

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]

September 10th, 2015

Estimated price:

€1.62

Diaxonhit provides update on HIV test

Share price (€)

0.59

(as of Sep. 10th, 2015)

High/Low (€)

1.04/0.53

(since Jan. 1st, 2015)

Market Cap. (€M)

43.0

(as of Sep. 10th, 2015)

Estimated Net Cash

4.0

(€M)

Valorisation

118.1

(€M)

Number of shares (M)

72.9

Estimated price (€)

1.62

3-month average daily volume

710.500

Free Float

84.5%

Since 2014, Diaxonhit has been participating in the HIV consortium PROTHEVIH, which aims at developing innovative drugs and diagnostic tests to improve the management of HIV patients. After project leader Innavirvax published promising results on the VAC-3S therapeutic vaccine, Diaxonhit announced it will have a first prototype of an HIV prognosis test in H1-2016 (DIAG-3S). The company needs to demonstrate that the naturally-secreted antibodies against the 3S peptide (highly conserved on the HIV virus) can be used as an early marker of prognosis in HIV-infected patients. After validating the test, Diaxonhit could market DIAG-3S as early as 2018. Following this announcement, we adjusted our target price to €1.62/share.

Promising results of Innavirvax's VAC-3S therapeutic vaccine

In April 2014, Diaxonhit announced its participation in the PROTHEVIH consortium led by French privately-held company Innavirvax. The PROTHEVIH consortium's goal is to develop a therapeutic vaccine for HIV-infected patients. Diaxonhit's role is to develop 2 diagnostic tests: a companion diagnostic test (CO-3S) whose role is to measure the immunization status of patients who would receive the VAC-3S vaccine; and a prognostic test measuring the level of naturally secreted anti-3S antibodies, a marker of patient prognosis.

In July 2015, Innavirvax announced encouraging results from the VAC-3S Phase I/IIa study, whereby the therapeutic vaccine could decrease the HIV viral load, increase the percentage of CD4+ T cells, decrease the percentage of CD8+ T cells, and increase the CD4/CD8 ratio, a biomarker in immune restoration in HIV patients. Diaxonhit announced that a first prototype of the DIAG-3S diagnostic test could be ready in H1-2016, after which the company would initiate a clinical study to validate the test. Diaxonhit has already received €200K of the €1.7M it is eligible to get from Bpifrance to finance the project.

HIV infection and management, a worldwide challenge to control the pandemic

Therapy improvements in the past years have considerably increased the life expectancy of HIV-infected patients. However, it is estimated that in 2014, 37 million people worldwide were living with HIV, 2 million of which were newly infected (WHO). It is also estimated that 51% of HIV-infected patients are not aware of their condition. In the US and EU, it is estimated that there are 2.3 million people currently living with HIV. There is no cure for HIV and current therapies consist of a combination of antiviral drugs which help reduce and control the viral load. However, such drugs need to be taken orally on a daily basis and the interruption of the antiviral therapy usually leads to a quick increase of the viral load in HIV-infected patients. Antiviral therapy is therefore a lifetime therapy and the HIV virus can also become resistant to such drugs. Reducing the viral load of HIV-patients remains a priority in HIV-infected patients to minimize the risk of infection, and also restore immune functions to prevent opportunistic infections that can lead to death.

Euronext since Jan. 1st, 2015

Diaxonhit	0.0%
Alys France*	+18.5%
Next Biotech	+38.6%
CAC Pharma.&Bio.	+17.9%
CAC 40	+7.6%
Alternext Allshares	+20.3%

* 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>

Positioning and market potential of DIAG-3S

DIAG-3S is a diagnostic test that would measure naturally-secreted antibodies against the highly conserved 3S peptide of the HIV virus. Diaxonhit aims at demonstrating that the level of anti-3S antibodies can be used as an early biomarker of patient prognosis. Therefore, patients that have already been diagnosed with HIV infection could subsequently be monitored by the DIAG-3S test, and have their therapy optimized according to the results.

To evaluate the market opportunity of the DIAG-3S test, we only considered the US and EU regions. In our model, there are 2.2 million people that are believed to be infected by the HIV virus (Sources: population estimates from census.gov and prevalence from AVERT) but we considered that only 80% were aware of their condition. Considering that 90% of these patients are actually being treated, we estimated a target population of 1.6 million patients. Because DIAG-3S would be an early marker of patient prognosis, we only considered patients that are less advanced in their disease, typically those with a CD4 count above 350 cells/mL (80% of HIV patients receiving treatment. Source: VESPA 2 study), representing a population of 1.3 million patients. With a 30% market penetration, and a price of €100 per test, per patient in the EU, and €200 for the US region, we obtain a peak sales figure of €60M.

This model does not take into account other regions of the world where the test could be marketed, such as emerging countries. DIAG-3S would probably be marketed at a reduced price after licensing the rights to organizations that facilitate patient access to HIV drugs or IVD tests. Moreover, the DIAG-3S can be developed and marketed independently of Innativirvax's VAC-3S therapeutic vaccine. Should Innativirvax be successful in bringing the product to the market, the market potential of DIAG-3S could be increased. For instance, the DIAG-3S could be utilized to monitor the level of anti-3S antibodies in VAC-3S-treated patients, and help clinicians determine whether patients require a boost or not. This upside has not been included in this DIAG-3S model.

Other important news events

- Diaxonhit to get maximum value from its therapeutic assets

Diaxonhit had historically used its splice array platform to develop diagnostic tests and new drug candidates. Since the reorganization of its R&D activity at the end of 2013, Diaxonhit has been dedicating its R&D efforts to IVD tests exclusively. However, the company still has numerous therapeutic assets, resulting from a 12-year long collaboration with Allergan. Diaxonhit recently received a €500k milestone payment from Allergan for filing an Investigational New Drug application. Earlier this year, Diaxonhit also announced the licensing of drug candidates in the field of oncology, to Felicitec Pharmaceuticals. Diaxonhit is eligible for milestone payments and royalties on sales should these drug candidates successfully reach the market.

- IVD test sales up 6% in H1-2015

On July 22nd, 2015, Diaxonhit published its H1-2015 revenues. The company reported €15.3M in IVD test sales, a 6% increase compared to H1-2014. The total revenues for the semester are €15.8M, including the €500k milestone payment received from Allergan. Diaxonhit has a catalog of IVD products, distributed by the Ingen Biosciences sales team. Diaxonhit is the French leader in HLA testing for organ transplantation. Last year, Diaxonhit renewed its key distribution agreement for several years with One Lambda/ThermoFisher Scientific for marketing HLA tests in France.

Valuation

We increased our valuation of Diaxonhit to €114.1M (enterprise value) to account for the DIAG-3S diagnostic test, which could be marketed as early as 2018. Our revenue model consists in direct sales in France, distribution in other countries

of the EU, and sales as a Laboratory-Developed Test in the US. This does not include other regions of the world which could bring significant upside. We also considered a 45% chance for the test to reach the market since Diaxonhit has yet to finalize the prototype (H1-2016) and validate its performance in a clinical study. Our valuation for DIAG-3S is €8.8M. Our estimates on other products (BJI Inoplex, Dx15, Allomap), and Ingen Biosciences have not changed since our last report. Including an estimated net cash of €4.0M, we value Diaxonhit at €1.62/share.

Stock Performance

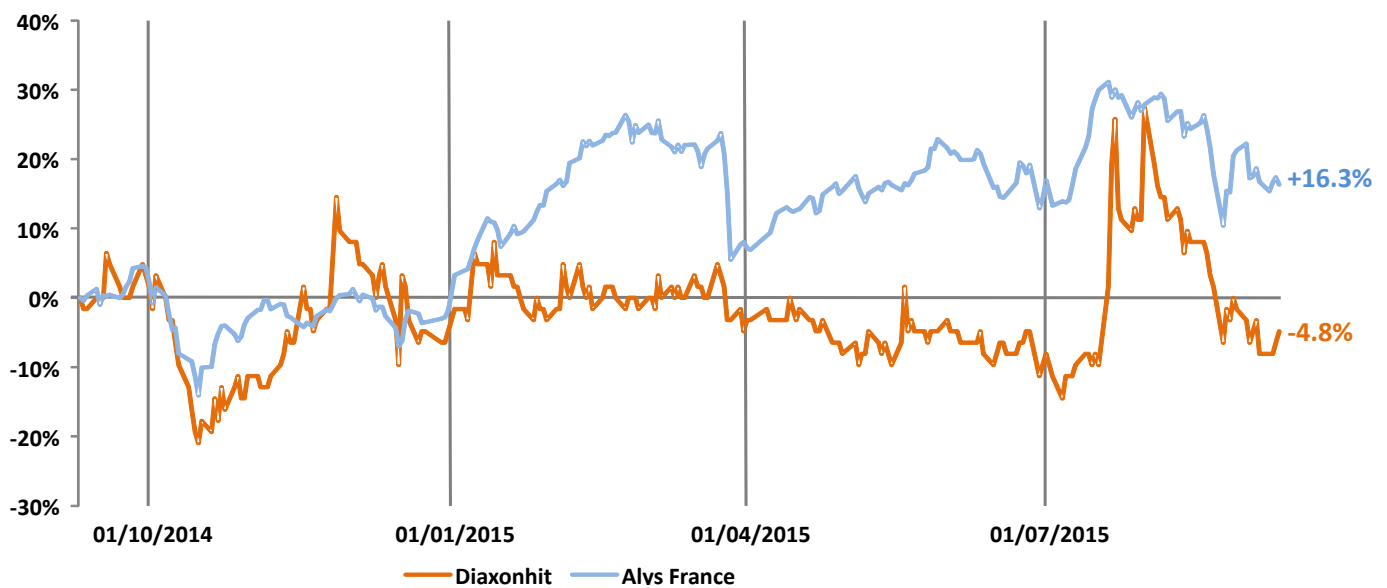


Figure 1: One-year chart dated September 10th, 2015, comparing the performance of Diaxonhit's stock with French smallcaps of the life sciences and healthcare sector (Alvs France index).

In the first half of 2015, Diaxonhit's share price has remained stable, around €0.60. Thanks to the FeliciteX licensing agreement, Diaxonhit's share price gained 8.6% on May 19th, 2015 with a high trading volume (more than 5 million shares exchanged hands). In July, with the €500k milestone payment, and the DIAG-3S press release, Diaxonhit's share price quickly rose to its year high (€1.04) and closed at €0.79 on July 31st, 2015. However, since then, the share price has decreased to €0.59, mainly because of the macroeconomic context in August 2015. For comparison, the Alvs France index and Next Biotech index have gained 18.5% and 38.6%, respectively since the beginning of the year.

Financials

Earnings Per Share	2014	2015e	2016e	2017e
EPS	-0.09	-0.07	-0.06	-0.03

Income Statement	2014	2015e	2016e	2017e
Revenues	31.72	30.78	32.46	36.73
EBIT	-5.38	-5.62	-5.28	-3.41
Net Income	-5.48	-4.94	-4.6	-2.73

Balance Sheet	2014	2015e	2016e	2017e
Non-Current Assets	16.28	14.85	13.43	12.0
Stocks	2.01	2.13	2.28	2.52
Account Receivables	4.76	5.04	5.41	6.13
Other Receivables	3.24	3.08	3.25	3.67
Other current assets	0.09	0.09	0.09	0.09
Cash and cash equivalents	14.13	11.9	9.02	7.2
Current Assets	24.22	22.23	20.04	19.62
Total Assets	40.5	37.09	33.47	31.62
Total Equity	19.93	19.62	18.87	16.38
Convertible Bonds	6.99	3.64	0.3	0.05
Repayable Advance	1.03	1.33	1.63	1.93
Provisions	1.48	1.63	1.79	1.97
Financial Debt	1.87	1.33	0.78	0.33
Account Payable	5.74	5.86	6.26	6.93
Other Debt	3.45	3.67	3.84	4.02
Total Liabilities	20.57	17.46	14.6	15.23
Total Equity and Liabilities	40.5	37.08	33.47	31.62

Cash Flow Statements	2014	2015e	2016e	2017e
Net Income	-5.48	-4.94	-4.6	-2.73
Cash Flow from Operating activities	-3.37	-2.79	-2.65	-1.2
Cash Flow from Investing activities	-0.26	-0.33	-0.33	-0.33
Cash Flow from Financing activities	11.77	0.89	0.1	-0.3
Change in Cash	8.15	-2.23	-2.88	-1.82

Résumé en français

Depuis 2014, Diaxonhit participe au consortium PROTHEVIH, dont le but est de développer un vaccin thérapeutique et des tests de diagnostic innovants, pour améliorer la prise en charge des patients infectés par le virus du SIDA (VIH).

Innavirvax, leader du consortium, a publié des résultats prometteurs de phase I/II sur le vaccin thérapeutique VAC-3S. En effet, des patients ayant reçus le vaccin ont vu à la fois leur charge virale diminuer, tout en ayant une restauration de la fonction immunitaire (augmentation du taux de cellules T CD4+, diminution du taux de cellules T CD8+).

Suite à ces résultats encourageants, Diaxonhit dont le rôle dans le consortium PROTHEVIH est de développer des tests de diagnostic, a annoncé qu'un premier prototype de son test DIAG-3S sera prêt dès le premier semestre 2016. DIAG-3S est un test qui mesurera la présence d'anticorps sécrétés naturellement par les patients séropositifs, contre le peptide 3S, très conservé dans le virus du SIDA. Diaxonhit compte démontrer que ces anticorps peuvent être utilisés comme marqueur précoce de l'évolution de la maladie, et permettre d'adapter le traitement des patients. Une étude de validation clinique du test pourrait débuter en 2016 et permettrait une commercialisation en 2018.

Selon nos estimations, le pic de vente du DIAG-3 pourrait atteindre 60M€ en ne considérant que les Etats-Unis et l'Union Européenne. Notre modèle ne prend pas en compte les régions en voie de développement. D'autre part, si le vaccin d'Innarvivax arrivait sur le marché, le potentiel de ventes du DIAG-3S en serait augmenté car ce test pourrait être utilisé dans le suivi des patients vaccinés par le VAC-3S. Ce potentiel n'a pas été inclus dans notre modèle, qui pourrait être ajusté lorsque nous aurons plus de visibilité sur l'avancement clinique du VAC-3S (fin 2015). Nous avons ajusté notre valorisation de Diaxonhit à 1,62€/action.

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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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