



# EDISON



## Edison healthcare quarterly

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Robin is the head of the biotech, med-tech and life science team at Edison Investment Research. He has over 15 years' experience covering the biotech, pharmaceuticals and healthcare sectors both as an investment analyst and as a journalist on specialist industry and financial publications. He was formerly biotech analyst for Durlacher Corporation, a contributor to Financier Worldwide, a co-founder and editor of Biopoly and editor of Scrip World Pharmaceutical News.

**Lala Gregorek**



Lala joined Edison's healthcare team in January 2010 from Canaccord Adams, where the focus of her coverage as a life sciences analyst was on UK and European biotech stocks. Before graduating with an M.Phil in bioscience enterprise from Cambridge University, she worked in risk management as a credit analyst covering European financial institutions and hedge funds at Dresdner Kleinwort and Lehman Brothers. Lala also holds a BA (Hons) in biological sciences from Oxford University.

**Dr Mick Cooper**



Mick joined Edison's healthcare team in January 2010, after working for three years at Blue Oar Securities as the pharmaceuticals & biotechnology equity analyst, where he covered a wide range of healthcare companies. He holds a doctorate from Cambridge University and completed an MBA at INSEAD business school in France after working as a parliamentary researcher. Mick is also a CFA charterholder.

**Christian Glennie**



Christian joined Edison's healthcare team in January 2012 and has 11 years' experience covering the global biotech/pharmaceutical sector as an analyst and a journalist. He came to Edison having held senior analyst and editorial roles at EvaluatePharma and EP Vantage. Christian also has prior experience as a marketing analyst at Zeneca Agrochemicals.

**Franc Gregori**



Franc is a pharmacist who started his career with Boots, Eli Lilly and Pfizer before moving into the City as an analyst. He has worked with Robert Fleming, BZW and BNP Paribas, where he was involved in a number of major transactions. He joined Edison's healthcare team from Charles Stanley, where he focused his coverage on small- and mid-cap life sciences stocks. Franc gained his pharmaceutical qualifications from the Welsh School of Pharmacy and King's College London.

**Dr John Savin**



John is an analyst working on biotech, pharma, medical device and diagnostics companies. As founder CEO of Physiomics plc, he devised the strategy, raised funds and took the company to AIM in 2004. At Greig Middleton, John was director in charge of the pharma and biotech analyst team and worked with corporate finance on fund-raising, IPOs and corporate restructuring. He has an industry background in sales and marketing with GE Healthcare and AstraZeneca and is a co-author on a number of scientific publications.

**Emma Ulker**



Emma has a strong background in broking, having worked for five years as an equity sales assistant at Société Générale on the European sales desk. After this she worked for Thomson Financial where she helped to ensure the integrity of financial data across all instruments. Emma is a qualified linguist with an MA in technical and specialised translation in Spanish and French. In addition, Emma recently earned the Investment Management Certificate, CFA level 4.

**Dr Wang Chong**



Wang is a physician with over 21 years of experience in the healthcare industry. He is also experienced in M&A transactions and has helped negotiate multi-million-pound out-licensing deals with Unilever and Schering-Plough. His previous roles include CFO of Phytopharm, life sciences analyst at Canaccord Capital (Europe), CEO of Osmetech, leader of UK healthcare initiatives at management consultants Arthur D. Little, and commercial roles at Glaxo Wellcome and SmithKline Beecham.

**Chris Kallos**



Chris has 14 years' experience as an equities research analyst in both Australian and US stocks. He has covered small-, medium- and large-cap stocks across a number of sectors with a focus on healthcare/biotech, mining, recruitment and telecommunications. Chris holds a BPharm (Sydney), an MBA from the Australian Graduate School of Management (UNSW), and a Masters in Applied Finance (Macquarie). He is a CFA charterholder and graduate of the Australian Institute of Company Directors.

**Dr Michael Aitkenhead**



Michael is a qualified physician with over 12 years' experience in the healthcare industry, including five years in clinical medicine and seven years in biopharmaceutical equity research. He was formerly a European pharmaceuticals analyst at the Royal Bank of Scotland (RBS) in London, and prior to this was a European biotechnology analyst with Piper Jaffray. Michael received his medical degree from the University of Otago, New Zealand, and subsequently completed an MBA at Judge Business School, University of Cambridge.

**Dr Jason Zhang**



Jason joined Edison's healthcare team in October 2012, after working as a biotech analyst at many investment banking firms, most recently Burrill & Company, and previously BMO Capital Markets, Prudential Equity Group and Stephens.

**Pooya Hemami**



Pooya is a licensed optometrist with over five years of experience in life sciences equity research. Prior to joining Edison, he covered the Canadian healthcare sector as a research analyst at Desjardins Capital Markets. He holds a doctor of optometry degree from the University of Montreal, and an MBA (finance concentration) from McGill University. He received his CFA charter in 2011.

**Dr Philippa Gardner**



Philippa joined Edison's healthcare team in January 2013, having previously worked as a biotechnology analyst on award-winning teams both at Jefferies and at Lehman Brothers. She has eight years' experience as a sell-side analyst covering European biotechnology, life science and mid-cap pharma stocks and has worked on a number of IPOs. Philippa holds a doctorate in biochemical engineering from UCL, with her research sponsored by GE Healthcare in Sweden.

# Immuno-oncology 2: The combos come

7 November 2013

Immuno-oncology – which groups immune checkpoint blockers with immunotherapies and cancer vaccines – is undoubtedly becoming the highest-profile area of drug development from the investor's point of view. This has been driven by the remarkable data seen in early clinical studies of the anti-PD-1/PDL-1 agents that has marked out this drug class as the potential future cornerstone of therapy for many solid tumours. Checkpoint inhibitors have eclipsed cancer vaccines, but we consider there could be merit if the two approaches are combined. 2014 should see a number of key study readouts of anti-PD-1 agents, as well as the start of new studies that look set to define the emerging competitive landscape. In this report, we update our recent overview.

## Immune checkpoint blockers to dominate the space

Investor attention is undoubtedly focused on the immune checkpoint blockers. Bristol-Myers Squibb's anti-PD-1 agent, nivolumab, has shown remarkable activity and duration of response in melanoma and several other indications this year, which has propelled it up the industry rankings to become the most valuable oncology project and its two close competitors, Merck & Co's anti-PD-1 antibody MK-3475/ lambrolizumab and Roche's anti-PDL-1 antibody, RG7446 (MPDL3280A), follow closely behind.

## Combinations expected to come to the fore

The anti-PD(L)-1 agents appear to be on a path towards becoming a cornerstone of therapy for many metastatic cancers, although it is still too early to tell whether they will be used in combination or sequence with existing therapies. 2014 should see key study readouts for the three anti-PD(L)-1 agents that could inform this debate, as well as the start of studies that look set to define the competitive landscape. There is heightened interest in combinations of immune checkpoint blockers, principally nivolumab with Yervoy (ipilimumab). However, one of the more interesting early approaches involves the Edison-covered biotech firm Innate Pharma, whose anti-KIR antibody is undergoing separate Phase I/II studies with nivolumab and with ipilimumab.

## Implications for cancer vaccines

Checkpoint inhibitors have largely eclipsed cancer vaccines and there is a high degree of scepticism about whether the latter agents will succeed as monotherapies. However we consider there is merit in combining cancer vaccines with checkpoint inhibitors, an approach that is still in its infancy. Such combinations should make sense and could benefit a number of smaller companies in the Edison-covered universe. These include Bavarian Nordic (Prostvac), Mologen (MG-1601), Prima Biomed (CVac), Transgene (TG4010) and Viralytics (Cavatak).

*Edison intends to hold a seminar to explore investment opportunities in immunotherapy in the near future.*



Robin Davison

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Prices as at 25 October 2013

## Combos to come to fore in immuno-oncology

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The burgeoning field of immuno-oncology, encompassing immune checkpoint blockers and immunotherapies/cancer vaccines, is the highest-profile area of drug development from the investor's point of view. This has been driven by the remarkable early clinical data from Bristol-Myers Squibb's nivolumab, Merck & Co's MK-3475/lambrolizumab and Roche's RG7446 (MPDL3280A), which have marked out the putative PD(L)-1 inhibitor class as one that should set a new standard in cancer treatment. Many observers now consider these agents are likely to become a cornerstone of therapy for many, perhaps even most, solid tumours.

Nivolumab has rapidly ascended the industry rankings and is considered the second most valuable drug in development, behind Gilead's HCV drug sofosbuvir. This is based on its current peak sales forecasts that are in the \$3-4bn range, rising to c \$6bn/year if, as seems likely to be the case, it is combined with Yervoy (ipilimumab, BMS). RG7446 and lambrolizumab rank in fourth and sixth positions in the same table, with peak sales projections for both in the \$3bn/year range.

Results from the early studies of the anti-PD(L)-1 agents have been impressive, with response rates seen in the 20-50% range, which would typically compare with less than 10% for chemotherapy in the same settings. Furthermore, in patients selected for high expression of the PD-L1 biomarker, the anti-PD(L)1 therapies have shown even higher rates, in the 40-80% range.

Most of the studies to date have been of monotherapy. Yet the real potential of these drugs may lie in their use in combination, either with other immuno-oncology agents, cancer vaccines or other types of cancer drugs. The leading immuno-oncology combination at present is BMS' dual checkpoint combination, nivolumab/ipilimumab. This has shown, at least in melanoma, faster and deeper responses than ipilimumab alone, highlighting the potential benefits of combination. It is not yet known whether this will translate to other tumour types.

One of the most interesting earlier combinations involves Innate Pharma. Innate's anti-KIR antibody, lirilumab, is licensed to BMS and is undergoing separate Phase I/II studies in combination with nivolumab and with ipilimumab. A positive result in either one of these two studies could ensure lirilumab is developed as a combination with what is likely to become one of the industry's next potential blockbusters. A strong result in *both* studies would pave the way for a triple therapy, which would undoubtedly propel Innate Pharma to the very top tier of the European biotech sector.

Various studies involving combinations with the Roche and Merck anti-PD(L)-1 drugs may shortly emerge. 2014 should see a number of key Phase III study readouts for the anti-PD(L)-1 class, and more importantly a number of pivotal study starts, which may define the competitive landscape for the class. The work on drug combinations with immune checkpoint blockers is more advanced with approved cancer therapies, including agents such as Avastin (bevacizumab, Roche). The first studies of these combinations have started and others are likely to start in 2014.

Interestingly, a closely watched BMS Phase III trial for Yervoy as monotherapy in post-chemo castration-resistant prostate cancer narrowly missed statistical significance on overall survival. The study showed a median OS of 11.2 vs 10 months for placebo (HR=0.85, p=0.053), based on the ITT group.<sup>1</sup> Median PFS was significant (HR=0.70). Pre-specified subgroup analyses suggested that Yervoy may be more active in patients with less advanced disease (no visceral disease and favourable markers like alkaline phosphatase and elevated haemoglobin). However, longer term the agent's future in mCRPC may be more likely in combination, possibly with GM-CSF or potentially a cancer vaccine such as Bavarian Nordic's Prostavac in our view.

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<sup>1</sup> A post hoc analysis of per protocol patients narrowly achieved significance (HR=0.84, p=0.0498).

## Cancer vaccines eclipsed unfairly

Checkpoint inhibitors have largely eclipsed cancer vaccines and there is undoubtedly a high degree of scepticism about whether the latter agents will succeed as monotherapies. However, there is growing interest in whether they can be combined with checkpoint inhibitors. The combination of the two approaches does have logic and if it occurs, it could have positive implications for a number of companies in the Edison-covered universe, including Bavarian Nordic, Prima Biomed, Mologen and Transgene.

The scepticism around cancer vaccines stems from the high historic failure rate. It is believed that one of the reasons behind this is that products have been studied in too advanced stages of disease, when patients are immuno-suppressed due to disease itself or the side effects of chemotherapy. A separate problem is that the commonly employed evaluation criteria, such as RECIST, were developed to assess the effectiveness of chemotherapy and are poor at capturing immune system-driven tumour response.

A number of key Phase III studies of cancer vaccines are expected to report in the next 12 months, which if successful, could change this sentiment. However, the news has not been very good in recent months. For example, GlaxoSmithKline (GSK) reported that its MAGE-A3 vaccine failed to meet one of its two co-primary endpoints (disease-free survival, DFS) in the DERMA Phase III trial in melanoma. The study evaluated the MAGE-A3 cancer immunotherapeutic in Stage IIIB/C melanoma patients with macroscopic nodal disease, whose tumours expressed the MAGE-A3 gene<sup>2</sup> and had their tumours removed surgically. GSK plans to continue the DERMA trial until the second co-primary endpoint (DFS in the gene signature positive subpopulation) is assessed. This may show whether the subset of MAGE-A3 positive patients benefits from the treatment. Results are expected in 2015.

The Australian biotech Prima BioMed reported inconclusive results in a Phase II trial (CAN-003) in ovarian cancer, which emerged despite the fact it had already advanced CVac into a Phase III study (CANVAS). Results from the 63-patient open-label CAN-003 trial failed to show an expected numerical difference in median PFS, although the results did confirm safety and an immune response. Moreover, the data indicated a seemingly contradictory trend in patients in first vs second remission. Prima intends to reconfigure CANVAS as a smaller Phase II study and enrol only second remission patients; it will also move to an overall survival primary endpoint.

Nevertheless, there has been some positive news in the area as well. Merck KGaA recently disclosed plans to initiate a new Phase III trial (START2) of its MUC1 antigen-specific immunotherapy tecemotide (L-BLP25/Stimuvax, licensed from Oncocyte). The new study will be conducted in patients who have received concurrent (rather than sequential), chemo-radiation, a subgroup where there was an efficacy signal in the earlier START1<sup>3</sup> study. The new Phase III trial is for patients with unresectable, locally advanced Stage III NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemotherapy with concurrent radiotherapy (CRT).

There are over 40 cancer vaccines in various stages of clinical trials, including 19 in Phase III studies (an updated universe is shown in Exhibit 1). There are a few Phase III readouts coming up, the highest profile being New Link Genetics' Phase III trial (IMPRESS) of algenpantucel-L in post-resection, Stage I/II pancreatic cancer patients. Data are due before the year end.

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<sup>2</sup> MAGE-A3 is expressed in about 65% of Stage III melanomas.

<sup>3</sup> Exploratory analysis of a predefined subgroup of patients who received tecemotide after CRT showed median OS of 30.8 vs 20.6 months (n=806; HR: 0.78, p=0.016).

**Exhibit 1: Edison immuno-oncology universe**

Category	Drug name	Company	Technology description	Status	Main indications
<b>Vaccines</b>					
Single antigen peptide	NeuVax (Nelipepimut-S or E75)	Galena Biopharma	Synthetic Her2/neu peptide vaccine	Phase III	Adjuvant treatment of Her2+ breast cancer
	Rindopepimut (CDX-110)	Celldex Therapeutics	Peptide vaccine containing EGFRv3-specific peptide sequence conjugated to KLH	Phase III	Newly diagnosed glioblastoma
	Tecemotide (L-BLP25/Stimuvax)	Merck KGaA/Oncothyreon	Liposome formulation containing core peptide of the MUC1 TAA	Phase III	Phase III in NSCLC; Phase II in mPC
	GSK1572932A	GSK	Cancer vaccine against MAGE-A3 antigen	Phase III	NSCLC
	AE37	Genexx Biotechnology	Peptide vaccine containing fragment of HER2	Phase II	Her2- breast cancer
	ONT-10	Oncothyreon	Liposomal formulation of peptide containing two epitopes of MUC1A	Phase I	Solid tumour
Multi-epitope peptide	IMA901	immatics Biotechnologies	Vaccine containing 10 tumour-associated peptides (TUMAPs)	Phase III	mRCC
	PVX-410	OncoPep	Peptide vaccine covering four short peptide sequences of an MM surface antigen	Phase I	Smoldering multiple myeloma (SMM)
	ImMucin	Vaxil BioTherapeutics	21mer synthetic vaccine composed of the signal peptide domain of the MUC1	Phase I/II	Multiple myeloma
	IMA950	immatics Biotechnologies	Multi-peptide vaccine containing 11 tumour-associated peptides from glioblastomas	Phase I	Glioblastoma
Multi-epitope protein complex	HSPPC-96	Agenus	Heat shock protein-peptide complexes made from a person's own tumour tissue	Phase II	Glioblastoma
Single protein	Imprime PGG	Biothera	A soluble Beta-1,3/1,6 immunomodulatory glucan that targets neutrophils	Phase III	K-ras wild type colorectal cancer
Single antigen fusion protein	GSK2132231A	GSK	Fusion protein between MAGE-3 and lipidated protein D	Phase III	Adjuvant Melanoma
	ALT-801	Altor BioScience	A p53-specific scTCR/IL-2 fusion protein	Phase II	Metastatic melanoma
	CDX-1401	Celldex Therapeutics	Fully human mAb against dendritic cell receptor DEC-205 linked to NY-ESO-1	Phase I	Solid tumour
Single antigen, anti-idiotypic mouse mAb	Racotumomab	Recombio SL	Anti-idiotypic mouse mAb that mimics NGc gangliosides	Phase III	Advanced lung cancer
Multi-antigen mixture	POL-103A	Polynoma LLC	Vaccine comprising a combination of purified antigens shed from three melanoma cell lines	Phase III	Stage IIb, IIc, and III Melanoma
Multi-epitope, DNA based	VGX-3100	Inovio Pharmaceuticals/GSK	Electroporation-based therapy with DNA vaccine containing epitopes of HPV16 and 18, E6 and E7	Phase II	Cervical cancer
	SCIB1	Scancell	Plasmid DNA expressing Tyrosinase-Related Protein 2 (TRP2) + two helper T cell epitopes	Phase II	Melanoma
Single gene, DNA based	IL-12 plasmid	OncoSec Medical	Electroporation-mediated plasmid DNA IL12	Phase II	Merkel cell cancer
	VXM01	Vaximm GmbH	VEGFR-2 DNA vaccine	Phase I	Pancreatic cancer
	GX-188E	Genexine	DNA therapeutic vaccine GX-188E administered by electroporation	Phase I	Cervical intraepithelial neoplasia grade 3 (CIN3)
Multi-epitope, RNA based	RBL001/RBL002	BioNTech (Ribological GmbH)	Naked RNA-based vaccine targeting two tumour-associated antigens	Phase I	Solid tumour
	CV9104	CureVac GmbH	Vaccine composed of six RNAActive-based compounds, each encoding for an antigen that is overexpressed in prostate cancer	Phase II	mCRPC and NSCLC
Multi-gene, virus vector	Prostvac	Bavarian Nordic	Recombinant poxviruses containing PSA, B7.1 (CD80), lymphocyte function-associated antigen (LFA)-3, and ICAM-1	Phase III	mCRPC
	TG4010	Transgene	MVA vector containing MUC1 and IL-2	Phase III	Stage II/IIIB NSCLC
Single gene, virus vector	ProstAtak	Advantagene.	Adenoviral vector that expresses a herpes simplex virus thymidine kinase gene	Phase III	Localised prostate cancer
	TroVax	Oxford BioMedica	Adenoviral vector for tumour antigen 5T4	Phase II	Ovarian, mesothelioma
Single gene, listeria	CRS-207	Aduro BioTech (BioSante)	Attenuated form of Listeria monocytogenes expressing tumour-associated antigen mesothelin.	Phase I	Malignant pleural mesothelioma
Multi-epitope, listeria	ADXS-HPV	Advaxis	Live attenuated Listeria monocytogenes expression HPV epitopes	Phase II	Cervical, head and neck cancers
Single gene, baker's yeast	GI-4000	Globelimmune	Genetically modified yeast that expresses mutated RAS protein	Phase II	Pancreatic cancer
	GI-6301		Whole heat-killed yeast modified to express brachyury protein	Phase I	Solid tumour
	GI-6207		Whole heat-killed yeast modified to express CEA	Phase I	Thyroid cancer
Allogeneic tumour cells expressing single gene	Algenpantucel-L (HyperAcute pancreas)	NewLink Genetics	Irradiated pancreatic tumour cells modified to express alpha 1,3-galactosyltransferase	Phase III	Resectable or locally advanced unresectable pancreatic cancer
	Tergenpumatucl-L (HyperAcute Lung)		Irradiated NSCLC tumour cells to express alpha 1,3-galactosyltransferase (aGT)	Phase II/III	NSCLC (second line)

Category	Drug name	Company	Technology description	Status	Main indications
Allogeneic tumour cells expressing multiple gene	HS-110	Heat Biologics	Live cancer cells modified to secrete HSP gp96 and associated chaperoned antigens	Phase II	NSCLC
	GVAX	Aduro BioTech (BioSante)	GM-CSF-transduced androgen-sensitive prostate cancer cell line (LNCaP) and a CRPC cell line (PC3)	Phase II	Phase II for pancreatic, MDS/AML and local PC (failed in Phase III for PC)
	MG-1601	Molgen	Tumour cells modified to express IL-7, GM-CSF, CD80 and CD154 with proprietary dSLIM immunomodulator	Phase I/II	RCC
Allogeneic fibroblast cell lines expressing multiple cancer genes	Unknown	Immune Cell Therapy	Semi-allogeneic fibroblasts transfected with autologous tumour-derived DNA	Phase I	NSCLC
Autologous tumour cells express multiple genes	FANG	Gradalis	Adjuvant bi-shRNAfurin and GMCSF augmented autologous tumour cell vaccine	Phase II	Ovarian, melanoma and colorectal cancer
Autologous modified tumour cells	OVAX	AVAX Technology	Autologous, DNP-modified ovarian cancer vaccine	Phase II	Ovarian cancer
<b>Cytokines</b>					
IFN-alpha	Intron-A	Merck & Co	Recombinant IFN-a2b	Approved	Hairy cell leukaemia, adjuvant melanoma, follicular lymphoma
	Roferon-A	Roche	Recombinant IFN-a2a	Approved	Hairy cell leukaemia, chronic myelogenous leukaemia (CML)
IL-2	Proleukin	Prometheus (Nestle)	Recombinant IL-2	Approved	Metastatic RCC
<b>Dendritic cells</b>					
DC with defined antigen and protein	Provenge	Dendreon	Autologous PBMCs incubated in vitro with PA2024, a recombinant fusion protein composed of PAP and GM-CSF	Approved	Asymptomatic or minimally symptomatic mCRPC
	CVac	Prima Biomed	Autologous DC attached to tumour-specific cell surface protein, mucin-1	Phase II	Ovarian cancer
DC with undefined peptide antigens	ICT-107	ImmunoCellular Therapeutics	Autologous DCs pulsed with peptides eluted from the surface of cultured autologous brain tumour cells	Phase II	Glioblastoma
DC with defined antigen	DN24-02	Dendreon	Autologous PBMCs incubated in vitro with Her2/Neu	Phase II	HER2+ urothelial carcinoma
	DC-Vax-L	NorthWest Biotherapeutics	Autologous DC pulsed with tumor lysate antigen	Phase III	GBM
	DCVax-Prostate		DC cells and prostate specific membrane antigen (PSMA)	Phase III	Prostate cancer
DC with antigens and cytokines	a-type-1 polarised DC vaccine	Unknown	Autologous DCs activated with a cocktail of cytokines and growth factors	Phase I	Glioma
DC with cytokines	INTUVAX (COMBIG-DC)	Immunicum AB	Allogeneic, immortalised DCs stimulated with toll-like receptor IFN-Gamma	Phase I	mRCC
<b>Immune checkpoint blockers</b>					
Antagonist to inhibitory factors	Yervoy (ipilimumab)	BMS	Anti-CTLA-4 mAB	Phase III	NSCLC, prostate, SCLC
	Tremelimumab	AstraZeneca		Phase II	Malignant mesothelioma
	Nivolumab	BMS/Ono	Anti-PD1 mAB	Phase III	Melanoma, NSCLC, RCC
	Lambrolizumab	Merck & Co		Phase III	second-line NSCLC, melanoma
	RG7446/MPDL3280A	Roche	Anti-PD-L1 mAB	Phase II	second-line NSCLC
	BMS-936559	BMS		Phase I	Solid tumour
	MGA271	Macrogenics/Servier	Anti-B7-H3 mAB	Phase I	Solid tumour
Competitor to inhibitory factor	Lirilumab	BMS/Innate Pharma	Anti-KIR mAB	Phase II	AML and solid tumours
	IMP321	ImmuTune	Soluble LAG-3, plus six melanoma antigens	Phase II	Melanoma
Inhibitor of inhibitory factor (small molecule)	AMP-224	GSK/Amplimmune	PD-L2 Ig fusion protein	Phase I	Solid tumour
	Indoximod	NewLink Genetics	Inhibitor of indoleamine 2,3 dioxygenase (IDO)	Phase II	Metastatic prostate cancer
	INCB024360	Incyte		Phase I/II	Melanoma, ovarian
	CT-011	CureTech/BMS		Phase I	Solid tumours

Source: Edison Investment Research

## Immune checkpoint blockers

Of course, combinations of immune checkpoint inhibitors and cancer vaccines also require the former to get to market. We have identified some 22 company sponsored pivotal or potentially pivotal studies of checkpoint inhibitors (see Exhibit 2). Nivolumab is in seven different registration trials in three different tumour types: two in squamous NSCLC (second line in combination with docetaxel, and third-line as monotherapy, readouts due in second half of 2014), one in metastatic RCC. BMS is conducting a similar number of registration studies with Yervoy, in various settings of melanoma, squamous first-line NSCLC and small cell lung cancer. Roche's RG7446 could

potentially reach the market in 2016/17 in second-line NSCLC, assuming a large Phase III placebo-controlled study will be required. However, it could come sooner if the agencies accept filings on the basis of response rates in single-arm studies.

Roche is also in a better position to catch up with an early and aggressive move into combinations. Currently it is already studying RG7446 with Avastin (bevacizumab) ± FOLFOX in advanced solid tumours (presumably colorectal cancer) and separately with Zelboraf (vemurafenib) in treatment-naïve BRAFV600-mutation positive metastatic melanoma. It is also expected to initiate a number of combination studies with RG7446 and internal compounds as well ones obtained via licensing. It recently disclosed promising preclinical data of RG7446 in combination with two different and undisclosed (for obvious competitive reasons) new medical entities, which will undoubtedly enter trials soon.

**Exhibit 2: Selected Phase II/III trials of immune checkpoint blockers\***

Drug	Indication	Setting	Trial details	Results
Yervoy (Ipilimumab)/BMS	Melanoma	High-risk stage III, post surgery.	950-pt Phase III trial of ipilimumab vs placebo	4/2015
		Progression after achieving disease control	138-pt Phase II trial of ipilimumab re-treatment vs chemotherapy (physician's choice)	6/2016
		Extensive disease	1,100-pt Phase III trial of etoposide/platinum ± ipilimumab	3/2017
		First-line (stage IV).	1,100-pt Phase III trial of paclitaxel/carboplatin ± ipilimumab	12/2016
		Small cell lung cancer	Chemo-naïve	600-pt Phase III trial of ipilimumab vs placebo
	NSCLC	Post docetaxel	800-pt Phase III. Ipilimumab vs placebo	2/2017
		CRPC		160-pt Phase I/II studies of ipilimumab ± nivolumab
	Previously untreated		915-pt Phase III trial (CheckMate-067) of nivolumab vs nivolumab/ipilimumab vs ipilimumab	10/2016
	TNBC, SCLC, gastric and pancreatic		Post Yervoy	390-pt Phase III trial (CheckMate 037) of nivolumab vs physician's choice of either DTIC or paclitaxel/carboplatin
	Nivolumab/BMS	Melanoma	First-line stage III/IV	150-pt Phase II study (CheckMate 069) of nivolumab +/- ipilimumab. Enrol BRAF V600+ and wild type
Previously untreated, unresectable or metastatic			410-pt Phase III (CheckMate 066) of nivolumab vs DTIC	9/2015
Second-line, squamous			264-pt Phase III of nivolumab vs docetaxel	8/2014
Second-line non-squamous			574-pt Phase III of nivolumab vs docetaxel	11/2014
NSCLC		Pre-treated adv. or metastatic.	822-pt Phase III of nivolumab vs everolimus	2/2016
		Second-line	920-pt Phase II/III of lambrolizumab vs docetaxel	9/2015
RCC		Advanced	645-pt Phase III of lambrolizumab vs ipilimumab.	7/2016
Lambrolizumab/Merck & Co		NSCLC	>second-line	180-pt Phase II of MPDL3280A vs docetaxel
	Melanoma	>second-line PD-L1 positive, untreated	Planned Phase III study	
RG7446/Roche	NSCLC	>second-line	100-pt Phase II of MPDL3280A single arm	5/2015
		PD-L1 positive, untreated	180-pt Phase II in tremelimumab vs placebo	Mid-2015
		Unresectable, second/third line		
	Second-line	Planned Phase III study (SUNRISE)	N/A	
Tremelimumab/AstraZeneca	Mesothelioma			
Bavituximab/Peregrine	NSCLC			

Source: Edison Investment Research. Note: \*Company sponsored and randomised studies only.



## Upcoming newsflow

### Exhibit 3: Expected near-term newsflow catalysts for pharma/biotech

November		
Biotie	1 Nov	Q313 results
SOBI	5 & 7 Nov	Capital Markets Event
Biotie	6 Nov	Nalmefene – Lundbeck Q313
Paion	6 Nov	Q313 business update
MorphoSys	7 Nov	Q313 results
ThromboGenics	7 Nov	Q313 business update
4SC	7 Nov	Q313 results
Topotarget	7 Nov	Q313 results
ALK-Abello	8 Nov	Q313 results
Bionor Pharma	8 Nov	Q313 results
aap Implantate	11 Nov	Q313 results
GW Pharmaceuticals	11 Nov	Sativex – Almirall Q313
Vectura	11 Nov	Respiratory pipeline – Almirall Q313
BTG	12 Nov	H113 interim results
Evotec	12 Nov	Q313 results
BTG	13 Nov	Lemtrada – FDA Adcom: sBLA for disease modifying label in relapsing MS
Algeta	14 Nov	Q313 results
Bavarian Nordic	14 Nov	Q313 results
Allergy Therapeutics	14 Nov	AGM
Ablynx	14 Nov	Q313 results
Nanobiotix	15 Nov	Q313 results
Vectura	19 Nov	H113 interim results
Optos	21 Nov	FY13 results
GW Pharmaceuticals	Nov	FY13 results
Lombard Medical	Nov	Formal US launch of Aorfix
Oxford BioMedica	Nov	Q313 IMS
Paion	Nov	Q313 results
Phylogica	Nov	AGM
Vernalis	Nov	Q313 IMS
December		
BTG	4 Dec	FDA PDUFA date for Varisolve
Consort Medical	4 Dec	H113/14 interim results
Stallergenes	11 Dec	Oralair FDA AdComm
ALK-Abello	12 Dec	Grazax FDA AdComm
Unspecified		
CytRx		Final results of aldoxorubicin Phase IIb trial in front-line STS
CytRx		Start of aldoxorubicin Phase II trial in second-line GBM
CytRx		Start of aldoxorubicin Phase II trial in Kaposi's sarcoma
GW Pharmaceuticals		Headline results from GWP42006 Phase I study
GW Pharmaceuticals		Potential start of GWP42004 Phase IIb trial in diabetes
GW Pharmaceuticals		Start of THC:CBD Phase Ib/IIa study in glioma
Mesoblast		Start of Phase III trial with Revascor in CHF
Sygnis		Launch of products by Qiagen containing QualiPhi
Transgene		Top-line results from first stage of Phase II/III TIME study with TG4010 in NSCLC
Transgene		Update on further development of Pexa-Vec
Viralytics		Start of Phase I/II STORM study with IV Cavatak
Conferences etc		
	1-5 Nov	AASLD Liver Meeting - Washington
	4-6 Nov	Bio-Europe – Vienna
	5-10 Nov	American Society of Nephrology and Kidney Week 2013 – Atlanta
	7-10 Nov	Society for Immunotherapy of Cancer Annual Meeting – Maryland
	11-14 Nov	Credit Suisse Healthcare Conference – Arizona
	16-19 Nov	American Academy of Ophthalmology – New Orleans
	19 Nov	Consilium Communications and Covington & Burling Annual Healthcare Conference – London
	19 Nov	Simmons & Simmons and Hume Brophy Healthcare Conference – London
	20-21 Nov	Jefferies Global Healthcare Conference – London
	3-4 Dec	FT Pharmaceutical and Biotechnology Conference – London
	3-4 Dec	Piper Jaffray Healthcare Conference – New York
	7-10 Dec	American Society of Haematology (ASH) – New Orleans
	10-11 Dec	Oppenheimer & Co Annual Healthcare Conference – New York
	12 Dec	Genesis – London

Source: Edison Investment Research

## Company coverage

Company	Note	Date published
<a href="#">4SC</a>	Outlook; Update	14/08/2013; 11/10/2013
<a href="#">aap Implantate</a>	Outlook	17/10/2013
<a href="#">Aastrom BioSciences</a>	Update; Update	02/04/2013; 23/05/2013
<a href="#">Abcam</a>	Outlook; Update	07/07/2011; 21/09/2011
<a href="#">Ablynx</a>	Update; Update	10/10/2012; 12/03/2013
<a href="#">Addex Therapeutics</a>	Update; Update	05/03/2013; 19/04/2013
<a href="#">Algeta</a>	Update; Update	19/06/2012; 20/05/2013
<a href="#">Alexza Pharmaceuticals</a>	QuickView; Outlook	23/05/2013; 27/08/2013
<a href="#">Allergy Therapeutics</a>	Update; Update	17/05/2013; 29/10/2013
<a href="#">AmpliPhi Biosciences</a>	QuickView; QuickView	09/07/2013; 14/08/2013
<a href="#">Animalcare Group</a>	Update; Outlook	03/04/2013; 03/10/2013
<a href="#">ArQule</a>	Update; Update	01/08/2013; 08/10/2013
<a href="#">Arrowhead Research</a>	Update; Update	02/10/2013; 18/10/2013
<a href="#">Athersys</a>	QuickView; Outlook	09/08/2013; 25/10/2013
<a href="#">Bellus Health</a>	Update; Update	01/07/2013; 22/07/2013
<a href="#">BioAlliance Pharma</a>	Update; Update	08/07/2013; 25/09/2013
<a href="#">BioInvent</a>	Update; Update	04/02/2013; 14/03/2013
<a href="#">Bionomics</a>	Update; Update	27/06/2013; 07/08/2013
<a href="#">Bionor Pharma</a>	QuickView; Outlook	23/08/2013; 03/10/2013
<a href="#">Biotie Therapies Corp</a>	Update; Update	07/06/2013; 14/10/2013
<a href="#">BTG</a>	Update; Update	01/07/2013; 24/07/2013
<a href="#">Can-Fite BioPharma</a>	Outlook	23/10/2013
<a href="#">Circadian Technologies</a>	Update; Update	13/05/2013; 05/09/2013
<a href="#">Cleveland BioLabs</a>	Update; Update	19/08/2013; 04/10/2013
<a href="#">Consort Medical</a>	Outlook; Update	23/04/2013; 21/06/2013
<a href="#">Cytos Biotechnology</a>	Update; Update	28/05/2013; 18/10/2013
<a href="#">CytRx Corporation</a>	Update; Update	02/10/2013; 10/10/2013
<a href="#">Deltex Medical</a>	Update; Update	15/04/2013; 15/07/2013
<a href="#">Derma Sciences</a>	QuickView; Outlook	13/02/2013; 19/09/2013
<a href="#">Diaxonhit</a>	Update; Update	31/05/2013; 17/10/2013
<a href="#">e-Therapeutics</a>	Update; Update	20/05/2013; 23/10/2013
<a href="#">EpiCept</a>	Update; Update	16/10/2012; 22/11/2012
<a href="#">Epigenomics</a>	Update; Update	02/01/2013; 14/06/2013
<a href="#">Epistem Holdings</a>	Update	31/03/2011
<a href="#">Evolva</a>	Update; Outlook	02/01/2013; 08/05/2013
<a href="#">Evotec</a>	Update; Update	19/08/2013; 19/09/2013
<a href="#">Futura Medical</a>	Outlook; Update	02/10/2013; 22/10/2013
<a href="#">GW Pharmaceuticals</a>	Update; Update	01/10/2013; 03/10/2013
<a href="#">Hutchison China Meditech</a>	QuickView; Outlook	03/04/2013; 07/10/2013
<a href="#">Hybrigenics</a>	Update; Update	15/04/2013; 07/05/2013
<a href="#">ImmuPharma</a>	Update; Outlook	26/10/2011; 05/07/2012
<a href="#">Imperial Innovations</a>	Update; Update	02/01/2013; 24/07/2013
<a href="#">Innate Pharma</a>	Update; Update	24/05/2013; 02/07/2013
<a href="#">LeMaitre Vascular</a>	Update; Update	05/08/2013; 04/11/2013
<a href="#">Lombard Medical Technologies</a>	Update; Update	06/06/2013; 11/09/2013
<a href="#">Mast Therapeutics</a>	Update; Outlook	11/03/2013; 03/07/2013
<a href="#">Medcom Tech</a>	Update; Update	10/04/2013; 13/06/2013
<a href="#">Medigene</a>	Update; Update	17/05/2013; 31/05/2013
<a href="#">Mologen AG</a>	Update; Update	17/04/2013; 16/10/2013
<a href="#">MorphoSys</a>	Update; Outlook	07/02/2013; 08/08/2013
<a href="#">Nanobiotix</a>	Update; Update	10/06/2013; 16/09/2013
<a href="#">Neovacs</a>	Update; Update	17/05/2013; 17/10/2013
<a href="#">NovaBay Pharmaceuticals</a>	Update; Update	13/05/2013; 27/09/2013

<a href="#">Omega Diagnostics</a>	Update; Update	08/07/2013; 04/11/2013
<a href="#">Oncolytics Biotech</a>	Update; Update	14/06/2013; 03/10/2013
<a href="#">OvaScience</a>	Update; Update	04/04/2013; 12/08/2013
<a href="#">Oxford BioMedica</a>	Update; Update	29/08/2013; 17/10/2013
<a href="#">Paion</a>	Update; Update	11/07/2013; 10/09/2013
<a href="#">Phylogica</a>	Update; Outlook	11/05/2012; 23/01/2013
<a href="#">Proteome Sciences</a>	Update; Outlook	01/02/2013; 04/10/2013
<a href="#">SkyePharma</a>	Outlook; Update	04/07/2013; 14/10/2013
<a href="#">Stratec Biomedical</a>	Update; Update	18/07/2013; 02/08/2013
<a href="#">Sucampo Pharmaceuticals</a>	Update; Update	01/05/2013; 10/09/2013
<a href="#">Sunesis Pharmaceuticals</a>	Outlook; Update	21/03/2013; 03/04/2013
<a href="#">Sygnis Pharma</a>	QuickView, Outlook	10/12/2012; 31/05/2013
<a href="#">Synta Pharmaceuticals</a>	Update; Update	03/04/2013; 27/06/2013
<a href="#">TiGenix</a>	Update; Update	26/04/2013; 12/09/2013
<a href="#">Topotarget</a>	Update; Update	26/03/2013; 19/08/2013
<a href="#">Transgene</a>	Update; Update	07/06/2013; 17/09/2013
<a href="#">Vectura</a>	Update; Update	09/10/2012; 28/11/2012
<a href="#">Verastem</a>	Update; Update	12/06/2013; 19/07/2013
<a href="#">Vernalis</a>	Update; Update	16/07/2013; 24/09/2013
<a href="#">Viralytics</a>	Outlook; Update	12/08/2013; 24/09/2013
<a href="#">Willex</a>	Update; Update	14/03/2013; 14/06/2013

#### Investment trusts

<a href="#">BB Biotech</a>	Update; Investment trust review	31/07/2012; 07/03/2013
<a href="#">Biotech Growth Trust (The)</a>	Investment trust review	26/07/2012; 26/04/2013
<a href="#">International Biotechnology Trust</a>	Investment trust review	25/10/2012; 07/06/2013
<a href="#">Worldwide Healthcare Trust</a>	Investment trust review	15/10/2012; 01/08/2013

To view the June edition of the Investment Trusts Quarterly, featuring biotechnology and healthcare trusts, see the [investment companies and trusts](#) sector profile on our website.

#### QuickViews

To view the following QuickViews see the [healthcare](#) sector profile page on our website.

AB Science	06/02/2012; 13/02/2013
Achillion	12/03/2012; 18/10/2012
Acorda Therapeutics	05/11/2012
Active Biotech	21/02/2012
Aegerion Pharmaceuticals	10/06/2013
Alchemia	25/03/2013; 07/06/2013
Algeta	20/05/2013
ALK-Abello	14/11/2012; 07/02/2013
Alkermes	05/11/2012; 05/02/2013
Alnylam Pharmaceuticals	10/02/2012
Amarin	21/11/2012; 13/12/2012
Aratana Therapeutics	23/10/2013
Ariad Pharmaceuticals	05/03/2012
Array BioPharma	08/02/2013; 30/07/2013
Anthera	24/02/2012
AVEO Pharmaceuticals	10/08/2012; 15/02/2013
Basilea	07/09/2012; 08/02/2013
Benitec Biopharma	15/10/2012
BioCryst Pharmaceuticals	20/02/2012; 25/07/2013

BioLineRx	20/02/2012; 12/12/2012
Biota Holdings	11/04/2012
Celldex Therapeutics	12/03/2012
Clinigen	02/04/2013; 26/07/2013
Clinuvel	05/01/2012
Curis	31/01/2012
Cytori Therapeutics	10/10/2012
Dechra Pharmaceuticals	23/02/2012
Endocyte	18/04/2012; 18/12/2012
EKF Diagnostics	23/03/2012
Esperion Therapeutics	14/08/2013
Exact Sciences	27/11/2012
Galapagos	05/03/2012
Genfit	07/03/2013; 24/07/2013
Genmab	12/03/2012; 09/01/2013
GI Dynamics	14/11/2012
Gilead Sciences	13/02/2013
Halozyme Therapeutics	05/07/2013
Idenix	11/01/2012
Immunodiagnostic Systems Holdings	29/11/2011; 28/06/2012
Incyte Corporation	05/11/2012; 01/03/2013
Infinity Pharmaceuticals	06/01/2012; 30/01/2012
Insmed	05/07/2013
Ion Beam Applications	20/03/2013; 23/10/2013
Ironwood Pharmaceuticals	22/10/2012
KaloBios Pharmaceuticals	23/07/2013
Karolinska Development	25/02/2013; 02/07/2013
Keryx Biopharmaceuticals	05/03/2012
LCA-Vision	31/01/2013; 04/09/2013
MagForce	03/02/2012
Medivir	01/11/2013
Merrimack Pharmaceuticals	17/04/2013
Mesoblast	22/03/2013; 21/10/2013
MethylGene	27/11/2012
MolMed	18/02/2013
Nektar Therapeutics	08/02/2013
Newron Pharmaceuticals	21/06/2013; 12/09/2013
NicOx	22/03/2012
Nordion	29/10/2012; 31/05/2013
Novogen	30/10/2013
NPS Pharmaceuticals	07/01/2013
Oncothyreon	05/06/2013
Onyx Pharmaceuticals	05/11/2012; 04/01/2013
Optos	21/05/2013
Orexo	05/07/2013; 30/10/2013
Paladin Labs	02/11/2012
Patheon	14/11/2012
Pharmaxis	30/01/2012; 08/03/2013
Photocure	22/02/2012; 01/06/2012
Prima BioMed	02/07/2013; 08/10/2013
Prosensa	05/09/2013; 15/10/2013
QRxPharma	28/03/2012; 06/03/2013
Resverlogix	29/04/2013; 14/06/2013
REVA Medical	21/06/2013
Sangamo BioSciences	03/02/2012; 18/02/2013
Sarepta Therapeutics	07/03/2012; 31/07/2012
Scancell	07/12/2012; 17/07/2013

Sirtex Medical	19/04/2013
Source Bioscience	27/03/2012; 22/07/2013
Stallergenes	12/03/2013; 06/08/2013
Stem Cell Therapeutics	13/08/2013
Synergy	14/11/2012
Tekmira Pharmaceuticals	16/11/2012; 15/04/2013
Threshold Pharmaceuticals	28/01/2013; 03/07/2013
ThromboGenics	14/01/2013; 09/09/2013
Tissue Regenix	11/10/2012
Trimel Pharmaceuticals	05/11/2013
UCB	25/01/2013
United Drug	19/11/2012; 24/09/2013
Vertex Pharmaceuticals	06/11/2012; 26/04/2013
ViroPharma	03/10/2012
Vivalis	15/01/2013
Vivus	23/02/2012
Zealand Pharma	22/11/2012; 18/02/2013
Zeltia	26/04/2012; 25/02/2013

#### **Alternext stocks covered**

Biosynex  
 CARMAT  
 Cellectis  
 Cerep  
Diaxonhit  
 Genfit  
 GenOway  
Hybrigenics  
 IntegraGen  
 MEDICREA International  
Neovacs  
 Novacyt  
 Qiagen Marseille  
 Spineway  
 Theradiag  
 Vexim  
 Visiomed Group

## Company profiles

**Sector: Pharma & healthcare**

Price: €1.75  
 Market cap: €88m  
 Forecast net cash (€m): 4.5  
 Forecast gearing ratio (%): N/A  
 Market: FRA

**Share price graph (€)**

**Company description**

4SC is a Munich-based drug discovery and development company focused on the development of small-molecule compounds for treating cancer and autoimmune diseases. Its R&D pipeline has three NCEs in active clinical development.

**Price performance**

%	1m	3m	12m
Actual	(9.9)	1.5	(11.1)
Relative*	(13.1)	(6.3)	(28.8)

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## 4SC (VSC)

**INVESTMENT SUMMARY**

4SC's investment case hinges on the successful development, partnering and commercialisation of resminostat for front-line hepatocellular carcinoma (HCC). There is a clear rationale for targeting front-line HCC and, as such, we are optimistic that 4SC will secure financing and/or a partner to conduct a pivotal Phase II/III study. We project peak resminostat sales of €789m. Separately, the company's active Phase I programmes (4SC-202, 4SC-205) have delivered promising interim data and will render final results in H213. Our rNPV is €122m or €2.41/share.

**INDUSTRY OUTLOOK**

4SC's resminostat is emerging as a leader in solid tumour indications within the HDACi class. The company's recent decision to prioritise resminostat development in first-line HCC is supported by the clinical data, existing partnerships and competitive developments.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.8	(17.1)	(17.3)	(43.1)	N/A	N/A
2012	4.4	(11.7)	(11.8)	(25.6)	N/A	N/A
2013e	5.0	(11.7)	(11.7)	(23.2)	N/A	N/A
2014e	5.0	(7.1)	(7.1)	(14.1)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €1.49  
 Market cap: €46m  
 Forecast net debt (€m): 2.0  
 Forecast gearing ratio (%): 4.0  
 Market: Xetra

**Share price graph (€)**

**Company description**

aap is a German medical technology company focused on developing, manufacturing and selling products for bone fractures. These include the recently launched Loqteq trauma plating system, in addition to bone cements.

**Price performance**

%	1m	3m	12m
Actual	14.5	15.5	21.2
Relative*	10.4	6.7	(2.9)

\* % Relative to local index

**Analyst**

Dr Philippa Gardner

## aap Implantate AG (AAQ)

**INVESTMENT SUMMARY**

aap's strategy to simplify and focus the business on the key areas of trauma and biomaterials (bone cement) should drive top-line growth and margin expansion. Continued roll-out of the Loqteq trauma plates should help cement aap's position as a specialised medtech player, aided by strategic relationships with physicians and global medtech partnerships (including Zimmer and Smith & Nephew). We forecast a doubling of current sales to around €80m by 2020, with peak Loqteq sales of €40m and operating margins reaching around 25% from 14% today. Our model suggests the share price is broadly underpinned by the base existing business providing downside protection.

**INDUSTRY OUTLOOK**

Loqteq is aap's internally developed and recently launched trauma plating system. Loqteq's locking and compression technology improves fracture repair by providing more stable fixation, even in weak bones or multi-fragment fractures. The existing market for locking plate technology is estimated at up to \$1bn in the US alone and is dominated by DePuy Synthes (J&J). Loqteq's innovative design could offer a number of advantages over the nearest competitor, including increased surgeon flexibility and potential clinical advantages upon plate removal.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	29.2	4.1	2.7	7.78	19.2	13.7
2012	36.4	6.1	4.9	13.80	10.8	6.5
2013e	40.1	7.3	6.0	16.94	8.8	7.4
2014e	44.5	8.1	6.7	19.85	7.5	6.2

**Sector: Pharma & healthcare**

Price: 509.5p  
 Market cap: £1017m  
 Forecast net debt (£m) N/A  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**

**Company description**

Abcam produces and sells antibodies and other protein tools for use in research via its website. Its main clients are universities, research institutes and pharmaceutical companies across the world.

**Price performance**

%	1m	3m	12m
Actual	4.6	8.4	33.4
Relative*	1.9	5.7	13.1

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Abcam (ABC)

**INVESTMENT SUMMARY**

Abcam achieved c 25% revenue growth in FY13, or 11.8% on an underlying basis, adding back the pre-acquisition sales of its most recently acquired companies. The underlying rate of growth is similar to that in FY12 (11.5%), despite the effect of adding the faster-growing Epitomics business and the total catalogue size increasing by 31.5%. This reflects the more challenging market conditions that the company is facing because of austerity measures. Abcam has a programme of investment initiatives in place, which could boost near-term growth, including marketing and operational changes and planned new product launches. Our forecasts are under review.

**INDUSTRY OUTLOOK**

More biological research is conducted into proteins, increasing the demand for protein research tools. However, the funding of academic research is coming under greater pressure as governments look to reduce their debts. Abcam is the market leader for research antibodies, but has a limited market position in the wider protein research tools market.

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	97.8	40.4	39.3	16.2	31.5	29.0
2013	122.2	49.1	47.1	18.7	27.2	19.6
2014e	N/A	N/A	N/A	N/A	N/A	N/A
2015e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$5.23  
 Market cap: US\$90m  
 Forecast net cash (US\$m) 14.2  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**

**Company description**

Alexza Pharmaceuticals is a US-based company developing products for acute CNS disorders using its proprietary Staccato aerosol rapid drug delivery system. Lead product Adasuve is approved in the US and EU.

**Price performance**

%	1m	3m	12m
Actual	1.8	16.0	2.3
Relative*	(2.1)	11.4	(17.8)

\* % Relative to local index

**Analyst**

Pooya Hemami

## Alexza Pharmaceuticals (ALXA)

**INVESTMENT SUMMARY**

Alexza's investment case rests on the commercial prospects for Adasuve, a potentially disruptive new product for acute agitation in adult schizophrenia or bipolar disorder patients. Adasuve (Staccato loxapine) was launched in Germany and Austria by Ferrer, and its US launch by Teva is expected in Q114. Adasuve offers speed and dosing reliability advantages, and we estimate global sales of over \$200m by 2018. Its potential underpins our valuation of \$6.77/share, with upside from successful development of further products using Alexza's proprietary Staccato inhaled delivery platform (such as AZ-002, which will enter a Phase II study in H213 for acute repetitive seizures).

**INDUSTRY OUTLOOK**

Alexza's valuation is highly geared to Adasuve's prospects, and uptake will be driven by stakeholders' recognition of the benefits from the drug's rapid time to therapeutic effect vs existing non-invasive drugs used for agitation (eg lower risk of patient or staff injury, or of property damage).

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	5.7	(33.2)	(36.5)	(538.25)	N/A	N/A
2012	4.1	(24.5)	(34.9)	(279.65)	N/A	N/A
2013e	46.5	10.0	(3.7)	(21.99)	N/A	N/A
2014e	8.5	(19.0)	(22.8)	(129.33)	N/A	N/A



**Sector: Pharma & healthcare**

Price: 7.5p  
 Market cap: £31m  
 Forecast net cash (£m): 4.1  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**

**Company description**

Allergy Therapeutics is a speciality pharmaceutical company focused on preventing and treating allergy. It is revenue generating and currently sells mainly into Germany, but has international aspirations.

**Price performance**

%	1m	3m	12m
Actual	(15.5)	(22.1)	(38.8)
Relative*	(17.7)	(24.0)	(48.1)

\* % Relative to local index

**Analyst**

Wang Chong

## Allergy Therapeutics (AGY)

**INVESTMENT SUMMARY**

Allergy Therapeutics' investment case hinges on its effort to secure a US partner for Pollinex Quattro (PQ). The US allergy immunotherapy (AIT) market is potentially large, but undeveloped. PQ, an ultra-short-course subcutaneous injection, will potentially enter this market after two oral products, Grazax (Alk-Abello/Merck & Co) and Oralair (Stallergenes), both of which are in regulatory review. Allergy is continuing the partnering process and exploring alternatives to commercialise PQ in the US. FY13 revenue was c 5% lower at £39.3m (2012: £41.3m), net profit after tax was £0.5m (2012: £0.8m) and the end of year net cash position stood at £1.1m. A successful licensing deal for PQ in the US would transform Allergy's prospects.

**INDUSTRY OUTLOOK**

Pollinex Quattro (c 50% of revenue) is an ultra short-course allergy vaccine, given as four shots over three weeks, which has comparable efficacy to existing vaccines (typically requiring 16-50 injections under specialist supervision pre-hayfever season).

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	41.3	3.1	1.2	0.41	18.3	8.4
2013	39.3	2.1	0.8	0.23	32.6	10.3
2014e	40.8	2.4	1.2	0.25	30.0	7.5
2015e	42.5	3.2	1.9	0.39	19.2	11.1

**Sector: Pharma & healthcare**

Price: US\$0.50  
 Market cap: US\$100m  
 Forecast net cash (US\$m): 2.3  
 Forecast gearing ratio (%) N/A  
 Market OTC

**Share price graph (US\$)**

**Company description**

AmpliPhi BioSciences is a US company developing bacteriophages, viruses that kill bacteria. A Phase I study for AmpliPhage-002 is planned for Q114, with a Phase II trial in wound infection in H214.

**Price performance**

%	1m	3m	12m
Actual	(8.3)	(25.1)	156.3
Relative*	(11.8)	(28.0)	105.8

\* % Relative to local index

**Analyst**

Christian Glennie

## AmpliPhi Biosciences (APHB)

**INVESTMENT SUMMARY**

AmpliPhi has secured an exclusive licence with the University of Leicester (UK) to develop bacteriophages (naturally occurring viruses that kill bacteria) targeting Clostridium difficile. This expands AmpliPhi's overall bacteriophage portfolio, which is also being developed against skin infections due to Staphylococcus aureus (phase I/II studies with the US army planned in 2014) and Pseudomonas infections in cystic fibrosis (CF) (Phase II to start in 2014). A \$7m private placement with RA Capital/Third Security, a research collaboration with the US army, and a strategic collaboration with Intrexon provide a solid base to advance the pipeline.

**INDUSTRY OUTLOOK**

Resistance to conventional chemical antibiotics is a serious problem and pharma companies are increasingly seeking alternatives. AmpliPhi is the only company to have completed a controlled Phase I/II study with bacteriophages. TOBI (Novartis) and Cayston (Gilead) are approved drugs for Pseudomonas in CF (FY12 sales \$317m and \$107m, respectively).

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.1	(3.7)	(4.0)	(8.40)	N/A	N/A
2012	3.8	(0.8)	(1.2)	(2.14)	N/A	N/A
2013e	0.5	(4.2)	(4.2)	(2.79)	N/A	N/A
2014e	0.8	(4.7)	(4.7)	(2.25)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 180.0p  
 Market cap: £37m  
 Forecast net cash (£m): 4.2  
 Forecast gearing ratio (%): N/A  
 Market: AIM

**Share price graph (p)**

**Company description**

Animalcare Group is a leading supplier of veterinary medicines and identification products to the companion animal market in the UK, Europe and other selected markets.

**Price performance**

%	1m	3m	12m
Actual	4.4	27.7	34.8
Relative*	1.7	24.4	14.3

\* % Relative to local index

**Analyst**

Franco Gregori

## Animalcare Group (ANCR)

**INVESTMENT SUMMARY**

Animalcare Group is enacting a strategy of exiting low-margin, commoditising markets and investing in higher value-adding product development. It has built a portfolio of companion animal medicines that has achieved sufficient mass to become a creditable player in the UK veterinary market. This is now a major factor for its continued growth faster than the UK market. These new products are also set to drive a phased expansion into selected European markets. Animalcare is midway through its development programme, where the greater differentiation offers distinct competitive advantages and should result in a wave of new veterinary medicines from 2017.

**INDUSTRY OUTLOOK**

The UK companion animal pharmaceutical market appears to have been surprisingly resilient over the past five years, posting a CAGR of 3.9% from 2007-12 despite the notable tightening of household budgets over the period. The latest National Office of Animal Health (NOAH) data to March 2013 show MAT growth of 2.3%, but more recent, albeit anecdotal, evidence suggests the market has remained flat.

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	10.9	2.5	2.3	9.3	19.4	14.5
2013	12.1	2.9	2.7	10.5	17.1	12.2
2014e	12.5	2.9	2.7	10.2	17.6	14.3
2015e	12.5	2.6	2.3	8.9	20.2	14.9

**Sector: Pharma & healthcare**

Price: US\$2.39  
 Market cap: US\$150m  
 Forecast net cash (US\$m): 90.2  
 Forecast gearing ratio (%): N/A  
 Market: NASDAQ

**Share price graph (US\$)**

**Company description**

ArQule is a US biotech company engaged in developing small molecule drugs for cancer. Its lead product, tivantinib, is entering a pivotal Phase III trial for HCC. Tivantinib is partnered with Daiichi Sankyo and Kyowa Hakko Kirin.

**Price performance**

%	1m	3m	12m
Actual	(2.0)	(2.8)	(4.8)
Relative*	(5.8)	(6.7)	(23.5)

\* % Relative to local index

**Analyst**

Jason Zhang

## ArQule (ARQL)

**INVESTMENT SUMMARY**

Confirmation that tivantinib offers a statistically significant benefit in terms of progression-free and overall survival in high c-MET, NSCLC has brought renewed hope that the drug may have utility in this subset of patients. We have reduced the success rate of the HCC trial, hence the valuation due to the IDMC's recommendation of dose modification.

**INDUSTRY OUTLOOK**

ArQule is a US biotech company focused on the development of cancer therapeutics. Its lead product, tivantinib, is being evaluated as a monotherapy or in combination with other cancer therapy in a variety of solid tumour types. ArQule utilises a proprietary structure-based drug design technology known as the ArQule Kinase Inhibitor Platform (AKIP).

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	47.3	(9.3)	(10.2)	(19.32)	N/A	N/A
2012	36.4	(9.0)	(9.6)	(14.42)	N/A	N/A
2013e	15.4	(28.8)	(29.5)	(41.72)	N/A	N/A
2014e	8.2	(38.3)	(39.4)	(55.43)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$7.99  
 Market cap: US\$290m  
 Forecast net cash (US\$m) 27.3  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**

**Company description**

Arrowhead Research Corporation is a clinical-stage targeted therapeutics company with development programmes in oncology, obesity and hepatitis B. It has acquired various platform technologies for RNAi delivery (Roche) and peptide targeting (Alvos).

**Price performance**

%	1m	3m	12m
Actual	47.4	172.7	259.9
Relative*	41.8	161.9	189.0

\* % Relative to local index

**Analyst**

Jason Zhang

## Arrowhead Research Corporation (ARWR)

**INVESTMENT SUMMARY**

ARC-520's attractive safety profile in healthy volunteers enables Arrowhead to proceed to a single-dose, Phase IIa, pilot efficacy trial in HBV patients in Hong Kong, likely in Q413 or Q114, pending regulatory approval. A \$60m (net) financing on the back of this Phase I data provides sufficient cash to support ARC-520 until Phase IIb data and advances more new drug candidate(s) into human testing. We have updated our valuation to reflect the Phase I results and the impact of the new financing.

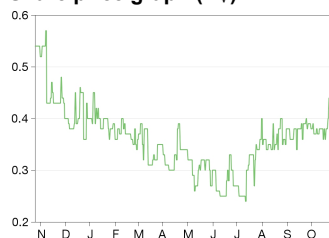
**INDUSTRY OUTLOOK**

Gene silencing is a potentially exciting area for new product development, with targeted therapies offering better disease control and fewer side effects than current medications. Large and medium-sized pharmaceutical companies are likely to invest in this field via collaborations, of which Arrowhead would be a beneficiary.

Y/E Sep	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.3	(8.2)	(7.4)	(29.4)	N/A	N/A
2012	0.1	(18.1)	(20.9)	(179.4)	N/A	N/A
2013e	0.3	(19.4)	(22.4)	(99.5)	N/A	N/A
2014e	0.2	(22.8)	(23.7)	(67.6)	N/A	N/A

**Sector: Pharma & healthcare**

Price: C\$0.41  
 Market cap: C\$20m  
 Forecast net cash (C\$m) 15.0  
 Forecast gearing ratio (%) N/A  
 Market TSX

**Share price graph (C\$)**

**Company description**

Bellus Health is a Canadian pharmaceutical company developing drugs for rare diseases. Its lead candidate, Kiacta, is in a pivotal Phase III trial for AA amyloidosis. BLU8499 is expected to start a Phase IIa study in AD in 2014.

**Price performance**

%	1m	3m	12m
Actual	(16.0)	5.0	90.9
Relative*	(18.2)	2.4	61.8

\* % Relative to local index

**Analyst**

Pooya Hemami

## Bellus Health (BLU)

**INVESTMENT SUMMARY**

Bellus Health's lead candidate, Kiacta, is in a Phase III trial for amyloid A (AA) amyloidosis, an orphan drug indication affecting up to 50,000 patients worldwide. We estimate the probability of success at 60%, given positive efficacy trends in a previous Phase II/III study and modifications in the pivotal study to increase its statistical power and target more responsive patients. Bellus is fully funded until the Kiacta study results, expected in 2017. In 2013, Bellus acquired Thallion Pharma, a developer of Shigamabs antibodies for Shiga-toxin E.Coli (STEC) infections, for C\$6.3m in cash, subject to adjustments; Bellus plans to start a Phase II Shigamabs trial within 24 months. Bellus entered a cash-neutral collaboration in October 2013 with AmorChem to develop therapeutics for AL amyloidosis.

**INDUSTRY OUTLOOK**

The potential for premium pricing for Kiacta and a seven- to 10-year exclusivity period underscore the primary investment case, although with results in 2017, a long-term view is required.

Y/E Dec	Revenue (C\$m)	EBITDA (C\$m)	PBT (C\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	3.1	(0.6)	(1.7)	(7.75)	N/A	N/A
2012	2.3	(3.6)	(3.5)	(11.03)	N/A	N/A
2013e	1.6	(3.6)	(3.3)	(5.91)	N/A	N/A
2014e	1.2	(4.1)	(3.8)	(5.96)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$3.99  
 Market cap: US\$82m  
 Forecast net cash (€m) 10.9  
 Forecast gearing ratio (%) N/A  
 Market Euronext Paris

**Share price graph (US\$)**

**Company description**

BioAlliance Pharma is a French drug development company focused on orphan cancer and supportive care treatments. It has two FDA-approved specialty products and three clinical-stage orphan oncology candidates.

**Price performance**

%	1m	3m	12m
Actual	0.0	6.7	(4.1)
Relative*	(1.8)	(1.2)	(23.7)

\* % Relative to local index

**Analyst**

Dr Philippa Gardner

## BioAlliance Pharma (BIO)

**INVESTMENT SUMMARY**

BioAlliance develops drugs for orphan oncology indications and to treat infections. Most of its products are widely used medicines in new formulations for use in novel indications. Its lead oncology product, Livatag, is in a Phase III for liver cancer and has passed the third Data Safety Monitoring Board (DSMB) assessment, so that the safety concerns following the Phase II trial have receded; preliminary efficacy data are due in H116. Its second oncology product, Validive for oral mucositis, is in Phase II with data due in H114. Also, it had its second US product approval with Sitavig (a treatment for cold sores) in April. The company has recently raised €8.4m net to accelerate development of Livatag and Validive and been awarded a €4.3m grant for Livatag. The additional funds should enable BioAlliance to operate to late-2014.

**INDUSTRY OUTLOOK**

BioAlliance targets niche markets with its products, which either address significant unmet medical needs or have a clear point of differentiation over current treatments. The former are the more valuable, but the latter still have considerable commercial potential.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	3.2	(15.3)	(14.6)	(83.00)	N/A	N/A
2012	4.0	(12.1)	(11.5)	(65.00)	N/A	N/A
2013e	3.8	(13.1)	(12.8)	(66.42)	N/A	N/A
2014e	6.3	(10.7)	(10.4)	(50.48)	N/A	N/A

**Sector: Pharma & healthcare**

Price: SEK2.87  
 Market cap: SEK244m  
 Forecast net cash (SEKm) 69.0  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ OMX Mid Cap

**Share price graph (SEK)**

**Company description**

BioInvent is a human therapeutic antibody company based in southern Sweden. It has a lead product, BI-505 in Phase I for multiple myeloma.

**Price performance**

%	1m	3m	12m
Actual	8.7	25.3	15.7
Relative*	6.8	18.7	(7.4)

\* % Relative to local index

**Analyst**

Dr John Savin

## BioInvent International (BINV)

**INVESTMENT SUMMARY**

On 30 September, BioInvent had SEK40m of cash after raising SEK23m gross at SEK2.10/share in Q3 giving working capital until the end of 2013. Sales in the first nine months were SEK32m with a reported loss of SEK39m. The BI-505 Phase I dose-escalating and safety study indicated a dose of 10mg/kg. BI-505 is in a 10-patient Phase IIa in "smouldering" multiple myeloma. Two preclinical antibodies have entered development: ADC-1013, a co-development to stimulate an anti-cancer immune response, and BI-1206, a candidate against CD32b. This may be effective in non-Hodgkin's Lymphoma.

**INDUSTRY OUTLOOK**

BioInvent wants to partner BI-505. A GenMab Phase I deal gained \$55m upfront and \$88m in equity with milestones and a 10%+ royalty. The n-CoDeR licence with Mitsubishi Tanabe has been extended with further fee income. Another partner has paid a clinical milestone on an n-CoDeR antibody on Phase I entry. Bayer extended its 2008 agreement on therapeutic antibody development in October and paid a significant fee.

Y/E Dec	Revenue (SEKm)	EBITDA (SEKm)	PBT (SEKm)	EPS (öre)	P/E (x)	P/CF (x)
2011	125.0	(66.0)	(67.0)	(1.00)	N/A	N/A
2012	43.0	(148.0)	(151.0)	(1.92)	N/A	N/A
2013e	45.0	(24.0)	(29.0)	(0.39)	N/A	N/A
2014e	47.0	(23.0)	(28.0)	(0.38)	N/A	N/A

**Sector: Pharma & healthcare**

Price: A\$0.77  
 Market cap: A\$315m  
 Forecast net cash (A\$m) 21.1  
 Forecast gearing ratio (%) N/A  
 Market ASX, OTC

**Share price graph (A\$)**

**Company description**

Bionomics is an Australian biotech company focused on developing biopharmaceuticals for cancer and CNS indications. Its lead compound is VDA BNC105 (Phase II); the anxiolytic IW-2143 (Phase I) is partnered with Ironwood.

**Price performance**

%	1m	3m	12m
Actual	2.0	96.2	152.3
Relative*	(0.2)	82.8	112.4

\* % Relative to local index

**Analyst**

Robin Davison

## Bionomics (BNO)

**INVESTMENT SUMMARY**

Bionomics expects the Phase II trial of BNC105 in renal cell carcinoma to render data by early 2014. Additionally BNC101, a mAb directed to LGR5 and lead cancer stem cell programme, is expected to enter the clinic in 2014. Cash of A\$22.5m at end-June 2013 should fund operations through to mid-2015. Our risk-adjusted net present value of Bionomics' pipeline remains A\$275m, which after adjusting for cash, indicates an overall value of A\$300m or A\$0.72/share.

**INDUSTRY OUTLOOK**

Bionomics' lead compound is the small molecule vascular disrupting agent, BNC105, which is in separate Phase I/II trials for renal cell carcinoma and ovarian cancer. An anti-anxiety agent BNC210 (renamed IW-2143) is licensed to Ironwood Pharmaceuticals, which is currently conducting a Phase Ia/Ib study. A cancer stem cell targeting agent, BNC101, is in late-preclinical development.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	3.7	(9.3)	(9.5)	(2.7)	N/A	N/A
2012	8.9	(3.3)	(2.5)	(0.7)	N/A	N/A
2013e	10.5	(8.4)	(8.4)	(2.1)	N/A	N/A
2014e	7.8	(11.1)	(11.1)	(2.7)	N/A	N/A

**Sector: Pharma & healthcare**

Price: NOK2.84  
 Market cap: NOK641m  
 Forecast net cash (NOKm) 108.8  
 Forecast gearing ratio (%) N/A  
 Market Oslo

**Share price graph (NOK)**

**Company description**

Bionor Pharma is a Norwegian biotechnology company focused on developing peptide vaccines for infectious diseases. The lead product, Vacc-4x, is currently in Phase II development for the treatment of HIV.

**Price performance**

%	1m	3m	12m
Actual	(8.1)	(11.4)	(17.8)
Relative*	(13.0)	(17.7)	(28.2)

\* % Relative to local index

**Analyst**

Dr Philippa Gardner

## Bionor Pharma (BIONOR)

**INVESTMENT SUMMARY**

Bionor Pharma's ambitious aim to develop Vacc-4x as the first functional cure for HIV is supported by previous data and collaborations with leading institutes. A comprehensive 'Kick, Kill and Boost' strategy is in place and recent funding should allow Bionor to take Vacc-4x through the critical steps before partnering. Vacc-4x is one of the furthest advanced HIV therapeutic vaccines in development and the current development strategy encompasses all the elements required to achieve a functional cure for HIV. These include releasing dormant HIV reservoirs (Kick), encouraging HIV destruction via an immune response elicited by Vacc-4x (Kill) and strengthening the immune system to maximise its attack on HIV (Boost).

**INDUSTRY OUTLOOK**

There are approximately 1.1m HIV-infected patients in the US, and around one million in developed Europe. The global antiretroviral treatment (ART) market was worth around \$17bn in 2012. In the US only 25% of HIV patients are virally suppressed, despite 33% receiving ART treatment.

Y/E Dec	Revenue (NOKm)	EBITDA (NOKm)	PBT (NOKm)	EPS (fd) (öre)	P/E (x)	P/CF (x)
2011	109.5	57.4	61.3	33.12	8.6	N/A
2012	4.2	(58.2)	(55.2)	(29.43)	N/A	N/A
2013e	4.3	(61.0)	(60.3)	(28.95)	N/A	N/A
2014e	1.6	(63.5)	(63.3)	(28.99)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €0.33  
 Market cap: €149m  
 Forecast net cash (€m) 0.7  
 Forecast gearing ratio (%) N/A  
 Market OMX

**Share price graph (€)**

**Company description**

Biotie Therapies is a Finnish/US biotech company focused on CNS disorders. Selincro (alcohol dependence) is marketed in Europe (partner: Lundbeck); tozadenant (Parkinson's) will start Phase III in H115 (partner: UCB).

**Price performance**

%	1m	3m	12m
Actual	(5.7)	(2.9)	(17.5)
Relative*	(7.0)	(14.2)	(35.8)

\* % Relative to local index

**Analyst**

Christian Glennie

## Biotie Therapies (BTH1V)

**INVESTMENT SUMMARY**

Biotie holds an option to acquire Neurelis for its intranasal diazepam to treat acute epileptic seizures and is seeking similarly advanced CNS candidates, which could be commercialised by Biotie, particularly in the US. Partner Lundbeck has launched alcohol dependence drug Selincro in the UK, Italy, Norway, Finland, Poland and the Baltic countries, with further EU launches expected in 2013/14 - Biotie receives milestones (€2m/key market) and royalties. Phase III studies for tozadenant (A2a antagonist) in Parkinson's disease are planned for H115, with costs reimbursed by partner UCB (>\$100m over six years). A Phase II proof-of-concept study for BTT-1023 (VAP-1 antibody), in primary sclerosing cholangitis, is planned. Biotie has c €43m in cash.

**INDUSTRY OUTLOOK**

Selincro is a new treatment concept for alcohol dependence, providing an alternative to complete abstinence, often not an attainable goal. The Phase IIb data for tozadenant are robust and competitive against current and pipeline Parkinson's agents.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	1.0	(28.3)	(20.8)	(3.58)	N/A	N/A
2012	4.8	(21.8)	(23.0)	(5.54)	N/A	N/A
2013e	24.2	0.3	(0.1)	(0.02)	N/A	N/A
2014e	23.6	(5.2)	(5.5)	(1.22)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 407.3p  
 Market cap: £1472m  
 Forecast net cash (£m) 27.9  
 Forecast gearing ratio (%) N/A  
 Market LSE

**Share price graph (p)**

**Company description**

BTG is a UK-based biopharmaceutical company with a direct commercial presence in US acute care medicine and interventional oncology. It has a number of internal and partnered R&D programmes.

**Price performance**

%	1m	3m	12m
Actual	5.5	7.2	17.1
Relative*	2.8	4.5	(0.7)

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## BTG (BTG)

**INVESTMENT SUMMARY**

BTG's acquisitions of TheraSphere and EkoSonic represent an inflection point for the company's Interventional Medicine (IM) business. The addition of two profitable, growing and complementary platforms to its existing portfolio could take IM sales to c £450m within 10 years. We value BTG at £1.86bn, or 516p per share. With marketed assets worth 357p per share, this implies downside protection and material upside to the current price.

**INDUSTRY OUTLOOK**

BTG presents a defensive growth business whose valuation is underpinned by the DCF value of its marketed assets. The acquisitions of TheraSphere and EKOS have created a leading IM business with critical mass and significant growth potential.

Y/E Mar	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2012	197.0	57.7	57.6	14.9	27.3	27.6
2013	233.7	75.1	70.4	18.9	21.6	21.9
2014e	284.3	66.5	64.4	15.9	25.6	40.8
2015e	351.5	90.6	88.0	18.6	21.9	27.5

**Sector: Pharma & healthcare**

Price: NIS10.62  
 Market cap: NIS171m  
 Forecast net cash (NISm) 2.1  
 Forecast gearing ratio (%) N/A  
 Market Tel Aviv Stock Exchange

**Share price graph (NIS)**

**Company description**

Can-Fite is an Israel-based drug development company with a platform technology surrounding A3AR agonists, with two clinical-stage oral drug candidates, CF101 and CF102, being advanced for inflammatory diseases and oncology, respectively.

**Price performance**

%	1m	3m	12m
Actual	33.2	44.1	1.4
Relative*	29.2	36.6	(7.1)

\* % Relative to local index

**Analyst**

Pooya Hemami

## Can-Fite BioPharma (CFBFF)

**INVESTMENT SUMMARY**

Can-Fite's investment case rests on the prospects for novel orally bioavailable A3 adenosine receptor (A3AR) agonist, CF101, in trials for blockbuster potential inflammatory conditions, including rheumatoid arthritis (RA) and psoriasis. There is unmet medical need in both these conditions given the high costs and/or safety risks with established systemic therapies. Positive Phase II data have been shown for CF101 in psoriasis and dry eye syndrome (DES). Clinical study readouts from a Phase IIb study in RA and a Phase III programme in DES are expected in December 2013, which if positive, could trigger value-enhancing partnership negotiations and provoke a re-rating in the stock.

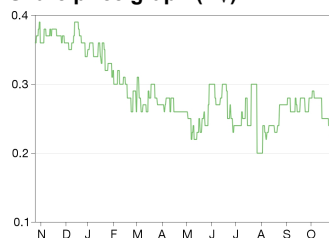
**INDUSTRY OUTLOOK**

Given the large size of targeted markets, Can-Fite's programmes if successful could provide multi-fold long-term investor returns. RA and psoriasis markets are highly competitive, however, and CF101 may need to show differential advantages vs potential new market entrants to gain a significant market position.

Y/E Dec	Revenue (NISm)	EBITDA (NISm)	PBT (NISm)	EPS (fd) (a)	P/E (x)	P/CF (x)
2011	1.8	(18.0)	(16.8)	(1.51)	N/A	N/A
2012	0.0	(22.3)	(21.9)	(2.08)	N/A	N/A
2013e	0.0	(29.2)	(29.2)	(2.13)	N/A	N/A
2014e	0.0	(33.7)	(34.1)	(2.23)	N/A	N/A

**Sector: Pharma & healthcare**

Price: A\$0.23  
 Market cap: A\$11m  
 Forecast net cash (A\$m) 3.8  
 Forecast gearing ratio (%) N/A  
 Market ASX

**Share price graph (A\$)**

**Company description**

Circadian's focus is on its VEGF-C and VEGF-D portfolio, with a receptor blocking antibody (IMC-3C5) in Phase I trials with ImClone (Lilly), and a VEGF-C targeting antibody (VGX-100) due to enter glioblastoma trials in late-2011.

**Price performance**

%	1m	3m	12m
Actual	(13.5)	(10.0)	(36.6)
Relative*	(15.3)	(16.1)	(46.6)

\* % Relative to local index

**Analyst**

Dr John Savin

## Circadian Technologies (CIR)

**INVESTMENT SUMMARY**

FY13 results to 30 June showed revenues of \$1.15m made up of sales and royalty income of A\$0.62m, with finance income of A\$0.5m. Cash outflow fell 6% to A\$5.38m helped by a A\$1.32m tax refund. The targeted cash burn for FY14 is A\$5-8m, June 2013 cash was A\$11m, so the company has over a year's funding available. Management is seeking additional investment into operating businesses, sale of assets and IP licensing.

**INDUSTRY OUTLOOK**

Circadian has three operating companies: Ceres Oncology, Opthea and Precision Diagnostics. Ceres is developing VGX-100. The Phase I VGX-100 only dose arm has completed recruitment to 30mg/kg with the VGX-100 plus Avastin arm completing in 2013. VGX-100 is expected to enter Phase II in Q114 for secondary lymphoedema, with interim data mid-2014. Opthea is developing VGX-300 in wet AMD, with trials starting 2015. Precision is developing a speciality diagnostic business. New US academic research supports VEGF-C as an escape route from Avastin, which could help close a VGX-100 deal.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2012	0.5	(8.6)	(7.6)	(10.8)	N/A	N/A
2013	0.6	(7.0)	(6.5)	(9.7)	N/A	N/A
2014e	0.7	(9.3)	(9.1)	(14.7)	N/A	N/A
2015e	0.7	(9.5)	(9.4)	(15.5)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$1.40  
 Market cap: US\$63m  
 Forecast net cash (US\$m) 2.4  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**



**Company description**

Cleveland BioLabs is a clinical-stage US biotechnology company focused on biodefence and oncology. Entolimod (CBLB502) is being developed as both a radiation countermeasure (pivotal studies) and a cancer treatment (Phase I).

**Price performance**

%	1m	3m	12m
Actual	(13.0)	(16.2)	(20.5)
Relative*	(16.4)	(19.5)	(36.1)

\* % Relative to local index

**Analyst**

Christian Glennie

## Cleveland BioLabs (CBLI)

**INVESTMENT SUMMARY**

A \$10m loan agreement with Hercules Capital (\$6m upfront) extends Cleveland's cash runway into Q214 (from Q114), while a US government (BARDA) development contract (c \$50m) is awaited for Entolimod, a radiation medical countermeasure. This would help to fund the remaining studies required to gain approval for Entolimod under the FDA's Animal Efficacy Rule. A pre-EUA filing is planned for mid-2014 and procurement contracts could be secured in 2015. Entolimod (TLR5 agonist) is also in Phase I studies as a targeted anti-cancer agent, boosted by a recent \$4.6m Russian government contract. Phase I curaxin candidate CBL0137 targets FACT, a novel potential marker and target for aggressive cancers.

**INDUSTRY OUTLOOK**

Entolimod is the most advanced radiation countermeasure in development. To date, five biodefence products have gained approval under the FDA's animal efficacy rule, and \$2.6bn has been committed by the US government to develop/procure counterterrorism agents through the \$5.6bn Project BioShield Act.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	8.8	(25.6)	(25.1)	(73.20)	N/A	N/A
2012	3.6	(30.5)	(30.1)	(69.37)	N/A	N/A
2013e	8.4	(25.3)	(24.8)	(48.04)	N/A	N/A
2014e	15.0	(20.6)	(20.9)	(40.36)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 885.0p  
 Market cap: £259m  
 Forecast net cash (£m) 30.0  
 Forecast gearing ratio (%) N/A  
 Market LSE

**Share price graph (p)**



**Company description**

Consort Medical is an international medical devices business. Having divested King Systems (for up to \$170m in cash), it once more consists of the Bepak operations (inhalation and injection technologies).

**Price performance**

%	1m	3m	12m
Actual	4.0	13.0	15.7
Relative*	1.3	10.2	(1.9)

\* % Relative to local index

**Analyst**

Franco Gregori

## Consort Medical (CSRT)

**INVESTMENT SUMMARY**

Consort Medical's investment case hinges on Bepak's growth prospects, with the new product flow from the development pipeline set to underpin double-digit earnings growth over the medium term. The prospects appear very promising, although commercial sensitivity means that the visibility, both in terms of timings and revenue potential, is low. The company's core strength in respiratory devices, and growing expertise in nasal delivery systems and autoinjectors are not the only drivers. Although having a much lower profile, Nicovent's Oxette tobacco-free 'cigarette' device could be a valuable revenue generator. Consort Medical's strong balance sheet is also worthy of mention.

**INDUSTRY OUTLOOK**

Bepak is a leader in producing medical devices for the pharmaceutical industry, with proven expertise in high-volume, high-quality manufacture of regulated products. Bepak's core drug-delivery franchise is inhalation, although it has diversified into auto-injectors, nasal delivery and point-of-care diagnostics through the Atlas Genetics investment.

Y/E Apr	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (fd) (p)	P/E (x)	P/CF (x)
2012	93.5	25.5	16.8	54.4	16.3	10.3
2013	95.0	28.2	19.8	60.0	14.8	9.7
2014e	99.6	23.8	16.8	41.7	21.2	11.4
2015e	N/A	N/A	N/A	N/A	N/A	N/A



**Sector: Pharma & healthcare**

Price: CHF3.86  
 Market cap: CHF87m  
 Forecast net debt (CHFm) 19.6  
 Forecast gearing ratio (%) 159.0  
 Market Swiss Stock Exchange

**Share price graph (CHF)**

**Company description**

Cytos Biotechnology is a public biopharmaceutical company focused on the development of targeted immunotherapies. Its lead candidate, CYT003, is a first-in-class biologic in Phase II development as a potential new treatment for allergic asthma.

**Price performance**

%	1m	3m	12m
Actual	(2.3)	12.5	8.7
Relative*	(4.6)	7.3	(12.9)

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## Cytos Biotechnology (CYTN)

**INVESTMENT SUMMARY**

Cytos will raise up to CHF17.6m in new equity to advance its lead asset, CYT003, for allergic asthma. The new funds will ensure it is well capitalised ahead of CYT003 Phase IIb results in moderate-to-severe patients (Q214). Assuming the data are positive, the strengthened cash balance should provide Cytos with greater leverage in partnering discussions. Moreover, positive results should mean that – assuming the share price rises as expected – existing debt due in 2015 will be converted (CHF13.2m loan note) and the rest paid down (CHF23m convertible bond), providing Cytos with sufficient time to out-license CYT003.

**INDUSTRY OUTLOOK**

The potential of immunotherapies is increasingly being recognised, especially in respiratory (most notably asthma), cancer and auto-immune indications.

Y/E Dec	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHFc)	P/E (x)	P/CF (x)
2011	1.6	(19.3)	(20.1)	(382.0)	N/A	N/A
2012	1.1	(15.0)	(11.7)	(66.7)	N/A	N/A
2013e	1.2	(20.7)	(25.0)	(124.1)	N/A	N/A
2014e	1.2	(12.7)	(20.8)	(102.9)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$2.63  
 Market cap: US\$107m  
 Forecast net cash (US\$m) 37.1  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**

**Company description**

CytRx is focused on oncology. Lead programme, aldoxorubicin, is Phase III-ready for second-line STS, in an ongoing Phase IIb study in front-line STS, and expected to enter Phase II for GBM and Kaposi's sarcoma in Q413.

**Price performance**

%	1m	3m	12m
Actual	(8.0)	9.6	10.0
Relative*	(11.5)	5.3	(11.6)

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## CytRx (CYTR)

**INVESTMENT SUMMARY**

CytRx has raised \$24.1m (net) to accelerate the development of aldoxorubicin, following recent positive data for the drug in front-line soft tissue sarcoma (Phase IIb) and glioblastoma (preclinical). In Q413, CytRx will start a Phase II study in second-line GBM that could render data in Q314. It will also initiate a Phase II trial in AIDS-related Kaposi's sarcoma. Finally, in Q413, we expect final PFS data from the Phase IIb study in front-line STS – initial response data favour aldoxorubicin over doxorubicin, which we hope will translate into a clinically meaningful PFS benefit.

**INDUSTRY OUTLOOK**

CytRx has a strong rationale for advancing aldoxorubicin, a tumour-targeted doxorubicin conjugate, into a pivotal Phase III study for second-line STS. Initiation of Phase III development is supported by positive Phase I/II data in advanced STS; doxorubicin's efficacy in STS; limited competition; high unmet medical need; and a clear regulatory pathway due to the Special Protocol Assessment received from the FDA.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.3	(22.0)	(21.8)	(76.81)	N/A	N/A
2012	0.1	(19.0)	(18.9)	(69.44)	N/A	N/A
2013e	0.1	(22.2)	(22.1)	(68.19)	N/A	N/A
2014e	0.1	(25.3)	(25.2)	(61.93)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 16.8p  
 Market cap: £28m  
 Forecast net debt (£m): 1.0  
 Forecast gearing ratio (%): 39.0  
 Market: AIM

**Share price graph (p)**

**Company description**

Deltex Medical is a UK medical device company that manufactures and sells the CardioQ-oesophageal Doppler monitor and disposable probes for haemodynamic monitoring to reduce recovery times after high-risk and major surgery.

**Price performance**

%	1m	3m	12m
Actual	(5.0)	12.6	(37.4)
Relative*	(7.4)	9.8	(46.9)

\* % Relative to local index

**Analyst**

Dr John Savin

## Deltex Medical Group (DEMG)

**INVESTMENT SUMMARY**

Revenues in H1 were £2.9m with a reported loss of £1.4m. Management expects a strong H2 performance exceeding 40% growth on UK surgical probes; if so, UK surgical sales could exceed £3m with UK ICU probes adding £0.8m. International sales are H2 weighted and rather unpredictable. The H1 US Premier study costs of £0.3m may rise to £0.5m in H2, and £0.8m for 2013 as it gets fully underway. The big shift is in monitor revenues, which are lumpy but generally substantially lower due to lower sales volumes and price cuts, with most being placed to drive probe sales. There may be £0.4m of non-cash monitor sales in H2 for US clinical trials.

**INDUSTRY OUTLOOK**

The NHS market remains patchy. In England and Wales, the target is for a "trajectory" to use intraoperative fluid management (IOFM) in 80% of 77,556 patients. In the US, the FDA has approved the ODM+ monitor, used for both Doppler and arterial pulse pressure monitoring. Deltex is now funding a dedicated trainer at a third major US hospital to support use.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	6.3	(0.8)	(1.1)	(0.71)	N/A	N/A
2012	6.8	(0.8)	(1.3)	(0.80)	N/A	N/A
2013e	7.3	(1.3)	(1.7)	(1.07)	N/A	N/A
2014e	8.3	(0.8)	(1.1)	(0.65)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$11.90  
 Market cap: US\$205m  
 Forecast net cash (US\$m): 24.7  
 Forecast gearing ratio (%): N/A  
 Market: NASDAQ

**Share price graph (US\$)**

**Company description**

Derma Sciences is a specialty medical device/pharmaceutical company. It focuses on developing and commercialising traditional and novel advanced wound care products, including MEDIHONEY and TCC-EZ.

**Price performance**

%	1m	3m	12m
Actual	(8.5)	(20.0)	6.9
Relative*	(11.9)	(23.1)	(14.2)

\* % Relative to local index

**Analyst**

Jason Zhang

## Derma Sciences (DSCI)

**INVESTMENT SUMMARY**

Using cash generated from the slow-growing but stable traditional wound care business unit, Derma Sciences was able to invest in its advanced wound care unit, which has seen an annual growth rate of 40-55%. The company has also started a Phase III trial of DSC127, a drug developed for diabetic foot ulcers, which could generate peak sales of \$400m+, and is the largest value driver for the stock. We value the company at \$357.3m (\$20.7 per basic share), which is significantly higher than the current market value.

**INDUSTRY OUTLOOK**

Derma Sciences operates in three segments of the wound care business, traditional wound care, advanced wound care and pharmaceutical wound care. The slow-growing, but cash-positive TWC unit provides the company with investment capital for the fast-growing AWC unit, which has seen a five-year (2007-12) CAGR of 53.2% and is expected to continue to grow in the 30-40% range in the next few years.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	62.6	0.4	(2.5)	(31.6)	N/A	N/A
2012	72.6	(8.9)	(12.2)	(78.4)	N/A	N/A
2013e	82.2	(20.6)	(24.5)	(143.5)	N/A	N/A
2014e	95.3	(23.3)	(26.1)	(148.0)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €0.65  
 Market cap: €37m  
 Forecast net cash (€m) 1.0  
 Forecast gearing ratio (%) N/A  
 Market Alternext Paris

**Share price graph (€)**

**Company description**

Diaxonhit is a French fully integrated leader in in-vitro diagnostics from the discovery to commercialisation with products in infectious diseases, Alzheimer's disease and cancer. It is also developing therapeutic products for neurodegeneration.

**Price performance**

%	1m	3m	12m
Actual	(8.5)	1.6	(40.3)
Relative*	(10.1)	(5.9)	(52.5)

\* % Relative to local index

**Analyst**

Wang Chong

## Diaxonhit (ALEHT)

**INVESTMENT SUMMARY**

Diaxonhit's integration of the Exonhit and InGen BioSciences appears to be making good progress towards the formation of a fully integrated IVD company. Diaxonhit is implementing its strategy of growing its distribution activities using the existing sales organisation by in-licensing proprietary products, adding new exclusive contracts and expanding territories, while accelerating the development of novel diagnostic products. Diaxonhit ended H113 with cash of €5.9m, which combined with a SocGen €6.5m equity line should be sufficient for nearly two years. H113 operating expenses were €10.5m, a reduction of €400k. Diaxonhit has a cash runway to complete the AclarusDx clinical studies and market the product in France.

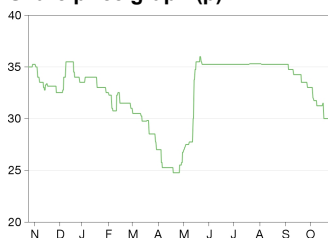
**INDUSTRY OUTLOOK**

The molecular diagnostic market is worth c \$1.5bn and growing at c 6% as diagnostic products enable patients to receive better treatments. Pharmaceutical companies are also forming more R&D partnerships with biotech companies with promising platform technologies, which increases the likelihood of Diaxonhit entering new R&D collaborations.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	5.0	(7.3)	(7.8)	(21.8)	N/A	N/A
2012	5.4	(6.1)	(6.4)	(17.1)	N/A	N/A
2013e	31.3	(9.0)	(9.2)	(15.7)	N/A	N/A
2014e	34.0	(9.1)	(9.4)	(15.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 30.0p  
 Market cap: £79m  
 Forecast net cash (£m) 41.2  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**

**Company description**

e-Therapeutics is a drug discovery and development company with a proprietary network pharmacology discovery platform and a clinical pipeline (with potential to be out-licensed post-Phase II).

**Price performance**

%	1m	3m	12m
Actual	(10.5)	(14.9)	(14.3)
Relative*	(12.8)	(17.0)	(27.3)

\* % Relative to local index

**Analyst**

Franc Gregori

## e-Therapeutics (ETX)

**INVESTMENT SUMMARY**

e-Therapeutics is well placed, with funding in place (net cash of £45m) to support current spending plans through to 2018, by which time major value inflection points should be reached. ETS2101 is particularly promising, with 33 patients now enrolled in the parallel US (glioma) and UK (solid tumours) Phase I trials. Data are expected in Q413 and Q114 respectively. A 160-pt Phase IIb non-inferiority study of the antidepressant ETS6103 has initiated, with data expected in H115. Output from the newly bolstered discovery platform should broaden the R&D pipeline in parallel with the planned ETS2101 Phase II programme.

**INDUSTRY OUTLOOK**

Network pharmacology could potentially revolutionise drug discovery and shorten the path to market by minimising technical risks (failure on safety or efficacy grounds) and drug development costs. e-Therapeutics is well positioned, with limited direct competition and growing industry interest in systems biology-based multi-target approaches to drug discovery.

Y/E Jan	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	0.0	(4.0)	(3.9)	(2.5)	N/A	N/A
2013	0.0	(5.2)	(5.0)	(3.0)	N/A	N/A
2014e	0.0	(8.8)	(8.3)	(2.9)	N/A	N/A
2015e	0.0	(8.9)	(8.5)	(2.7)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €4.63  
 Market cap: €56m  
 Forecast net debt (€m) 5.0  
 Forecast gearing ratio (%) 154.0  
 Market FRA

**Share price graph (€)**

**Company description**

Epigenomics is a German molecular diagnostics company focused on early detection of cancer. Its main product is Epi proColon, a blood-based DNA test for colorectal cancer that uses a sophisticated PCR assay to detect methylated copies of the septin9 gene.

**Price performance**

%	1m	3m	12m
Actual	38.0	184.2	414.8
Relative*	33.1	162.5	312.5

\* % Relative to local index

**Analyst**

Emma Ulker

## Epigenomics (ECX)

**INVESTMENT SUMMARY**

After acceptance and notification of priority review status for its PMA submission, Epigenomics' blood-based Epi proColon is now under final review by the FDA. The date for the advisory board panel is expected to be set shortly. The PMA was based on two large studies that showed sensitivity (across all CRC stages) of 68-72% at a specificity of 80-82%. However, the overall performance data may not be the key determinant of success in the market. The ability to identify early-stage CRC and the presumed patient preference for blood-based vs stool-based tests may prove to be as important in addressing poor current screening compliance. Epigenomics' H113 cash position stood at €3.56 and it has since entered into a financing agreement with Yorkville to issue up to €5m in convertible notes and completed a €4.2m private placing, which should fund the company well into FY14, by which time the FDA should have approved Epi proColon.

**INDUSTRY OUTLOOK**

Epi proColon offers patients a simple and convenient alternative to faecal occult blood testing and should increase compliance for colorectal screening by addressing individuals not currently participating in screening programmes. Epi proLung is an aid in the diagnosis of lung cancer from bronchial lavage using the SHOX2 biomarker.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	1.4	(7.9)	(8.3)	(96.9)	N/A	N/A
2012	1.0	(10.8)	(10.9)	(125.3)	N/A	N/A
2013e	2.0	(11.0)	(11.1)	(108.0)	N/A	N/A
2014e	13.1	(3.6)	(3.7)	(34.6)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 335.0p  
 Market cap: £32m  
 Forecast net debt (£m) N/A  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**

**Company description**

Epistem has a profitable contract services business and an emerging clinical biomarker technology with Sanofi as a big client. Epistem is preparing to launch Genedrive, its novel molecular diagnostic device, initially in the TB market.

**Price performance**

%	1m	3m	12m
Actual	(11.3)	(42.2)	(39.8)
Relative*	(13.6)	(43.7)	(49.0)

\* % Relative to local index

**Analyst**

Emma Ulker

## Epistem Holdings (EHP)

**INVESTMENT SUMMARY**

Epistem recognised £5.4m of revenue in FY13, broadly in line with FY12. The year-end cash balance was £6.5m. Its supply and distribution agreement for global ex-US sales of GeneDrive with Becton Dickinson was terminated. Epistem continues to make clinical and regulatory preparations for the planned commercial launch of GeneDrive for TB through Xcelris in India and the Indian sub-continent. There are relatively minor issues to be resolved with GeneDrive software and further clinical testing is taking place in Spain. Preclinical testing for the Indian market is set to start this year. Epistem has recently been awarded a European grant for the development of an HCV test for GeneDrive.

**INDUSTRY OUTLOOK**

Epistem believes GeneDrive (a DNA-based diagnostic point-of-care system) will change the shape of DNA diagnostics. GeneDrive has now been CE marked, but published data are very limited. The TB market seems a good one as other tests are unreliable or expensive.

Y/E Jun	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	5.6	(0.6)	(0.7)	(2.9)	N/A	N/A
2013	5.4	(1.2)	(1.5)	(12.5)	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A
2015e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: CHF0.88  
 Market cap: CHF213m  
 Forecast net cash (CHFm) 21.7  
 Forecast gearing ratio (%) N/A  
 Market Swiss Stock Exchange

**Share price graph (CHF)**

**Company description**

Evolva is Swiss biosynthesis company. It has a proprietary yeast technology platform, which it uses to create and manufacture high-value speciality molecules for nutritional and consumer products.

**Price performance**

%	1m	3m	12m
Actual	(5.4)	20.5	161.2
Relative*	(7.6)	14.9	109.2

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Evolva (EVE)

**INVESTMENT SUMMARY**

Evolva has an innovative biosynthesis platform focused on developing new production methods for nutritional and consumer health products. Its key programme is for the sweetener stevia, partnered with Cargill (up to \$7.5m in milestones and the right to a 45% participation in the final business), is progressing ahead of schedule. It could be launched in 2015/16 and will initially be targeted at the \$4bn beverage sweetener market. It also has a vanilla project (partnered with IFF, which should be launched in H114), and ones for resveratrol (on market) and saffron. It has nutritional alliances with Ajinomoto and Roquette as well. Its legacy pharmaceutical product, EV-077, is being partnered with Serodius. Evolva had a cash position of CHF31.8m at H113 after raising CHF31.3m in equity in March, which could take it to profitability.

**INDUSTRY OUTLOOK**

The manufacturers of nutritional and consumer health products are always interested in cheaper production methods, especially if the product is natural and has health benefits. Evolva is primarily targeting this market.

Y/E Dec	Revenue (CHFm)	EBITDA (CHFm)	PBT (CHFm)	EPS (CHFc)	P/E (x)	P/CF (x)
2011	11.1	(22.4)	(25.5)	(13.4)	N/A	N/A
2012	7.0	(16.8)	(18.8)	(7.8)	N/A	N/A
2013e	8.9	(15.1)	(17.0)	(7.1)	N/A	N/A
2014e	10.2	(14.3)	(16.2)	(6.7)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €3.91  
 Market cap: €511m  
 Forecast net cash (€m) 75.0  
 Forecast gearing ratio (%) N/A  
 Market FRA

**Share price graph (€)**

**Company description**

Evotec is a drug discovery business that provides outsourcing solutions to pharmaceutical companies, including Boehringer Ingelheim, Pfizer and Roche. It has operations in Germany, the UK and the US.

**Price performance**

%	1m	3m	12m
Actual	21.1	53.0	46.2
Relative*	16.7	41.3	17.1

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## Evotec (EVT)

**INVESTMENT SUMMARY**

Evotec recently raised €30m in new equity to accelerate its CureXTargetX strategy, which is focused on drug discovery alliances with academia. The additional capital will allow Evotec to build more alliances more rapidly, thereby enhancing its long-term growth prospects. There are now three CureX and two TargetX initiatives, one of which (CureBeta) has already resulted in a major alliance with Janssen. We expect further collaborations and/or deals in H213. Also, four products could enter clinical development over the next 18 months, including an EVT100 product for the treatment-resistant depression partnered in Janssen. Our DCF valuation is €480m.

**INDUSTRY OUTLOOK**

Pharmaceutical companies are outsourcing drug discovery activities to improve their productivity and decrease the fixed costs associated with them. Evotec's growth depends on its ability to provide a high-quality integrated service.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	80.1	12.0	7.5	5.6	69.8	42.6
2012	87.3	9.1	1.3	0.4	977.5	37.7
2013e	93.4	15.3	8.0	6.2	63.1	61.5
2014e	100.9	15.7	8.3	5.6	69.8	31.0

**Sector: Pharma & healthcare**

Price: 63.5p  
 Market cap: £49m  
 Forecast net cash (£m): 1.0  
 Forecast gearing ratio (%): N/A  
 Market: AIM

**Share price graph (p)**

**Company description**

Futura Medical is a UK-based healthcare company developing non-prescription topical products in sexual healthcare and pain relief management, based on its proprietary DermaSys delivery technology.

**Price performance**

%	1m	3m	12m
Actual	(9.9)	(6.6)	30.9
Relative*	(12.3)	(9.0)	11.0

\* % Relative to local index

**Analyst**

Franco Gregori

## Futura Medical (FUM)

**INVESTMENT SUMMARY**

Futura Medical is approaching a key inflection point as its principal product is set for market launch. CSD500, a performance-enhancing condom, is licensed to Church & Dwight, the US consumer group that owns the market-leading Trojan brand, for North America and selected European territories. Further licensing deals for other markets are expected in the near term. CSD500 has recently received its CE mark, clearing the way for it to be marketed in all European countries (as well as a number of other markets). The low-cost business model means that even a modest success could prove transformational for the company's finances.

**INDUSTRY OUTLOOK**

Futura Medical is a UK-based healthcare group focused on topical pharmaceutical drugs and medical devices that incorporate existing chemical entities and can be sold over the counter. The development portfolio consists of six products that range from PET500, a topical spray to delay premature ejaculation that is being launched by Ansell in the US, to the recently added TIB200 and SPR300, which are superior formulations of existing topical pain-relieving gels.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	0.2	(2.1)	(2.2)	(2.5)	N/A	N/A
2012	0.1	(2.5)	(2.6)	(2.9)	N/A	N/A
2013e	0.4	(2.0)	(2.1)	(2.3)	N/A	N/A
2014e	1.4	(0.8)	(0.9)	(0.7)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 158.0p  
 Market cap: £280m  
 Forecast net cash (£m): 37.2  
 Forecast gearing ratio (%): N/A  
 Market: AIM

**Share price graph (p)**

**Company description**

GW Pharmaceuticals is a UK speciality pharma company focused on developing cannabinoids as pharmaceuticals. Lead product Sativex is marketed in a number of European countries for multiple sclerosis-associated spasticity.

**Price performance**

%	1m	3m	12m
Actual	105.2	225.8	122.9
Relative*	99.9	217.6	89.0

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## GW Pharmaceuticals (GWP)

**INVESTMENT SUMMARY**

GW Pharma is focused on fully exploiting the potential of its lead cannabinoid drug, Sativex, and its broad cannabinoid-based R&D pipeline. Following its US IPO and raise, GW is well capitalised to execute its commercial strategy (maximising the value of Sativex) and R&D plans (advancing its five cannabinoid therapies). The commercial prospects for Sativex in MS spasticity have recently improved in both the EU (German pricing issue resolved) and US (opening of an IND to run a Phase III study in 2014). Including these opportunities increases our Sativex peak sales forecast to £512m (\$820m).

**INDUSTRY OUTLOOK**

GW is the leader in the field of cannabinoid medicines, which have the potential to become novel therapies for a broad range of diseases. Cannabinoids are diverse chemical compounds that GW extracts from different cannabis plant varieties (chemotypes) it has bred. Sativex is GW's lead medicine; we estimate it will achieve 5-10% market share in its approved indications.

Y/E Sep	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	29.6	3.7	3.3	2.7	58.5	97.6
2012	33.1	2.8	2.2	2.6	60.8	153.1
2013e	23.7	(8.2)	(8.7)	(2.4)	N/A	N/A
2014e	23.6	(6.0)	(6.6)	(2.2)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 635.0p  
 Market cap: £331m  
 Forecast net debt (US\$m) 4.3  
 Forecast gearing ratio (%) 5.0  
 Market

**Share price graph (p)**

**Company description**

Hutchison China MediTech is the healthcare arm of Hutchison Whampoa (with 30% listed on AIM) that capitalises on the economic and demographic shifts in China with novel high-technology therapies, TCM drugs, organic foods and consumer products.

**Price performance**

%	1m	3m	12m
Actual	14.4	36.6	42.7
Relative*	11.5	33.1	21.0

\* % Relative to local index

**Analyst**

Franco Gregori

## Hutchison China MediTech (HCM)

**INVESTMENT SUMMARY**

Historically Hutchison China MediTech's investment case rested principally on the prospects for the China Healthcare division, as this business tapped into one of the fastest-growing healthcare markets in the world. However, the progress being achieved across a number of pipeline projects means that it is MediPharma, the R&D unit, that should increasingly become the focus of investor attention as it could add significant value over the coming year. Additionally, the appreciation in land values has benefited China Healthcare's production sites, which are now in prime residential locations. These property windfalls should be more than sufficient to fund the desired expansion of manufacturing capacity.

**INDUSTRY OUTLOOK**

Favourable demand trends, coupled with the supportive environment for clinical research, mean the prospects for Chinese healthcare companies are compelling. Demographics and government support will continue to drive demand, while the clinical, regulatory and technological environments are highly conducive to novel drug development. Hutchison China MediTech is well placed to benefit from these rich seams of opportunity.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	29.3	7.5	5.2	1.8	566.3	85.4
2012	22.4	3.0	0.9	(14.0)	N/A	N/A
2013e	31.0	4.6	2.0	(7.0)	N/A	171.2
2014e	33.0	3.0	0.4	(8.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €0.65  
 Market cap: €14m  
 Forecast net cash (€m) 4.1  
 Forecast gearing ratio (%) N/A  
 Market Alternext Paris

**Share price graph (€)**

**Company description**

Hybrigenics is a French biotech company. It provides protein-protein and small molecule analysis services and is conducting anti-cancer studies on lead drug inecalcitol, primarily in CLL and prostate cancer.

**Price performance**

%	1m	3m	12m
Actual	0.0	4.8	(27.8)
Relative*	(1.8)	(2.9)	(42.6)

\* % Relative to local index

**Analyst**

Emma Ulker

## Hybrigenics (ALHYG)

**INVESTMENT SUMMARY**

Hybrigenics' key value driver is its vitamin D3 analogue inecalcitol in development primarily for prostate cancer and chronic lymphocytic leukaemia (CLL). Interim results from the PII trial in CLL showed that 60% of patients responded to treatment. Meanwhile, Hybrigenics acquired the yeast-two hybrid assets of key competitor Dualsystems and set up a US subsidiary to cement its services growth strategy. It also acquired the genomics assets of Imaxio to complement its proteomics-led research services. H113 revenue increased 8% to €1.75m, of which services increased by 11% to €1.55m. Post-period, a €1.3m private placing issued to Pradeyrol Developpement takes the cash reach into 2014.

**INDUSTRY OUTLOOK**

Inecalcitol is being developed in three major indications and faces competition from existing drugs and those in development. However, its good safety profile could give it an advantage. Hybrigenics is pushing into the innovative field of systems biology, applying its expertise for protein-gene analysis to better understand diseases and their therapies.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	6.6	(2.0)	(2.5)	(14.2)	N/A	N/A
2012	5.9	(2.3)	(2.4)	(13.2)	N/A	N/A
2013e	6.6	(2.4)	(2.6)	(10.3)	N/A	N/A
2014e	6.7	(2.0)	(2.1)	(6.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$1.99  
 Market cap: US\$25m  
 Forecast net debt (US\$m) N/A  
 Forecast gearing ratio (%) N/A  
 Market OMX, OTCQX US

**Share price graph (US\$)**



**Company description**

Immune Pharmaceuticals (formerly EpiCept) is a specialty pharmaceutical company focused on the development and commercialisation of pharmaceutical products for cancer treatment and pain management.

**Price performance**

%	1m	3m	12m
Actual	(32.4)	(32.6)	(50.2)
Relative*	(35.0)	(35.3)	(60.0)

\* % Relative to local index

**Analyst**

Wang Chong

## Immune Pharmaceuticals (EPCT)

**INVESTMENT SUMMARY**

Immune Pharmaceuticals is an Israel-based biopharma company, which acquired EpiCept in a reverse-merger. It is primarily focused on developing antibodies for inflammatory disease and cancer. Its main product, bertilimumab, is ready to enter Phase II trials for ulcerative colitis (UC) and has potential in Crohn's disease and severe asthma. The other clinical programmes are AmiKet and Crolibulin. Amiket is a topical cream ready for Phase III in chemotherapy induced peripheral neuropathy, but the company hopes to partner the product. Crolibulin is a vascular disruption agent in Phase II for anaplastic thyroid cancer. The company also has the NanomAbs platform technology, similar to that of Bind Therapeutics, which has potential advantages over the current antibody drug conjugate technology.

**INDUSTRY OUTLOOK**

Bertilimumab is one of relatively few biological therapies in development for UC. Aside from two approved biologicals for UC - Remicade and Humira - there are two candidates in registration and seven competing agents currently undergoing Phase II studies.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	1.0	(14.1)	(15.3)	(22.9)	N/A	N/A
2012	7.8	(0.6)	(1.8)	(3.0)	N/A	N/A
2013e	N/A	N/A	N/A	N/A	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: 447.0p  
 Market cap: £445m  
 Forecast net debt (£m) N/A  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**



**Company description**

Imperial Innovations is a technology transfer, incubation and venture investment company. It invests in ventures from Imperial College London, Cambridge and Oxford Universities and UCL. The majority of its investments are bio/med tech.

**Price performance**

%	1m	3m	12m
Actual	41.9	67.7	43.0
Relative*	38.2	63.5	21.3

\* % Relative to local index

**Analyst**

Robin Davison

## Imperial Innovations (IVO)

**INVESTMENT SUMMARY**

Imperial Innovations' investment portfolio value rose by £33m to £188.2m at 31 July and showed a fair value gain of £10.8m (ie net of £22m new investment). Cash at year end was £65.6m, which with the £15m second tranche of a £30m EIB loan available to draw down, means £80m of funds are available for investment. Innovations expects to see a number of liquidity events for key portfolio holdings in the coming months, which are set to become the driver for value creation. Oxford Immunotec, its sixth-largest holding, has filed an S1 for a reportedly \$86m IPO on NASDAQ. If successful, the offering may crystallise an uplift in the value of Innovations' 8% stake. Innovations' strategy is to exploit the currently receptive financial markets to step up a number of IPOs and other liquidity events, as well as undertake more new and larger investments in its maturing portfolio companies.

**INDUSTRY OUTLOOK**

The investment case centres on the real value of the portfolio and the success of the strategy of investing in maturing companies. Portfolio companies are valued per International Private Equity and Venture Capital Valuation guidelines, hence there is potential for significant value creation if exits are achieved at valuations in excess of these.

Y/E Jul	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	4.3	(6.2)	(4.0)	(6.3)	N/A	N/A
2013	3.3	(6.9)	(5.9)	(7.3)	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A
2015e	N/A	N/A	N/A	N/A	N/A	N/A



**Sector: Pharma & healthcare**

Price: €2.35  
 Market cap: €90m  
 Forecast net cash (€m) 16.4  
 Forecast gearing ratio (%) N/A  
 Market NYSE Euronext

**Share price graph (€)**



**Company description**

Innate is a French biotech, developing first-in-class immunotherapy drugs for cancer and inflammatory diseases by developing new monoclonal antibodies targeting receptors and pathways controlling the activation of innate immunity.

**Price performance**

%	1m	3m	12m
Actual	(2.1)	(3.3)	11.4
Relative*	(3.9)	(10.4)	(11.4)

\* % Relative to local index

**Analyst**

Wang Chong

## Innate Pharma (IPH)

**INVESTMENT SUMMARY**

Innate Pharma's investment case largely depends on clinical development milestones being achieved with lirilumab (IPH2102) in Phase II for cancer and IPH2201 in Phase I for inflammatory diseases, licensed to Bristol-Myers Squibb (BMS) and Novo Nordisk respectively. Data from a Phase I study with IPH2101 in acute myeloid leukaemia showed a significant overall survival benefit in patients receiving higher doses. Also, BMS started two large Phase I trials (n=150) in solid tumours (NSCLC, RCC, CRC, ovarian and melanoma) in combination with its anti-PD1 antibody and ipilimumab (Yervoy). Innate has two other products in preclinical studies, IPH33 and IPH41, and aims to out-license the former this year for the treatment of chronic respiratory inflammation. The company has also developed an antibody-drug-conjugate technology, which could lead to new partnering opportunities. It had €24.7m at H113, sufficient to run to mid-2015.

**INDUSTRY OUTLOOK**

Innate Pharma is a leader in the development of new monoclonal antibodies that target receptors and pathways controlling the activation of innate immunity cells.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	11.7	(6.7)	(7.0)	(18.5)	N/A	7.1
2012	14.3	(2.5)	(3.2)	(8.5)	N/A	N/A
2013e	12.4	(4.5)	(4.9)	(13.0)	N/A	N/A
2014e	11.5	(5.9)	(6.4)	(16.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 59.5p  
 Market cap: £9m  
 Forecast net cash (£m) N/A  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**



**Company description**

Ixico is a UK-based medical technology company, focused on imaging and diagnostic tools for dementia and CNS conditions.

**Price performance**

%	1m	3m	12m
Actual	13.3	(10.2)	(88.3)
Relative*	10.4	(12.5)	(90.0)

\* % Relative to local index

**Analyst**

Christian Glennie

## Ixico (IXI)

**INVESTMENT SUMMARY**

Ixico commenced trading on the AIM market of the London Stock Exchange on 15 October 2013, following its reverse takeover of Phytopharm. Ixico now holds approximately £5.5m in cash, and with its public listing, has the financial flexibility to advance its existing dementia diagnostics business, while assessing new opportunities through product licensing, collaborations and corporate activity. Ixico's imaging and diagnostic tools are used predominantly for dementia, to help select patients for clinical trials and to assess the safety/efficacy of new drugs. Ixico's customers are pharmaceutical companies (seven of the top 15), with potential to commercialise these agents in the wider clinical diagnostic market. Ixico recorded £3.6m in revenues for the year ended 31 May 2013.

**INDUSTRY OUTLOOK**

Ixico's key technologies, TrialWire and TrialTracker, have been used to collect patient data from more than 400 hospital sites worldwide, in several of the largest clinical trials of Alzheimer's disease treatments.

Y/E Sep	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	N/A	N/A	N/A	N/A	N/A	N/A
2013	N/A	N/A	N/A	N/A	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A
2015e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$7.62  
 Market cap: US\$116m  
 Forecast net cash (US\$m) 17.2  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**



**Company description**

LeMaitre Vascular is a global provider of medical devices and implants for the treatment of peripheral vascular disease. The company develops, manufactures and markets vascular devices to address the needs of vascular surgeons.

**Price performance**

%	1m	3m	12m
Actual	14.1	12.6	25.3
Relative*	9.7	8.1	0.6

\* % Relative to local index

**Analyst**

Jason Zhang

## LeMaitre Vascular (LMAT)

**INVESTMENT SUMMARY**

LeMaitre Vascular reported Q2 revenue of \$16m, representing y-o-y growth of 11%, slightly ahead of our estimate of \$15.5m. XenoSure sales were \$2m, a 56% increase from a year ago, which led to the company's increase in guidance of the product to \$7.3m from \$7.1m previously. The company also increased its 2013 total revenue guidance to \$62.3m from \$62.1m previously, but maintained its full-year operating income guidance of \$5m. Gross margin (70.4%) came down slightly during the quarter, but could climb back to the historical 72-74% range once the XenoSure manufacturing transition is complete, likely in H214.

**INDUSTRY OUTLOOK**

LeMaitre operates in markets with single-digit volume growth and increasing pricing constrains. However, the company is able to beat the secular trend by focusing on niche markets, increasing reach through sales rep growth and geography, and offering multiple complementary lines of products through acquisitions and R&D.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	57.7	8.3	6.9	13.40	56.9	37.3
2012	56.7	7.4	7.4	16.44	46.4	24.5
2013e	62.4	9.3	9.1	20.72	36.8	24.6
2014e	68.0	10.0	10.1	24.78	30.8	13.3

**Sector: Pharma & healthcare**

Price: 205.5p  
 Market cap: £92m  
 Forecast net cash (£m) 21.5  
 Forecast gearing ratio (%) N/A  
 Market AIM

**Share price graph (p)**



**Company description**

Lombard Medical Technologies is a manufacturer and supplier of cardiovascular implants. The lead product, Aorfix, a flexible endovascular stent graft for the treatment of AAA, is commercialised in Europe and recently received FDA approval.

**Price performance**

%	1m	3m	12m
Actual	19.8	21.6	24.2
Relative*	16.7	18.5	5.3

\* % Relative to local index

**Analyst**

Emma Ulker

## Lombard Medical Technologies (LMT)

**INVESTMENT SUMMARY**

The US launch of Aorfix has the potential to transform Lombard. Over 50% of minimally invasive AAA repair procedures via EVAR are performed in the US and the unique high-angle label (over 60°) is a key competitive advantage - strong clinical evidence and US expertise in EVAR are also key drivers. Approval in Japan, the second-largest global market, is on track for H114 through a partner with strong physician relationships. Lombard recently announced plans to expand production facilities in order to meet anticipated demand for Aorfix. We forecast a threefold increase in revenue in the first two years of US and Japanese launches and estimate that end-of-June cash of £34.3m will fund Lombard to break even in 2016.

**INDUSTRY OUTLOOK**

Lombard will compete with larger US corporations to achieve further penetration in the \$1.3bn global AAA market on the basis of US FDA approval for Aorfix. The 0-90° label and clinical evidence provide a potential competitive edge for Aorfix in the endovascular aneurysm repair-receptive US market.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	4.0	(11.0)	(11.1)	(60.1)	N/A	N/A
2012	3.9	(8.3)	(8.9)	(42.2)	N/A	N/A
2013e	5.1	(14.6)	(14.6)	(40.2)	N/A	N/A
2014e	14.5	(7.4)	(7.6)	(15.7)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$0.50  
 Market cap: US\$41m  
 Forecast net cash (US\$m) 43.0  
 Forecast gearing ratio (%) N/A  
 Market NYSE AMEX

**Share price graph (US\$)**

**Company description**

Mast Therapeutics is a development-stage US pharmaceutical company focused on developing MST-188, undergoing a Phase III study for sickle cell disease.

**Price performance**

%	1m	3m	12m
Actual	0.0	0.0	0.0
Relative*	(3.6)	(7.6)	(19.9)

\* % Relative to local index

**Analyst**

Christian Glennie

## Mast Therapeutics (MSTX)

**INVESTMENT SUMMARY**

A \$26m net equity financing in June extends Mast's cash runway to 2015 when the pivotal Phase III study (EPIC) of MST-188, to treat severely painful 'crisis' episodes in patients with sickle cell disease (SCD), is expected to complete. Mast also plans to start a Phase II study in late-2013/early-2014 with MST-188 for acute limb ischaemia (ALI) (60 patients, 15-18 months). MST-188 has further potential in resuscitation following major trauma, acute decompensated heart failure, stroke and blood transfusions. End-Q213 cash of \$53m is sufficient to complete the EPIC and ALI studies, and positive results could help to secure partners (especially ex-US) and/or fresh finance.

**INDUSTRY OUTLOOK**

MST-188 is the only NME in Phase III studies and could be the first approved therapy to reduce the duration of crisis episodes. Pfizer and Novartis have licensed rights to two mid-stage SCD candidates, indicating major pharma interest, and \$230m has been invested in SCD-focused companies since October 2011.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.0	(13.4)	(13.3)	(47.06)	N/A	N/A
2012	0.0	(15.5)	(15.6)	(32.66)	N/A	N/A
2013e	0.0	(21.7)	(21.7)	(32.13)	N/A	N/A
2014e	0.0	(24.5)	(24.5)	(23.84)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €2.95  
 Market cap: €29m  
 Forecast net debt (€m) 1.6  
 Forecast gearing ratio (%) 10.0  
 Market MAB

**Share price graph (€)**

**Company description**

Medcom Tech distributes a wide range of innovative orthopaedic products across Spain, Portugal and Italy. Its portfolio includes knee and hip implants, plates and screws to repair bone and spine fractures, and advanced types of bone cement.

**Price performance**

%	1m	3m	12m
Actual	38.5	65.7	53.6
Relative*	30.4	39.8	21.8

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Medcom Tech (MED)

**INVESTMENT SUMMARY**

Medcom Tech is maintaining strong growth despite Spain's challenging trading conditions. Underlying sales grew by 10.7% in H113 to €9.7m and EBITDA increased by 5.9% to €1.5m. The company is benefiting from the optimisation of its sales force and strengthening of its balance sheet over the last year. Net debt was €3.3m at H113 compared to €5.5m at FY12 so working capital constraints have been removed. Medcom Tech is also expanding its sales operations beyond Iberia and Italy in Europe and into Latin America. It has also established a new subsidiary, Medcom Flow, which will launch an innovative laryngoscope and intubation device, Totaltrack in November; the product will be sold directly by Medcom Tech, where it has a salesforce, and elsewhere by distributors.

**INDUSTRY OUTLOOK**

The Spanish orthopaedic market is estimated to be worth €400m. The market was growing at c 5% pa before the implementation of austerity measures, but is now estimated to be declining by c 5%. The ageing population, political pressure and technical innovations partially offset budget constraints.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	14.5	1.5	0.3	2.0	147.5	N/A
2012	16.8	2.3	0.5	4.0	73.8	8.9
2013e	19.5	4.0	2.5	17.3	17.1	5.0
2014e	22.3	5.3	4.0	28.3	10.4	8.9

**Sector: Pharma & healthcare**

Price: €3.85  
 Market cap: €38m  
 Forecast net cash (€m) 11.2  
 Forecast gearing ratio (%) N/A  
 Market Deutsche Börse

**Share price graph (€)**

**Company description**

Medigene is a German biotech company. Veregen (genital warts) is marketed through global partners, while RhuDex (autoimmune disorders) and EndoTAG-1 (breast cancer) are in development.

**Price performance**

%	1m	3m	12m
Actual	1.1	7.6	(6.4)
Relative*	(2.6)	(0.7)	(25.0)

\* % Relative to local index

**Analyst**

Christian Glennie

## Medigene (MDG1)

**INVESTMENT SUMMARY**

Medigene has a solid base to embark on a new phase of development, initially focused on progressing RhuDex to proof-of-concept data in primary biliary cirrhosis (PBC), a potentially lucrative orphan drug market. A six-month Phase II study will start in H114 and headline results should be available by end-2015. The genital warts ointment Veregen is sold in the US, multiple countries in Europe and Asia, through partnerships (€12m in-market sales in FY12). Further launches/partnerships are expected in 2013/14. SynCore Biotechnology is a global partner for EndoTAG-1, a novel composition of paclitaxel, and will conduct a global Phase III study in triple negative breast cancer, to start in H214. End-Q213 cash of €15m is sufficient to H115.

**INDUSTRY OUTLOOK**

RhuDex's development path in PBC, an orphan drug indication, offers a potentially lucrative market opportunity with limited pipeline competition.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	4.7	(16.6)	(15.5)	(105.88)	N/A	5.3
2012	6.3	(9.3)	(10.3)	(111.99)	N/A	N/A
2013e	8.5	(7.5)	(9.4)	(98.87)	N/A	N/A
2014e	11.0	(7.1)	(8.9)	(90.89)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €10.61  
 Market cap: €164m  
 Forecast net cash (€m) 13.7  
 Forecast gearing ratio (%) N/A  
 Market FRA

**Share price graph (€)**

**Company description**

Mologen's lead products are MGN1703 for metastatic colorectal cancer maintenance and MGN1601, an allogeneic renal cancer cell vaccine. Both use dSLIM and MIDGE.

**Price performance**

%	1m	3m	12m
Actual	(10.2)	(16.5)	(18.3)
Relative*	(13.4)	(22.8)	(34.6)

\* % Relative to local index

**Analyst**

Dr John Savin

## Mologen (MGN)

**INVESTMENT SUMMARY**

Mologen develops anti-cancer immune maintenance therapies aiming to give long-lasting responses. The investment case rests on a deal on the lead project, MGN1703, which has high-quality, Phase II metastatic colorectal cancer data showing a statistically significant reduction in the hazard ratio (HR) of progression. An MGN1703 deal would fund development of MGN1601, a cell-based vaccine for metastatic renal cancer. MGN1601 could be an orphan drug with no generic version possible sold directly by Mologen.

**INDUSTRY OUTLOOK**

Final data in metastatic colorectal cancer (mCRC), taking into account investigator assessments, showed the HR for progression-free survival on maintenance was 0.55 (p=0.04) and the HR for progression-free survival from start of induction therapy was 0.50 (p=0.02). This is better than initially concluded. An MGN1703 lung cancer Phase II is ready to start in H114 and a US Phase I is underway. Mologen aims to partner MGN1703, but may progress into Phase IIb/III independently of a deal. Mologen has started development of MGN1404 for melanoma. This uses a DNA construct (MIDGE) to deliver TNF genes into tumours with a high-velocity water jet.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.1	(6.8)	(7.0)	(56.6)	N/A	N/A
2012	0.1	(6.9)	(7.2)	(51.6)	N/A	N/A
2013e	0.1	(10.0)	(10.2)	(66.5)	N/A	N/A
2014e	0.1	(13.6)	(13.7)	(88.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €57.29  
 Market cap: €1496m  
 Forecast net cash (€m) 361.9  
 Forecast gearing ratio (%) N/A  
 Market FRA

**Share price graph (€)**

**Company description**

MorphoSys is a German biotechnology company that uses its proprietary antibody platforms to produce human antibodies for therapeutic use across a range of indications for partners and to develop its own pipeline.

**Price performance**

%	1m	3m	12m
Actual	1.0	12.2	125.6
Relative*	(2.6)	3.6	80.7

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## MorphoSys (MOR)

**INVESTMENT SUMMARY**

MorphoSys has a broad portfolio of 19 antibodies in clinical studies (Novartis has just started a pivotal trial with bimagrumab), including three proprietary products with considerable potential. In June, its lead proprietary product, MOR103, was licensed to GSK in a €450m deal for development in rheumatoid arthritis and multiple sclerosis. A month later, it partnered MOR202 with Celgene in an \$818m co-development agreement for multiple myeloma and other haematological cancers. A Phase II study with MOR208 in Non-Hodgkin's lymphoma is ongoing, after promising efficacy in Phase I in chronic lymphocytic leukaemia. MorphoSys has a net cash position of c €300m following the two deals, and has just raised €84m via a private placing to support the MOR208 programme, other proprietary programmes and potential acquisitions as well as fulfil its commitments with MOR202's development.

**INDUSTRY OUTLOOK**

The pharmaceutical industry is out-licensing more drug discovery and developing more biological products, as it looks to increase R&D productivity and create better products that are more resistant to generic competition. Both trends should benefit MorphoSys.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	81.7	17.8	20.9	69.4	82.6	45.9
2012	51.9	8.8	7.1	27.9	205.3	634.4
2013e	77.2	8.9	10.3	37.7	152.0	17.6
2014e	63.7	(24.1)	(21.3)	(54.1)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €5.79  
 Market cap: €62m  
 Forecast net cash (€m) 4.4  
 Forecast gearing ratio (%) N/A  
 Market Euronext Paris

**Share price graph (€)**

**Company description**

Nanobiotix is a French nanotechnology company developing radiotherapy enhancers for the treatment of cancer. Lead product NBTXR3 is currently in Phase I clinical development in Europe and is partnered with PharmaEngine in Asia-Pacific.

**Price performance**

%	1m	3m	12m
Actual	(6.3)	(1.7)	(3.5)
Relative*	(8.0)	(8.9)	(23.3)

\* % Relative to local index

**Analyst**

Dr Philippa Gardner

## Nanobiotix (NANO)

**INVESTMENT SUMMARY**

Nanobiotix's nanotechnology products could enhance radiotherapy. The NanoXray technology consists of three products that can be incorporated into current treatment without any changes to medical practice. Lead product NBTXR3 is in a Phase I soft tissue sarcoma trial in Europe, and has approval for an EU Phase I head and neck trial. A €2.8m grant for liver cancer was recently awarded. It is partnered with PharmaEngine in Asia-Pacific and a US partnership is targeted for 2014. Follow-on products NBTX-IV and TOPO, with different modes of administration, are in preclinical and early research, respectively. Nanobiotix has sufficient cash to fund operations to mid-2014.

**INDUSTRY OUTLOOK**

Radiotherapy is a cornerstone cancer treatment used in around 50% of all cancer patients. NanoXray aims to improve the benefits of current radiotherapy without increasing the risks. The purely physical mechanism of action is supported by clinical data that have demonstrated encouraging efficacy with no serious adverse events.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	1.4	(5.0)	(5.2)	(68.2)	N/A	N/A
2012	1.0	(5.0)	(5.2)	(64.7)	N/A	N/A
2013e	1.6	(7.8)	(8.0)	(73.3)	N/A	N/A
2014e	2.0	(8.1)	(8.2)	(74.4)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €1.94  
 Market cap: €38m  
 Forecast net cash (€m) 3.0  
 Forecast gearing ratio (%) N/A  
 Market Alternext Paris

**Share price graph (€)**

**Company description**

Neovacs is a biotech company focused on the development of targeted active immunotherapies for the treatment of severe chronic autoimmune and inflammatory diseases.

**Price performance**

%	1m	3m	12m
Actual	13.5	4.3	(16.1)
Relative*	11.4	(3.4)	(33.3)

\* % Relative to local index

**Analyst**

Wang Chong

## Neovacs (ALNEV)

**INVESTMENT SUMMARY**

Neovacs is initiating a Phase IIb trial with its lead product TNF-Kinoid in rheumatoid arthritis (RA). The aim is to maintain momentum of the programme while it seeks a partner. The Kinoid approach has potentially significant commercial advantages versus existing anti-TNF products in this large, but highly competitive therapeutic area. The ability to partner this drug, which has also been in Phase II for Crohn's disease, is central to Neovacs's investment case. A partnership would be expected to transform its fortunes and allow further development of the IFN-Kinoid in lupus. We estimate that H113 cash of €8.3m is sufficient to complete the forthcoming Phase IIb RA trial. Miguel Sieler, former chairman and CEO of Bayer France, has just succeeded Guy-Charles Fanneau De La Horie as CEO.

**INDUSTRY OUTLOOK**

Neovacs's kinoids are immunotherapeutic products. Its lead product, TNF-kinoid, is being targeted at the anti-TNF market for the treatment of rheumatoid arthritis and Crohn's disease, which is worth over \$20bn. For lupus, there are limited treatments available; the FDA has just approved the first new treatment for this indication in 50 years.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.4	(10.2)	(10.2)	(52.0)	N/A	N/A
2012	0.1	(8.2)	(8.3)	(45.6)	N/A	N/A
2013e	0.0	(9.1)	(9.1)	(39.8)	N/A	N/A
2014e	0.0	(9.2)	(9.2)	(39.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$1.75  
 Market cap: US\$65m  
 Forecast net cash (US\$m) 9.8  
 Forecast gearing ratio (%) N/A  
 Market NYSE AMEX

**Share price graph (US\$)**

**Company description**

NovaBay Pharmaceuticals is a US company developing a new class of topical anti-infective agents. NVC-422 is the lead candidate, undergoing two Phase IIb trials in impetigo and viral conjunctivitis.

**Price performance**

%	1m	3m	12m
Actual	0.6	22.4	35.7
Relative*	(3.3)	17.5	8.9

\* % Relative to local index

**Analyst**

Christian Glennie

## NovaBay Pharmaceuticals (NBV)

**INVESTMENT SUMMARY**

NovaBay's auriclosene (NVC-422), a novel topical anti-infective, has produced positive Phase II data from a 67-patient study in urinary catheter blockage and encrustation. Based on these study results, the company plans to continue discussions with the FDA about next steps. Two further Phase II trials should read out by mid-2014: a 300-patient impetigo study being conducted by partner Galderma (results Q413) and a 450-patient trial in viral conjunctivitis (data H114). A 250-patient Phase IIa study in bacterial conjunctivitis started in Q213. Global partners are being sought for NeutroPhase, a wound-cleansing agent with FDA 510(k) clearances – Pioneer Pharma is a strategic partner (5.6% shareholder) in China/South-East Asia. NovaBay's Q213 cash of \$11.4m should extend to mid-2014.

**INDUSTRY OUTLOOK**

Resistance to conventional antibiotics is a serious problem and pharma companies are increasingly seeking alternative methods of combating bacterial (and viral) infections. NovaBay's Aganocide compounds hold the potential to overcome and avoid these resistance issues.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	11.0	(4.8)	(4.4)	(16.88)	N/A	N/A
2012	6.9	(8.8)	(8.5)	(28.74)	N/A	N/A
2013e	8.0	(13.1)	(12.8)	(34.28)	N/A	N/A
2014e	6.8	(16.0)	(15.7)	(38.95)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 15.1p  
 Market cap: £16m  
 Forecast net cash (£m): 2.1  
 Forecast gearing ratio (%): N/A  
 Market: AIM

**Share price graph (p)**

**Company description**

Omega is a UK-based company focused on developing and marketing in-vitro diagnostic products in infectious and autoimmune diseases and for food intolerance. Intolerance tests account for over 40% of revenues.

**Price performance**

%	1m	3m	12m
Actual	(9.7)	(4.0)	(0.8)
Relative*	(12.0)	(6.4)	(15.9)

\* % Relative to local index

**Analyst**

Dr John Savin

## Omega Diagnostics (ODX)

**INVESTMENT SUMMARY**

Omega's trading update for H114 reported sales of £5.59m, up 1% on H113. Segment performance was mixed with food intolerance 9% higher, infectious disease down 12% and allergy steady at 2%. The Visitect CD4 test manufacturing scale-up has technical issues and may not be complete during FY14. The weaker H1 means that we have trimmed FY14 forecasts to £11.5m from £12m. This forecast may rise if the Visitect issues are resolved.

**INDUSTRY OUTLOOK**

The Visitect CD4 PoC test will undergo evaluation once the final manufacturing line is running and the protocol set. As yet, there are some technology transfer issues that management aims to resolve by late December. Allergy iSYS development has proved complex, but the earlier "imprecision issues" have been resolved and a final protocol established. This has enabled Omega to hire three extra scientists plus iSYS systems to undertake assay validation. The time line is for a 40-test menu to be available by the end of FY14, implying significant sales from H215.

Y/E Mar	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2012	11.1	1.3	1.0	1.2	12.6	15.5
2013	11.3	1.1	0.8	1.3	11.6	12.8
2014e	11.5	1.0	0.7	0.9	16.8	24.0
2015e	13.8	2.1	1.8	1.5	10.1	27.4

**Sector: Pharma & healthcare**

Price: C\$2.90  
 Market cap: C\$246m  
 Forecast net cash (C\$m): 16.3  
 Forecast gearing ratio (%): N/A  
 Market: NASDAQ, TSX

**Share price graph (C\$)**

**Company description**

Oncolytics Biotech is a Canadian company focused on developing Reolysin, a pharmaceutical formulation of the oncolytic reovirus, for the treatment of a wide variety of human cancers (Phase III trial in head and neck cancer).

**Price performance**

%	1m	3m	12m
Actual	5.5	(4.3)	38.8
Relative*	1.0	(9.5)	27.4

\* % Relative to local index

**Analyst**

Wang Chong

## Oncolytics Biotech (ONC)

**INVESTMENT SUMMARY**

Oncolytics has announced promising Phase II squamous cell carcinoma of the lung (SCCLC) trial data, which supports further randomised trials in this indication following the recent positive data. Oncolytics has two ongoing Phase II trials in non-small cell lung cancer (NSCLC) and SCCLC and lung adenocarcinoma. Data from the lead Phase II squamous cell head and neck cancer trial are expected soon. At H113 it had a cash position of C\$38.2m.

**INDUSTRY OUTLOOK**

Oncolytics's rivals are the companies developing oncology products in the same therapeutic areas, but there are some interesting viral oncolytic companies, including Jennerex, Genelux and Viralytics, suggesting a new era in cancer treatment. Oncolytics is one of the two leaders in the area, with Amgen the other after its acquisition of BioVex for up to US\$1bn.

Y/E Dec	Revenue (C\$m)	EBITDA (C\$m)	PBT (C\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.0	(28.7)	(28.3)	(39.9)	N/A	N/A
2012	0.0	(36.6)	(36.3)	(47.3)	N/A	N/A
2013e	0.0	(37.4)	(37.2)	(43.9)	N/A	N/A
2014e	0.0	(36.6)	(36.3)	(42.2)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$9.93  
 Market cap: US\$181m  
 Forecast net debt (US\$m): N/A  
 Forecast gearing ratio (%): N/A  
 Market: NASDAQ

**Share price graph (US\$)**

**Company description**

OvaScience is a US-based life sciences company focused on developing and commercialising new treatments for female infertility. Product candidates are based on the discovery of germline stem cells in human ovaries.

**Price performance**

%	1m	3m	12m
Actual	0.4	(23.6)	N/A
Relative*	(3.4)	(26.6)	N/A

\* % Relative to local index

**Analyst**

Dr Michael Aitkenhead

## OvaScience (OVSC)

**INVESTMENT SUMMARY**

OvaScience's near-term investment case rests on the successful development and commercialisation of its lead product, AUGMENT, to improve the success rate of in vitro fertilisation (IVF). The US path forward for AUGMENT remains unclear after FDA queried its regulatory status as a lower-risk (361 HCT/P) product. OvaScience has halted its US AUGMENT clinical trial and may have to file an Investigational New Drug (IND) application. Separately, OvaScience plans to initiate ex-US development of AUGMENT in 2014, but has not disclosed the target territories, trial design, and development timelines. Our forecasts and valuation are under review.

**INDUSTRY OUTLOOK**

OvaScience's product candidates hold the potential to improve the current IVF process (AUGMENT) and provide a new treatment paradigm for infertility (OvaTure). In particular, we believe AUGMENT could substantially improve the success rate of IVF, where procedure numbers are growing due to delayed childbearing and rising infertility awareness.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	N/A	N/A	N/A	N/A	N/A	N/A
2012	0.0	(12.1)	(12.1)	(209.0)	N/A	N/A
2013e	N/A	N/A	N/A	N/A	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: 2.6p  
 Market cap: £37m  
 Forecast net cash (£m): 4.4  
 Forecast gearing ratio (%): N/A  
 Market: LSE

**Share price graph (p)**

**Company description**

Oxford BioMedica has a leading position in gene-based therapy. The LentiVector technology is wide ranging and underpins much of the development pipeline, notably the ophthalmology projects (in collaboration with Sanofi).

**Price performance**

%	1m	3m	12m
Actual	20.9	82.5	4.0
Relative*	17.8	77.9	(11.8)

\* % Relative to local index

**Analyst**

Franc Gregori

## Oxford BioMedica (OXB)

**INVESTMENT SUMMARY**

Oxford BioMedica is currently funded through to Q214, which is important since Sanofi is expected to make the key decision on whether to opt in on RetinoStat around that time. The recent go-ahead to resume patient recruitment into the ocular clinical trials (including RetinoStat) is welcomed as a rapid resumption was critical. This decision on RetinoStat (for wet age-related macular degeneration) is seen as the determinant of Oxford BioMedica's outlook. Meanwhile, the production agreement with Novartis and a milestone from Pfizer provide welcome cash flows and help validate Oxford BioMedica's expertise.

**INDUSTRY OUTLOOK**

Gene therapy can correct dysfunctional cells and/or create endogenous therapeutic protein factories. The LentiVector platform is a flexible and efficient system that is particularly promising in ophthalmology indications, where a single administration could safely provide a sustained (or even permanent) effect.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	7.7	(10.1)	(10.3)	(0.9)	N/A	N/A
2012	7.8	(9.1)	(9.5)	(0.7)	N/A	N/A
2013e	5.3	(9.8)	(10.3)	(0.6)	N/A	N/A
2014e	1.9	(11.2)	(11.8)	(0.7)	N/A	N/A



**Sector: Pharma & healthcare**

Price: €0.94  
 Market cap: €24m  
 Forecast net cash (€m) 8.2  
 Forecast gearing ratio (%) N/A  
 Market FRA

**Share price graph (€)**

**Company description**

Paion is a biopharmaceutical company specialising in the development of anaesthesia products. It has four NCEs in its R&D portfolio, with the lead programme, remimazolam, partnered with Ono Pharmaceutical in Japan and Yichang in China.

**Price performance**

%	1m	3m	12m
Actual	(3.1)	41.1	17.8
Relative*	(6.5)	30.4	(5.6)

\* % Relative to local index

**Analyst**

Emma Ulker

## Paion (PA8)

**INVESTMENT SUMMARY**

Paion has started a 90-patient Phase II study for its sedative remimazolam in general anaesthesia. Paion will finance the trial at a cost of €2-4m, and is in discussions to find a partner for a pivotal European Phase III trial. In Japan, partner Ono Pharmaceutical is expecting Phase II/III anaesthesia data in Q114 needed for the European data package and recently confirmed that recruitment into a Phase III study is complete. Paion has signed two new partnership deals: in South Korea with Hana Pharma and in Russia and CIS with R-Pharm, to develop remimazolam. Each deal yields an upfront payment of €1m plus milestone payments and royalties. Including the Phase II trial cost and based on H113 results, Paion's estimated cash reach is into Q115. H113 cash stood at €14.2m.

**INDUSTRY OUTLOOK**

Remimazolam has important advantages over competing products, including fast onset and offset of action with lower risk of cardiopulmonary events than the standard of care propofol and a reversal agent exists if there is over sedation. Morphine-6-glucuronide has an interesting competitive profile, although Paion is funding only the maintenance of its patents at present.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	3.2	(6.2)	(6.9)	(25.9)	N/A	N/A
2012	26.8	19.2	18.6	64.2	1.5	1.5
2013e	1.5	(9.2)	(9.0)	(34.0)	N/A	N/A
2014e	1.0	(5.9)	(5.8)	(21.4)	N/A	N/A

**Sector: Pharma & healthcare**

Price: A\$0.02  
 Market cap: A\$8m  
 Forecast net cash (A\$m) 2.0  
 Forecast gearing ratio (%) N/A  
 Market ASX

**Share price graph (A\$)**

**Company description**

Phylogica is a drug discovery company with a proprietary technology platform based on naturally derived Phylomer peptides. Its business model centres on drug discovery collaborations with pharma partners, including Roche, MedImmune, Pfizer and Janssen.

**Price performance**

%	1m	3m	12m
Actual	11.8	(9.5)	(13.6)
Relative*	9.4	(15.7)	(27.3)

\* % Relative to local index

**Analyst**

Chris Kallos

## Phylogica (PYC)

**INVESTMENT SUMMARY**

Phylogica's strategy is to use its Phylomer peptide drug discovery platform to become a discovery partner for large pharma. The investment case rests on its ability to monetise its proprietary platform by achieving milestones from its collaborations and securing further deals. Its collaboration with Janssen expanded in July and a new alliance has been formed with Cubist to identify antimicrobial Phylomers. Phylogica has also had alliances with Roche/Genentech, Pfizer and MedImmune. Its proprietary technology for identifying cell-penetrating peptides could help it form more deals. Phylogica raised A\$1.6m in October 2012, receives significant R&D tax concessions (c A\$1.8m in FY13) and aims to become cash self-sustaining in 2013. In July, Richard Hopkins was promoted from CSO to CEO, with Paul Watt (former CEO) becoming the CSO.

**INDUSTRY OUTLOOK**

Peptides have some advantages of small molecules (stability, formulation flexibility and COGS) and the binding specificity of antibodies, but their key benefit is the ability to address intractable intracellular targets. Phylomer libraries are a source of novel peptide drug leads, which, due to their diversity yield better quality and quantity hits vs random peptide libraries.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	2.4	(3.5)	(3.5)	(1.2)	N/A	N/A
2012	1.9	(3.9)	(3.9)	(0.9)	N/A	N/A
2013e	4.2	(1.8)	(1.9)	0.0	N/A	N/A
2014e	4.9	(1.3)	(1.3)	0.1	20.0	N/A

**Sector: Pharma & healthcare**

Price: 40.0p  
 Market cap: £79m  
 Forecast net debt (£m): 6.0  
 Forecast gearing ratio (%): 378.0  
 Market: AIM

**Share price graph (p)**

**Company description**

Proteome Sciences is a protein biomarker contract research organisation. It has a broad patent portfolio covering isobaric mass-tagging in mass spectrometry and biomarkers for various neurological and oncology indications.

**Price performance**

%	1m	3m	12m
Actual	(13.5)	(2.4)	3.9
Relative*	(15.8)	(4.9)	(11.9)

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Proteome Sciences (PRM)

**INVESTMENT SUMMARY**

Proteome Sciences has a broad IP portfolio covering mass spectrometry techniques and biomarkers, which is being commercialised. The company earns royalties and manufacturing payments from Thermo Fisher Scientific, which sells Proteome's TMT products. PS Biomarker Services carries out protein assays and biomarker discovery for pharmaceutical companies, including Eisai and J&J. Proteome Sciences out-licenses its proprietary biomarkers non-exclusively to diagnostic companies as well. Its sales in FY12 increased by 13% to £1.2m and its sales growth is expected to accelerate in FY13, in part because of the new \$2.1m deal with Thermo Fisher Scientific for cancer pathway profiling assays. There is also the possibility of its preclinical CK1d inhibitors being partnered for Alzheimer's disease. It raised £1.6m in equity in August following an approach from an institutional investor.

**INDUSTRY OUTLOOK**

Pharma companies are expanding their biomarker programmes due to pressure from regulators and to improve productivity. Protein biomarkers promise to be particularly useful as they provide a direct read-out of changes occurring in a person.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	1.0	(4.1)	(4.5)	(2.1)	N/A	N/A
2012	1.2	(4.8)	(5.2)	(2.2)	N/A	N/A
2013e	3.3	(2.4)	(2.8)	(1.1)	N/A	N/A
2014e	8.4	2.0	1.6	1.3	30.8	75.8

**Sector: Pharma & healthcare**

Price: 92.0p  
 Market cap: £42m  
 Forecast net debt (£m): 82.5  
 Forecast gearing ratio (%): 129.0  
 Market: LSE

**Share price graph (p)**

**Company description**

Skyepharma is an expert oral and inhalation drug-delivery company. It combines proven scientific expertise with validated proprietary drug-delivery technologies to develop innovative oral and inhalation pharmaceutical products.

**Price performance**

%	1m	3m	12m
Actual	(6.1)	41.0	8.9
Relative*	(8.6)	37.4	(7.7)

\* % Relative to local index

**Analyst**

Franc Gregori

## Skyepharma (SKP)

**INVESTMENT SUMMARY**

Skyepharma's outlook is closely linked to the progress of the recently launched new products, most notably flutiform. Its performance (particularly in Europe) will define Skyepharma's future. The recent trading statement confirms the sales uptake in Europe is still matching Mundipharma's expectations. Launch preparations for Japan, and other markets, are under way and planned for 2014. These admittedly still-early signs augur well for the refinancing of any remaining debt when the 2017 bond repayment is due.

**INDUSTRY OUTLOOK**

flutiform is expected to contribute over half Skyepharma's royalty income by 2017, plus profit from supply of the product. flutiform is an inhaled combination of fluticasone and formoterol for treating asthma, and its progress in Europe is rightly the focus of investor attention. flutiform has been approved in 21 European countries and launched in 12. Further launches, including in France, are expected in 2014. Kyorin, the Japanese partner, has received approval and is also expected to launch next year. Sanofi, the partner for Latin America, has begun filings for approval with first launches over 2014-15.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	55.2	14.7	1.9	5.4	17.0	1.7
2012	49.9	15.3	(14.2)	(27.8)	N/A	1.5
2013e	61.2	10.8	(6.4)	(15.5)	N/A	4.9
2014e	66.8	19.5	1.6	(2.6)	N/A	2.5

**Sector: Pharma & healthcare**

Price: €32.65  
 Market cap: €384m  
 Forecast net cash (€m) 13.5  
 Forecast gearing ratio (%) N/A  
 Market Deutsche Börse

**Share price graph (€)**



**Company description**

Stratec Biomedical designs and manufactures OEM diagnostic instruments. Design and assembly of systems from modules is in central Germany and Switzerland. There is a US subsidiary, a UK middleware company and a Berlin business.

**Price performance**

%	1m	3m	12m
Actual	5.9	16.6	(0.8)
Relative*	2.1	7.7	(20.5)

\* % Relative to local index

**Analyst**

Dr John Savin

## Stratec Biomedical (SBS)

**INVESTMENT SUMMARY**

Stratec designs and manufactures sophisticated automated instruments, and crucially, software for global companies like DiaSorin and Siemens. Year to date Q313 revenues were €90.4m with EBIT of €13.4m, 14.8%. In Q3, EBIT rose to 16.2%. This was helped by reduction of the service part order backlog after the water ingress in May. The three subsidiaries are doing well, with only the US optical business reporting a ytd loss. Stratec has a full Q4 order book and expects to meet or exceed its €127m minimum revenue guidance, revised after a July contract cancellation. The guided 2013 EBIT is a range of 14.0-15.5%.

**INDUSTRY OUTLOOK**

A critical part of Stratec's valuation is growth in construction sales as this covers core costs and grows the profitable service parts business. Innovative products such as the digital Quanterix system (due for clinical launch from H214) may avoid the tough mainstream market. Quanterix's Simoa was launched for research use on 30 July; two other launches have occurred in the last 12 months. A further major design and manufacture contract is expected to be signed in Q413 and will require higher-volume manufacturing investment in the Swiss site.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	116.6	27.1	23.7	154.1	21.2	19.4
2012	122.4	22.2	19.4	137.1	23.8	59.7
2013e	131.1	24.6	21.7	147.8	22.1	19.4
2014e	145.7	30.8	28.0	189.6	17.2	23.9

**Sector: Pharma & healthcare**

Price: US\$6.53  
 Market cap: US\$277m  
 Forecast net debt (US\$m) N/A  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**



**Company description**

Sucampo Pharmaceuticals is a US-based company developing and commercialising medicines based on prostones. Amitiza (GI disorders), partnered with Takeda (US) and Abbott (Japan), and Rescula (ophthalmology) are key products.

**Price performance**

%	1m	3m	12m
Actual	8.1	(3.3)	20.0
Relative*	4.0	(7.1)	(3.6)

\* % Relative to local index

**Analyst**

Christian Glennie

## Sucampo Pharmaceuticals (SCMP)

**INVESTMENT SUMMARY**

The expansion of Sucampo's constipation drug Amitiza franchise is reflected in plans to initiate a Phase III programme in paediatric patients, and the start of a pivotal study with a liquid formulation. We estimate FY13 sales (by US partner Takeda) at \$285m, and Amitiza is the only oral drug available for opioid-induced constipation (OIC). Amitiza holds potential from its commercial roll-out in Japan (launched by Abbott Japan in November 2012) and in Europe (directly in the UK and Switzerland; with further partnerships possible). Sucampo launched glaucoma drug Rescula (unoprostone) in the US in February 2013. Rescula is also being studied in Japan in a Phase III trial for retinitis pigmentosa, a significant unmet need.

**INDUSTRY OUTLOOK**

Historical safety issues with using Rx drugs, for c 10m US patients with constipation disorders seeking alternatives to dietary/lifestyle changes and OTC therapies, give Amitiza's established track record (>7m prescriptions over seven years) a key differentiating factor.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	54.8	(17.7)	(19.9)	(41.36)	N/A	N/A
2012	81.5	8.3	6.2	11.61	56.2	39.0
2013e	N/A	N/A	N/A	N/A	N/A	N/A
2014e	N/A	N/A	N/A	N/A	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$4.84  
 Market cap: US\$250m  
 Forecast net cash (US\$m): 6.2  
 Forecast gearing ratio (%): N/A  
 Market: NASDAQ

**Share price graph (US\$)**

**Company description**

Sunesis Pharmaceuticals is US biotech company focused on the development of anticancer drugs. Its lead compound, vosaroxin, is in a Phase III study for relapsed/refractory AML.

**Price performance**

%	1m	3m	12m
Actual	5.2	(19.1)	7.8
Relative*	1.2	(22.3)	(13.4)

\* % Relative to local index

**Analyst**

Jason Zhang

## Sunesis Pharmaceuticals (SNSS)

**INVESTMENT SUMMARY**

Sunesis's near-term investment case depends entirely on the outcome – due in H114 – of the VALOR study of vosaroxin in relapsed/refractory acute myeloid leukaemia (AML). The study has now completed its enrolment of 712 patients. Headline results are due in H114 after reaching 562 events and locking the final study database. Expectations for success in VALOR are high following last year's cohort expansion. Q213 gross cash of \$49.6m is sufficient to H214, well beyond the VALOR study read-out. We value Sunesis at \$438m.

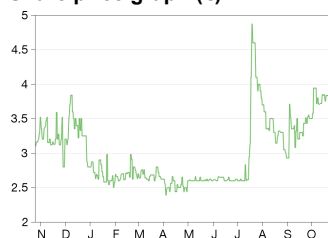
**INDUSTRY OUTLOOK**

Vosaroxin is one of eight agents in Phase III studies for various AML settings, but is the lead compound in the relapsed/refractory setting. The recent failure of Clavis's Phase III study of elacytarabine removes a competitive threat to vosaroxin and confirms that cytarabine will remain the backbone of AML therapy. There is more competition in the front-line AML setting.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (c)	P/E (x)	P/CF (x)
2011	5.0	(25.8)	(26.1)	(56.2)	N/A	N/A
2012	3.8	(31.9)	(33.7)	(56.1)	N/A	N/A
2013e	8.0	(30.8)	(34.0)	(66.1)	N/A	N/A
2014e	8.0	(24.2)	(26.1)	(48.4)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €2.65  
 Market cap: €28m  
 Forecast net debt (€m): 0.9  
 Forecast gearing ratio (%) : 13.0  
 Market: FRA

**Share price graph (€)**

**Company description**

Sygnis is a Spanish/German company developing tools for molecular biologists. Its main focus is in the field of polymerases for the amplification and sequencing of DNA. Its lead product, QualiPhi, is partnered with Qiagen.

**Price performance**

%	1m	3m	12m
Actual	(21.8)	(29.5)	(11.4)
Relative*	(24.6)	(34.9)	(29.0)

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Sygnis Pharma (LIOK)

**INVESTMENT SUMMARY**

Sygnis develops molecular biology chemistry products targeted at the fast-growing DNA analysis and sequencing markets. The core IP is a range of engineered DNA polymerase enzymes, a specialist area where it has leading scientific expertise. The lead product, QualiPhi, has superior activity to the currently marketed phi29 enzyme (global market size: \$50m). It is licensed for amplification of DNA to Qiagen, the global leader in DNA preparation. The first QualiPhi kits could be launched from Q3. A second enzyme for amplification of DNA and RNA and sequencing of damaged DNA, PrimPol, may be partnered in 2013 and may offer more upside in a less-crowded market. A novel protein interaction analysis platform, DoubleSwitch, is also being licensed. The company has just raised €2.7m in equity to fund the continuing operations of the business.

**INDUSTRY OUTLOOK**

The trend towards personalised medicine, technological improvements and scientific advances has resulted in the DNA sequencing market being worth over \$1.5bn and growing at c 20%. Sygnis's products are being developed for this fast-growing market.

Y/E Mar	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	0.0	(0.8)	(0.8)	(11.0)	N/A	N/A
2012	0.2	(1.3)	(1.4)	(18.4)	N/A	N/A
2013e	1.4	(1.8)	(1.8)	(18.7)	N/A	N/A
2014e	2.4	(0.9)	(1.1)	(10.2)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €0.28  
 Market cap: €35m  
 Forecast net debt (€m) 6.7  
 Forecast gearing ratio (%) 19.0  
 Market Euronext Brussels

**Share price graph (€)**

**Company description**

TiGenix produces cell therapeutics. Its lead Phase III development candidate, Cx601, treats perianal fistulas in Crohn's disease. ChondroCelect is approved and sold direct in the EU for knee cartilage repair.

**Price performance**

%	1m	3m	12m
Actual	16.7	7.7	(66.3)
Relative*	14.1	(1.3)	(72.5)

\* % Relative to local index

**Analyst**

Dr John Savin

## TiGenix NV (TIGB)

**INVESTMENT SUMMARY**

TiGenix has pruned core costs to invest in marketing to get extra Spanish and some UK sales. R&D (€6.7m) fell 9.6% as the Cx611 Phase IIa trial ended, but may rise in 2014 if further studies are initiated. Administration fell 20% to €2.5m. Cash operating expenses for FY13 (R&D, admin, sales) are expected to be €16m. Net cash outflow after financing is expected to be about €10m. Following the gross €6.5m funding in July 2013 at €0.25/share, TiGenix had €8.9m in cash. This is sufficient to last into H114 before any deals and non-dilutive funding.

**INDUSTRY OUTLOOK**

Sales may reach €5.2m in 2013 given the 55% H1 growth. 2014 sales might be €7.5-9m, which could move ChondroCelect into cash neutrality by H214. Cx601 for fistulising Crohn's disease is in partnering talks and a US deal is possible. This would enable a further trial for FDA approval. Cx611 produced excellent exploratory Phase IIa data in April. Further trials may enable partnering, possibly for refractory rheumatoid arthritis.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	1.1	(14.9)	(14.4)	(21.0)	N/A	N/A
2012	4.1	(13.8)	(14.0)	(17.4)	N/A	N/A
2013e	5.2	(14.5)	(14.8)	(13.2)	N/A	N/A
2014e	7.5	(13.8)	(14.1)	(11.1)	N/A	N/A

**Sector: Pharma & healthcare**

Price: DKK2.59  
 Market cap: DKK371m  
 Forecast net cash (DKKm) 22.7  
 Forecast gearing ratio (%) N/A  
 Market OMX

**Share price graph (DKK)**

**Company description**

Topotarget is a Danish drug development company in the field of oncology. It is focused on developing belinostat with its partner, Spectrum Pharmaceuticals.

**Price performance**

%	1m	3m	12m
Actual	(2.3)	(8.8)	5.7
Relative*	(6.7)	(16.8)	(11.8)

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Topotarget (TOPO)

**INVESTMENT SUMMARY**

Topotarget is only developing belinostat, partnered with Spectrum Pharmaceuticals. The pivotal Phase II trial, BELIEF for peripheral T-cell lymphoma (PTCL), met its primary end point with an overall response rate of 26%, similar to that seen with pralatrexate (Folotyn) and romidepsin (Istodax), approved in the same indication in recent years. Belinostat's safety profile appears to be superior to the latter two drugs. The filing of the NDA has been delayed from Q313 to Q413 to fine tune the submission, but the clinical data mean it is increasingly likely that Topotarget will receive a \$10 milestone and 1m Spectrum shares in Q114 for acceptance of the filing and a further \$25m in H214 for the approval of belinostat in PTCL. Topotarget has sufficient funds to operate into H214 without the expected milestones after raising DKK26.5m in April.

**INDUSTRY OUTLOOK**

Topotarget's belinostat is a histone deacetylase inhibitor (HDACi). Two drugs have been approved and c 10 others are in clinical development. Belinostat has a favourable safety profile and could be the first HDACi approved for solid tumours in combination therapy.

Y/E Dec	Revenue (DKKm)	EBITDA (DKKm)	PBT (DKKm)	EPS (DKK)	P/E (x)	P/CF (x)
2011	65.6	(28.0)	(31.2)	(0.22)	N/A	N/A
2012	2.4	(77.6)	(80.2)	(0.60)	N/A	N/A
2013e	2.2	(42.7)	(45.7)	(0.32)	N/A	N/A
2014e	1.3	(44.9)	(45.5)	(0.32)	N/A	N/A

**Sector: Pharma & healthcare**

Price: €9.55  
 Market cap: €304m  
 Forecast net cash (€m) 0.7  
 Forecast gearing ratio (%) N/A  
 Market Euronext Paris

**Share price graph (€)**

**Company description**

Transgene is a French drug discovery and development company focused on the treatment of cancer and infectious diseases with immunotherapies. It has four products in Phase II development.

**Price performance**

%	1m	3m	12m
Actual	3.4	(3.3)	24.8
Relative*	1.5	(10.5)	(0.7)

\* % Relative to local index

**Analyst**

Dr Mick Cooper

## Transgene (TNG)

**INVESTMENT SUMMARY**

Transgene is approaching a key time. TG4010 is in a Phase IIb/III trial in non-small cell lung cancer, which could lead to Novartis exercising the option to in-license the drug at the end of FY13, following data in Q413. Unfortunately, its second drug Pexa-Vec (an oncolytic virus) has just failed a Phase IIb trial in hepatocellular carcinoma. A detailed analysis of all of the Pexa-Vec data from nine trials in total is underway to decide on how or whether to develop Pexa-Vec further. Its pipeline also includes TG4040 in Phase II for HCV and TG4001, which should start a Phase IIb study in HPV-related head and neck cancers in Q413. Transgene has formed a long-term production collaboration with Sanofi to enable it to become a fully integrated pharmaceutical company within four years. It has sufficient cash to operate to the end of FY14.

**INDUSTRY OUTLOOK**

There is considerable interest in immunotherapies - both therapeutic vaccines and oncolytic viruses, especially for the treatment of cancers - after the approval of Provenge and Yervoy. They are generally well tolerated and are showing promising levels of efficacy.

Y/E Dec	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	14.4	(42.1)	(42.9)	(137.1)	N/A	N/A
2012	13.1	(39.4)	(42.4)	(136.4)	N/A	N/A
2013e	13.4	(44.9)	(48.2)	(152.4)	N/A	N/A
2014e	11.9	(46.6)	(49.2)	(154.9)	N/A	N/A

**Sector: Pharma & healthcare**

Price: US\$10.71  
 Market cap: US\$274m  
 Forecast net cash (US\$m) 125.3  
 Forecast gearing ratio (%) N/A  
 Market NASDAQ

**Share price graph (US\$)**

**Company description**

Verastem is a biopharmaceutical company focused on discovering and developing novel drugs that selectively target cancer stem cells (CSCs). Its lead drug is VS-6063, a FAK inhibitor, currently in Phase II testing.

**Price performance**

%	1m	3m	12m
Actual	(16.7)	(28.2)	30.5
Relative*	(19.9)	(31.0)	4.7

\* % Relative to local index

**Analyst**

Jason Zhang

## Verastem (VSTM)

**INVESTMENT SUMMARY**

Verastem continues to make impressive clinical progress with the official initiation of the pivotal trial, COMMAND, of defactinib in second-line mesothelioma, and the start of the Phase II trial in KRAS-mutated NSCLC. Together with ongoing Phase I/II trials in ovarian cancer, these trials could generate clinical results, if positive, that will add value to the stock. We value the company at \$425m or \$15.3/diluted share.

**INDUSTRY OUTLOOK**

Verastem is a leader in the discovery and development of drugs that selectively target CSCs. It established a proprietary screening and assay platform and through it discovered CSC-specific targets and compounds. Its pipeline includes VS-6063 and VS-4718, two FAK inhibitors, and VS-5584, a PI3K/mTOR dual inhibitor.

Y/E Dec	Revenue (US\$m)	EBITDA (US\$m)	PBT (US\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2011	0.0	(13.7)	(13.7)	(10.57)	N/A	N/A
2012	0.0	(32.2)	(32.0)	(0.68)	N/A	N/A
2013e	0.0	(36.7)	(36.6)	(1.38)	N/A	N/A
2014e	0.0	(37.8)	(37.7)	(1.29)	N/A	N/A

**Sector: Pharma & healthcare**

Price: 28.8p  
 Market cap: £127m  
 Forecast net cash (£m): 70.6  
 Forecast gearing ratio (%): N/A  
 Market: AIM

**Share price graph (p)**

**Company description**

Vernalis is a UK development-stage pharma company with a late-stage US cough cold pipeline, and an early to mid-stage R&D pipeline of CNS and cancer projects. Its primary focus now is to build a US-based commercial business for the former.

**Price performance**

%	1m	3m	12m
Actual	0.0	38.6	16.2
Relative*	(2.6)	35.1	(1.5)

\* % Relative to local index

**Analyst**

Franco Gregori

## Vernalis (VER)

**INVESTMENT SUMMARY**

Vernalis's outlook hinges on the development of a range of prescription-only cough cold formulations for the US market. An NDA filing for the first product, CCP-01, is likely in mid-2014, suggesting approval ahead of the 2015/16 winter cough and cold season. Vernalis's strategy to also realise value from the drug development and research units is bearing fruit, with progress on a number of fronts. Tight cost control, coupled with a healthy cash balance of £85.7m at H113, means Vernalis is funded through to expected profitability.

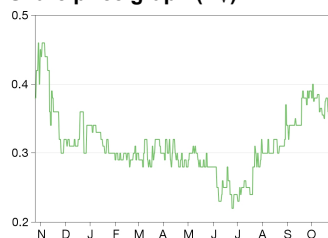
**INDUSTRY OUTLOOK**

Vernalis is pursuing a strategy that aims to create value directly from its legacy R&D portfolio and research expertise, as well as through M&A/in-licensing that should enable it to achieve financial self-sustainability over the medium term.

Y/E Dec	Revenue (£m)	EBITDA (£m)	PBT (£m)	EPS (p)	P/E (x)	P/CF (x)
2011	12.2	(6.0)	(6.3)	(3.4)	N/A	N/A
2012	14.6	(2.6)	(4.7)	(0.8)	N/A	N/A
2013e	13.0	(7.2)	(7.6)	(1.1)	N/A	N/A
2014e	12.0	(10.4)	(10.7)	(1.8)	N/A	N/A

**Sector: Pharma & healthcare**

Price: A\$0.35  
 Market cap: A\$31m  
 Forecast net cash (A\$m): 0.2  
 Forecast gearing ratio (%): N/A  
 Market: ASX, OTCQX US

**Share price graph (A\$)**

**Company description**

Viralytics is an ASX-listed biopharmaceutical developing virus applications using a common cold producing virus to target late-stage melanoma. The Phase II CALM trial is evaluating administration of lead candidate, Cavatak.

**Price performance**

%	1m	3m	12m
Actual	(10.3)	18.6	(9.1)
Relative*	(12.2)	10.6	(23.5)

\* % Relative to local index

**Analyst**

Chris Kallos

## Viralytics (VLA)

**INVESTMENT SUMMARY**

The US Phase II CALM study of intratumoural Cavatak in advanced melanoma has met its primary endpoint early, with a promising 33% response rate. The study remains on track for full enrolment in Q413 and should render final data by end 2014. Positive CALM data pave the way for a randomised Phase II study in late-stage melanoma and should increase partnering interest. Separately, the Phase I/II STORM study of intravenous Cavatak in advanced solid tumours is expected to start in Q413 following UK regulatory approval. Our valuation remains at A\$61m.

**INDUSTRY OUTLOOK**

The emergence of targeted and immunotherapy agents in recent years is redefining the treatment paradigm in metastatic melanoma. Recent positive mid- to late-stage clinical data for oncolytic virotherapy (including Viralytics' Cavatak) are raising hopes of regulatory approvals and commercial reality for this class of anti-cancer agents.

Y/E Jun	Revenue (A\$m)	EBITDA (A\$m)	PBT (A\$m)	EPS (fd) (c)	P/E (x)	P/CF (x)
2012	0.9	(4.6)	(4.3)	(6.4)	N/A	N/A
2013	2.5	(3.9)	(3.7)	(4.5)	N/A	N/A
2014e	1.7	(5.1)	(4.9)	(5.6)	N/A	N/A
2015e	2.2	0.2	0.1	0.2	175.0	188.6

**Sector: Pharma & healthcare**

Price: €1.17  
 Market cap: €37m  
 Forecast net cash (€m) 2.8  
 Forecast gearing ratio (%) N/A  
 Market FRA

**Share price graph (€)**



**Company description**

Wilex develops therapeutic and diagnostic products for cancer. Lead development programmes are Redectane, Rencarex and Mesupron. Its Heidelberg subsidiary sells novel anti-cancer toxin-linker chemistry.

**Price performance**

%	1m	3m	12m
Actual	(2.4)	(11.1)	1.4
Relative*	(5.9)	(17.9)	(18.8)

\* % Relative to local index

**Analyst**

Dr John Savin

# WILEX (WL6)

**INVESTMENT SUMMARY**

H113 cash was €12.9m; H1 cash flow was €10.7m, so Wilex has cash into 2014 before deals or project funding. Partnering of Mesupron is essential to progress the project. Redectane for kidney cancer imaging should enter a second US Phase III once funding is secured. The Heidelberg Pharma subsidiary offers novel chemistry links between antibodies and therapeutic payloads and is expected to grow from the FY12 revenues of €1.9m. Under a licensing agreement with Roche covering development of a novel class of antibody conjugates, Heidelberg will receive upfront milestone and royalty payments for each candidate selected for further development. Wilex has retained Burrill Securities to assist in project financing across all projects.

**INDUSTRY OUTLOOK**

Analysis of the ARISER 864-patient Phase III Rencarex data has shown a disease-free survival advantage with a hazard ratio of 0.51 in patients with a high CAIX score (over 2.6). A further Phase III will be required and a new global partner will be sought. The US diagnostic subsidiary has been divested for the repayment of a \$2.5m loan and a single-digit royalty. This will remove overhead while giving a CAIX diagnostic for the proposed Rencarex study.

Y/E Nov	Revenue (€m)	EBITDA (€m)	PBT (€m)	EPS (c)	P/E (x)	P/CF (x)
2011	11.7	(12.8)	(13.6)	(65.8)	N/A	N/A
2012	16.1	(6.2)	(7.4)	(21.9)	N/A	N/A
2013e	13.6	(5.9)	(6.7)	(20.0)	N/A	N/A
2014e	5.0	(17.4)	(18.3)	(58.5)	N/A	N/A



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