Company Analyst Report

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Aurgalys is contracted by Diaxonhit to provide equity research

Diaxonhit

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Aurgalys

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June 7th, 2013

Share Price: €0.72

(as of Jun. 7th, 2013)

Estimated price: €1.65

High/Low since 01.01.13 (€)	1.13/0.69
Market Cap (€m)	40.3
Estimated Cash Position (€m)	8.0
Estimated market cap. (€m)	92.6
Number of Shares (m)	56.0
Estimated price (€)	1.65
Volume 3 months average	127,000
Free Float	59.4%
Dividend Forecast 12 months (€)	0.0

Diaxonhit strengthens its product portfolio with AlloMap

Since the acquisition of Ingen Biosciences in December 2012, Diaxonhit has clearly set its intentions on becoming a European leader in diagnostics. After securing two public tenders worth up to €25.0 million in revenues over the next 4 years, Diaxonhit has obtained exclusive marketing rights in Europe with the licensing of AlloMap, a blood test for the diagnosis of heart transplant rejection. Diaxonhit already has an established sales force with a strong presence in hospital care and this new asset will complement their existing product portfolio dedicated to organ transplants. The AlloMap licensing agreement is in line with the strategy announced by Diaxonhit to enlarge its product portfolio with the objective of reaching profitability in 2015. Following this licensing deal, we have raised our valuation of Diaxonhit to €92.6 million or €1.65 per share.

A strategic licensing deal for Diaxonhit

On June 4th, 2013, Diaxonhit announced the licensing of AlloMap, a heart transplant rejection diagnostic test developed by the company XDx. Diaxonhit will have exclusive rights to market AlloMap in Europe.

Diaxonhit already has a strong position in the field of organ transplants in France (70% market share) with the distribution of transplant-related diagnostic products. This was confirmed recently with the company securing major public tenders from the Etablissement Français du Sang (French blood bank) and the Assistance Publique – Hôpitaux de Paris. These two deals represent revenues of up to €13.8 million and €11.0 million respectively over the next four years.

With a sales force highly specialized in hospital care, Diaxonhit is able to expand its product line dedicated to organ transplants. This agreement is in line with Diaxonhit's strategy of acquiring products complementary to the existing portfolio and by favoring licensing deals over distribution rights.

XDx's choice to partner with Diaxonhit reflects the company's experience in the hospital care business and ability to secure strategic licensing deals.

Under the agreement, Diaxonhit will have exclusive rights for marketing AlloMap in Europe while XDx will receive upfront, commercial milestones and royalties on net sales. Its established sales force in France, Belgium and Switzerland will allow Diaxonhit to market AlloMap directly in these areas. Until the company expands its European territories through strategic acquisition, it is likely that Diaxonhit will rely on distributors to cover other major European countries.

diaxonhit

Specialty Diagnostic Solutions

Heart transplants in Europe

There are approximately 2,000 people receiving a heart transplant every year in Europe, a number that has stabilized over the past few years. The majority of these transplants (70%) are being performed in Germany, France, Italy, Spain and the United Kingdom (Source: Global Observatory on Donation and Transplantation). More than 55% of the patients receiving a donor heart are 50 years and older (Source: International Society of Heart and Lung Transplants, ISHLT). Irreversible heart failure and coronary artery disease are the main causes for heart transplants.

Patient survival after heart transplant has increased over the years since the first transplant in 1967 by Barnard. As seen in Figure 1, patient survival is around 87% after 1 month, 77% after a year, 66% after 5 years, and slightly above 50% after 10 years.

Euronext since January 1st, 2013

Diaxonhit	***-20.00%***
CAC 40	*+6.36%*
Next Biotech	*-9.85%*
CAC Pharma & Bio	*+3.12%*
Alternext All Shares	*+3.36%*

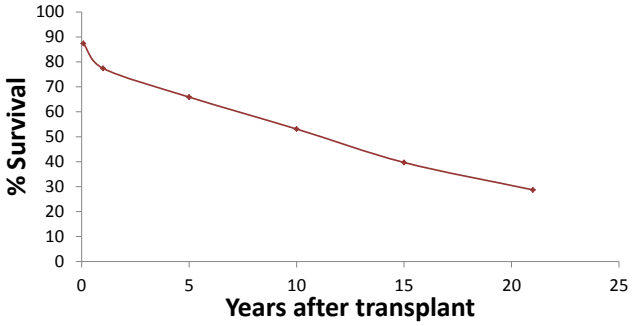

Figure 1: Heart transplant survival curve (Source: Spanish Heart Transplant Registry)

In the first year, the main causes of death are from infections, multiple organ dysfunction, and organ rejection, the latter being monitored with the help of heart biopsies. As seen in Table 1, such biopsies are numerous in the first month following transplant to adjust immunosuppressive drug therapy and are less frequent as the risk of rejection diminishes with time.

Table 1: Heart biopsy schedule after transplantation (Source: ISHLT)

Biopsy number	Frequency
1,2,3,4,5	Every week
6,7,8	Every 2 weeks
9,10	Every 3 weeks
11,12,13	Every 4 weeks
Subsequent biopsies during first year	Every 5 to 6 weeks
Subsequent biopsies after first year	Every 6 months

AlloMap blood test to replace invasive heart biopsies

Biopsies are achieved by inserting a wire through a vein in the neck after local anesthesia. Each biopsy consists in collecting four samples of heart tissue that are sent for analysis. The company XDx in the US developed AlloMap, an innovative diagnostic test for the detection of heart transplant rejection in low-risk patients.

AlloMap for the diagnosis of heart transplant rejection

AlloMap has the advantage of being less invasive than biopsies as it only requires a blood sample (less than 10 mL). It relies on quantitative Real-Time Polymerase Chain Reaction (qRT-PCR) technology which measures the expression level of 11 genes of interest and 9 control genes in blood cells. The result of the analysis is a test score ranging from 0 to 40. The higher the number, the higher the risk of acute cellular rejection (ACR).

AlloMap was first available in the US in 2005 after XDx's reference laboratory obtained the CLIA certification allowing the company to perform diagnostic tests on human patients. It was FDA-approved in 2008 following the first clinical study named CARGO (Cardiac Allograft Rejection Gene expression Obervational study) that took place in the US.

AlloMap obtained CE marking in 2011 allowing XDx to market the product in Europe. A second clinical study (CARGO II) was carried out from 2006 to 2011 in 13 European and 4 North American transplant centers on 741 heart transplant recipients. The results confirmed the performance of AlloMap obtained in the first US-based CARGO study.

In 2010, AlloMap was recommended in the International Society of Heart and Lung Transplantation's guidelines for the non-invasive detection of ACR (between 6 months and 5 years post-transplant) following a study demonstrating the non-inferiority of AlloMap compared to heart biopsies.

Therefore, AlloMap is a useful alternative to heart biopsies, improving compliance for heart transplant recipients when monitoring the risk of organ rejection.

Valuation of Diaxonhit

Valuation of €92.6 million for Diaxonhit

Following the licensing of AlloMap by Diaxonhit, we have reassessed our valuation of the company. We estimate the value of Diaxonhit to be €92.6 million or €1.65 per share (56,005,437 shares outstanding as of June 10th, 2013).

The value of products Aclarus Dx, BJI Inoplex, and TQS, has not been changed. A summary of the valuation of Diaxonhit by product can be found in Table 2.

Table 2: Diaxonhit's valuation by product

2013	Value (M€)	% Value	Value /share (€)	Peak Sales Estimate (M€)	Launch Date
Aclarus Dx* (1)	37.1	40.1	0.67	80	2014
BJI Inoplex* (1)	21.5	23.2	0.39	25	2014
AlloMap* (2)	6.2	6.7	0.11	10	2013
TQS* (3)	5.3	5.7	0.10	8	Marketed
Ingen Products** (4)	22.4	24.3	0.41	-	-
Total	92.6	100.0	1.65		

*calculated using the rNPV method. **calculated using a DCF analysis. (1) Worldwide sales. (2) Sales in Germany, France, United Kingdom, Italy, and Spain. (3) Worldwide sales except France, Belgium, Switzerland. (4) Sales in France, Belgium and Switzerland.

Company growth through licensing to strengthen product portfolio

For the valuation of AlloMap, we only considered the top 5 countries of the European Union in terms of population, which represent most of the market (Germany, France, United Kingdom, Italy, and Spain) and assumed a constant number of heart transplants since the amount of heart recipients has plateaued for the past few years. AlloMap has been recommended for the follow-up of patients (15 years old or older) between 6 months and 5 years after transplants (ISHLT). Therefore, only this patient group has been taken into account for our valuation model (risk-adjusted Net Present Value). They represent about 1,400 people.

There are approximately 20,000 people in the US (Source:OPTN Annual Report) that are currently living with a functional heart transplant and XDx claims that around 10,000 people have been tested with AlloMap so far, representing a 50% market share. The assumption of equivalent market penetration was used, keeping in mind that AlloMap's market performance in the US could have been impaired by the competition of

heart biopsies themselves. Although AlloMap improves patient compliance for ACR diagnosis, physicians may have slowed the adoption of the test since AlloMap replaces a procedure that brings them high revenues (between $4,000 and $5,000 for the biopsy compared to $3,000 for AlloMap). It is unlikely that such scenario would occur in Europe or at least in France since transplant care is performed in public hospitals.

AlloMap costs around $3,000 in the US or around €2,000. We made the assumption that the product would cost around €1,500 in Europe. A higher selling price for the test would positively impact the NPV of AlloMap. Our peak sales estimate for AlloMap is around €10.0 million. With a discount rate of 12% we obtained an NPV of €6.2 million for AlloMap.

Expected News Events

- H2 2013: AlloMap product launch in France
- Q4 2013: Dialog study and US study results for Aclarus Dx
- 2013/2014: CE marking for BJI Inoplex
- 2014: Aclarus Dx and BJI Inoplex product launch

(Diaxonhit: ALTERNEXT PARIS - Alternext - Local Securities – Ordinary stock – Continuous trading – One-year chart dated June 7th, 2013)

We raised the company's valuation to €1.65 per share following AlloMap licensing, representing a 129.2% upside compared to June 7th price of €0.72. Note that Dx15, currently in development for thyroid cancer diagnosis, will not be valued until a molecular signature has been identified. Moreover, future acquisitions to expand the activities of Diaxonhit in Europe have not been priced in but when such events occur, they would significantly contribute to the value of the company.

The past few months have not been uneventful for Diaxonhit's share price. In mid-April, financial markets were shaken following rumors of Germany losing its triple A rating. Diaxonhit's shares were negatively impacted and have remained below €0.80 ever since. The announcement of the AlloMap licensing agreement on June 4th, 2013 generated above average volume with more than 1.35 million shares traded on June 4th and 5th. Diaxonhit's share quickly rose to an intraday high of €0.81 on June 4th (+9.46%) but gains were attenuated by the end of the day with the stock closing at €0.77 (+4.05%). On June 7th, 2013, Diaxonhit's shares closed at €0.72.

Résumé en français

Le 4 juin 2013, Diaxonhit a obtenu la licence exclusive pour la commercialisation du produit AlloMap en Europe auprès de la société américaine XDx. Cette licence s'inscrit dans la stratégie de croissance de la société qui vise à devenir un leader européen du diagnostic. AlloMap est un test de diagnostic pour le suivi des transplantés cardiaques qui permet d'évaluer le risque de rejet du greffon. Avec AlloMap, Diaxonhit ajoute un produit complémentaire à son catalogue de produits destinés aux soins hospitaliers et plus particulièrement dans le domaine de la transplantation. Diaxonhit a déjà conforté son leadership dans ce secteur avec 70% de part de marché dans les tests HLA. Ceci a été confirmé par les appels d'offres récemment remportées par Diaxonhit auprès de l'Etablissement Français du Sang et de l'AP-HP, représentant jusqu'à 25 M€ de chiffre d'affaires sur 4 ans.

L'accord prévoit un versement à la signature ainsi que des milestones commerciaux et des redevances sur les ventes. Grâce à sa force de vente déjà établie en France, en Belgique et en Suisse, Diaxonhit pourra vendre AlloMap en direct sur ces territoires. Il est probable que Diaxonhit fasse appel à des distributeurs pour couvrir les autres territoires européens en attendant l'acquisition stratégique de sociétés ayant déjà une force de vente dans ces pays.

Environ 2.000 greffes du cœur sont réalisées en Europe chaque année, l'Allemagne, la France, l'Italie, l'Espagne et le Royaume-Uni représentant 70% du marché. Le taux de survie à 10 ans est d'un peu plus de 50% pour les transplantés cardiaques. Les principales causes de décès suite à une greffe du cœur sont les infections, la défaillance multi-organique et le rejet du greffon. Les patients qui doivent recevoir un traitement immunosuppresseur à vie pour limiter les risques de rejet doivent effectuer des biopsies régulières du cœur transplanté. Les biopsies sont nombreuses dans les semaines et mois suivant la greffe (une quinzaine de biopsies dans la première année), puis de manière moins fréquente les années suivantes (environ 2 par an).AlloMap se substitue aux biopsies en étant moins invasif pour les patients.

AlloMap est un test génétique de diagnostic innovant permettant de mesurer les risques de rejet grâce à un simple échantillon de sang. Ce test repose sur la technique de la PCR (Polymerase Chain Reaction) en temps réel qui permet de mesurer l'expression de 11 gènes d'intérêt et de 9 gènes de contrôle dans les cellules sanguines. Il en résulte un score compris entre 0 et 40 ; un score élevé indiquant des risques de rejet élevés. Le test est disponible aux Etats-Unis depuis 2005, a été approuvé par la FDA depuis 2008 et a obtenu le marquage CE en 2011 pour la commercialisation en Europe. Environ 10.000 patients ont déjà été testés par AlloMap aux Etats-Unis. Depuis 2010, suite à une étude clinique démontrant la non-infériorité d'AlloMap comparé à la biopsie, le test est recommandé par l'International Society of Heart and Lung Transplantation pour le suivi des patients après une greffe de cœur (de 6 mois à 5 ans après la greffe).

Suite à la licence accordée pour AlloMap, nous augmentons notre valorisation de la société Diaxonhit à 92,6 M€ ou 1,65€ par action (actuellement 56.005.437 actions). Nous n'avons pas modifié la valorisation des produits Aclarus Dx, BJI Inoplex. Pour Allomap nous avons pris en compte les patients transplantés ayant reçu une greffe entre 6 mois et 5 ans auparavant dans le top 5 des pays de l'Union Européenne en termes de population (Allemagne, France, Royaume-Uni, Italie, Espagne), ce qui représente environ 5.000 patients. Nous avons considéré un prix de 1.500€ pour AlloMap en Europe sachant que ce test coûte environ 3.000$ aux Etats-Unis (environ 2.000€). Avec une pénétration du marché de 50%, nous estimons le pic de vente à environ 10 M€ pour ces 5 pays. La NPV d'AlloMap avec un taux d'actualisation de 12% est de 6,2 M€.

2013	Valeur (M€)	% Valeur	Valeur /action (€)	Pic de Vente (M€)	Date de mise sur le marché
Aclarus Dx* (1)	37,1	40,1	0,67	80	2014
BJI Inoplex* (1)	21,5	23,2	0,39	25	2014
AlloMap* (2)	6,2	6,7	0,11	10	2013
TQS* (3)	5,3	5,7	0,10	8	Commercialisé
Ingen Products (4)**	22,4	24,3	0,41	-	-
Total	**92,6**	**100,0**	**1,65**		

*calcul par la méthode rNPV. **calcul par la method DCF. (1) Ventes dans le monde entier. (2) Ventes en Allemagne, France, Royaume-Uni, Italie et Espagne. (3) Ventes dans le monde entier sauf France, Belgique et Suisse. (4) Ventes en France, Belgique et Suisse.

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