Lifesciences Review

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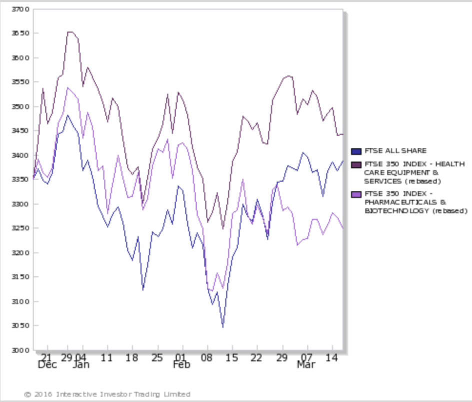

FTSE 350 Pharma & Biotech	**CY2016**	**CY2017**
PE	15.3	14.4
P/Book	5.6	5.5
EV/Sales	3.5	3.4
EV/EBITDA	10.1	9.9
FTSE 350 Health Care Eqpt and Services	**CY2016**	**CY2017**
PE	19.9	17.8
P/Book	2.5	2.4
EV/Sales	0.9	0.8
EV/EBITDA	13.9	11.9
FTSE All Share	**CY2016**	**CY2017**
PE	15.3	14.4
P/Book	5.6	5.5
EV/Sales	3.5	3.4
EV/EBITDA	10.1	9.9

Source: Bloomberg

Down but not out

Stocks in the life sciences industry have struggled to regain their sparkle following the autumn 2015 sell off triggered by Hilary Clinton's comments on drug pricing with the NASDAQ Biotechnology Index down some 22% since the beginning of the year. Indeed both sides of the presidential race have now targeted pharmaceutical companies with Donald Trump campaigning for price negotiations between drug manufacturers and Medicare.

One area of development however that is likely to continue to enjoy premium pricing is orphan drugs/rare diseases where incentives need to remain high to make it worthwhile for developers to bear the risks. **BioMarin (NASDAQ:BMRN)** continues to progress its portfolio and has recently received Orphan Drug Designation for BMN 270, a novel gene therapy for sufferers of haemophilia A, currently in Phase 1/2. Investors in **Sarepta (NASDAQ:SRPT)** will be anxiously awaiting the results of the FDA review of Sarepta's New Drug Application (NDA) for eteplirsen for Duchenne muscular dystrophy due to start on 25 April.

Novel antibiotics represent another area that a swathe of US legislation and initiatives have incentivised since the introduction of the U.S. GAIN (Generating Antibiotics Incentives Now) Act in 2012. Increasing resistance to some of the most commonly prescribed antibiotics is one of the greatest challenges facing modern medicine. AIM quoted **Motif Bio's (LON:MTFB)** lead product iclaprim which already has strong clinical data behind it, is aiming for FDA approval in 2018 and stands to be a powerful weapon in the fight against hospital acquired infections. The company strategy includes plans to develop an oral formulation and in-licence further novel antibiotic candidates.

The relative performance chart depicted on the left shows that the FTSE 350 Healthcare Equipment and Services sector has not only outperformed the equivalent Pharma & Biotech sector but also the wider market over the last quarter. Indeed for the more risk adverse investor, companies such as **Venn Life Sciences* (LON:VENN)**, a growing Contract Research Organisation, with strong levels of contracted revenues offer a smoother yet still compelling growth profile.

Other service providers to the industry such as **Instem (LON:INS),** a provider of IT solutions to the global early development healthcare market are also benefitting from an ever changing and complex regulatory environment. The company recently announced two new contracts for its submit™ solution suite worth a combined value of approximately $0.8million, which will be largely recognised in the current financial year. These contracts have been driven by the FDA's SEND (Standard for Exchange of Nonclinical Data) initiative which was ratified in December 2014 and whose implementation is becoming a market imperative for the entire drug development industry.

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For those looking for companies with likely pivotal news flow in the current year **BELLUS Health* (TO:BLU)** is due to release top line data from The KIACTA™ Phase 3 Confirmatory Study for the treatment of AA amyloidosis completed in Q2, a rare disease for which there is currently no treatment. The shares are up 70% in over the last three months.

Earlier stage players at important junctions include **Sareum Holdings* (LON:SAR)** whose lead Checkpoint Kinase 1 (CHK1) programme targeting lung, pancreatic and other cancers, in partnership with the CRT Pioneer Fund could begin dosing patients in a phase 1 trial the current half year subject to regulatory approval. The shares have performed well of late and are 136% above the price of the last equity placing done at 0.25p last May.

In the broader fight against cancer, the American Society of Clinical Oncology has named immunotherapy, the process of engineering a patient's own immune cells to attack cancer, as its "Cancer Advance of the Year". Companies seeking to bring early drugs to market in this new class include **Amgen (NASDAQ:AMGN)** with AMG319 investigating squamous cell carcinoma, Celgene **(NASDAQ:CELG)** who paid $1bn last June for 10% of Juno Therapeutics and rights to sell its therapies (one of the largest up front licensing deals in the history of the industry) and **Scancell Holdings (LON:SCLP)** who recently raised £3.4m in a placing priced at a 17% discount to the prevailing market price.

Oxford Biomedica (LON:OXB) the gene and cell therapy group has recently expanded its collaboration with Immune Design Corp., a clinical-stage immunotherapy company focused in oncology, as well as a non-exclusive, royalty-bearing, intellectual property licence to Immune Design. The licence involves the use of lentiviral vector-based products for the in vivo treatment or prevention of cancer. The company raised £8.1m in February at 6.3p, a 10% discount to the prevailing share price. We understand that Directors made a material contribution to the fundraising.

Oncolytics Biotech's (TO:ONC) REOLYSIN®'s (oncolytic virus) primary mechanism of action is as a directed cytotoxin in cancer cells with Ras pathway activating mutations thereby reducing tumour burden or size but it has also been shown to upregulate the immune system thereby extending overall survival, making this rather a unique candidate. REOLYSIN® is being investigated for multiple cancers and also in combination with checkpoint inhibitors. Management believes that a drug application could be filed as early as 2018.

Life sciences companies with a diversified portfolio are well favoured by investors, such as **Prometic Lifesciences* (TO:PLI).** Its lead small molecule candidate PBI 4050 is in or heading to the clinic for multiple fibrotic and diabetes related conditions. The latest indication to be targeted is Scleroderma, a chronic fibrotic condition for which there is no cure. PBI 4050 has shown great promise in a preclinical model. The shares have rallied stongly of late, up circa 29% in the last month. We also expect Prometic to achieve progress this year within its pipeline of plasma derived therapeutics. Plasminogen is set to complete a Phase II-III trial under an accelerated pathway protocol agreed by the FDA for Plasminogen deficiency, a rare genetic condition. It is also being investigated for diabetic foot ulcers. At least three further candidates are due to enter the clinic this year.

NASDAQ continues to hold appeal for some companies who feel it is a natural home for Biotechs despite the poor performance of the index of late. Companies including Motif Bio and Prometic Lifesciences are both considering a listing on the technology biased American exchange, and **Hutchison China Meditech (LON:HCM)** has recently launched a $101.25m fundraise via the issue of American Depositary Shares.

GW Pharma (LON:GWP) has had a dual quote on AIM and NASDAQ since 2013. The developer of cannabinoid medicines saw its shares more than double earlier this month following positive results from a phase 3 pivotal study in the treatment of Dravet syndrome - a rare and severe form of epilepsy in children with no FDA-approved treatments.

Although fundraising activity in the sector has been relatively quiet year to date on AIM this is in the context of Health Care and Biotech/Pharma being the most active issuing sector in 2015 raising a total of over $2bn, some 37% of all funds raised on AIM last year. For compelling deals that make good business sense we believe that investors are still willing to reach into their pockets.

One company pursuing the functional food ingredient route, with lower regulatory hurdles, is **OptiBiotix Health* (LON:OPTI)**, whose proprietary platforms place it in a strong position to exploit opportunities to modify the human microbiome for the prevention and management of human disease. It has recently partnered with Manchester University to further broaden the areas of health it is targeting with the jointly owned SkinBiotix targeting multi-billion dollar markets in areas such as skincare and wound care. Elsewhere the Chancellor's sugar levy to be imposed upon sugar-sweetened drinks shines a spotlight on the development of the company's sweet calorie free healthy sugars which are going through taste tests this year.

Other companies exploring the human microbiome include **Seres Therapeutics (NASDAQ:MCRB)** which in January struck a deal with Nestle Health worth up to a total of $1.9bn including an upfront payment of $120m.

The London market has also been the scene of recent major corporate activity with the proposed £441m merger of **Vectura (LON:VEC)** and **Skyepharma (LON:SKP).** The tie-up will create a lung disease group with expertise across different inhaler technologies and a combined market value of more than £1bn. In a presentation to Analysts, CEO James Ward-Lilley suggested that whilst the Vectura share price did not offer the most opportunistic moment to complete the deal, the strategic rationale remained compelling, and therefore the overriding motive for Vectura, the dominant party in the deal who will own circa 58% of the enlarged entity.

A smaller player in the respiratory space, **Verona Pharma (LON:VRP)** has this month announced positive headline data from a Phase IIa dose-finding clinical study using the Company's new proprietary nebulised formulation of RPL554, currently in development as a nebulised treatment for acute exacerbations in chronic obstructive pulmonary disorder (COPD) patients in a hospital or home-care setting. The response was highly statistically significant ($p<0.0001$) at all doses tested. The company now expects a Phase II clinical study examining nebulised RPL554 as an add-on treatment to standard bronchodilators and to report top-line data in Q2 2016.

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