

Quick Note

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Aurgalys is contracted by Diaxonhit to provide equity research

Diaxonhit

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Aurgalys

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April 29th, 2014

Share Price: €0.85

(as of Apr. 29th, 2014)

Estimated price:

€1.54

High/Low since 01.01.14 (€)	1.12/0.66
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Market Cap (€m)	51.4
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Estimated Cash Position (€m)	3.5
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Estimated market cap. (€m)	93.2
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Number of Shares (m)	60.4
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Estimated price (€)	1.54
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Volume 3 months average (m)	1.3
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Free Float	73.1%
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Dividend Forecast 12 months (€)	0.0
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Diaxonhit, to develop two diagnostic tests in HIV consortium

Earlier this year, Diaxonhit clearly set up its strategy of becoming a leader in *in-vitro* diagnostics by focusing its R&D efforts towards the development of diagnostic tests. Diaxonhit announced it will receive €1.7M from the French Public Investment Bank (BPI France) for its participation in a research consortium led by French privately-owned InnaVirVax, dedicated to the development of a therapeutic vaccine against HIV-1. Diaxonhit's mission is to design a companion diagnostic test for InnaVirVax's VAC-3S vaccine, as well as a test for the detection of early markers of disease progression. This project complements Diaxonhit's product portfolio that includes BJI Inoplex for prosthetic joint infection diagnosis (CE mark expected Q4-2014), Dx15 for thyroid cancer diagnosis (clinical validation on going, CE mark expected Q4-2015) and Allomap for heart transplant rejection monitoring (product launch in H2-2014). This announcement is also confirmation of Diaxonhit's expertise in developing molecular and non-molecular diagnostic tests. In this quick note, we will review Diaxonhit's products in development.

Diaxonhit receives €1.7M for its involvement in the PROTHEVIH consortium for AIDS

The aim of this project is to develop a therapeutic vaccine (VAC-3S) against HIV-1, as well as diagnostic tools for personalized follow-up of patients. Diaxonhit and two government-funded laboratories joined the consortium led by privately-owned InnaVirVax, which developed the VAC-3S vaccine. Diaxonhit was selected for its expertise in developing molecular and non-molecular diagnostic tests for infectious diseases. The company will be entrusted with 2 missions: (i) to develop a companion diagnostic test (CO-3S) for VAC-3S to measure patient response to the vaccine; (ii) to develop a diagnostic kit for early markers of disease progression (DIAG -3S) in order to optimize patient follow-up. Of the €9M received by the consortium, Diaxonhit is entitled to receive €1.7M over the 56-month period of the program.

By supporting this project, BPI France recognizes what a major scientific challenge AIDS is, with high human and economic costs. For instance, WHO estimates that more than 35.3 million people live with HIV worldwide, including 2.3 million newly infected in 2012. Moreover, HIV infection is thought to be responsible for the deaths of 36 million people since the beginning of the epidemic, most of them in low-

income countries. The VAC-3S vaccine developed by InnaVirVax intends to support the patient's immune system by impairing the mechanisms responsible for the depletion of T lymphocytes during HIV-1 infection. InnaVirVax, located in the Genopole biocluster in the south of Paris, recently started a phase II clinical trial with this candidate, with results anticipated in two years.

The involvement of Diaxonhit in this project demonstrates its expertise in this area and is in line with its strategy of becoming a major European player in the *in-vitro* diagnostic landscape.

Euronext since January 1st, 2014

Diaxonhit	+28.8%
Alys France*	+18.8%
CAC 40	+4.7%
Next Biotech	+30.7%
CAC Pharma & Bio	+0.8%
Alternext All Shares	+19.3%

*Index of French smallcaps (less than €1B market cap)
in the healthcare and life sciences sector listed on
Euronext Paris.

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

Two proprietary products in the starting blocks

• BJI Inoplex, CE mark expected Q4-2014

Diaxonhit aims to get CE marking for BJI Inoplex in Q4-2014 and to start its marketing shortly after. BJI Inoplex is a diagnostic test for hip and knee prosthetic joint infection. 3.5 million hip and knee prostheses are implanted annually around the world, including 220,000 cases in France alone. Bacterial infection is a rare complication but with severe consequences for the patients who need to be rapidly treated to avoid damages to the prosthesis and its replacement, leading to high healthcare costs (around €25,000 for a second surgery). Diaxonhit's BJI Inoplex is the first innovative non-invasive and multi-parameter diagnostic test developed to detect bacterial infections on prosthetic joints within two hours. Based on a combination of protein antigens, BJI Inoplex can detect 90% of bacteria commonly found in prosthetic joint infection with a simple blood analysis, compared to current methods that require microbial culture of a sample of synovial fluid that can last several weeks. The French Haute Autorité de Santé has recently stressed the urgent nature of prosthetic joint infection and has updated its recommendations regarding its management. Diaxonhit's BJI Inoplex test could be an alternative to current diagnostic procedures that could not only efficiently diagnose bacterial infection but also identify which strain is involved, allowing physicians to adapt the antibiotic treatment to the patient.

• Dx15 for thyroid cancer diagnosis: clinical validation ongoing

Earlier this year, Diaxonhit announced it successfully identified genetic signatures for its Dx15 thyroid cancer diagnostic tests, using its proprietary hGWSA technology. Diaxonhit is currently dedicating its R&D team to the clinical validation of these genetic signatures in order to get CE marking at the end of 2015, a prerequisite for its commercialization in Europe.

Thyroid cancer is a cancer with generally good prognosis if detected early with a 10-year survival between 75% and 93%. Removal of the thyroid gland has been very effective in treating cancer patients. Fine Needle Aspiration (FNA) is commonly performed on thyroid nodules detected through routines examination to confirm or to definitively exclude malignancy risk. It is estimated that 70% of nodules analyzed by FNA would turn out to be benign while 5% of them would be classified as malignant, leading to the removal of the thyroid gland.

However, in about 25% of cases, FNA samples are indeterminate, meaning that the benign or malignant nature of the nodule cannot be identified. As a precaution, the removal of the thyroid gland is recommended. Since post-thyroidectomy analyses reveal that 60% to 80% of the samples were actually benign, the prophylactic thyroid ablation causes a high number of unnecessary surgeries, with

*BJI Inoplex, CE mark
expected Q4-2014*

*Dx15, CE mark
expected Q4-2015*

significant healthcare costs and discomfort for patients, including possible surgical complications and life-long hormone therapy.

Dx15 is a genetic test under development, for the diagnosis of indeterminate thyroid nodules which would help cytopathologists in identifying whether the indeterminate FNA samples are benign or malignant. Diaxonhit claims the performance of its tests supersedes that of its American competitors. The ongoing clinical validation study has been designed to confirm the relevance of Dx15 and its utility for clinicians.

Allomap for heart transplant rejection monitoring

The marketing of licensed products is also part of Diaxonhit's growth strategy, illustrated with the Allomap license obtained from the American company XDX. This test is a molecular assay on blood samples, designed to monitor heart transplant rejection and will help reduce the numerous invasive biopsies usually performed on the newly transplanted heart. Diaxonhit, which owns the exclusive European rights, intends to start its marketing in H2-2014. Allomap, already sold in the US since 2005, will strengthen and complement the existing product portfolio dedicated to organ transplant. The product should benefit from the established and experienced sales force in this field, allowing Diaxonhit to claim 70% of the HLA test market in France.

Valuation of Diaxonhit

Our €93.2M valuation of Diaxonhit includes BJI Inoplex, Dx15, Allomap, and Ingen subsidiary distribution activity. Diaxonhit has yet to market proprietary products. Should the company be successful in marketing BJI Inoplex and in developing its other diagnostic tests, Diaxonhit would confirm its aim of becoming a leader in the field of diagnostics. Therefore, 2014 and 2015 represent important milestones for the company.

Expected News Events

- H2-2014: Launch of Allomap in France, Belgium, Switzerland, Germany and Austria
- Q4-2014: CE Mark for BJI Inoplex
- 2014: license and distribution agreements of new products

Résumé en français

Diaxonhit s'est clairement inscrite comme une société aspirant à devenir un leader du diagnostic in-vitro, en annonçant en début d'année la concentration de ses efforts de R&D sur le développement de tests de diagnostic. La société a annoncé sa participation à un consortium dédié au développement d'un vaccin thérapeutique contre le VIH-1 et des outils de diagnostic adaptés au suivi personnalisé des patients, et recevra à ce titre, 1,7M€ de BPI France sur les 9M€ prévus pour ce projet. Le consortium qui a pour chef de file la société InnaVirVax, basée à Evry au Génomipole, comprend en plus de Diaxonhit, deux institutions publiques de recherche. Diaxonhit sera en charge de développer un test de diagnostic compagnon du vaccin thérapeutique VAC-3S développé par InnaVirVax, permettant de suivre la réponse des malades à ce traitement. La société devra également développer un test de détection d'un marqueur précoce d'évolution de la maladie qui permettra d'optimiser la prise en charge des patients. Le choix de Diaxonhit est une reconnaissance de son expertise et de son expérience dans le développement de tests diagnostics moléculaires et non moléculaires. InnaVirVax a débuté fin 2013 une étude clinique de phase II du VAC-3S, avec des résultats attendus dans les deux ans.

Ce projet vient compléter le portefeuille de produits de Diaxonhit :

- *Le BJI Inoplex est un test rapide et non invasif permettant de détecter 90% des souches bactériennes infectieuses des prothèses articulaires, à partir d'un échantillon sanguin. Le marquage CE et sa commercialisation sont attendus fin 2014. La Haute Autorité de Santé, a récemment insisté sur le caractère urgent de cette maladie nosocomiale car si non traitée, elle peut limiter le fonctionnement de la nouvelle articulation et à terme provoquer son remplacement. Le BJI Inoplex s'inscrit donc comme un nouvel outil permettant une meilleure prise en charge des patients.*
- *Le Dx15, deuxième produit le plus avancé de Diaxonhit est en cours de validation clinique, avec un marquage CE attendu au T4-2015. Lorsque les médecins ne peuvent pas déterminer le caractère malin ou bénin d'un nodule thyroïdien, l'ablation préventive de la thyroïde est recommandée, alors que la plupart du temps, ces cas indéterminés se révèlent bénins. Grâce à la technologie hGWSA, permettant l'identification de signatures génomiques spécifiques des cellules cancéreuses, le Dx15 permettrait de lever cette incertitude et donc de réduire le nombre de thyroïdectomies inutiles. Ceci impliquerait donc une réduction des risques inhérents à toute opération chirurgicale, une réduction des coûts et éviterait un traitement à vie par hormonothérapie pour les patients opérés inutilement.*

La stratégie de croissance de Diaxonhit s'appuie également sur la vente de produit sous licence. Ainsi la société prévoit le lancement des ventes au 2e semestre 2014, du test Allomap, permettant le suivi non invasif du risque de rejet chez les transplantés cardiaques. Ce test dont la société détient les droits exclusifs pour l'Europe, vient enrichir un portefeuille spécialisé dans le domaine des transplantations. En effet, Diaxonhit bénéficie de l'expérience et de l'implantation de sa force de vente auprès des centres hospitaliers, qui lui a permis de conquérir 70% du marché des tests HLA en France. Ainsi, 2014 sera une année importante pour l'évolution de la société vers les objectifs qu'elle s'est fixés.

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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 Thérapeutique), diagnostic tests (Alys Diagnostic) and medical devices (Alys Medtech). You can find our reports on our website at <http://www.aurgalys.com/aurgalys-indices/>

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