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Navigating the Lifesciences Labyrinth

Healthcare Equipment & Services	Latest	F'cast
P/E	21.51	18.02
PEG	2.42	2.00
Pr/Revenue	25.35	n/a
Pr/Book	6.6	n/a
Pharmaceuticals & Biotechnology	**Latest**	**F'cast**
P/E	85.48	31.96
PEG	5.12	6.24
Pr/Revenue	125.1	n/a
Pr/Book	7.17	n/a
FTSE All Share	**Latest**	**F'cast**
P/E	53.07	18.85
PEG	4.01	4.19
Pr/Revenue	17.75	n/a
Pr/Book	3.58	n/a

Source: Digital Look

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The lifesciences sector is often uncorrelated with market sentiment; with both defensive elements and high risk biotech binary plays sitting side by side in the same sector. There are many different drivers and variables in the sector; whether it be the regulatory environment, investor sentiment or the political backdrop and endorsement to the general R&D industry as a whole. Some may say these points are prevalent amongst other sectors too, but I would argue not to the extent of how the biotech sector is swayed.

AIM has been somewhat kind to the sector so far in 2014 with some of the market's best performing shares being from the Life Sciences stable – 4D Pharma (DDDD) and Tiziana Life Sciences (TILS) both delivering over 200% gains to investors since their IPOs earlier in the year. Investors have also been supportive of the sector in the secondary market with sizeable amounts raised from both RetroScreen Virology (RVG) raising £33.60m and Benchmark Holdings (BMK) raising £70m. In contrast the Main market's newest addition to the sector, Circassia (CIR), raised c£200m from investors which has had a muted performance since its March 2014 IPO.

When observing the mechanics behind biotech deals there has always been a certain degree of "sheep mentality" when gauging investor appetite. And quite rightly so, the market needs biotech specialist investors (whom are largely made up of medically trained professionals) to cornerstone these deals and give the wider investor universe some degree of comfort over the credibility of the company they are looking to invest in. Companies in the retail, engineering, support services sectors, for some example, have the luxury of a visible P&L, some sort of balance sheet, customer contracts and cash forecasts – all of which can provide a degree of credibility and assertion behind an investment proposition.

With many of the aforementioned, they are considered somewhat of a luxury when reviewing biotech companies. Instead, investors are greeted with stem cell technologies, small molecule therapies, tissue engineering and biomarkers to name but a few; only to be left to the conundrum of how to value the market potential of these areas. Without the presence of a biotech specialist investor on the shareholder register, it has been very difficult for companies to raise meaningful amounts from the market.

The frustration does not end there, there has long been an aura of envy amongst corporates and investors when drawing comparisons on the biotech sector between US and the UK. UK biotechs often remark that their company is "only" valued at £50 million market cap when their direct peer in the US is valued at just shy of £1 billion market cap. UK investors were somewhat hesitant to ride the biotech wave that has been ever present in the US, and this was perhaps somewhat justified over the summer when the Federal Reserve relayed their concerns over the level of valuations the sector was attracting. This scornful reception for the much loved sector wiped nearly $40bn off NASDAQ's biotech index and the sector has been slow to recover since.

It is a sector that offers few certainties, such as the failed AbbVie/Shire takeover. But maybe this wide spread uncertainty is the attraction? As demographics are forever changing amongst private client broker portfolios, there will always be investors looking for alpha and ten baggers in their portfolio.

And this is where we arrive at our "biotech conundrum" because the life sciences sector in its current state presents investors with a classic chicken and egg situation. Specialist investors who cornerstone the biotech deals need liquidity in the market to get comfortable but the usual providers of that liquidity will not participate without the comfort of a specialist investor.

By Niall Pearson

Economic outlook

Mark Carney in his November quarterly update reported seeing no material impact on UK business confidence. He also reported that wages looked set to rise above the rate of inflation for the first time in five years. Meanwhile inflation (CPI) is running at 1.2% well below the target 2% and with commodity prices falling, rate hike expectations would appear to have been pushed out towards the second half of 2015 which all sounds like we are ready to go to the party… except that he also reported the UK as importing "dis-inflation" from Europe. Looking across the North Sea, the European Commission has recently cut its woefully optimistic growth forecast for the Eurozone to 0.8% (from 1.2%) for this year and to 1.1% (from 1.7%) for 2015 citing a continuing weakness in France and Italy. Many pundits still argue that this is still too optimistic. Marco Buti, Director General of the Commission's economics department said, "…We see growth … coming to a stop in Germany… protracted stagnation in France and contraction in Italy…" The ECB has remained reluctant to get the QE bat out, but Mario Draghi is now apparently considering buying government debt, and maybe even other asset classes, to complement the €300bn fund to invest in projects to 'get the economy going'. A positive step certainly, but it seems that without wholesale political and economic reform recovery, it will still be a long time before any positive results can be felt. The UK, US and others may be ready to go to the party, but the EU has not even gone upstairs, let alone decided what to wear.

To what extent any of this macro stuff impacts the UK Life Science sector is moot. However there is estimated to be around £600m of "EIS/VCT" money still trying to get invested which might yet be important. At the moment, most of that money is looking for businesses with revenues which excludes much of the small cap Life Science sector. A year ago it was only interested in companies with earnings. In a year's time (when even more money has been raised in March) who knows? Maybe some life science companies can get a meaningful share of this investment pool. This is important. For small companies "EIS/VCT" money is often the bridge between start up/angel investors and the main stream institutional investors, and the absence of it in the Life Science sector could perhaps be seen as part of the problem for the smaller biotechs who inevitably struggle to get to a size where they can be invested in by institutions.

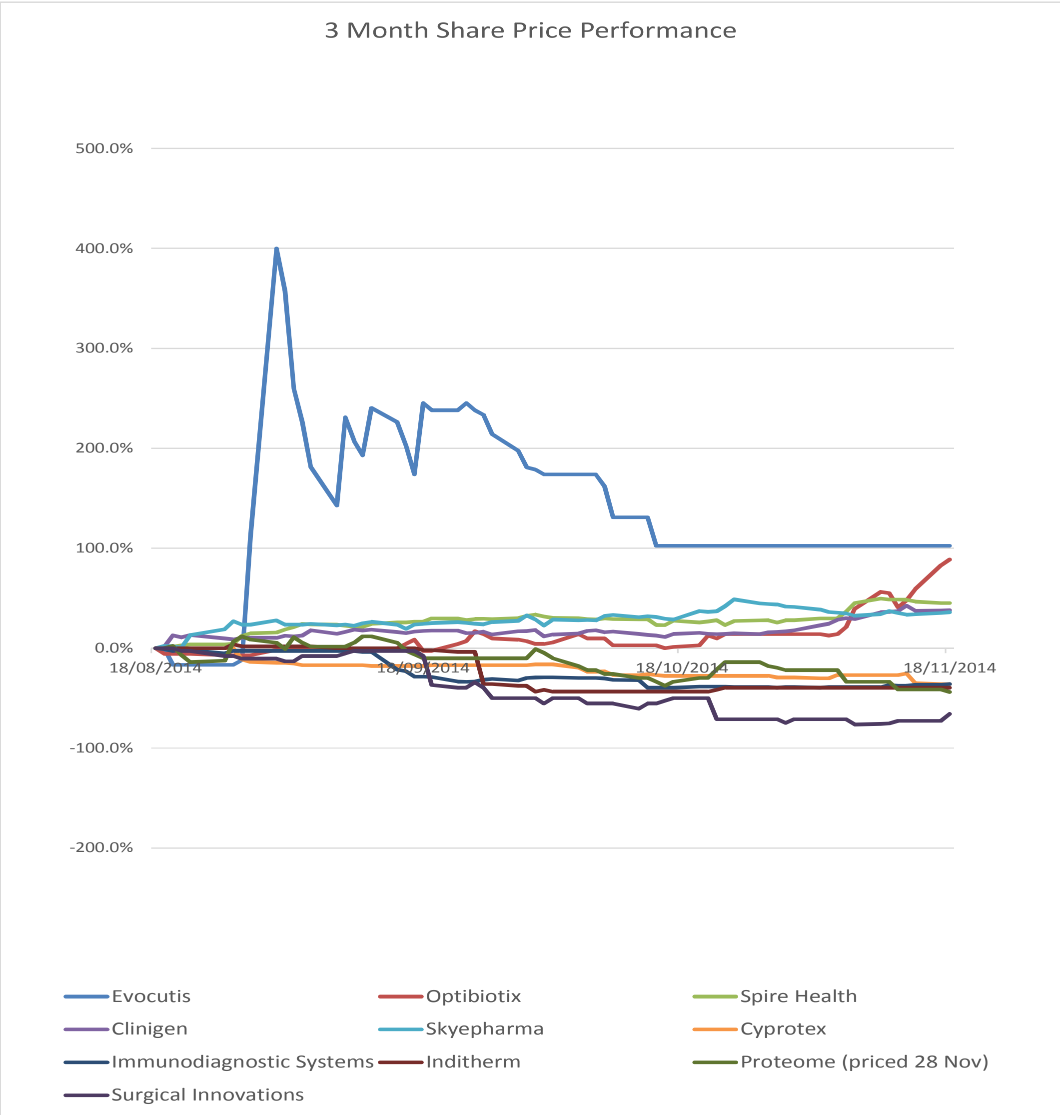
Meanwhile, there have been some very successful deals this year which will also attract more interest from investors currently on the side lines. Oxford Bio-medical's $90m (headline) deal with Novartis and Adaptimmune's $350m (headline) deal with GSK have shown that deals can be done even in the smaller end of the market. Coming to market this year, Circassia Pharma (CIR), Horizon Discovery (HZD), and C4X (C$XD) are IPOs that have struggled a bit in the aftermarket. Cambian (CMBN), Tiziana (TILS) and Optibiotix (OPTI), on the other hand, have all gone very well, and on balance the overall result is positive.

By William Lynne

Top 5 risers and fallers

As at 1535 on 18 November 2014	*3 month Share price movement*
Evocutis	102.38%
Optibiotix	83.10%
Spire Health	45.14%
Clinigen	37.54%
Skyepharma	35.08%
Cyprotex	(35.77%)
Immunodiagnostic Systems	(36.48%)
Inditherm	(39.62%)
Proteome *(priced 28 Nov)*	(36.25%)
Surgical Innovations	(72.63%)

Source: Fidessa



Source Fidessa

Top 5 Risers

Evocutis (LON:EVO 0.425p/£1.48m 3mth +102.38%)

Following on from the disposal earlier in the year of LabSkin™, SYN1113 and related assets Evocutis is now essentially a cash shell. LabSkin™ is a living skin equivalent model system which seeks to emulate normal human skin. LabSkin™ is a full thickness 3D cell culture model which offers a platform for non-animal cosmetic testing, clinical microbiological experimentation and in vitro skin research. It was developed at the University of Leeds, and became the Group's property when it acquired the entire issued share capital of Leeds Skin on 24 May 2011. SYN1113 is a compound which was developed for cosmetic use in controlling acne and other skin blemishes. SYN1113 was the most advanced of the Company's compounds. It completed several clinical and consumer use tests in the period 2010 to 2012. On completion of the disposal, Evocutis was granted 864,706 shares in AIM listed Venn Life Sciences Holdings. At the General Meeting in September a string of Board changes were announced including the appointment of smallcap veteran David Lenigas as executive chairman. The GM approved a subscription at 0.12p raising £210k, and a change in investment policy encompassing projects in the natural resources sector.

OptiBiotix Health (LON:OPTI 16.75p/£12.1m 3mth +83.1%)

OptiBiotix Health develops compounds which modify the human microbiome - the collective genome of the microbes in the body - to prevent and manage human disease. Its development pipeline consists of compounds seeking to tackle obesity, high cholesterol and diabetes. At the IPO in August the Company raised £3.3m at 8p. Since then OptiBiotix has signed an agreement with the University of Reading for the commencement of human studies on its first product, a capsular food supplement to reduce cholesterol. This is in addition to the successful early studies on the Company's weight management formulation in yoghurts, announced at the end of October 2014. The data from the results of these studies will be available by the end of Q3 2015. OptiBiotix has also appointed Dr Sofia Kolida as Head of Research. Dr Kolida's career has focused on the investigation of the role of the gut microbiome in human health and disease.

Most recently the company has announced the appointment of Dr Gareth Barker as Non-Executive Director. Dr Gareth Barker is Vice President of Human Nutrition and Health for DSM Nutritional Products Europe AG, the global science-based nutrition company, within Europe, Africa and the Middle East. Prior to this he has worked in a number of roles for DSM including Global Head of Marketing for DSM's Human Nutrition and Health Division and Sales Director in the Asia Pacific region, with responsibilities including launch strategies for Nutraceuticals. Gareth's career has given him extensive experience and understanding of global markets within the health and nutrition sector.

Spire Healthcare Group (LON:SPI 316.45p/£1.27bn 3mth +45.14%)

The second largest operator in the UK independent acute healthcare sector by revenue with 39 private hospitals and 13 clinics across England, Wales and Scotland was brought to market in July, raising £315m at 210p. The interims to 30 June showed revenue up 10.5% to £417.2m and adjusted EBITDA up 9.3% to £79.9m. The outlook stated that revenue (from all payer groups) and adjusted EBITDA continue to grow rapidly, and there is strong cash flow generation from operations. In September the Competiition and Markets Authority cleared the acquisition of St Anthony's Hospital in North Cheam, Surrey. Spire expects to increase the number of theatres at St. Anthony's from 4 to 6 over time and to achieve a 25%-30% ROCE by 2018. On 6 November Spire issued a trading statement stating that revenue for the full year is expected to be in the range of £825 million to £840 million, and that trading is in line with expectations. All development projects are on schedule and net debt at 30 September 2014 was better than expectations at £435 million. On the same day Spire announced a comprehensive contract renewal with Bupa UK for at least four years.

Clinigen Group (LON:CLIN 545.25p/£450.2m 3mth +37.54%)

On 20 August, the specialty global pharmaceutical company announced the acquisition of the global rights to the oncology support therapy, Ethyol® (amifostine) from AstraZeneca. In 1995, the US Food and Drug Administration (FDA) granted Ethyol a New Drug Application ('NDA') and in 2013, Ethyol revenue was approximately $4.9 million. Under the terms of the agreement, Clinigen will assume full responsibility for the distribution of the product with immediate effect. AstraZeneca, working closely with Clinigen, will continue to manufacture the product whilst the NDA and Investigational New Drug ('IND') authorisations are transferred and the technical transfer to a third party manufacturer is completed. The acquisition will be paid for in milestone related stage payments linked to the transfer of manufacturing. The financial terms of the agreement were not disclosed.

On 18 September, Clinigen launched a new First-in-Class Antibiotic VIBATIV® (telavancin) for MRSA related Hospital-Acquired Pneumonia across Europe. A week later the company's preliminary results to 30 June showed like for like revenues on a constant exchange rate basis up 7.5%. Reported revenues were up by 3% to £126.6m (FY13: £122.6m). Improving margins helped underlying earnings grow 22% to 24.5p and total dividends for the year grew 19% to 3.1p.

On 29 September, the company announced that it had received the FDA's First Ever Drug Shortage Assistance Award in recognition of its contribution in addressing a US shortage of its Foscavir® (foscarnet sodium) injection. Clinigen's efforts related to the US shortage included making Foscavir® available on a named patient basis whilst acquiring the new drug application and submitting post-approval supplements to restart manufacturing with acceptable compliance records. These actions by Clinigen resolved a critical drug shortage affecting patients.

Skyepharma (LON:SKP 338.875p/£355.17m 3mth +35.08%)

On 13 August the expert oral and inhalation drug delivery company acquired the global rights and related intellectual property to a novel inhaled therapy from Pulmagen Therapeutics. Skyepharma will apply its proven expertise in inhaled drug development to develop a first product (SKP-2075) for chronic obstructive pulmonary disease (COPD) through to the completion of a phase II efficacy and safety trial sized to produce clinically significant data. It will then seek to out-licence SKP-2075 to a pharmaceutical partner for late-stage development and commercialisation. Pulmagen will receive a share of Skyepharma's potential future revenues and launch milestones from the successful exploitation of the acquired platform. The Group anticipates spending approximately £14 million to develop SKP-2075 up to completion of the phase II trial.

H1 results to June showed revenues up 10% to £34.4m and operating profit up 187% to £13.2m. During the periodm flutiform® was launched in eight further countries and approved in four more. In September the company’s partner Mundipharma presented the results of a phase III study showing efficacy and tolerability of flutiform® in children aged 5 to <12. In an October IMS, Skyepharma stated that overall trading to date has continued to perform in line with the Board's expectations. As anticipated, revenue during the period has benefited from increased flutiform® supply sales, higher royalties from flutiform® and the new GSK inhalation products and a share of higher EXPAREL® net sales.

Top 5 Fallers

Surgical Innovations Group (LON:SUN 1.625p/£7.9m 3mth -72.63%)

On 19 September, the leading creator of innovative medical technology addressing unmet clinical needs in minimally invasive surgery updated on trading saying that as a consequence of continued reductions in OEM revenues and slower than anticipated revenues from the US dealer network, coupled with the Board's strategic decision to reduce inventories within the customer supply chain, it is anticipated that full year revenue and profit will be significantly below market expectations. The H1 results released in September for the 6 months to June showed revenue of £1.765m down 54.5% and EBITDA of £38k vs £1.1m. An October trading update revealed further asset write downs and that £0.6m of previously recognised revenue would have to be reversed. On 18 November, the company announced a £1.5m fundraising from the company's Interim Managing Director Managing Director Chris Rea and Getz Bros & Co (BVI) Inc through a subscription of £0.526m at 1.3p with the remainder in convertible loan notes.

Inditherm (LON:IDM 4p/£2.04m 3mth -39.62%)

In September the provider of innovative heating solutions for medical and industrial applications reported H1 results to 30 June 2014. Revenue in the first half of 2014 of £998k was almost unchanged on the same period last year, but with a shift in sales mix reducing gross profit by 14%. With overheads increasing by 15%, reflecting planned investment in sales & marketing, the Company closed the period with a loss before tax of £173k. Trading levels in the Medical business in the first half of 2014 were down 20% on the same period in 2013, without the previous year's benefit of large NHS orders and projects carried over from 2012. During the period, Inditherm used its extra resources, added last year, to support the development of the export markets, with extra focus and direction applied towards territories with the greatest potential. In the outlook Inditherm stated that 'the first half performance has been heavily influenced by the capital constraints in the NHS, combined with the demands related to cost saving projects which often affect the priority that Inditherm's proposition is given. Nevertheless we are finding that the more recent publications relating to real case studies in UK hospitals are helping to generate renewed interest in the perioperative sector. This combined with new marketing initiatives and our Managed Service offer gives us encouragement that we can return to a more buoyant sales level in the year ahead, although we do not anticipate that the erratic order patterns will disappear.'

Immunodiagnostic Systems (LON:CRX 312.5p/£91.25m 3mth -36.48%)

The solution provider to the clinical laboratory diagnostic market updated on trading on 14 October saying that it was continuing to see a low level of placements and an acceleration in the decline in manual revenues as well as suffering from unfavourable FX movements. Therefore, it is anticipated that revenues for the year ending 31 March 2015 would be below current expectations and in the range of £45m - £47m, which includes an anticipated adverse currency impact of circa £1.5m compared to 2013/14. The H1 results to 30 September (announced 25 November) showed revenue down 17.8% to £22.1m and adjusted EBIT of £3.2m vs £5.2m. In the outlook Immunodiagnostic Systems stated that the 'near-term trading conditions for the Group remain challenging but we strongly believe that the path to sustainable growth is through execution of the Group's strategic plan. We will continue to pursue our two key objectives of increasing the breadth and depth of our assay menu and launching the Mark II IDS-iSYS instrument and we look forward to keeping shareholders updated on further progress in these areas.'

Proteome Sciences (LON:PRM 23.75p/£60.8m 3mth -36.25%)

On 12 November a trading update was issued by the specialist in applied proteomics and peptidomics offering high sensitivity, proprietary technologies for protein and peptide biomarker discovery, validation and assay development. In the Company's interim results for the six months ended 30 June 2014, announced on 30 September 2014, it was reported that the start date of several contracts expected earlier in the year had been delayed and that it continues to be difficult to be precise over the timing of when the full revenue contribution from these contracts will be reflected. This situation has continued and, as a result, it is anticipated that revenue for the current year will be lower than market expectations and somewhat lower than the revenues achieved in 2013. The delayed revenues referred to above are expected to be reflected in 2015, supported by strong underlying growth in biomarker services and TMT®.

Commercial discussions to outlicense the diagnostic applications for MCI/AD detection have commenced with a number of interested parties who have signed confidentiality agreements. The CK1d dossier has been completed and the process to progress the outlicensing programme with pharmaceutical companies has started. Both are high value applications in Alzheimer's disease and should provide a combination of signature fees, milestone payments and royalties. Proteome expects to have fuller visibility of these in 2015.

Part of Geoff Ellis's role post his September appointment as Finance Director is to manage the commercial sales and marketing activities. He has undertaken a review and implemented plans to drive sales by sharpening the focus on the key services, products and workflows.

The Company's cash position remains healthy with cash at bank as at 31 October 2014 being £1.72m excluding the £0.50m R&D Tax Credit. Proteome is seeing further underlying growth in its pipeline and core technologies and remains confident that this should be reflected in revenues in 2015 and beyond.

Cyprotex (LON:CRX 39.5p/£8.86m 3mth -35.77%)

In August, the specialist ADME-Tox Contract Research Organisation released interim results to June. Revenues were up 19% to £5.4m and the company recorded an operating loss of £584k vs a profit of £317k due to greater depreciation charges, increased R&D activity and one off costs associated with the CeeTox acquisition. In September, Vyprotex launched a new in vitro screening service for determining skin sensitisation using the KeratinoSens™ test method which is a potential alternative to animal testing in the cosmetics and personal care markets. Also in September was the announcement of Cyprotex's membership and its selection as a testing facility in the CiPA (Comprehensive in vitro Proarrythmia Assay) initiative. The aim of the CiPA initiative is to devise new approaches for cardiac safety testing. In October, Cyprotex revealed the expansion of its toxicology capabilities to include high content 3D tissue analysis and advanced mitochondrial toxicity analysis following investment in new instruments.

In the November trading update, Cyprotex stated that the Company has experienced further unforeseen delays with its development work which, coupled with lower than anticipated demand for acquired services, will have an impact on revenues and as a consequence, profitability. Following this, the Company now expects revenues for the year ended 31 December 2014 to be around £11.7 million with EBITDA just above break-even.

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