

STREET SCIENCE

Buoyed by unprecedented success in hepatitis C, the biotech and pharma sectors had a strong 2014. And to hear ace Evercore ISI analyst **Dr. Mark Schoenebaum** tell it, everything's in place for growth in 2015 and beyond. Here, he takes both a look back and a look forward

Give us your 2014 headline for biotech and pharma.

It was the year of launch executions. You saw the launch of hepatitis C from Gilead and the continued launch of Biogen's Tecfidera. But if you want one headline for 2014, it was the hep. C launch, which was the best launch of all time for any drug by far. Gilead just smothered it. They beat the iPhone even. They're going to do something like \$12 billion in 2014. It's just \$1 billion short of being the biggest drug of all time in its very first year. That's never been done before.

So we can probably guess your pick for company of the year.

It'd have to be Gilead. I mean, I've never seen a launch like that. Gilead was the best biotech but [Eli] Lilly was the best pharma and no one thought it would be a year ago. They had some pipeline hits.

At the same time, what happened with hep. C raised more questions about pricing and, specifically, about whether payers will start pushing back...

That unearthed all kinds of questions about the sustainability of drug pricing. The question was whether payers would become more sophisticated in terms of controlling drug pricing or not. Back in March, the world thought that the payers would. That's when [US Rep.] Henry Waxman wrote a letter to Gilead, and Express Scripts started making noise and Gilead fell to 65 and whole sectors, especially on the biotech side, fell totally out of bed. Since then, the sec-

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tors have almost doubled from those levels. You can see how bad things can get when people worry about drug pricing. That's something that people are going to pay a lot of attention to next year.

Which other therapeutic categories enjoyed a strong year?

We learned a lot about immuno-oncology, probably the biggest thing in drug development right now. I don't know what I said last year, but I probably would have said that last year, too (laughs). People are and were hyperfocused on developments across

the big four immuno-oncology companies: Merck, Bristol-Myers, AstraZeneca and Roche. It's the biggest innovation we're seeing right now.

What were some of the stealth hits, for lack of a better way to put it, in 2014?

Everyone asks, "What's the new large-cap going to be?" In 2014 it was Vertex. Vertex had good data on their doublet CF Program for Delta F508 heterozygous patients. It is now a \$30-billion company—the size Gilead was before they went with hep. C and the size Biogen was before Tecfidera. There is no longer any question of whether they'll be profitable. It is now a question of how profitable they will be.

How about the flip side of that last question—what companies didn't have as good a year as you expected?

I thought Pfizer would be a better stock than it was. Pfizer went after AstraZeneca and that seemed to surprise a lot of people. Personally,



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I'm not sure people should have been surprised, but nonetheless the street felt like Pfizer did a poor job preparing people for that eventuality. People felt like it was a 180-degree reversal of their strategy. I would tend to disagree with that but that's the way the market felt. It seemed to tick off shareholders.

Another thing that happened this year is that Bristol-Myers' lead in immuno-oncology shrank. They are still the leader in my opinion and they are clearly the leader at least in lung cancer, which right now is the biggest market, but their lead shrank. I think that was inevitable. Other than that there weren't too many letdowns. It was a good year.

You brought up Pfizer's pursuit of AstraZeneca. What level of M&A activity can we expect in the year ahead?

You know, the same stuff. You'll see one or two big deals a year and half a dozen small deals. People overthink that, I think.

What else is top-of-mind for you as we head into 2015?

In addition to watching clinical data unfold from the oncology agents, we will also begin to pay attention to actual sales numbers for these drugs. This will move from sort of a science experiment to a commercial experiment. We will have to keep an eye on drug pricing there, too, because these are going to be really expensive drugs.

So the pressure around pricing will remain consistent?

I think the hep. C market will be held up as kind of the case study for drug pricing. Anything that happens in hep. C is going to obviously affect the hep. C stocks but it's going to affect multiples across

biopharma, period. It's going to be extrapolated to all drug pricing. Also, everyone is preparing for the launch of biosimilar Epogen next year, which is going to be fascinating to watch because it plays on the same theme: What's going to happen with pricing?

Who are your companies to watch in 2015?

In terms of big-time data events that transform companies, like hep. C did to Gilead or immuno-oncology did to Bristol, it's probably Biogen and the anti-LINGO antibody. They will have their phase-two data for that in January. If it happens to be astonishingly positive data—it would have to be clearly positive, unassailable positive data—that would be transformative for Biogen. Biogen also has an Alzheimer's antibody that we'll see data for around January. That's more of a long shot, but if it happened to hit it would be utterly transformative as well.

And Pfizer again—the valuations imply they'll never invent another drug in our lifetime. I think the management team is very clever and will act to move the stock higher over the next year or so. No one else is watching them right now, but I think they're the ones to watch.

How about therapeutic sectors?

There will be a laser focus on lipids. Mainly that's Regeneron with their partners Sanofi and Amgen in the PCSK9 antibodies. Those will go in front of the FDA panel and likely be approved, and we'll probably see the launches in the second half of 2015. There's going to be a very robust debate among investors about how big this class is going to be. I've seen estimates of anywhere from \$2 billion to \$20 billion. No one agrees on how many people are going to be willing to inject themselves for cholesterol management. ■