Over the past four decades, a type of bacteria known as methicillin-resistant Staphylococcus aureus (MRSA) has become prevalent in healthcare settings, putting vulnerable patients at risk and imposing a disproportionate economic burden on hospitals. About 30% of people in the U.S. are colonized in the nose with S. aureus, whereas less than 2% of people are colonized with MRSA. But this pathogen poses a serious public health concern because it does not respond to certain antibiotics, such as methicillin and penicillin, and infections can be life threatening. Each year, there are hundreds of thousands of MRSA-related hospitalizations in the U.S., costing hospitals billions of dollars for prolonged hospital stays.

Durata Therapeutics was launched in 2009 to tackle this problem. The goal of the biopharmaceutical company is to acquire, develop and commercialize clinical stage and approved therapeutics to treat infectious diseases in hospitals and acute care settings. At the center of the company’s development program is dalbavancin, a second-generation investigational antibiotic product candidate designed to treat patients with acute bacterial skin and skin structure infections (ABSSSIs) caused by Staphylococcus bacteria, including MRSA, as well as certain types of Streptococcus bacteria.

Enduring effect may cut costs
Dalbavancin has a chemical makeup that is distinct from that of its relative vancomycin. Whereas vancomycin is a glycopeptide, consisting of glycans attached to peptides, dalbavancin is a lipoglycopeptide, which consists of lipophilic side chains attached to glycopeptides. As a result, dalbavancin is significantly more potent and has a longer half-life than vancomycin. Indeed, the company’s name was inspired by the long duration of dalbavancin’s antibacterial activity.

Because of the drug’s characteristics, it only needs i.v. administration once a week rather than twice daily. As a result, patients may have shorter hospital stays or may avoid hospital admission altogether, reducing the cost of care. Moreover, lower re-admission rates would decrease the financial burden on hospitals caused by penalties imposed by Medicare.

“Dalbavancin will significantly impact how patients are treated, where they’re treated and the cost of doing so,” said Durata CEO Paul Edick. “When I found out about this drug, I said, ‘Where do I sign’. I’ve been in this business for 35 years, and you don’t get to change the way doctors practice medicine very often in the pharmaceutical business.”

Controversy spawns opportunity
Four years before Durata was established, dalbavancin was snagged by Pfizer as part of its acquisition of Vicuron Pharmaceuticals. At the end of 2009, Durata got its hands on dalbavancin when it acquired Vicuron from Pfizer for $10 million—a deal that came about because of a hiccup related to FDA approval procedures. In 2006, the FDA was under fire for the way it approves antibiotics—specifically its reliance on non-inferiority clinical trials, which are designed to compare a new drug with a proven drug to determine whether the new drug is less effective by a certain margin. The controversy stemmed from severe and fatal cases of liver injury that were reported in patients taking Sanofi’s antibiotic Ketek telithromycin, which prompted the FDA to remove two of the three previously approved indications for the drug.

In the wake of this controversy, the FDA requested that Pfizer provide additional data for dalbavancin. But in 2008, Pfizer announced that it was globally withdrawing all dalbavancin marketing applications for the treatment of complicated ABSSSIs in adults, including an NDA in the U.S. and an MAA in Europe. “Antibiotic development in 2007 and 2008 pretty much ground to a halt, and dalbavancin was caught in that vortex,” Edick said. “In 2009, Pfizer made a strategic decision to move away from the development of anti-infectives.”

Promising prospects
Once Durata took advantage of this opportunity and acquired Vicuron, it initiated two Phase III clinical trials to test the safety and efficacy of dalbavancin for the treatment of ABSSSIs caused by susceptible Gram-positive bacteria. The company used the new draft guidance on non-inferiority trials issued by the FDA in 2010. So far, the preliminary data are promising. At the beginning of 2013, the company announced that in the clinical trials, two i.v. doses of dalbavancin given one week apart had effects similar to those of vancomycin given twice daily for two weeks. Dalbavancin stopped the spread of lesions and reduced fever within three days of initiation of therapy, and it improved clinical outcomes by the end of treatment. Moreover, Phase I data showed that dalbavancin appeared to be well tolerated when administered to healthy subjects as a weekly i.v. infusion for a total of up to eight weeks.

The company will seek regulatory approval for dalbavancin in the U.S. and then in the EU by submitting an NDA and MAA in the second half of 2013. Edick hopes that dalbavancin will be approved in the first half of 2014, and the company subsequently intends to commercialize the drug in the U.S. and pursue partnerships for commercialization outside North America. Durata also plans to develop and investigate dalbavancin for the treatment of other conditions, including osteomyelitis, diabetic foot infection and pneumonia.

Some may argue that dalbavancin could cost more than currently available antibiotics, but Edick points out the importance of considering the total price tag. “The problem is that those cheap antibiotics that cost pennies can actually cost a great deal of money in order to administer. One of the difficulties we’ve had for decades in the pharmaceutical business is getting people to look at the cost of the total treatment, not just the cost of the drug,” he said. “This is a very unique situation where the branded drug will cost more than the generics, but the cost of delivering it and the cost of treating patients should decrease dramatically.”

As Durata celebrated its one-year anniversary of going public in July 2013, Edick is optimistic about its future and the ability of dalbavancin to not only reduce the exorbitant economic burden of antibiotic treatment on hospitals and Medicare but also help healthcare providers change their business model to offer more outpatient services. “The drug can change the way medicine is practiced,” Edick said. “That happens once in a lifetime.”