

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]

January 27th, 2016

Estimated price:

€1.62

Share price (€)
(as of Jan. 27th, 2016)

0.44

High/Low (€)
(since Jan. 1st, 2016)

0.55/0.41

Market Cap. (€M)
(as of Jan. 27th, 2016)

33.3

Estimated Net Cash
(€M)

2.3

Estimated Market Cap.
(€M)

123.0

Number of shares (M)

75.7

Estimated price (€)

1.62

3-month average daily
volume

355,000

Free Float

84.5%

Proprietary products to drive Diaxonhit's growth in 2016

Diaxonhit is a company developing, producing, and marketing in vitro diagnostic (IVD) tests. Diaxonhit's expertise in IVD development resides in genomics and proteomics technologies. The company has a dual business model comprised of the distribution of a wide range of IVD tests in France, Belgium and Switzerland through its Ingen subsidiary, and with the development of innovative IVD tests. The company has generated a well-balanced portfolio of proprietary products and licensed IVD tests (Figure 1), and expects to create value through internal growth (proprietary products, increase in revenues, improved margins, etc.), and external growth through company or IVD assets acquisition. This report focuses on Diaxonhit's current IVD product portfolio, and provides an update on their development. Our target price for Diaxonhit is €1.62/share.

European Central Laboratory ready to receive first Allomap test

Diaxonhit recently announced the successful technology transfer of the CareDx's Allomap test to the European Central Laboratory, located in the University Hospitals of Strasbourg, France. Allomap is a non-invasive diagnostic test for heart transplant rejection monitoring, which only requires a blood sample. Allomap, recommended by the International Society for Heart and Lung Transplantation (ISHLT), can help reduce the number of heart biopsies, which are regularly performed after surgery (up to 20 times in the first year) to verify whether the transplanted heart is rejected or not. It can also be used to adjust the immunosuppressant therapy. During the last ISHLT meeting, CareDx and Diaxonhit announced that an increase in the Allomap score between 6 and 9 months after heart transplantation is highly predictive of long term patient survival, thus providing essential information to adapt the management of these patients.

Allomap has been available in Europe since July 2014 and previous biopsy samples were sent to CareDx's central laboratory in the US. Now, with a functioning European Central Laboratory, Diaxonhit will be able to sell the Allomap diagnostic test (€2,000/test) making higher margins. Moreover, the French health authority is also financing a medico-economic study (PRME program) which could help obtain reimbursement for the Allomap test in France.

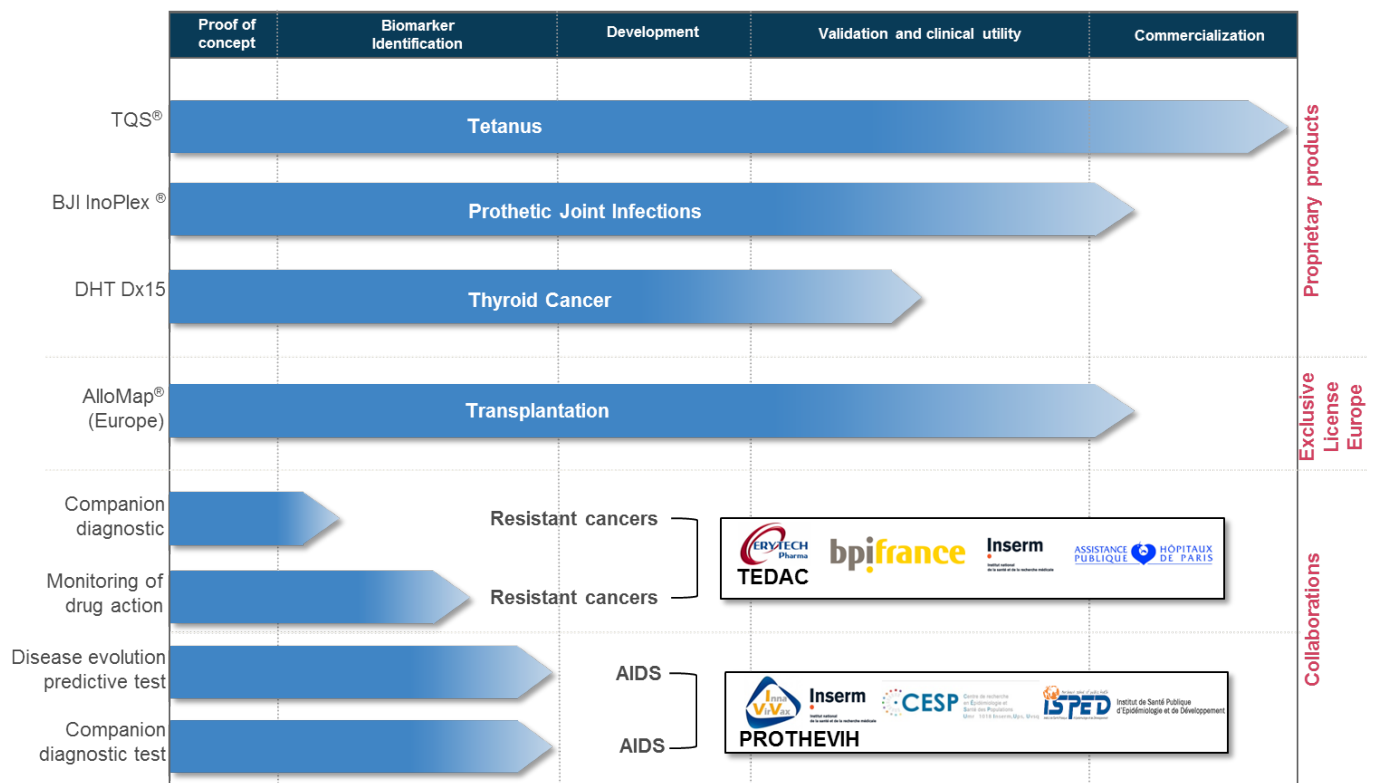


Figure 1. Diaxonhit's product portfolio (Source : Diaxonhit)

More than 1,000 patients already recruited for Dx15 study

Dx15 is a diagnostic test for thyroid cancer. Current practice for thyroid cancer diagnosis usually involves fine-needle aspiration of a thyroid nodule to obtain a sample, which is then analyzed by microscopy. The majority (70%) of fine-needle aspiration samples reveal that thyroid nodules are benign, while 5% of them turn out to be cancerous. However, 25% of the samples are undetermined and the recommendation for these patients is to remove the thyroid gland, as a precaution. Subsequent analyses usually reveal that the majority of these undetermined samples were actually benign. Unnecessary removal of the thyroid gland can have important consequences for patients: risks associated with surgery, including lifelong substitutive hormone therapy.

Diaxonhit successfully identified genetic signatures of thyroid

Euronext since Jan. 1st, 2016

Diaxonhit	-8.3%
Alys France*	-14.7%
Next Biotech	-14.6%
CAC Pharma.&Bio.	-3.4%
CAC 40	-5.5%
Alternext Allshares	-6.9%

* 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>

cancer, using its proprietary hGWSA technology, and developed a diagnostic test (Dx15) for undetermined fine-needle aspiration thyroid samples. With Dx15, Diaxonhit aims at providing a test that could ultimately reduce the number of unnecessary thyroidectomies. The company started a validation study (CITHY) on fine-needle aspiration samples in November 2014, and recently announced that more than 1,000 patients had already been recruited, in advance compared to the initial agenda. The results are expected in Q1-2017, followed by CE-marking and commercial launch the same year.

Finalization of HIV test prototype in H1-2016 (PROTHEVIH Consortium)

In April 2014, Diaxonhit announced its participation in the PROTHEVIH Consortium, which consists in developing a therapeutic vaccine against a highly conserved peptide (3S) on the HIV virus. Innavirvax, leading the consortium, is currently testing its VAC-3S vaccine in a Phase 2 clinical trial. Diaxonhit's role is to develop two diagnostic tests:

- DIAG-3S, to measure the level of naturally-secreted anti-3S antibody, for disease prognosis
- CO-3S, a companion diagnostic test, to monitor patient response to Innavirvax's VAC-3S vaccine

Following Innavirvax's promising results of its Phase I/II trial, published in July 2015, Diaxonhit announced that a first prototype of the DIAG-3S test would be available in H1-2016. Diaxonhit will then be able to validate the test in HIV-infected patients. This validation study aims to demonstrate that the level of naturally-secreted antibodies is an early marker of disease progression. This would provide a new diagnostic tool to improve HIV patient management and care. Should the validation study be successful, Diaxonhit could market DIAG-3S, independently of the completion of Innavirvax's VAC-3S clinical trials.

BJI Inoplex, a diagnostic test for prosthetic joint infection, already launched

Diaxonhit announced in January 2015, that it successfully obtained CE-marking for BJI Inoplex, a prosthetic joint infection diagnostic test. Twenty percent of patients receiving a joint prosthesis usually complain of pain after surgery, which could be a sign of a mechanical problem with the prosthesis, or bacterial infection. Mechanical issues with prostheses are easily resolved with minor surgical procedures while bacterial

infections require intensive surgery to remove infected tissue, antibiotic therapy and sometimes, replacement of the prosthesis.

The diagnosis of bacterial infection relies on microbial cultures from samples of the joint, and results usually require a few days. Microbial cultures can detect the presence of bacteria but do not necessarily indicate whether these bacteria are those causing the infection. Compared to microbial cultures, Diaxonhit's BJI Inoplex is a rapid (2 hours) and non-invasive diagnostic test (blood sample) for the most commonly found bacterial strains of prosthetic joint infections. BJI Inoplex also measures the level of antibodies against these bacteria, an indication that the immune system has been activated, thus confirming the infection.

BJI Inoplex is currently marketed in France, Belgium and Switzerland by Diaxonhit's sales force (Ingen). With the registration the test on the French registry for innovative medical procedures (RIHN), prescriptions of BJI Inoplex are financed thanks to dedicated resources for innovation. Diaxonhit has signed at least two distribution agreements with Sanbio (Benelux area, catalog price of €5,950/96 tests as of January 2016), and Rafer (Spain, Portugal).

TEDAC Consortium for cancer treatment monitoring

Diaxonhit also participates in the TEDAC Consortium, led by French Erytech Pharma (Euronext: ERYT), which develops an innovative asparaginase therapy to treat blood cancers (Acute Lymphoblastic Leukemia, ALL, and Acute Myeloid Leukemia, AML). Erytech's technology involves encapsulating the asparaginase enzyme in red blood cells which in turn starves the cancer cells that require the asparagine amino-acid to grow. Diaxonhit is developing two diagnostic tests to evaluate the susceptibility to therapeutic response, and a companion test to identify responders to Erytech's therapy. In 2014, Erytech announced top line positive Phase III results in ALL and filed an application for marketing authorization in September 2015.

IVD Sales up 4% in 2015

Diaxonhit reported IVD sales of €28.9M in 2015, a 4% increase compared to 2014. Since Allomap and BJI Inoplex benefit from reimbursement programs of the French Health Ministry (PREM and RIHN, respectively), these tests should drive Diaxonhit's revenue in 2016.

Upcoming News flow

- Q1-2016: End of recruitment of Dx15 validation study
- H1-2016: First Prototype of DIAG-3S diagnostic test
- Q4-2016: Dx15 validation study results

Valuation

We increased our valuation of Diaxonhit to €120.7M (enterprise value) due to rolling forward. Including an estimated net cash of €2.3M, we value Diaxonhit at €1.62/share.

Stock Performance

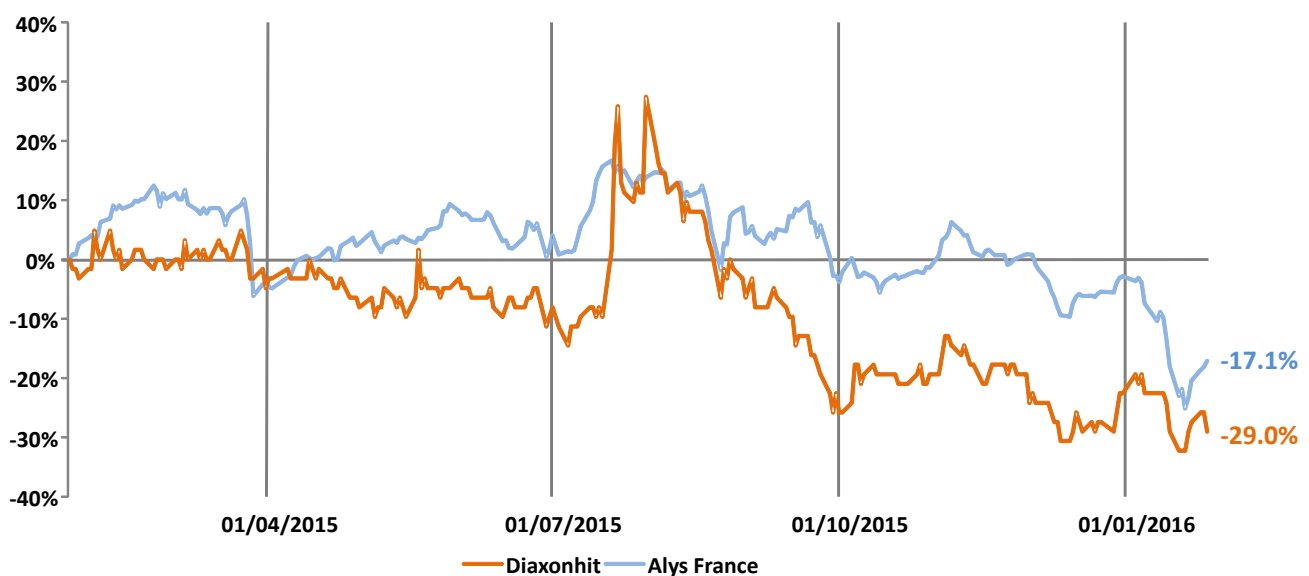


Figure 2: One-year chart dated January 27th, 2016, comparing the performance of Diaxonhit's stock with French smallcaps of the life sciences and healthcare sector (Alys France index).

In the first semester of 2015, Diaxonhit's stock has remained stable at around €0.60/share. In July 22nd, 2015, the share price reached a yearly high of €1.04 on high volume (more than 11 million shares were exchanged that day), after the company announced a milestone payment from Allergan. However, difficult macroeconomic events in the second half of 2015 (Chinese economy, Volkswagen fraud, oil prices, etc.) negatively impacted Diaxonhit's share, which closed at €0.48 on December 31st, 2015. At the beginning of 2016, Diaxonhit's shares also suffered from the global market sell off. On January 27th, 2016, Diaxonhit's shares closed at €0.44.

Financials

Earnings Per Share	2014	2015e	2016e	2017e
EPS	-0.09	-0.10	-0.07	-0.04

Income Statement	2014	2015e	2016e	2017e
Revenues	31.7	29.5	31.4	35.7
EBIT	-5.4	-7.8	-5.7	-3.7
Net Income	-5.5	-7.1	-5.0	-3.1

Balance Sheet	2014	2015e	2016e	2017e
Non-Current Assets	16.3	14.9	13.4	12.0
Stocks	2.0	2.3	2.2	2.5
Account Receivables	4.8	4.9	5.3	6.0
Other Receivables	3.2	2.9	3.1	3.6
Other current assets	0.1	0.1	0.1	0.1
Cash and Cash equivalents	14.1	10.2	6.6	4.4
Current Assets	24.2	20.4	17.3	16.6
Total Assets	40.5	35.3	30.8	28.6
Total Equity	19.9	17.5	16.3	13.5
Convertible Bonds	7.0	3.6	0.3	0.1
Repayable Advance	1.0	1.3	1.6	1.9
Provisions	1.5	1.6	1.8	2.0
Financial Debt	1.9	1.3	0.8	0.3
Account Payable	5.7	6.2	6.1	6.8
Other Debt	3.5	3.7	3.8	4.0
Total Liabilities	20.6	17.8	14.5	15.1
Total Equity and Liabilities	40.5	35.3	30.8	28.6

Cash Flow Statements	2014	2015e	2016e	2017e
Net Income	-5.5	-7.1	-5.0	-3.1
Cash Flow from Operating activities	-3.4	-4.5	-3.4	-1.5
Cash Flow from Investing activities	-0.3	-0.3	-0.3	-0.3
Cash Flow from Financing activities	11.8	0.9	0.1	-0.3
Change in Cash	8.1	-3.9	-3.6	-2.2

Résumé en français

Diaxonhit est une société spécialisée dans le développement, la production et la commercialisation de tests de diagnostic *in vitro* innovants. Les technologies employées par Diaxonhit reposent sur la génomique et la protéomique, et la société a su créer un portefeuille de produits équilibré, avec à la fois des produits en phase avancées de développement et des produits déjà commercialisés:

- **Allomap, pour le suivi des transplantés cardiaques:** Diaxonhit a annoncé le succès du transfert de technologie de CareDx (propriétaire du test Allomap) au laboratoire central européen (CHU de Strasbourg). Le rejet du greffon est traditionnellement évalué par de nombreuses biopsies, surtout dans les premiers mois suivant la chirurgie. Allomap est un test génétique non-invasif permettant de réduire le nombre de biopsies. Avec un laboratoire européen opérationnel, Diaxonhit va pouvoir mettre à disposition cette technologie innovante auprès des patients en Europe.
- **BJI Inoplex pour les infections de prothèses articulaires:** ce test propriétaire, lancé début 2015 permet la détection rapide d'une infection après la pose d'une prothèse articulaire. Lorsqu'un patient souffre de douleur après une chirurgie, il est important d'en déterminer rapidement la nature. En effet, une seconde intervention pour un problème mécanique est aisément résolu, comparée à une infection requérant une chirurgie lourde, nécessitant parfois un remplacement de la prothèse. En 2 heures, le test BJI Inoplex permet la détection d'une infection à partir d'un échantillon de sang alors que les techniques traditionnelles de microbiologie nécessitent plusieurs jours et ne sont pas spécifiques de l'infection.
- **Dx15 pour le cancer de la thyroïde:** Dx15 est un test génétique qui permettra de réduire le nombre d'ablation inutile de la thyroïde. Dans 20% des cas, il n'est pas possible de déterminer si un nodule thyroïdien est bénin ou malin. Par principe de précaution, la thyroïde est retirée alors qu'une analyse post-opératoire révèle que le nodule n'était pas cancéreux. Le test Dx15 en cours de validation clinique, est un test génétique qui permettra de lever cette incertitude sur les cas indéterminés
- **Consortium PROTHEVIH pour les patients infectés par le VIH:** Diaxonhit participe au consortium PROTHEVIH, mené par la société Innavirvax, et qui consiste à développer un vaccin thérapeutique contre le VIH. Le rôle de Diaxonhit est de développer deux tests de diagnostic *in vitro*. L'un est un test compagnon du vaccin développé par Innavirvax, l'autre, un test prédictif d'évolution de la maladie.
- **Consortium TEDAC en oncologie:** dans le cadre de ce consortium, Diaxonhit développe deux tests. Le premier est un test compagnon de la thérapie GRASPA d'Erytech Pharma, actuellement en cours d'enregistrement en Europe pour la leucémie aigüe lymphoblastique. Le deuxième test permettra le suivi de l'action médicamenteuse de GRASPA.

Diaxonhit a annoncé une augmentation de 4% des ventes de tests de diagnostic, pour un montant de 28,7M€, en 2015. Les ventes devraient être dynamisées en 2016 par les tests Allomap et BJI Inoplex, qui bénéficient de programmes de prise en charge financière pour des tests innovants. Nous maintenons notre valorisation de Diaxonhit à 1,62€/action.

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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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