FDA's Breakthrough Therapy Designation (fast track)

The Food and Drug Administration is focusing on getting more drugs to the market. Last year, the FDA started the **Breakthrough Therapy Designation**, providing a fast track for the development and review of drugs for serious or life-threatening conditions.

There are 35 to 40 programs that have received this designation so far. "The FDA is only granting one out of every three programs with this designation, so over the long term it will be a really big deal if a company is to receive that designation in terms of getting the drug to market faster."

Finally, the sector has a prospect of increased M&A activity. While traditionally the big pharmas were the acquirers of smaller biotechs, some biotechs have grown so large that they are now in the market to buy out smaller firms. This creates more competition in the market for the acquisition of those firms.

The two biggest biotech ETFs are **iShares Nasdaq Biotech** (IBB) and **SPDR S&P Biotech** (XBI). Both are very liquid and have reasonable expense ratios, 0.48% of assets for IBB and 0.35% for XBI.

But their compositions are somewhat different.

IBB holds 123 Nasdaq-listed stocks and is a market-cap weighted ETF. It is more diversified, with biotech accounting for 76% of the fund, pharma 17% and life sciences 7%.

Because it is market-cap weighted, its top five holdings are large independent biotechs: **Gilead Sciences** (GILD), **Biogen Idec** (BIIB), **Amgen** (AMGN), **Celgene** (CELG) and **Regeneron Pharmaceuticals** (REGN), each at 6% or 7% of the fund.

By comparison, XBI is made up of 69 stocks, nearly all biotechs. Its top five holdings are **Intercept Pharmaceuticals** (ICPT), **Ariad Pharmaceuticals** (ARIA), **Neurocrine Biosciences** (NBIX), **Sangamo BioSciences** (SGMO) and **Novavax** (NVAX).

The fund is equal-weighted, resulting in a bias toward smaller names, meaning more volatility and higher turnover.

4.2.2014