

HIGH SCIENCE, HIGH STAKES



THINKSTOCK

The year 2015 may have lacked a hall-of-fame debut on par with 2014's hep.-C launches, but the year featured its share of intrigue in the form of sky-high valuations forcing big organizations to adjust their M&A approach and more. In this Q&A, **Jon Gardner**, deputy news editor at EvaluatePharma's EP Vantage, reads the tea leaves and hands out some awards—including Company of the Year honors for a controversial candidate

MM&M: When you look back on 2015, what are the first things that come to mind?

Jon Gardner: What I see is a lot of strategic uncertainty. You have these high valuations on the biotech side making it very difficult for Big Pharma to make the acquisitions it would like to make. There's some frustration, absolutely. Whenever one of my colleagues or I ask somebody, "Are you ready to start buying again?" the reaction is typically, "No, not yet, maybe soon." I think they're hopeful that there's a shift about to happen but nobody is ready to take the plunge.

What M&A activity can we expect in the year ahead? The inversion issue appears to have died down a bit ...

In terms of inversions, with all the attention from politicians, companies don't seem to be quite as eager to give this a try—with the

exception of Pfizer, I guess. They don't think the timing is right. I think there are expectations that corporate tax law will change, maybe in 2017 or 2018, in a way that makes [inversions] more of a viable possibility in their minds.

Is that to say that we'll sort of be in wait-and-see mode for M&As?

Oh, of course not. Companies with one product, those small specialty pharma companies, are still a target. I'd point to the example of Sprout Pharmaceuticals, which got FDA approval for the female sexual dysfunction drug Addyi and then was acquired by Valeant. They were an interesting target—we can have an argument over whether that's going to be a successful drug or not—but those are the type of companies in the M&A game right now. They get approval or get close to approval, then they find themselves as hot properties for bigger specialty pharma companies like Allergan.

What were the big successes in 2015? What therapeutic categories had a quote-unquote good year?

To me the single biggest standouts were the PCSK9s, Repatha and Praluent. They got to market and they got to market pretty cleanly—maybe they didn't get as clean a label as they'd like in the US, but the initial uptake was very good. Category? The PD-1s and PD-L1s in oncology. There's also been a burst of interest in all things immuno-oncology, especially combining the PD-1 projects with all kinds of things—vaccines, oncolytic viruses, small molecules—to get a multiplicative effect.

What were the letdowns?

There was a sense with some companies of, "Hey, we gotta refill the pipelines. Everything we did prior to the [patent] cliff is running out." Biogen and Roche—I thought they were unstoppable but they had to pull back and do some restructuring. The biotech investors have had a spectacular run, but suddenly we've seen sort of that stall. What we're not seeing is valuations fall to a place where Big Pharma feels it can make some deals.

How about specific products or categories?

The good-cholesterol-raising drugs—we've now had three of these that have failed in trials with tens of thousands of patients. That's millions and millions of dollars gone and just one of those projects left to go. It's quite astounding that they have produced nothing. In Alzheimer's, it's a little of the same thing with the amyloid-beta-fighting drugs. It's not happening yet. There's reason to be very disappointed in what the pharma industry has done so far here.

But that's kind of the price of doing business, no?

The industry can't avoid spending on R&D. The game is where it's spent—whether it's in big-cap pharma or outsourcing to smaller

companies who do the developing. If R&D spending is an issue for somebody, the new idea is that they can spin out a promising project that they don't necessarily want to do themselves but still regard as worthy. For cases like that, Big Pharma is saying, "Okay, we're going to send you out on your own. If [the product] looks good in Phase II, we'll buy you back."

What therapeutic categories do you think will have Wall Street's attention this year?



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I think insulin—diabetes—will be closely watched. The way the basal insulin market has turned into this huge price competition over the past year is worrying a lot of people. I don't see any slowing down with orphan drugs. Every time I turn around I have to learn about a new rare disease that somebody has a new treatment hypothesis for—which is great, obviously. From a drug developer's perspective, a company that has a really exciting candidate in an area where nobody else is—that's always going to attract a lot of attention.

Award time. What's your pick for 2015 company of the year?

I scratched my head over this one for a while. You know how *Time* doesn't always give Person of the Year to somebody who's doing good for the world? Sometimes they give it to somebody who affects the world in a negative way. So I'm going with Valeant. They defined or personified so much of what happened in the industry this year. That's because of their acquisitive presence—their activity in M&A forced so many companies to be aware of what their strategy really was, whether they wanted to be bought out by Valeant or defend themselves from Valeant—and because of what happened when their practices came to light and received so much notice. It shone a light on some of the more unsavory things that a few companies in this

business have been known to do.

How about a pick for a company to watch in 2016?

I decided to go in the direction of advanced therapies for cancer: Kite Pharma and the other CAR-T companies. This is the year we're going to see emerging data. Right now we have nice theories and hypotheses, but this year we'll get more hard, clear analysis of whether [these drugs] will work scientifically and a clearer idea if they will work commercially. So that's my call on the biotech side. On the big-cap pharma side, how about Novo Nordisk? They'll have five or six launches during the next year or so. I mean, they've got so much going on, they're going to have to sideline [diabetes drug] Ryzodeg in the US because they don't have the capacity right now—because there are so many other promising things they're doing.

That's not a bad problem to have.

Ha—yeah, not bad at all. They simply cannot move it higher up on the priority chain for two years. Amazing. —Larry Dobrow