

Life Sciences News from Scotland's City of Discovery

March 2008

Cellartis and Pfizer to collaborate on new screening system

Cellartis has recently announced it has entered into a collaborative research agreement with Pfizer for the development of a novel model system for the detection of human toxicity *in vitro*.

The collaboration aims to generate a predictive developmental screening model for new chemical entities using the unique patented Cellartis human Embryonic Stem (ES) cell platform. Through this collaboration, Pfizer and Cellartis are embarking on potentially pioneering work on human relevant developmental toxicity models. It is important to identify toxic substances as early as possible in the drug development process and this collaboration may yield a solution long sought by the industry. The novel human ES cell-based system will enable the identification of genuine human developmental toxicity data at the pre-clinical *in vitro* stage.

Cellartis will take the lead in the development of the human ES cell model system and will conduct validation compound testing. Pfizer will provide expertise and capabilities in the design and optimization of the developmental toxicity prediction model. The collaboration provides Pfizer with access to specific human ES technology, based on Cellartis' patented human ES platform, for developing the toxicity screening system.

Cellartis receives an upfront fee as well as research funding from Pfizer. In addition, Cellartis retains the right to sublicense, make, use, and sell the developmental toxicity screening model.

Cellartis AB is a Swedish/British company focused on human embryonic stem cells for drug discovery, toxicity testing and regenerative medicine with the main objective to develop hepatocytes and cardiomyocytes from these cells. The company is the world's largest single source of defined hES cell lines, and has developed more than 30 well documented cell lines. Two cell lines are listed on the NIH Stem Cell Registry and 22 are approved by the UK Stem Cell Bank. In addition, Cellartis has built the world's first large-volume production facility for human ES cells.

Contact: Mats Lundwall, Chief Executive Officer, Cellartis, Maclagan House, 1 Würzburg Court, Medipark, Dundee, DD2 1FB, Scotland, UK.

Tel: +44 (0) 1382 569970

Fax: +44 (0) 1382 568242

Email: mats.lundwall@cellartis.com

Website: www.cellartis.com



Axis-Shield acquires Swiss distribution arm

Axis-Shield plc (LSE:ASD, OSE:ASD), has recently announced that it has purchased the Swiss distribution channel for its Point-of-Care (PoC) *in-vitro* diagnostics products from Nycomed Pharma AG, the Swiss sales subsidiary of Nycomed.

Axis-Shield will take over the distribution of Axis-Shield PoC products, including the Afinion™ and NycoCard™ ranges. The acquisition strengthens existing European direct sales capabilities and will bring revenue growth of approximately £2 million and contribute approximately £500,000 to pre-tax profits.

In addition, Axis-Shield has recently received FDA 510(k) marketing clearance for its Albumin/Creatinine Ratio (ACR) test on the award winning Point-of-Care Afinion™ system. The ACR test which is CE marked and currently available in Europe and the rest of the world, will now be launched in the USA. It complements the CLIA-waived Afinion™ HbA1c assay used for monitoring diabetes treatment in primary healthcare.

Contact: George Zajicek, Business Development Director,
Axis-Shield plc, Luna Place, Technology Park, Dundee,
DD2 1XA, Scotland, UK.
Tel: +44 (0) 1382 422000
Fax: +44 (0) 1382 561201
Email: george_zajicek@uk.axis-shield.com
Website: www.axis-shield.com



Lumicure secures £2.5 million investment

Lumicure Limited (Lumicure), the St Andrews leading developer of ambulatory light sources for skin treatment, has raised £2.5 million in a recent equity funding round. The funding syndicate was led by Longbow Capital LLP who with their private client Portfolio Service, and the Scottish Venture Fund, is providing the funds for Lumicure's expansion.

Lumicure's founders, Professor Ifor Samuel (University of St Andrews) and Professor James Ferguson (Tayside NHS Trust and the University of Dundee), have developed a light-emitting "sticking plaster" for the treatment of skin cancer. This new device, which builds on established photodynamic therapy treatment (PDT) methods, reduces pain and gives the patient the convenience of being treated at GP surgeries or at home rather than at hospital.

Lumicure's product adapts the latest organic light emitting polymer (OLEDs) panels that can be powered by simple pocket batteries. These can be worn by the patient in a similar way to a sticking plaster, while the battery is carried like an iPod. It is likely that Lumicure's product has major advantages in skin cancer and that the technology has broad potential in a range of skin treatments. The investment will allow the company to take the medical device for skin cancer through regulatory trials and develop products to expand into other medical and cosmetic applications.

Contact: Ian Muirhead, Chief Executive Officer, Lumicure Ltd.
Tel: + 44 (0) 771 498 0617
Email: i.muirhead@btinternet.com
Website: www.lumicure.com

ITI Life Sciences extend research programme

ITI Life Sciences has recently announced that it has extended its research programme designed to develop new transgenic mouse lines for use in the pharmaceutical industry to predict the effects of drug compounds in the human body.

The three-year £5.5 million Transgenic Screening and Safety Models (TSM) programme was initiated by ITI Life Sciences in February 2005 with commercial partners including CXR Biosciences (Dundee, Scotland) and TaconicArtemis GmbH (Cologne, Germany). The research programme, which has exceeded expectations by delivering 30 novel mouse lines, has now been extended for up to 14 months and will receive a further £2 million in funding from ITI Life Sciences. Ten of these lines are ready for commercialisation, with patent applications filed and all relevant external licences gained. The programme extension will allow ITI Life Sciences to complete the commercial packages for the other 20 lines.

Contact: Jim Greaves, ITI Life Sciences,
Innovation House, Technology Park,
Dundee, DD2 1TP, Scotland, UK
Tel: +44 (0) 1382 568064
Fax: +44 (0) 1382 568061
Email: jim.greaves@itilifesciences.com
Website: www.itilifesciences.com



CXR Biosciences raises growth capital

CXR Biosciences Ltd, has recently raised new investment of £1.3 million to support the global marketing of new technology platforms and services. The investment, led by Archangel Informal Investment, included the participation of the Scottish Co-investment Fund.

CXR Biosciences specialises in rapid and flexible drug screening and evaluation programmes to aid companies to select drug candidates or solve problems relating to chemical safety. The company has raised equity investment totalling £3.3 million, but has also used its £12 million in revenues to establish a world class infrastructure and technology base. CXR Biosciences and TaconicArtemis will host the US launch of the first transgenic screening and safety mouse models, as well as CXR's existing HRN™ mouse model, at the American Society of Toxicology conference in Seattle on March 16-19.

Contact: Tom Shepherd, Chief Executive, CXR Biosciences Ltd., Dundee Technopole, James Lindsay Place, Dundee, DD1 5JJ, Scotland, UK.
Tel: +44 (0) 1382 432163
Fax: +44 (0) 1382 432153
Email: tomshepherd@cxrbiosciences.com
Website: www.cxrbiosciences.com



Chiltern acquires the business of Drug Development Solutions Ltd.

Chiltern, the global contract research organization, has recently announced that it has acquired the business of Drug Development Solutions, a leading Phase 1 unit located at Ninewells Hospital and Medical School, Dundee.

The purchase of the Drug Development Solutions business supplements Chiltern's Clinical Research Unit in Slough near London. The business, which has completed over 700 Phase 1 trials, operates from premises in Dundee which offers 42 high intensity care beds with the ability to expand these to 60 and has been ISO 9001 certified since 1997. The business unit, which is now trading as Chiltern Early Phase Ltd., has special expertise in first in man studies and is a world leader in systemic drug phototoxicity studies in humans.

The unit is one of a small number in the United Kingdom that is located within a major hospital that can provide emergency medical services if required. This will allow the unit to attain the higher level of voluntary accreditation available for Phase 1 units from the UK regulator, the MHRA. The unit in Dundee offers safe, efficient and high quality Early Phase trials in a teaching hospital setting. The excellent regulatory climate, with approval times of approximately 14-21 days for Phase 1 trials, facilitates the performance of first-in-man studies in the U.K. and the highly experienced hospital-based unit offers best practice in this field.

Chiltern is a leading global Contract Research Organization with extensive experience conducting and staffing international Phase I to Phase IV clinical trials across a broad therapeutic range for a wide variety of clients. Chiltern provides services including Early Phase, Global Clinical Development, Late Phase, Biometrics, Medical and Regulatory Affairs and Resourcing Solutions.

The acquisition of the Dundee based Phase 1 unit allows Chiltern to offer leading edge Phase I services to a global client base and supplements the existing Early Phase capability and strong Phase II – IV capacities. The UK has long been a centre of excellence for Early Phase clinical pharmacology and once again offers a stable regulatory environment and internationally competitive approval timelines. Chiltern also looks plans to develop its collaboration with Ninewells Hospital and the University of Dundee Medical School.

Contact: Brian Sanderson, Medical Director, Chiltern Early Phase Ltd, Ninewells Hospital and Medical School, Dundee, DD1 9SY, Scotland, UK.

Tel: +44 (0) 1382 646317

Fax: +44 (0) 1382 645606

Email: brian.sanderson@chiltern.com

Website: www.chiltern.com



Cyclacel financial and clinical update

Cyclacel Pharmaceuticals, Inc. (NASDAQ: CYCC) has recently announced progress in its clinical programmes and that it has entered into a Committed Equity Financing Facility with Kingsbridge Capital Limited.

Kingsbridge Capital Limited, a private investment group, has entered into a Committed Equity Financing Facility in which it will provide Cyclacel with up to \$60 million of capital during the next three years through the purchase of newly-issued shares of Cyclacel's common stock. Cyclacel will determine the exact timing and amount of any financings under this agreement, subject to certain conditions.

The additional capital, which will be accessed under flexible terms, will help to drive the development of Cyclacel's pipeline which includes three clinical candidates in six different indications, as well as continuing the progress of its preclinical programmes. The company has recently initiated an open-label, multicentre, randomised Phase II trial of oral sapacitabine in elderly patients with acute myeloid leukaemia who are previously untreated or in first relapse. The study aims to identify a dosing schedule which produces a better 1-year survival rate in the event that all three dosing schedules of sapacitabine that are tested are active.

Contact: Paul McBarron, Executive Vice President, Cyclacel Pharmaceuticals, Inc., Dundee Technopole, James Lindsay Place,

Dundee, DD1 5JJ, Scotland, UK.

Tel: +44 (0) 1382 206062

Fax: +44 (0) 1382 206067

Email: pmcbarron@cyclacel.com

Website: www.cyclacel.com



BBI Holdings plc acquired by Inverness Medical Innovations, Inc.

Inverness Medical Innovations, Inc. ("IMI") has recently announced the acquisition of the entire issued and to be issued share capital of BBI Holdings plc ("BBI"), a leading supplier of products and services to the global diagnostic and healthcare industries with operations in Dundee. The purchase price consisted of cash of approximately £63.2 million and approximately 251,300 shares of Inverness common stock.

BBI was established in 1986 to manufacture gold colloids and conjugates for use primarily in point of care diagnostics tests. Following a management buyout in 2000, the business expanded its activities into developing new point of care tests on behalf of diagnostic companies and later into the manufacturing of test kits. The company floated on AIM in 2004, and further acquisitions have strengthened the position of its core diagnostic business and widened its operations into the manufacture of natural enzymes and sale of proprietary medical products.

BBI and IMI have enjoyed a close strategic working relationship in recent years, with IMI previously owning approximately 12 per cent. of BBI's issued ordinary share capital. The directors of both organisations believe the acquisition makes strong strategic sense and will allow both BBI and Inverness to further exploit the operational synergies that exist between them.

Contact: Richard Lamotte, Managing Director, BBI International Dundee, Alchemy House, Tom McDonald Avenue, Medipark, Dundee, DD2 1NH, Scotland, UK.

Tel: +44 (0) 1382 561000

Fax: +44 (0) 1382 561100

Email: info@bbigold.com

Website: www.bbigold.com



Designing drugs with a one-two punch

The dominant assumption in drug discovery for the past generation has been that the search for a single gene/gene product, effectively targeted by a drug will alleviate a disease. However, even with our molecular parts list in hand – the sequence of the human genome – finding individual genes that have a singular influence on many major diseases is proving elusive. In contrast a growing body of post-genomic biology is revealing is a far more complex picture of drug action. Large-scale gene-deletion observations have revealed phenotypic robustness of biological networks. The appreciation of networks in biology leads to the conclusion that therapies that perturb more than one node in a biological network have a greater chance of proving effective. Compounds that selectively act on two or more targets of interest could increase the confidence-in-rationale or the range of efficacy. Indeed, many effective drugs, in therapeutic areas as diverse as oncology, psychiatry and anti-infectives, are known to act on multiple-gene products rather than single targets.

Professor Hopkins's research is concerned with the development of 'network pharmacology' methods to design therapies that act on multiple targets. Broadly speaking, multiple targets can be pursued via two alternate routes: (i) Combining existing drugs with known, separate targets, (ii) designing novel drugs that act on more than one target.

Combination therapies offer some of the best near term opportunities to develop effective new medical products. The best combination therapies may involve combining two or more drugs from different companies. However there is no formal mechanism for companies to collaborate to search for new combinations of investigational drugs. Given the hundreds of thousands of possible combinations within our current pharmacopeia, the challenge is how do we prioritise which combinations should be tested?

In the long term Professor Hopkins is interested in how single agent drugs can be designed with the required polypharmacology. Traditionally, medicinal chemists have approached the design of ligands exhibiting multiple activities with trepidation. Ongoing developments in the fields of chemogenomics and network biology however, may enable a new approach to drug discovery to help rationally identify compounds that act on the level of the biological network rather than a single target, with the hope of developing more effective medicines for complex disease.

Contact: Professor Andrew L. Hopkins, *SULSA Professor of Translational Biology and Chair of Medicinal Informatics, Division of Biological Chemistry and Drug Discovery, College of Life Sciences, University of Dundee, Dundee, DD1 5EH, Scotland, UK.*
Tel: +44 (0) 1382 381010
Email: a.hopkins@dundee.ac.uk
Website: www.lifesci.dundee.ac.uk/bcdd



Monoclonal Antibody as novel therapy and biomarker for Acute Myeloid Leukaemia

A study at the University of Dundee in patients with AML has identified a new target for the diagnosis and treatment of AML. A monoclonal antibody has been developed against CD33 related receptor siglec 9 for the development of a novel therapeutic for the treatment of patients with proliferative diseases of the haematopoietic system e.g. AML. Patients with AML have been evaluated, and in addition to CD33, the target molecule, siglec 9, has been shown to be consistently expressed on AML blast cells whilst being absent from normal bone marrow cells. This has the potential to provide a more specific therapeutic target and diagnostic marker for AML. A patent application has been filed covering the anti-siglec mAb as the basis of a novel AML therapy.

Ref: D353 A partner is sought to further develop both the therapeutic and diagnostic / biomarker applications.

For further information please contact: Diane Taylor or Gillian Burch, Research and Innovation Services, University of Dundee, Dundee, DD1 4HN, Scotland, UK.

Tel: +44 (0) 1382 384664

Fax: +44 (0) 1382 386765

Email: gburch@dundee.ac.uk

Website: www.dundee.ac.uk/research

A novel anti-microbial drug target, Wza the translocon for E. coli capsular polysaccharides

Researchers at the University of St. Andrews and the University of Guelph have determined the structure of Wza; an auxiliary protein required for the export of extracellular polysaccharides (EPS) from the cytoplasm of bacteria.

EPSs in pathogenic bacterial polysaccharide capsules provide the key virulence determinants which allow bacteria to evade or counteract the host immune response. Elucidation of the structure and function of E. coli Wza in relation to EPS transport provides a rational platform on which to design novel anti-bacterial agents able to interact with Wza to inhibit export of EPS from the cytoplasm of bacteria.

St. Andrews would welcome enquiries from commercial parties interested in entering into a licensing arrangement. St. Andrews has applied for International patent protection.

For further information please contact: Lorna Sillar or Josephine Sutcliffe, Research and Enterprise Services, New Technology Centre, North Haugh, St Andrews, KY16 9SR, Scotland, UK.

Tel: +44 (0) 1334 462163

Fax: + 44 (0) 1334 462386

Email: Lorna.Sillar@st-andrews.ac.uk

Website: www.st-andrews.ac.uk/research-enterprise/

Contact BioDundee:

If you would like to receive future copies of the BioDundee Update, or if you have any views on the articles you would like to read please get in touch. We can also provide you with further information about local organisations, help you to make contact with potential partners and facilitate visits to the area. Contact us is any of the following ways;

Email: info@biodundee.co.uk

Website: www.biodundee.co.uk

Tel: +44 (0) 1382 434913

Mail: BioDundee, 3 City Square, Dundee, DD1 3BA, Scotland, UK

bio- Dundee
BIOTECH SCOTLAND

