Abbvie is buying Allergan – but not for its antibiotic franchise. They are more interested in Botox and other esthetic products that provide the vast majority of Allergan’s revenues. Abbvie has been out of the antibiotics area for 20 years. Allergan has been trying to sell its antibiotic franchise (that includes the North American rights to ceftazidime-avibactam) for over a year now without success. It looks like Abbvie has solved that little problem for them. The big question is, now that Abbvie will take over, what will happen to ceftaroline and ceftazidime-avibactam. Stay tuned.

Moving on. Since the vast majority of our antibiotic pipeline comes from biotech, I’ve been interested to hear from these companies on their reaction to the Achaogen bankruptcy and to the future of their business. This week I had a discussion with a CEO of a publicly held biotech on this topic. For obvious reasons, they preferred to speak “in background.” Our discussion focused on the causes of bankruptcies and what might be done to avoid them. I want to share our discussion with you.

One issue we discussed is the management of investor expectations. In the early days of a biotech, when they are usually privately funded, in order to lure new investors and the money needed to pursue their goals for their products, companies carry out marketing studies to bolster the idea that their products will have value and are therefore worth the investment. In my own experience, such studies are often poorly done and biased to inflate any realistic value of an antibiotic product.

They further do not usually take into account the costs that might be required to actually reach the projected revenues (marketing, sales force, manufacturing, etc). Or, if such costs are cited, they are also often unrealistic. As a company moves from private to public funding via an IPO, they become linked to their prior assessments of market size – or they are simply unwilling to come
back to reality. The investors, it turns out, are not very good at determining market size and costs either – so they often end up with projections that curiously jive with those of the company in whom they are investing. This, ultimately, leads to investor disillusionment and disappointment when a new antibiotic is launched into a distinctly challenging market.

And disappointment means falling stock price. Falling stock price leads to the inability to sustain spending that is required for the product launch and this all leads to a sort of death spiral. If a company has also taken on debt, the problem is further compounded.

In speaking about launch expenses, we entered a discussion of the community vs the hospital market. I remember that during my days at Wyeth, the marketing folks talked about the fact that they felt they had to sell every single prescription in the community. This required a lot of sales reps. Things have changed over the last 20 years. But even with the complicated pharmacy situation today, selling antibiotics in the community market is still very challenging and requires a much larger sales force than that required to sell to the hospital market. During our discussion, I brought up the model pioneered by Pfizer with linezolid. They leveraged the hospital to sell into the community via step down therapy and earlier discharge from the hospital. This worked because linezolid filled a unique niche of high medical need – it was the only orally available antibiotic proven effective in treating MRSA infections at the height of the MRSA pandemic.

But this niche is no longer there. There are a number of products available and linezolid is now generic. Further, for respiratory infections as targeted by Nabriva and lefamulin, the community market will be even more challenging. This will drive up the need for a large sales force and therefore drive up marketing costs. But with a market cap under $100 million, small, publicly held companies will have difficulty succeeding in the marketplace and investors will continue to flee.

To increase the chances of success, companies might do well to stay with the hospital market and to keep their sales force as small as they can while still getting their new product on hospital formularies (I’ll come back to this). Part of succeeding here will depend on price. A development strategy targeting a small population or an antibiotic that can only be used in a small population provides pressure to raise the price. But a high price is a deterrent to hospital formularies and pharmacies. Just look [3] at ceftazidime-avibactam in the US for example. The current DISARM [4] Act seems unlikely to change this calculus significantly, especially given that 70% of US hospitals are under 200 beds. Their ability to buy expensive antibiotics up front while waiting for the rare patient that requires treatment with them will be extremely limited. A competitive price for a product that can be used in a larger population consistent with good stewardship is still probably the best strategy.

The other area where small companies will need to save is in research. Market conditions and squeamish investors will tend to force companies to give up any research and development that is not specifically targeted at supporting the launch of their new product.

Biotech needs to spend much more time thinking about mergers. This would allow a small sales force to effectively sell more than one product. The problem is that the products have to be
viewed by physicians, patients, and pharmacists as adding value. Melinta sells several antibiotics, but they reported a meager $34 million in revenues and $34 million in expenses for the 3rd quarter of 2018 (last available data). These results may partly reflect the large sales force required to sell delafloxacin in the community (I’m guessing here). Melinta also has debt that requires servicing.

But putting several products with modest value together makes sense, especially if they can all be sold in the hospital market. What is one factor preventing mergers? Egos. Many biotech CEOs think that they can build a company based on one or maybe two antibiotic products. But this is probably unrealistic, and some would even say arrogant, given the market conditions today. Antibiotic biotechs must seriously consider merging to increase efficiency.

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