Antibiotic developer Melinta files for bankruptcy

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Chris Dall | News Reporter | CIDRAP News | Dec 27, 2019

Drug maker Melinta Therapeutics today filed for Chapter 11 bankruptcy, becoming the second antibiotic developer this year to be forced into bankruptcy because of financial problems.

The company said the filing is part of a restructuring agreement with lenders, and that it plans to continue operating while it works to complete the transaction through the Chapter 11 process.

"While we have successfully conserved cash and enhanced revenue over the past several quarters, we nevertheless anticipate challenges in meeting the company's obligations, including near-term compliance with certain covenants," Jennifer Sanfilippo, Melinta's interim CEO, said in company press release. "We are confident that this process will secure new ownership of the business with the financial resources to support the company's antibiotics portfolio and ensure these potentially life-saving products continue to get to patients in need."

The news, which comes 2 months after the Federal Drug Administration (FDA) approved the company's supplemental New Drug Application for delafloxacin for treatment of community acquired bacterial pneumonia (CABP), is not a surprise. Melinta said at the time of the FDA approval that the commercial launch of delafloxacin for CABP would be delayed because of the company's financial difficulties.

Delafloxacin is one of four antibiotics in Melinta's portfolio.

New antibiotics face 'daunting challenges'

The bankruptcy underscores the financial challenges faced by companies developing new antibiotics. Unlike drugs for chronic conditions, antibiotics are used infrequently and for short periods of time. And even though rising antibiotic resistance is threatening the effectiveness of many of the current drugs used to treat bacterial infections, new antibiotics are often held in reserve until older antibiotics fail, so that resistance doesn't emerge. As a result, new antibiotics don't produce enough revenue to be immediately profitable.

The lack of financial return on new antibiotics has led most large multinational pharmaceutical companies to abandon antibiotic development altogether, leaving smaller companies to fill the void. But like Melinta, these companies have struggled to make ends meet.

In April, biopharmaceutical company Achaogen filed for bankruptcy less than a year after the FDA had approved plazomicin, a new antibiotic seen as an important weapon against carbapenem-resistant Enterobacteria infections, which are among the most difficult bacterial infections to treat. While plazomicin hasn't sold well, the World Health Organization recently added the drug to its Essential Medicines List.

Infectious disease and antibiotic-resistance experts say the failure of these small companies, which are developing more than 90% of the antibiotics currently in the pipeline, are further proof of the need for changes in the way that drug makers are reimbursed for new antibiotics.

"The market, if left alone, will not fix itself," Allan Coukell, senior director of health programs at the Pew Charitable Trust, said in a statement. "Companies won't be able to make enough money selling these drugs, they'll get out of the business, they won't draw future investment."

"The bankruptcy announced today by antibiotic maker Melinta once again highlights the daunting challenges facing research and development of new infection-fighting drugs," the Infectious Diseases Society of America (IDSA) said in a news release, adding that the bankruptcy "decreases the likelihood that investors will risk supporting antibiotic research and development and underscores the need for swift federal government support and incentives to ensure the availability of effective antibiotics."

Pew and IDSA are among the proponents of the DISARM (Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms) Act, a bill introduced in Congress in June. The legislation calls for higher Medicare reimbursement for the use of new antibiotics, while also requiring hospitals that receive the increased payments to use the drugs appropriately.

But IDSA and others have suggested that it will take more than reimbursement reform to ensure that drug companies don't give up on antibiotic development. One approach is the creation of a market entry reward, which would provide a sizable up-front payment to companies that develop new, critically needed antibiotics. The idea behind the market entry reward is that it would guarantee companies a sufficient return on investment, even if clinicians keep new drugs in reserve.

"Reimbursement reform is an essential step, but the populations needing new antibiotics should remain relatively small, so novel approaches will be needed to provide a more predictable return on investment for the most urgently needed new antibiotics," IDSA said.

See also:

Dec 27 Melinta Therapeutics press release

Dec 27 IDSA news release