

Will 2019 Bring Positive Signals for the Declining Antibiotics R&D Market?

Dec. 27, 2018 by David Shlaes

Antibiotic R&D has had a particularly bad year starting with The Medicines Company who abandoned their antibiotic R&D efforts and sold their antibiotic assets to Melinta late last year right after getting approval for vabomere. This year both Sanofi and Novartis abandoned their antibiotic R&D efforts and divested their clinical and preclinical assets. Allergan, holder of the North American rights to ceftaroline, dalbavancin and ceftazidime-avibactam, also announced that they would divest their antibiotic assets. I have not heard that they were successful. Achaogen has now undergone two efforts at “restructuring” involving virtually eliminating all R&D and has essentially put up the “for sale” sign just after achieving approval for plazomicin. Finally, Melinta abandoned their antibiotic R&D efforts in the face of miserable sales of their recently launched antibiotics including delafloxacin and vabomere.

For the last decade, we have seen the emergence of biotech as the primary antibiotic discovery and development engine replacing the large pharmaceutical companies that have continued to flee the area. Now, it seems, even biotech has hit the brick wall of the broken antibiotic market.

Tetraphase Pharmaceuticals

Recently, Tetraphase gained approval for eravacycline, a new synthetic tetracycline with activity against resistant pathogens. They have priced the drug such that it will be easier for hospitals to put the drug on their formularies – but their limited label (only for intraabdominal infections) will still limit their sales prospects. Their current market cap is a miserable \$58 million. Will Tetraphase achieve a successful launch in the face of all the other antibiotic launch failures? 2019 will provide the answer.

Nabriva Therapeutics

Nabriva recently submitted two NDAs for two antibiotics. IV fosfomycin for urinary tract infection is used throughout the world but was never approved in the US. Nabriva purchased Zavante Therapeutics to obtain this asset and filed an NDA for complicated urinary tract infection this year. Lefamulin was discovered and developed by Nabriva (I was involved in getting lefamulin through early development) and targets community acquired pneumonia. Nabriva’s second NDA this year is for lefamulin. Nabriva’s current market cap is \$80 million. Once again, 2019 will be the critical year for this emerging biotech

company attempting to launch important new antibiotics.

Merck

What does 2019 have in store for the three large pharmaceutical companies that still maintain antibiotic R&D? This year a new biotech, Prokaryotics, licensed a number of preclinical antibiotic assets from Merck. What antibiotic discovery activity still remains at Merck? I am guessing that this is a minimal effort. At the same time, Merck continues to sell the antibiotics it acquired from Cubist, tedizolid and ceftolozane-tazobactam – but sales have been slow at best. Merck continues its development of imipenem-cilastatin-relebactam at a slow pace. Will Merck continue beyond 2019?

GSK

The antibiotic R&D effort at GSK has teetered on the edge of the precipice for years. A recent announcement that, with a new CEO, GSK will invest more in oncology and immuno-inflammation while continuing to focus on its top therapy areas: respiratory conditions, HIV and infectious diseases. Announcements like these in the past have not been harbingers of good news for antibiotics researchers.

Roche

Roche, the third large pharmaceutical company still committed to antibiotics R&D, like Novartis, has its main research site in Basel, Switzerland. But most of the antibiotic interest in the company comes from its Genentech subsidiary in California. Will Roche follow the Novartis example in 2019 or will Genentech convince management to persevere?

Without large pharma and their deep pockets, investors are more hesitant to invest in R&D projects. Public-private partnerships like CARB-X and others have, to a certain extent, taken on some of the burden from venture capitalists for antibiotic discovery activity. But even well-funded efforts like CARB-X are likely to come crashing into the sharp rocks of the broken antibiotics market and the lack of big pharma interest.

Given the events of the last year and the outlook for new antibiotic launches, I believe 2019 will be the most critical year since most of pharma abandoned antibiotics at the turn of the last century. I fear a catastrophic collapse of antibiotic R&D and commercialization in the absence of government efforts to bolster the broken marketplace for these essential medicines.

