INVESTOR'S BUSINESS DAILY

THURSDAY APRIL 9, 2015

TECHNOLOGY

Superbugs Turn Big Pharma, Gov't Focus To Antibiotics

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INVESTORS BUSINESS DAILY

Late last month, the Obama administration rolled out a five-point plan to combat drug-resistant bacteria, which it said causes 2 million infections and 23,000 deaths in the U.S. alone every year.

A report describing the plan, issued in response to President Obama's executive order last September, noted along the way that antibiotics haven't been getting much love from private businesses.

"Despite the urgent need for new antibiotics, the number of products in the drug-development pipeline is small and commercial interest remains limited," according to the report on the plan, called the National Action Plan for Combating Antibiotic-Resistant Bacteria. "The advancement of drug development — as well as non-traditional therapeutics and vaccines — will require intensified efforts to boost scientificresearch, attract private investment, and facilitate clinical trials of new drug candidates."

People in the industry say that's largely been true for the last decade. But even as those words were being written, things were changing. Increasingly, antibiotics development is attracting big money.

In January, **Merck** (NYSE:MRK) closed a $9.5 billion deal to acquire Cubist Pharmaceuticals, whose blockbuster drug Cubicin treats the Staphylococcus aureus (MRSA) virus, among others. That followed the November acquisition of Durata Therapeutics by **Actavis** (NYSE:ACT) for $675 million, as well as Cubist's own 2013 purchase of Optimer.

Tetraphase, Cempra Jumped

This encouraged Wall Street to see other small companies making these drugs as buyout targets, driving up their stocks. **Tetraphase Pharma** (NASDAQ:TTPH and **Cempra** (NASDAQ:CEMP), both of which are developing products specifically for drug-resistant strains, each have the highest-possible IBD Composite Rating of 99.

Even antibiotics makers like **Dipexium Pharmaceuticals** (NASDAQ:DPRX) and **Foamix Pharmaceuticals** (NASDAQ:FOMX) that are treating less-than-life-threatening conditions have been riding the wave.

According to many in the industry, what's helped turn things around has been something more controversial in other quarters: rising drug pricing.

"As a society, we're pretty comfortable paying $30,000, $40,000 a year for rheumatoid arthritis therapies, or $150,000 for cancer drugs that might extend life by six months or a year, but we're only paying $3,000 or $4,000 for a novel antibiotic that would save the life of someone who's otherwise very healthy," Oppenheimer analyst Akiva Felt told IBD. "There seems to be a growing consensus of stakeholders who are coming together to address this."

The White House plan supports basic research and improved testing and monitoring of existing infections, but doesn't directly address pricing. The government does not have the power to set drug prices itself, but can influence them through the reimbursement policies of Medicare and Medicaid.

That's the target of the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms Act, or Disarm Act, a bill introduced in Congress last year and sponsored by members of both parties. The Disarm Act requires "budget neutrality" for antimicrobial drugs, which would lift the incentive to prescribe the cheapest drug available.

For those companies sinking their money into developing these powerful new antibiotics, the Disarm Act is high on their wish list.

"We'd really like to see the Disarm Act get approved in some form, because helping with antibiotic reimbursement really would be a key thing for getting more appropriate usage, and really encourage companies to be involved in the space," Tetraphase CEO Guy Macdonald told IBD.

While all this may drive up medical costs, Felt notes that one aim of new antibiotic development is to get patients out of the hospital faster than with competing drugs, which could help mitigate costs.

IV Treatments Developed

Tetraphase and Cempra are developing drugs that come in both IV and oral formulations, with the idea that patients are initially treated by IV in the hospital and then sent home with the oral drug once the life-threatening phase has passed. Other companies are developing longer-acting IV drugs. For instance, last year **The Medicines Co.** (NASDAQ:MDCO) won approval for Orbactiv, a version of the antibiotic oritavancin that can treat serious skin infections with a single dose.

The government already has made moves to streamline the approval process for the new antibiotics. Durata's lead product, Dalvance, was the first product approved as a Qualified Infectious Disease Product (QIDP) when the FDA cleared it last May. QIDP was created under a previous legislative initiative to encourage antibiotics, the GAIN Act of 2012, that provide expedited review and five years of market exclusivity for new products treating serious infections. Subsequently, two new drugs from Cubist were approved under the program.

Apart from government actions, however, another question surrounding all this M&A in antibiotics is how committed the acquirers will remain to research and development of new products. Merck has said that next month it will shutter Cubist's discovery center in Lexington, Mass., laying off 120 workers out of the 450 in Cubist's R&D division. Analyst Felt awaits further signs of how big pharmas will handle their new antibiotic projects.

"The key to watch here is what Merck does," he said. "Cubist was by far the industry leader in R&D. They spent a lot of money there. They had a lot of the best and brightest working on problems. Hopefully, Merck continues that development, but it's a little too soon to say what happens."