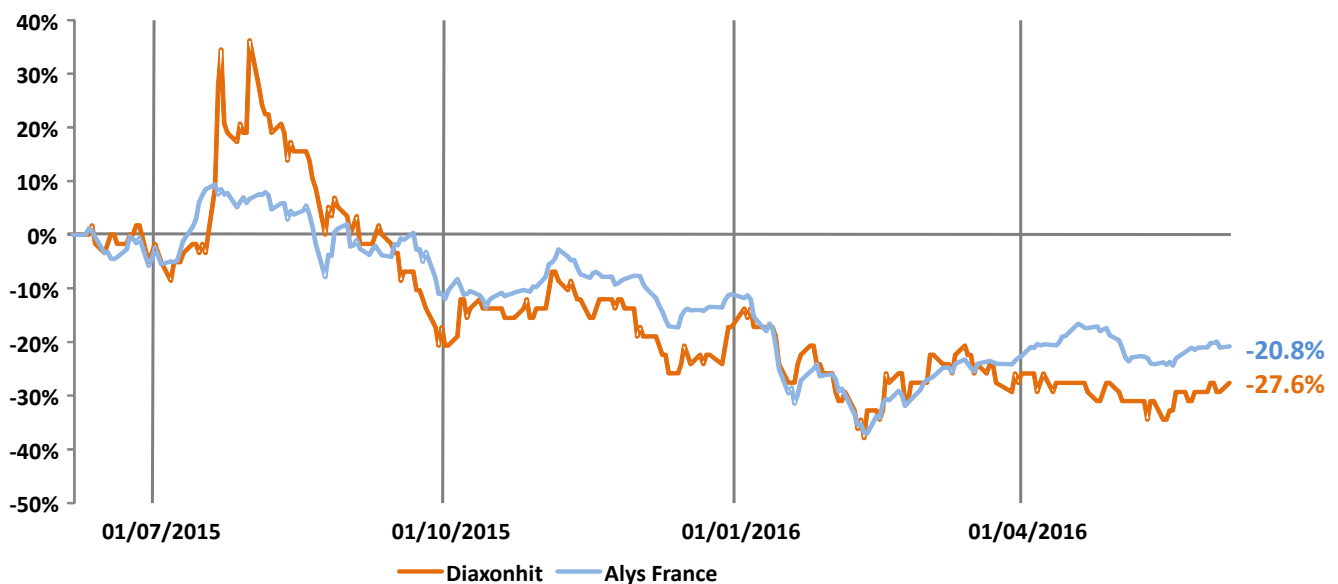


Figure 2: One-year chart dated June 6<sup>th</sup>, 2016, comparing the performance of Diaxonhit's stock with French smallcaps of the life sciences and healthcare sector (Alys France index).

## Financials

Earnings Per Share	2014	2015	2016e	2017e	2018e
EPS	-0.09	-0.08	-0.06	-0.04	-0.02

Income Statement	2014	2015	2016e	2017e	2018e
Revenues	31.7	30.2	31.5	34.2	38.4
EBIT	-5.4	-8.0	-4.6	-3.7	-1.6
Net Income	-5.5	-5.9	-4.3	-3.4	-1.3

Balance Sheet	2014	2015	2016e	2017e	2018e
<b>Non-Current Assets</b>	<b>16.3</b>	<b>14.3</b>	<b>12.6</b>	<b>10.9</b>	<b>9.3</b>
Stocks	2.0	2.1	2.2	2.4	2.6
Account Receivables	4.8	4.2	5.3	5.7	6.4
Other Receivables	3.2	3.4	3.2	3.4	3.8
Other current assets	0.1	0.1	0.1	0.1	0.1
<b>Cash and Cash equivalents</b>	<b>14.1</b>	<b>11.7</b>	<b>7.1</b>	<b>4.3</b>	<b>3.5</b>
<b>Current Assets</b>	<b>24.2</b>	<b>21.4</b>	<b>17.8</b>	<b>15.9</b>	<b>16.4</b>
<b>Total Assets</b>	<b>40.5</b>	<b>35.7</b>	<b>30.4</b>	<b>26.8</b>	<b>25.7</b>

<b>Total Equity</b>	<b>19.9</b>	<b>17.1</b>	<b>15.2</b>	<b>14.1</b>	<b>13.0</b>
Convertible Bonds	7.0	5.2	2.7	0.2	0.0
Repayable Advance	1.0	0.9	0.8	0.8	0.7
Provisions	1.5	1.3	1.4	1.5	1.7
Financial Debt	1.9	1.6	1.1	0.7	0.4
Account Payable	5.7	6.8	6.1	6.5	7.1
Other Debt	3.5	2.7	3.0	2.9	2.8
<b>Total Liabilities</b>	<b>20.6</b>	<b>18.6</b>	<b>15.2</b>	<b>12.7</b>	<b>12.7</b>
<b>Total Equity and Liabilities</b>	<b>40.5</b>	<b>35.7</b>	<b>30.4</b>	<b>26.8</b>	<b>25.7</b>

Cash Flow Statements	2014	2015	2016e	2017e	2018e
Cash Flow from Operating activities	-3.4	-2.4	-3.1	-1.4	0.3
Cash Flow from Investing activities	-0.3	0.0	-0.2	-0.3	-0.3
Cash Flow from Financing activities	11.8	0.0	-1.2	-1.1	-0.8
<b>Change in Cash</b>	<b>8.1</b>	<b>-2.4</b>	<b>-4.5</b>	<b>-2.8</b>	<b>-0.8</b>

## Résumé en français

Diaxonhit a inauguré fin mai le laboratoire central européen du test AlloMap, aux CHU de Strasbourg. AlloMap est un test génétique non-invasif permettant de réduire le nombre de biopsies nécessaires pour le suivi des transplantés cardiaques. En effet, afin de vérifier que la greffe n'est pas rejetée, des biopsies sur le nouveau cœur sont réalisées. Celles-ci sont très nombreuses dans la première année après transplantation, et sont source d'angoisse et de stress pour les patients.

Diaxonhit a également annoncé le recrutement des premiers patients d'une étude médico-économique française, visant à comparer le coût de la prise en charge des tests AlloMap, avec celui des biopsies. Cette étude, financée par le Ministère de la Santé (2,3 M€) consistera à recruter 216 patients. La moitié sera suivie par AlloMap, tandis que l'autre le sera par les biopsies. Diaxonhit pourrait ainsi générer jusqu'à 1,5M€ de revenus pour cette seule étude. Des résultats positifs permettront de soutenir une demande de remboursement en France, et de favoriser l'adoption du test par les cliniciens.

D'autre part, Diaxonhit compte également conduire des études similaires en Europe, notamment en Allemagne. La position centrale en Europe des CHU de Strasbourg faciliteront également l'acheminement des échantillons de tout le continent.

Notre objectif de cours pour Diaxonhit est de 1,60€/action.

## Notes



## Disclaimer

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## About Aurgalys indices

Aurgalys launched on October 2013, the Alys France index measuring the performance of the 40 French smallcap companies (less than €1B of market capitalization) listed on Euronext/Alternext Paris. Three other indices also measure the performance of companies dedicated to the development of therapeutic molecules (Alys Thérapeutics), diagnostic tests (Alys Diagnostics), medical devices (Alys Medtech) and Greentech (Alys Greenetch). You can find our reports on our website at <http://www.aurgalys.com/aurgalys-indices>



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