Drugmakers have a slew of treatments for afflictions related to sex and drugs. Now they may have one for rock ’n’ roll.

Novartis AG (NOVN) is developing a gene therapy that may reverse hearing loss by stimulating the regrowth of microscopic hair cells in the inner ear, allowing people to hear. The hairs are destroyed by prolonged exposure to loud noise, and don’t take root again naturally. Novartis treated the first patient in October after successful tests on rats.

While hearing loss is most common in the elderly, rates are high in the music industry and the military, and rising among teenagers who listen to music at high volume. Almost 13 percent of children and adolescents under 19 in the U.S. have permanent damage caused by excessive exposure to noise, according to the Centers for Disease Control and Prevention.

“A little too much Lady Gaga,” said Mark Fishman, the head of Novartis Institutes for BioMedical Research, which is developing the therapy. About 36 million people in the U.S. have some form of hearing loss, according to the Basel, Switzerland-based company.

A solution could mean big money for Novartis and GenVec Inc. (GNVC), its partner in developing the drug. Global sales of hearing aids and cochlear implants may reach a combined $9.5 billion globally by 2020, according to San Francisco-based Grand View Research, which provides information on industries including technology and health care.

U.S. Testing

Novartis plans to test its treatment on 45 patients in the U.S., with results expected by 2017, according to a description of the trial on clinicaltrials.gov, the National Institutes of Health’s database of studies. It’s too early to say when the treatment might be approved, Fishman said.

Hearing damage can be caused by regular exposure to sound of 80 to 90 decibels, said Jeffrey Holt, an associate professor of otology at Harvard University. Headphones used with portable music players can deliver as much as 120 decibels, he said in an interview.

“The more we learn about it, the more we realize that the safe levels are actually lower than we thought previously,” Holt said.

The auditory hair cells targeted by the Novartis drug are in the inner ear, where they convert vibrations caused by sound waves into electrical signals that are passed along the auditory nerve to the brain, which interprets them as sound. Excessive noise can harm the cells, as can some cancer treatments, antibiotics and bacterial infections.

Cochlear Implants

Hearing loss is currently treated with hearing aids, which Holt said “simply turn up the volume,” or cochlear implants such as those sold by Sydney-based Cochlear Ltd. (COH) Those devices translate sound waves into signals sent directly to the brain, but aren’t approved for all types of hearing loss. A treatment that regrows hair cells may be better, depending on cost and performance, Holt said.

Novartis gained the medicine, called CGF166, through a 2010 deal under which GenVec, based in Gaithersburg, Maryland, stands to receive as much as $214 million in payments, plus sales royalties.

GenVec “is an undervalued innovator in the gene therapy arena addressing indications with no therapeutic options,” Reni Benjamin, an analyst at HC Wainwright & Co., wrote in a note after clinical trials began. He predicts the stock will quadruple. GenVec is now valued at about $39 million.
Gene Treatments

The therapy uses a disabled cold-causing virus that enters so-called supporting cells in the inner ear, where it delivers its payload -- a gene called atonal-1 that tells the cells to grow into hair cells.

Scientists have been working for decades on using genes to treat maladies including cancer, HIV and blindness, with mixed results. A trial more than a decade ago of an experimental gene therapy cured 17 infants with a rare immune disorder, but caused leukemia in five patients, and killed one. Trial results from a second study, published last year, have shown no signs of leukemia.

Glybera, a treatment developed by Amsterdam-based UniQure B.V. (QURE) for a rare disorder that causes inflammation of the pancreas, became the first gene therapy product approved in Europe, in 2012.

Novartis, which has grown to a market value of about $250 billion by making pills for high blood pressure and cancer, is increasingly investing in cutting-edge technology. It’s working with the University of Pennsylvania on a cancer treatment that involves genetically engineering immune cells, and yesterday agreed to work with Intellia Therapeutics Inc. and Caribou Biosciences Inc., on gene editing technology.

Getting Novartis’s hearing-loss drug into a patient’s inner ear may prove to be the trickiest part of the treatment, according to Fishman. A surgeon must drill a tiny hole in a bone called the stapes, then inject the drug with a needle. It won’t help patients with genetic hearing loss.

While other treatments are being developed to treat hearing loss, by companies such as Amsterdam-based Audion Therapeutics, none have entered human trials, said Harvard’s Holt.

“There is a buzz about it,” said Holt. “Even if this one doesn’t work, just having a platform or a vehicle for delivering genes into the inner ear is an exciting prospect.”

To contact the reporter on this story: Simeon Bennett in Geneva at sbennett9@bloomberg.net

To contact the editors responsible for this story: Phil Serafino at pserafino@bloomberg.net David Risser, Chitra Somayaji