BioCentury
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3Q15 FINANCIAL MARKETS PREVIEW

TIERS, SOME FEARS

BY STEVE EDELSON, SENIOR EDITOR

With biotech more than six years into a bull run, most of the sector's bankers and buysiders remain comfortable in uncharted waters because generalists are not jumping ship en masse in search of different industries or asset classes. Instead, the specialists expect the generalist crowd will continue to move down into the next market cap tier of biotechs.

This search for performance has one camp of dedicated investors worried that it's going to be hard to justify buying some of the names they like in the $1-$4.9 billion space at current prices. Other specialists, however, cite multiple reasons for why biotech still has plenty of room to run, including the solid financial metrics and upcoming milestones for big caps.

The latter group also contends that industry's underlying science is light years ahead of where it was just a few years ago, and that the eye-popping premiums strategic investors are willing to pay for innovation — especially in the mid-cap space — mean many companies remain undervalued.

They also think good names are being passed over because they are no longer new and shiny, and thus are taking another look at companies that went public in 2013 or early 2014 and are focused on novel areas of biology or novel therapeutic modalities (see "Big News").

"Some people have the attitude that we're in a bubble and are almost accepting of imminent disaster," said Andrew Bogan of Bogan Associates. "Then there are the folks who are still making money and think biotech is the best thing to invest in. I don't think either of those cases is well thought out. There are definitely assets that are clearly overpriced compared to historical trends. But biotechs with cash flows and profits are not unreasonable at all."

Regardless, some bankers are urging companies to get any IPO or follow-on financings done before the end of July. Their rationale is August will be slow and waiting any longer puts companies in a queue that could be jeopardized if the first few deals of September set a negative tone.

PAUSE THEN APPLAUSE

The predicted 2Q15 sell-off arrived on schedule, as biotech indices shed 9% at the end of April. At the time, the consensus among biotech buysiders was some generalists were taking profits.

But the downturn only lasted four days and reversed course when Gilead Sciences Inc. blew the doors off its 1Q15 earnings.

There have been five corrections of at least 10% since the start of the 2009 biotech bull. Each lasted about five weeks, and none have put a major dent in the sector's upward trajectory (see "Raging Bull").

"The biotech indices are still in an uptrend on a weekly basis," said Craig Johnson, a senior technical research strategist at Piper Jaffray. "We've seen pullbacks but the longer-term uptrend is still intact."

Johnson thus does not think biotech indices hit a ceiling on March 19 and again on June 23. On those days, the NYSE's Arca Biotech index (BTK) hit all-time highs (4,243 on March 19 and 4,320 on June 23) and then promptly shed a few percentage points.

"You have support that will come in on the BTK at 4,000," he said.

The BioCentury 100 index added 6% in the second quarter, outpacing the 2% gain in the NASDAQ. The Dow Jones Industrial Average shed 1%.

For the year the BioCentury 100 is up 26%, dwarfing the NASDAQ's 5% gain and the 1% drop for the DJIA in 1H15 (see "Index Performance").

"It makes sense that biotech is still going strong," said Marshall Gordon of ClearBridge Investments. "Generalists have so few areas to get growth."

Ladenburg Thalmann's Edwin Gordon echoed that theme. "At the end of the day, until there's an alternate investment that can generate biotech-like returns, it's a foregone conclusion that you need to be invested in this sector," he said.

Dry power continues to flow into the space, as net inflows for 1H15 more than doubled the amount collected in 1H14 (see "Biotech Fund Flows").

In addition, big biotechs do not appear to be overvalued. The average P/E for the group valued at $5 billion or more was 26.2 (see "BT vs RX").

The average P/E to growth (PEG) ratio was 1.5 for big biotech.

While both P/E and PEG figures edged up from 1Q15, biotech still looks reasonable compared with other sectors where growth investors have played in the past, such as energy and telecommunications.

According to Standard & Poor's data, the PEG for the energy sector is 7.05, while telecom sits at 2.1.

"You want to own the big biotechs," said OrbiMed's Sven Borho. "There are a couple of really interesting product launches coming up from Vertex and the PCSK9 companies and I think expectations for these are pretty modest," so there could be room for upside surprises.

Vertex Pharmaceuticals Inc. kicked off the third quarter by receiving FDA approval for Orkambi lumacaftor/ivacaftor to treat cystic fibrosis in patients ages 12 and older who are homozygous for the F508 mutation in the CF transmembrane conductance regulator (CFTR) gene.

The population represents about 28% of CF patients in the U.S., much larger than prior populations for which Vertex's Kalydeco ivacaftor is approved.

In the PCSK9 space, hypercholesterolemia candidates from Amgen Inc. and the competing partnership of Regeneron Pharmaceuticals Inc. and Sanofi both received positive FDA panel recommendations in the second quarter.

Praluent from Regeneron and Sanofi has a July 24 PDUFA date, while the date for Amgen's Repatha is Aug. 27.

Borho does think the growth rate for the large caps may slow slightly. "Look, Gilead can't do 50% EPS growth every year," he said.

SHEDDING A TIER

The second quarter saw the continuation of a trend that began at the end of last year — big cap performance being overtaken by companies in the $1-$4.9 billion market cap band.

The $1-$4.9 billion group added 7.5% in 2Q15, while the big caps posted a 2.8% gain.

In 2Q15, 71 companies in the $1-$4.9 billion band were up, while 40 declined. For the big caps, there were 24 advancers and 13 decliners.

"The mid-caps are outperforming the large caps," said John Chambers of Roth Capital. "You have a confident investor base because of the financial metrics of the Gileads and Regenerons and Biogens. Those are always going to be safe haven stocks in any given year because of robust sales and stock buybacks. Now, people want to juice their portfolios and are doing so" with the next tier down.

Helping fuel appetite is the price that big biotech and pharma companies are willing to pay to access innovation in the mid-cap space. The two most cited examples were Synageva BioPharma Corp. and Juno Therapeutics Inc.

In May, Alexion Pharmaceuticals Inc. announced plans to buy Synageva for $9 billion in cash and stock. The valuation was more than double Synageva's $3.8 billion market cap prior to the deal announcement.

Alexion gained Kanuma sebelipase alfa, a recombinant human lysosomal acid lipase (LAL) enzyme replacement therapy (ERT) under Priority Review by FDA and accelerated assessment by EMA to treat LAL deficiency. Its PDUFA date is Sept. 8, and an EMA decision is expected this year.

Alexion also received a clinical asset and 12 preclinical programs.

Juno ended the quarter by announcing a massive deal with Celgene Corp. on June 29 to develop chimeric antigen receptor (CAR) T cell and T cell receptor (TCR) therapies for cancer and autoimmune diseases. Celgene paid $150.2 million in cash up front and purchased $849.8 million of newly issued Juno stock at $93, which was a 100% premium over Juno's close prior to the announcement (see "Celgene's Juno Juggernaut").

"YOU WANT TO OWN THE BIG BIOTECHS."

SVEN BORHO, ORBIMED

"I think everybody is looking for the next Juno or Synageva," said Linden Thomson of AXA Framlington. "It doesn't surprise me that the mid-caps have been the best," she added.

Overall, Borho said, "M&A interest will provide support for the mid-cap group. Interest is very, very high, and it's not going to slow down."

"When you see acquisition premiums of 50% or higher it tells you the equity market is mispricing deals on the low side," said Bogan. "You have to assume that the cash buyer has a better sense of what things are worth to their business than the typical financial investor has."

"In the small and mid-caps it's harder to value overall," said Thomson. "I felt the valuations of some were perhaps higher than they should be for their phase of development, but then you have a situation where the public investor says valuations should be X and the strategics pay X plus 100%."

RA Capital's Peter Kolchinsky added to the optimism, noting investors are taking their proceeds from M&A and putting them back to work in biotech.

"The day the Pharmacyclics acquisition occurred, $12 billion of value in the form of cold hard cash was deposited. That buys you a lot of companies in the sub-billion dollar space," he said. "Why do people assume that biotech has to revert to a historical mean? That would require $12 billion of value destruction."

In May, AbbVie Inc. completed its purchase of cancer company Pharmacyclics Inc. for $21 billion, including $12.2 billion in cash and $8.8 billion in AbbVie stock.

"The deal flow is far stronger right now than it was a year ago," said Ashish Contractor, an M&A-focused banker at Greenhill. "The slate of announcements in Q3 and Q4 will be just as strong if not stronger" than it was in the first half.

PRICE TO PAY

Nevertheless, the strong performance in the $1-$4.9 billion group has some buysiders concerned it's going to be hard to find acceptable price points for the names they like.

"The sector still has strong fundamentals but is a bit frothy right now," said Brad Loncar of Loncar Investments. "I've been selling into strength. I sold out of Ultragenyx in June and it's one of my favorite stocks in the whole market. I'm a long-term investor but you have to pay attention to price. Prices can only go so high."

Rare disease company Ultragenyx Pharmaceutical Inc. surged 65% in the second quarter. The company ended June 30 at $102.39 with a market cap of $3.7 billion.

"If I'm convinced the market is too high I'll buy puts on the sector as insurance. I haven't done that yet but it's at the top of my mind and I'm watching it closely," said Loncar.

He expects biotech to plateau for a stretch in the summer, and wouldn't be surprised by a 5-10% drop at some point in the next four to five months.

Oleg Nodelman of EcoR1 Capital worries about over-confidence in the market.

"What I hear is that everyone has figured out biotech — it keeps going up, maybe has a pullback for a week, people buy on weakness and then it goes up again," he said. "The assumption among many investors is that if something untoward happens, they'll see it before everyone else and will adjust. That's scary."

The problem, said Andy Smith of Mann Bioinvest, is generalists are going to end up owning clinical-stage stories and may not be prepared to handle trial failure rates.

"Investors didn't sign up for an 85% chance of failure, they signed up for success," he said.

"It's a part of investor behavior I've never agreed with — the notion that big biotechs like Gilead are too expensive so they go for something cheaper. If you really want growth, go to pharma," said Smith, who considers Gilead a pharma company for all intents and purposes.

"We're always extremely selective and we're being even more so in what we'll take risks on in this environment," said Nodelman. "I'll pass on opportunities knowing full well I might have to pay more down the line. If I'm looking for the next Amgen or Gilead or Celgene, who cares if I miss the first double?"

Other buysiders are not convinced public biotech valuations are out of whack.

"Some people point to how much the biotech sector has soared, but I look at it differently," said Kolchinsky. "I look at how much critical, valuable science is out there. There are remarkable clinical-stage assets compared to 2008. You have beta thalassemia patients who appear to have been cured. You have many targeted agents in cancer that are yielding durable responses. You have long Kaplan-Meier survival curves from immuno-oncology."

He added: "It's hard to justify why biotech needs a correction. If you look at biotech today and where it is with the science and did a bottoms-up analysis of every single company, you'd find a few overvalued and a few undervalued. But it's that way all the time. Does it mean the sector is overvalued? No."

"The sector has heated up because it's working again," said Bogan. "We actually are producing new and important drugs that modify disease. It sounds mundane but we really weren't doing that for the better part of a decade and it was getting scary."

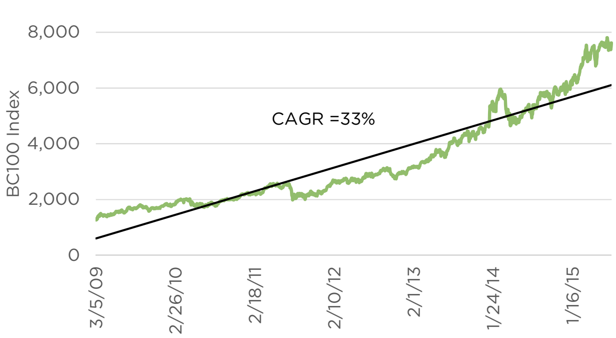
"I think there is support for higher levels of valuation in biotech, but I won't position my portfolio around that," said Marshall Gordon of ClearBridge. "I continue to look for data catalysts."

NEW ISSUES

On the heels of the sector's best-ever first half for IPOs and follow-ons, bankers expect a slightly more measured pace of offerings.

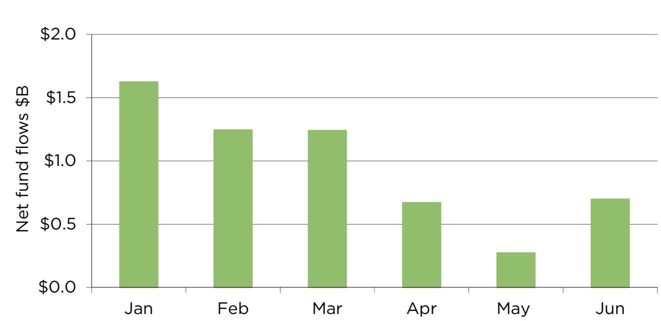
RAGING BULL

The biotech bull market now stands at 6.4 years, longer than any bull run since BioCentury created the BioCentury 100 index in the early 1990s. The next longest run, in 2003-08, stretched 5.4 years. The 1998-2000 run, leading up to the peak of the genomics bubble, lasted 1.5 years. *Source: BCIQ: BioCentury Online Intelligence*



BIOTECH FUND FLOWS

About $1.6 billion flowed into biotech funds last quarter, bringing total net inflows for the first half to $5.7 billion. This compares with $2.8 billion of net inflows in 1H14. The BioCentury 100 is up 26% in 1H15. *Source: EPFR Global*



In 1H15, the industry raised $24.1 billion in IPOs plus follow-ons. The first half of 2014 is a distant runner-up, with a total of $11.2 billion.

"There's activity across the board — from large follow-ons to IPOs to a healthy PIPE market," said Chambers. "We also have a lot of stability because investors are discerning, particularly with IPOs."

The banker did say the IPO market might slow down. "When you add 150 more companies, the finite number of funds in the market are going to need time to digest," he said.

"I THINK EVERYBODY IS LOOKING FOR THE NEXT JUNO OR SYNAGEVA."

LINDEN THOMSON, AXA FRAMLINGTON

The IPO space had perhaps the sector's most talked about — and polarizing — event of 2Q15: Axovant Sciences Ltd.'s $362.3 million offering. The company, with a single asset on the cusp of Phase III to treat symptoms of Alzheimer's, garnered a postmoney valuation of about $1.5 billion, then doubled on its first day.

The rocket ship had the general media and even some biotech specialists claiming biotech was in a bubble.

"Axovant was a high-flying thing that created a weather pattern unto itself," noted Sean Cessna of JMP Securities, one of the company's underwriters. "We saw generalists coming into that."

"Axovant is an example of people wanting to take risk and investing at any valuation that management decided to put on the book," said Nodelman.

Overall, the basket of biotechs that went public in 2Q15 performed better during the quarter than both the biotech indices and the broader markets (see "IPO Performance").

The 27 offerings that priced in 2Q15 were up a median of 10%. By comparison, 22 deals priced in the first quarter, and are down a median 3% for the year.

"We've raised more in IPOs this year than in 1H14, and the average size of IPO raises is 20-30% larger than the year prior," noted Ladenburg's Edwin Gordon. "It certainly appears there is a market and it remains receptive."

For IPOs and other types of financings, Chambers' advice is to move now.

"If you're going to do something, try for the end of July. August tends to dry up from a liquidity standpoint and after Labor Day it's all dictated by the first few deals that get done," he said. "A mispriced deal or bad after-market performance will set the stage for what people have to draft behind."

In Europe, Paul Tomasic of RBC Capital Markets expects more companies to pursue local IPOs rather than heading overseas to NASDAQ. The reason, he said, is U.S. listings generally are preceded by a crossover round that "takes time and introduces market risk."

Said Tomasic: "European companies are asking whether they should take the dilution twice — once in the crossover and then when they go public. Alternatively, they could go public in Europe later this year and use that as a stepping stone to the U.S. market."

MINOR MACRO CONCERNS

Among the bankers, buysiders and VCs contacted by BioCentury, none were overly concerned that macro issues — such as turmoil in Greece and China's stock markets and an impending gradual rise in interest rates in the U.S. — would derail the sector's performance or the ability of companies to tap the markets for capital.

"Interest rates are not a problem," said Loncar. "The important thing is the trajectory of rate hikes and [Fed Chair Janet] Yellen has reiterated that it's going to be gradual — it's not going to be like 5% a year. A gradual change is not going to make a huge difference in asset classes and is not going to make investors think 'now I can get a huge return in cyclicals above and beyond biotech.'"

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"Science won't slow down if a correction hits," said Kolchinsky. "With biotech as well capitalized as it is, many companies will still be able to run trials full speed ahead."

Similarly, VCs contacted by BioCentury were not worried about gradually rising interest rates affecting their ability to raise funds or seek exits for their companies.

MPM's Luke Evnin summed up the thinking: "Going from zero to something low doesn't cause a headwind," he said.

"Everyone is raising on three-year clips and there are a number in that window right now," said Atlas' Bruce Booth.

All biotech investors are starting to turn their attention to the 2016 presidential election in the U.S., although none said they are ready to change how they invest based on any political grandstanding about drug prices.

"We can't quite ignore it completely," Bogan said. "It's hard to see how any likely candidate in the current pool from either party would be worse than a lot of the rhetoric coming from the current administration."

But, Nodelman noted, "it's not a partisan issue and nobody will disagree — it's like kissing babies. To me it has the potential to be an overhang on the sector." bc

COMPANIES AND INSTITUTIONS MENTIONED

AbbVie Inc. (NYSE:ABBV), Chicago, Ill.
Alexion Pharmaceuticals Inc. (NASDAQ:ALXN), Cheshire, Conn.
Amgen Inc. (NASDAQ:AMGN), Thousand Oaks, Calif.
Axovant Sciences Ltd. (NYSE:AXON), Hamilton, Bermuda
Biogen Inc. (NASDAQ:BIIB), Cambridge, Mass.
Celgene Corp. (NASDAQ:CELG), Summit, N.J.
Gilead Sciences Inc. (NASDAQ:GILD), Foster City, Calif.
European Medicines Agency (EMA), London, U.K.
Juno Therapeutics Inc. (NASDAQ:JUNO), Seattle, Wash.
Regeneron Pharmaceuticals Inc. (NASDAQ:REGN), Tarrytown, N.Y.
Sanofi (Euronext:SAN; NYSE:SNY), Paris, France
Ultragenyx Pharmaceutical Inc. (NASDAQ:RARE), Novato, Calif.
U.S. Food and Drug Administration (FDA), Silver Spring, Md.
Vertex Pharmaceuticals Inc. (NASDAQ:VRTX), Boston, Mass.

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