

Analyst Report

Coverage Initiated February 7th, 2013

Aurgalys is contracted by Diaxonhit to provide equity research

Aurgalys

Mickael Dubourd, PhD, SFAF

Paris & Evry, France

Diaxonhit

ALTERNEXT PARIS: ALEHT [FR0004054427]

October 4th, 2016

Estimated price:

€1.25

Share price (€)
(as of Oct. 4th, 2016)

0.35

High/Low (€)
(since Jan. 1st, 2016)

0.55/0.34

Market Cap. (€M)
(as of Oct. 4th, 2016)

27.9

Estimated Net Cash
(€M)

1.3

Estimated Market Cap.
(€M)

99.7

Number of shares (M)

79.7

Estimated price (€)

1.25

3-month average daily
volume

187,000

Free Float

84.7%

Diaxonhit, promising short- and mid-term perspectives

Despite Diaxonhit's effort to reduce its operational expenses, the company's net loss increased in H1-2016 compared to H1-2015. This is attributed to a decreased in IVD (in vitro Diagnostics) sales for HLA testing, representing more than 70% of the company's revenue. Diaxonhit did however, increased sales of proprietary tests (BJI Inoplex, available in 18 countries), and quality control products (+30%). During its half year presentation, the company provided insights about its short- to mid-term perspectives for its proprietary products. Although the company did make progress in the development of its IVD tests, we reduced our target price to €1.25/share, after adjusting our valuation model, especially for the US market, which will take more time to capture than previously anticipated. However, we are still confident in Diaxonhit's strategy and business model.

BJI Inoplex, medico-economic studies to boost market adoption

BJI Inoplex, has been commercially available since 2015 for the diagnosis of prosthetic joint infections. Diaxonhit directly markets BJI Inoplex in France, where the test is currently benefiting from a specific reimbursement protocol for innovative IVD tests. The company is currently submitting a medico-economic study to the French healthcare authorities to support the reimbursement of BJI Inoplex, and increased its adoption by clinicians. In Europe, Diaxonhit has already secured 4 distribution agreements covering 18 European countries. Medico-economic studies are currently ongoing in Italy, Spain, and the Benelux area.

Dx15, clinical validation study ongoing, results by mid-2017

Last June, Diaxonhit announced that the recruitment of the Dx15 CITHY (thyroid cancer diagnosis) study was completed, with more than 1,700 thyroid samples collected from 1,500 patients from France, Italy, and Spain. This study aims at validating the Dx15 diagnostic test in clinical conditions. The performance of Dx15 will be measured by comparing the test

Euronext since Jan. 1st, 2016

Diaxonhit	-27.1%
Alys France*	-18.7%
Next Biotech	-17.3%
CAC Healthcare	-6.7%
CAC 40	-2.9%
Alternext Allshares	-0.1%

* 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>

results with postsurgical histopathological samples collected from those patients. Positive results would lead to Dx15 CE marking, a prerequisite for marketing the test in Europe. The company intends to publish CITHY results mid-2017. Diaxonhit presented preliminary observational data that strengthens the medical utility of a test such as Dx15.

HIV diagnostic tests, prototype validation in 2017

Innavirvax is developing a therapeutic vaccine, VAC-3S, for HIV-infected patients. In the PROTEVIH Consortium, Diaxonhit is developing 2 diagnostic tests for Innavirvax's VAC-3S. These two tests consist of a prognosis test which would help clinicians determine whether patients need immediate treatment or not, and a companion diagnostic test for VAC-3S, monitoring patient response to Innavirvax's therapy. Innavirvax's Phase IIb trial is expected to begin in the first half of 2017, which would provide the necessary samples to validate Diaxonhit's prototype.

The United States, key market for Diaxonhit

The US market is a key territory for the healthcare industry. The medical community is technology –driven and healthcare products are usually sold at a higher price tag when comparing with European prices. However, capturing the US market requires specific developments or approval channels for IVD tests.

For Dx15, the company intends to market the genetic test as a laboratory-developed test (LDT). This specific regulation would prevent Diaxonhit from getting approval from the PMA procedure (Pre-Marketing Approval), more costly and time-consuming. However, Diaxonhit would need to design a US-specific test, Dx17.

For BJI Inoplex, Diaxonhit could access the US market through the 510(k) procedure, consisting of demonstrating that the test is substantially equivalent to an already approved product or diagnosis procedure. Diaxonhit is currently evaluating the possibility of getting 510(k) approval for BJI Inoplex, which could lead to a faster access to the US territory compared to the LDT or PMA procedures.

During the half-year presentation, Diaxonhit stressed the importance of reaching the US market for its proprietary products, although the implementation of this strategy in this territory would require additional financial resources. Although initially postponed to reduce operational expenses, accelerating US operation could offer mid-term prospects for Diaxonhit.

Upcoming News flow

- Q4-2016: HIV IVD test prototype
- Q4-2016: Medico-economic study for BJI Inoplex in France

- H1-2017: start of VAC-3S Phase IIb trial and validation of IVD test prototype
- Q2/Q3-2017: Dx 15 Validation study results
- Q4-2017: Dx15 CE marking

Valuation

We decided to reduce our target price for Diaxonhit to €1.25/share. Following the H1-2016 results and presentation, we decided to modify our valuation model to account for the delays in the development of proprietary products (HIV tests, US-specific developments). For instance, we believe it will take more time to reach the US market, a key territory for Diaxonhit. Such delays are also the result of the company's goal to reach profitability in the near future (2018). Given the company's ambitions, it is likely that Diaxonhit would need to find adequate funding to launch new proprietary products in the near future (Dx15), and implement its US operations (BJI Inoplex and Dx17). Although we reduced our target price for the company, we believe that Diaxonhit has strong fundamentals with short-term news events (development of proprietary products) and enhanced mid-term potential (US market).

Stock Performance

Diaxonhit was not spared by the market sell-off affecting biotech stocks at the beginning of this year, which was further exacerbated by the Brexit referendum. The Company's shares have lost 27.1% since January 1st, 2016, trading at €0.35 as of October 4th, 2016. As a comparison, the Alys France index lost 18.7% over the same period.

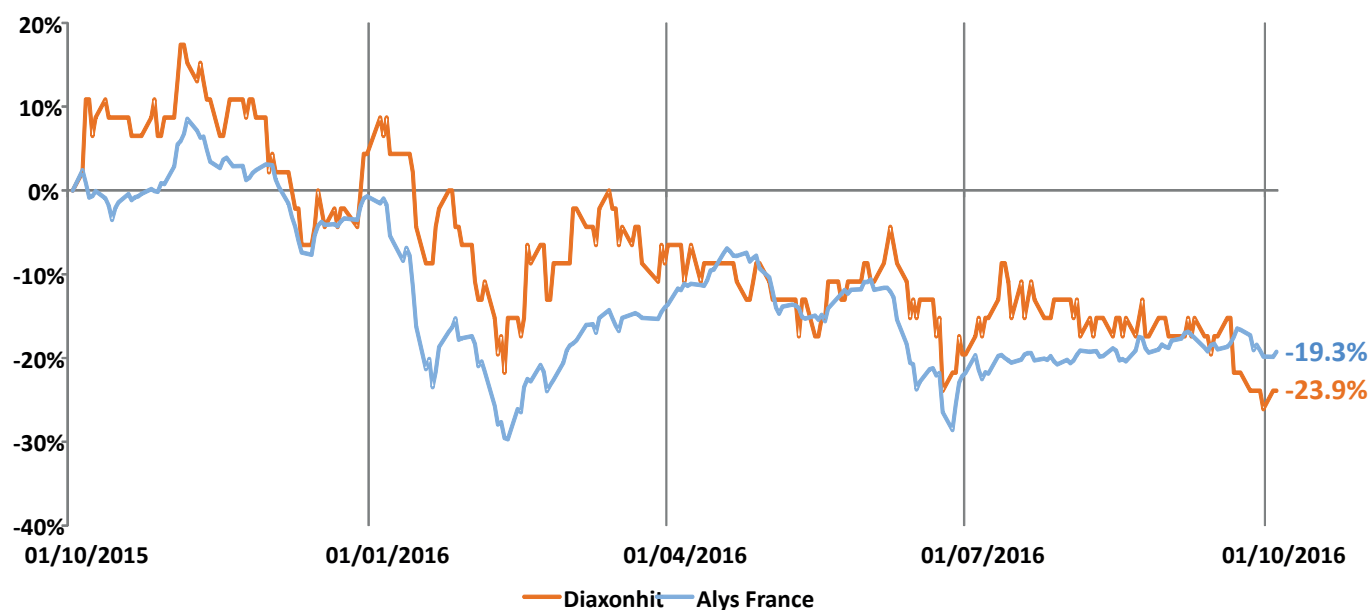


Figure 1: One-year chart dated October 4th, 2016, comparing the performance of Diaxonhit's stock with French smallcaps of the life sciences and healthcare sector (Alys France index).

Earnings Per Share	2014	2015	2016e	2017e	2018e
EPS	-0,09	-0,08	-0,10	-0,06	-0,04

Income Statement	2014	2015e	2016e	2017e	2018e
Revenues	31,7	30,2	30,1	31,8	34,1
EBIT	-5,4	-8,0	-7,7	-5,2	-4,0
Net Income	-5,5	-5,9	-7,1	-4,7	-3,5

Balance Sheet	2014	2015e	2016e	2017e	2018e
Non-Current Assets	16,3	14,3	12,0	9,8	8,0
Stocks	2,0	2,1	2,0	2,0	2,1
Account Receivables	4,8	4,2	4,4	4,6	4,9
Other Receivables	3,2	3,4	3,8	4,0	4,2
Other current assets	0,1	0,1	0,1	0,1	0,0
Cash and Cash equivalents	14,1	11,7	5,6	1,9	0,2
Current Assets	24,2	21,4	15,9	12,5	11,4
Total Assets	40,5	35,7	27,9	22,4	19,4

Total Equity	19,9	17,1	12,5	9,8	7,5
Convertible Bonds	7,0	5,2	3,2	1,2	0,0
Repayable Advance	1,0	0,9	0,8	0,7	0,5
Provisions	1,5	1,3	1,3	1,4	1,4
Financial Debt	1,9	1,6	1,1	0,5	0,3
Account Payable	5,7	6,8	6,8	6,7	7,5
Other Debt	3,5	2,7	2,1	2,1	2,1
Total Liabilities	20,6	18,6	15,4	12,6	11,9
Total Equity and Liabilities	40,5	35,7	27,9	22,4	19,4

Cash Flow Statements	2014	2015e	2016e	2017e	2018e
Net Income	-5,5	-5,9	-7,1	-4,7	-3,5
Cash Flow from Operating activities	-3,4	-2,4	-5,4	-2,4	-0,8
Cash Flow from Investing activities	-0,3	0,0	-0,3	-0,3	-0,3
Cash Flow from Financing activities	11,8	0,0	-0,4	-1,0	-0,6
Change in Cash	8,1	-2,4	-6,1	-3,7	-1,7

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Aurgalys

1, rue Pierre Fontaine
91058 Evry Cedex
France

www.aurgalys.com

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