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On July 15, 2014, on the ceremonial stage of her second Humphrey-Hawkins testimony, Janet Yellen singled out biotech (and social media) stocks for their "substantially stretched" valuations. Since that ex cathedra pronouncement, the Nasdaq Biotechnology Index has rallied by a cool 36%. At the press conference that followed the March 18 FOMC meeting, Peter Barnes of the Fox Business Network asked the chair for a biotech (and social media) valuation update. Was she still bearish? Yellen ducked.

Believe us, we know how she felt. A downbeat item on biotech featured in the Dec. 13, 2013, issue of *Grant's*. From that day till this, the NBI has climbed by no less than 60%. It is up by 13.2% in the year to date even after last week's 5%-plus pullback. For Yellen's information, 109 of the 150 component stocks in the NBI failed to show any positive net income in the past 12 months; the index commands a trailing price-earnings ratio of 429 times.

Now under way is an analysis of a trio of underachieving Nasdaq-listed biotech companies. MannKind Corp. (MNKD), Accelerate Diagnostics (AXDX) and Ironwood Pharmaceuticals (IRWD) are the names under the *Grant's* lens. We're bearish on the lot.

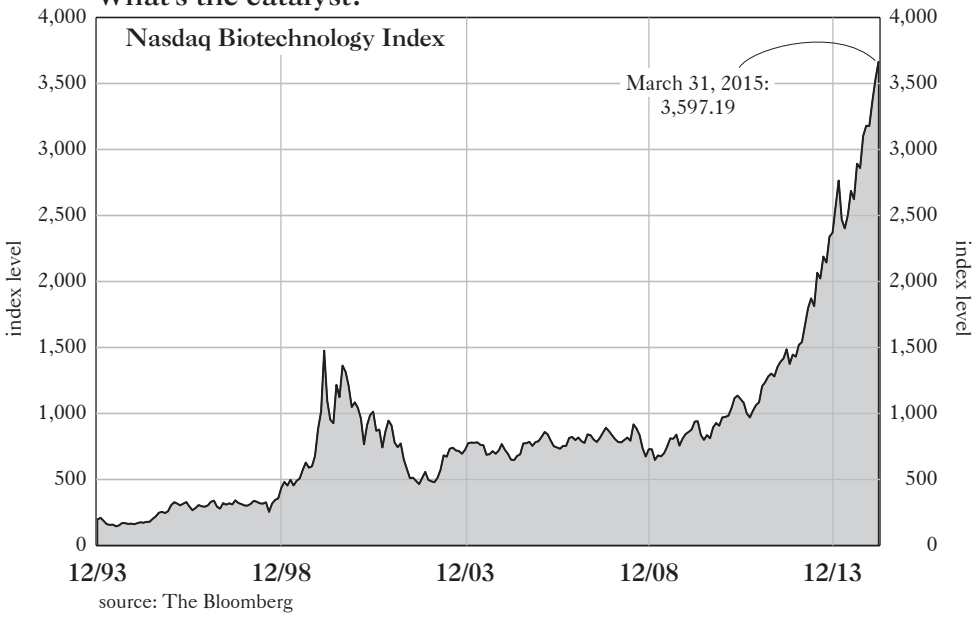
Are we, in our customary focus, perhaps overlooking something more important than familiar concerns of fundamental security analysis? Indeed we are, suggests Asthika Goonewardene, Bloomberg's senior analyst for biotech and specialty pharma. A new cycle of scientific discovery is unfolding.

"Historically," Goonewardene tells colleague Evan Lorenz, "the chance for getting from a Phase II drug to market is less than 50%. The thing is that we've gone through a level of innovation lately where the pipelines of these companies have been delivering. In a way, you could potentially say this sets a new bar for sentiment where people are looking at it and attribute a lot less risk to the pipeline. But have the companies delivered? Yeah. The large cap biotech companies—Gilead, Biogen, Amgen—they have been delivering good data."

Something else is new and different and—for as long as it lasts—bullish enthusiasts contend. The U.S. Food and Drug Administration is flashing the green light on drug approvals more than it once did. Handed a congressional mandate to wave through more novel compounds, the agency has snapped to attention. "We have applied an all-hands-on-deck mentality," John Jenkins, the director of the FDA's Office of New Drugs, says of the new regulatory zeitgeist. New the spirit may be. What is its staying power?

The Washington mind-set is as changeable as Wall Street's. In reaction to Merck & Co.'s 2004 decision to yank Vioxx from the market (the superlative pain killer had been found to raise the risk of heart attack and stroke in a small subset of imbibers), the FDA turned up its level of scrutiny on all new drug applications. "With that in mind," Lorenz relates, "Gilead Sciences Inc. disclosed on March 20 that nine patients taking its blockbuster cures for hepatitis C—Harvoni and Sovaldi—suffered abnormally slow heartbeats when also taking heart medication amiodarone. One patient died." It's not so farfetched that

What's the catalyst?



source: The Bloomberg

the regulatory pendulum could swing back to caution again.

As bureaucrats are susceptible to groupthink, so are investors. Exhibit 'A' in the article of herding is the demonstrated tendency of biotech stocks to rise and (sometimes, when nobody's looking) fall together. Oil and gas stocks logically move with the price of energy. No such fundamental cohesive force can explain the tendency of biotech stocks to trend.

"In biotech, every company has a different drug," an old hand in the sector tells Lorenz. "Every drug has a different mechanism of action. Every company has a different sequence in testing trials. Yet, they move as a herd, but they shouldn't. It is, or should be, 'Your drug works and my drug doesn't.'"

Lorenz described this paradox to Goonewardene. "It is a very M&A and deal-centric sector," the Bloomberg bull said in response. "Last year we had a record year for M&A in the sector and our research also shows it was a very strong year for licensing deals. Whenever these deals happen, obviously the valuations get pumped up. Then you have one particular company doing a deal, then all the companies within a particular space that have similar technology or similar targets, their valuations get bumped."

So, in a sense, the Fed is the catalyzing force. Bubbly stock prices put managements in an acquisitive mood. Ultra-low interest rates facilitate deal making. On Monday, Wall Street rang the bell on health-care transactions in excess of $17 billion. It was the busiest single day for takeovers in the history of the health-care field. Those "substantially stretched" valuations to which the chair alluded can be, in some part, ascribed to the chair herself.

MannKind is first up on our sampling of biotech short-sale candidates. On Feb. 3, 2015, the company, along with distribution partner Sanofi-Aventis Deutschland GmbH, launched Afrezza, the only inhalable insulin product on the market today. Afrezza does, as advertised, deliver insulin—the fast-acting kind that a patient might take at mealtime. What it does not do is to free the diabetic from the ordinary need to administer insulin by injection.

Afrezza may be unique, but it's not without precedent. Exubera, an inhaled insulin produced by Pfizer Inc., came into the world in September 2006. It departed the world 13 months later, leaving Pfizer with a $2.8 billion write-down.

What went wrong? "In short," an Oct. 28, 2007, Bloomberg dispatch reported, "Pfizer made a massive miscalculation about how patients with diabetes manage their disease. What initially attracted the company to Nektar's [i.e., Nektar Therapeutics'] invention was the idea that inhaled insulin would offer an attractive alternative to patients afraid to stick themselves with needles multiple times a day. But the needle sticks really aren't that much of a hassle, many patients report, and the needles themselves have gotten so thin that they cause virtually no pain."

Anyway, there's no getting around a mealtime prick on the finger to test for a patient's blood sugar. Injections may be a hassle. Finger pricks hurt.

To date, consumers would appear to be as skeptical of Afreeza as we are. Only 248 prescriptions (not 248 thousand) for the drug were written last week. "See for yourself," Lorenz suggests: "Just type 'BI PHRM' on a Bloomberg and select 'drug search.' Here you can monitor the demand, or lack thereof, for Afrezza via prescription volumes. This is par for the course for inhaled insulin. In the first nine months of 2007, Pfizer's Exubera only generated $12 million in sales."

As it's no small undertaking to launch a new drug, MannKind has in place a financing deal with its distribution partner. To ensure that the former can stump up its share of the losses, Sanofi has made available a $175 million loan facility priced at 8.5%. In its 2014 10-K report, MannKind discloses that, subsequent to Dec. 31, it has drawn $3 million of the Sanofi line. The year-end MannKind balance sheet shows $28.1 million of net debt.

Flattered by a $2.1 billion market cap, MannKind generated a net loss of $198.4 million, or $0.51 per share, in 2014. It will not produce a profit until 2018, if the analytical consensus is on the beam. "Bottom line, we still remain skeptical that the commercial potential of Afrezza is enough to warrant meaningful upside to valuation," J.P. Morgan analysts Cory Kasimov, Brittany Terner and Whitney Ijem write in a Feb. 24 note. To justify MNKD's current valuation, Afrezza's sales must rise to match the $2.5 billion to $3 billion in annual sales rung up by Novolog and Humalog, the leading mealtime insulin products, the analysts observe. Management would seem to be no more confident than Kasimov et al. Insiders have sold 689,633 shares year-to-date for proceeds of $4.5 million at an average price of $6.58.

Accelerate Diagnostics, candidate No. 2, is a company with a past. In the late 1990s, Accelr8 Technology (as the company then jauntily called itself) was a software developer bent on heading off a seemingly catastrophic Y2K event. The crisis of the computer clocks proved an anti-climax, and AXDX reinvented itself as the developer of a system providing for fast analysis of bacterial infections. The Accelerate ID/AST System would achieve in hours what existing technology required up to three days to complete, so claimed management.

Not until the great biotech share-price levitation did the market deign to take notice. As recently as March 2012, a share of AXDX languished at 77 cents. The price today is $22.50, yielding a market cap of $1 billion.

"The ID/AST System may be revolutionary," Lorenz relates, "but it isn't for that reason marketable. Informed buyers, having had a long look at the product, have chosen not to bite. Thus, on Dec. 13, 2007, Becton, Dickinson & Co. signed an exclusive agreement to develop and sell Accelerate's testing platform. On Sept. 24, 2009, Becton ended the relationship. On June 14, 2010, Novartis Vaccines and Diagnostics Inc. signed a letter of intent with Accelerate to develop AXDX's platform. On Sept. 30, 2011, Novartis, too, walked away."

"So two large companies have already evaluated this supposed game-changing tech, and both walked," Joe Spiegel, managing partner of Jackson, Wyo.-based Dalek Capital Management, who owns puts on AXDX, tells Lorenz. "Total R&D spend for AXDX over the years has been scant, further lending credence to my contention that the tech is worthless, and Becton and Novartis were wise to walk."

Accelerate was more successful as a Y2K software company than as a biotech platform. And it is more successful in marketing its shares than in selling its technology. It issued $45 million worth of stock in 2014, when it suffered a loss of $30.9 million, or 71 cents a share, and $20 million in stock in 2013, when it suffered a loss of $15.3 million, or 41 cents a share. The balance sheet shows $66.5 million of net cash.

Though the insiders have purchased 37,084 shares in the year to date for $671,473, at an average price of $18.11 apiece, the fact is that the company issues more stock than the front office buys.

Ironwood Pharmaceuticals Inc., analytical specimen No. 3, is a one-trick pony. Linzess, a treatment for irritable bowel syndrome, is that pony. To sell it in North America, management has partnered with Actavis plc; in Europe, with Almirall S.A.; and in Asia with Astellas Pharma Inc. and AstraZeneca AB.

Linzess generated $297 million in the United States last year. As for sales outside the 50 states, the company is mum. To judge by a small fourth-quarter inventory write-down on the Continent, European sales, at least, leave something to be desired.

"The partnership with Actavis is something of an odd structure," Lorenz points out. "Typically, when a larger company licenses a drug from a smaller company, the smaller company earns a revenue royalty. With Linzess, Actavis and Ironwood split the bottom line 50-50. From an accounting standpoint, Actavis consolidates 100% of sales and costs on its profit and loss statement. To the extent that Linzess generates a profit, Actavis pays half of that profit to Ironwood, which Ironwood recognizes as 'collaborative arrangements revenue.' In the event of a loss, Ironwood is on the hook for half; the funds it remits to Actavis it records as 'collaboration expenses.'"

It can't be a good sign that discounts to the net price of Linzess deepened over the final three quarters of 2014: to the mid-30% range from 23%. Neither does it exactly instill confidence that management has chosen to suspend future disclosure of the depth of discounting ("gross-to-net adjustments," in industry parlance).

On other operational details, too, management is choosing to shed less light or none at all. Thus, it will no longer say how much inventory is afloat in the wholesale channel (for "competitive and commercial reasons"). Neither will it divulge, as it had until this year, the split in R&D spending between itself and its commercial partners.

Anyway, Cantor Fitzgerald analyst Irina Rivkind Koffler advises Lorenz by e-mail, there's not much to show for those research outlays, which this year are expected to top $100 million. "We have been critical of management with regard to its high degree of R&D spending coupled with low productivity," she writes. "This high spending has necessitated several dilutive financing rounds and has not resulted in any new viable/valuable pipeline assets to date."

"Though the company gives no formal revenue guidance," Lorenz points out, "an indenture pertaining to the Ironwood first lien 11s of June 15, 2024, gives a clue as to what management is anticipating. The fine print directs Ironwood each quarter to pay the greater of 7.5% of net sales of Linzess in the United States or interest accrued. In other words, the bond starts to prepay as sales grow. Ironwood made its first principal payment of $1.1 million in the fourth quarter when domestic Linzess sales totaled $93.8 million.

"For accounting purposes," Lorenz goes on, "companies must classify any liabilities maturing in 365 days or less as short term. Thus, the balance sheet line item 'current portion of notes payable' allows us to calculate the implied level of domestic Linzess sales for 2015. It appears that management expects $415.4 million. This suggests a quarter-to-quarter growth rate of 4.1% for the 12 months of 2015. In the third and fourth quarters of 2014, quarter-to-quarter growth was 27% and 18%, respectively. The implied 2015 growth rates seem especially disappointing in view of a 9.5% price increase that the company put through in January.

"Linzess may face increased competition after 2015," Lorenz continues. "Synergy Pharmaceuticals Inc. expects to complete Phase III trials for something called Plecanatide by the third quarter and file for regulatory approval in the fourth. 'Plecanatide may have similar efficacy to Linzess but with lower rates of diarrhea,' Rivkind Koffler speculates. 'We would expect this drug to be widely used by patients who cannot tolerate Linzess but we don't expect this product to significantly curtail the Linzess opportunity.' That is to say, while the market opportunity for Linzess will not go away, Ironwood may have to settle for a smaller share of the market. Ironwood is testing a lower dose version of Linzess in a bid to mitigate the drug's side effects; it may come to market in 2016."

Altogether, 2016 promises to be memorable. It's the year that the Street expects Ironwood to generate net income—17 cents a share is the guess, compared to the loss of $189.6 million, or $1.39 a share, booked in 2014. It happens that 2016 is also the year in which Synergy expects to deliver its Plecanatide to market.

The times being supercharged, IRWD is trading at 94 times 2016 estimated earnings. The insiders being observant, they've sold 391,637 shares for proceeds of $6.1 million so far in 2015.

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