BREAKTHROUGH PROGRAM

MICRONOS

# Micronos


**Founder**
Ahmed Al-Qahtani Ph.D.
KFSH&RC

**Co-Founder**
Reid Rubsamen MD, MS, MHCM
CEO Flow Pharma, Inc.

**Team Member**
Anthony Tufaro, MD
Cleveland Clinic


## Startup Brief

Edura™Gentamicin Microspheres is a first-in-class, therapeutic drug delivery system to prevent surgical site infections (Figure 1). By achieving regulatory approval for clinical testing though FDA and SFDA filings by 2025, sufficient clinical testing could be performed over the subsequent five-year period to have FDA and SFDA approval to market of Edura™Gentamicin Microspheres as first-in-class therapeutic to prevent surgical site infections by 2030. The Edura™Gentamicin Microsphere drug delivery system has been developed through Technology Readiness Level 4. Proof of concept, efficacy, and safety have been demonstrated in laboratory animals (Figure 2). A full-scale manufacturing process for Edura™has been developed in Cleveland, Ohio. The Edura™microsphere drug delivery system is based on the encapsulation and subsequent controlled release of the aminoglycoside antibiotic gentamicin sulfate from a biodegradable microsphere composed of poly(lactide-co-glycolide) (PLGA). Edura™Gentamicin Microspheres are readily scalable using the manufacturing equipment already in place at Flow Pharma's facilities in Cleveland, Ohio. Additional spray-drying manufacturing equipment is commercially available from GEA Corporation in Germany and can be installed and operated anywhere in the world. Edura™customers are healthcare professionals, hospitals, and insurance companies, all of whom seek to lower healthcare costs as much as possible by improving patient outcomes. There are no direct commercial competitors for Edura™Gentamicin Microspheres for surgical site infection prevention.

## Problem

A surgical site infection (SSI) is an infection that occur post-operatively at or adjacent to the site of surgical incision. SSIs are almost always accompanied by pain and inflammation that in turn prevents the wound from fully healing. Patients with SSIs are hospitalized 7 to 11 days longer that patients without infection. SSIs can also lead to increasingly severe complications such as sepsis, organ failure, and death. It has been reported that SSIs account for 20% of all healthcare associated infections and are associated with a 2- to 11-fold increase in the risk of mortality, with 75% of SSI-associated deaths directly attributable to the infection. SSI occurs in approximately 0.5% to 3% of all patients undergoing surgery, and in approximately 6% of patients undergoing spine surgery. In the USA in 2018, the cost of an SSI was estimated to add $20,000 per admission, translating to an annual healthcare cost increase of $3.3 billion. Notably, paying for this increase is very often the burden of the hospital, as many SSI cases are considered to be hospital-acquired conditions and as such may not be covered by insurance.

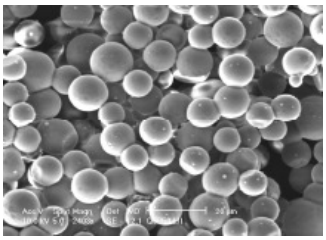

Figure 1. Electron micrograph showing Edura™Gentamicin Microspheres.

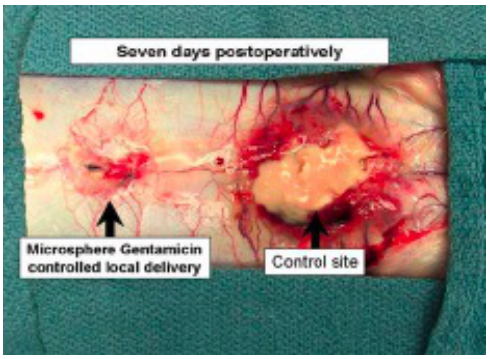


Figure 2. Representative post-mortem rabbit spine image after intra-operative S. aureus challenge of two adjacent spine surgery sites showing significant wound healing differences between a control- and gentamicin-microsphere treated site (1).

## Solution

Edura™was developed to address this unmet medical need. When Edura™microspheres are added to the surgical wound, the biodegradable microspheres slowly begin to dissolve and release the gentamicin into the surrounding tissue spaces, establishing a localized concentration of gentamicin that kills infectious agents such as Pseudomonas aeruginosa and Staphylococcus aureus, two potentially life-threatening bacteria. The Edura™ manufacturing process is completely automated. The microspheres are 100% synthetic, contain no animal products, and are applied to the surgical site directly before closure. Edura™microspheres are also able to release gentamicin when mixed with other wound-healing materials such as collagen and skin glues, supporting the use of combination wound-healing materials. When measured under standard incubation conditions of pH and temperature, Edura™ microspheres release approximately 97% of their contained. gentamicin dose over 14 days, providing long-lasting, localized antibacterial protection.

## Value Proposition

The Total Addressable Market (TAM) for surgical site infection-related products and services is equal to the additional cost of post-surgical wound care in the healthcare system, i.e., the cost of extra surgery, as well as increased duration of hospital stay. For the patient—as well as society—there is additional cost of lost productivity, as well as the intangible-but-very-real cost of the pain and suffering that occurs because of the infectious process. In 2018, SSIs added an estimated $3.3 billion to healthcare costs in the USA. This is the TAM, or the money that goes to pay for these costs. The serviceable available market (SAM), the number of these cases that are able to gain access to Edura™, is estimated to be one-third of those cases, or $1.1 billion. If only ten percent (10%) of this market is actually obtainable (the serviceable obtainable market, or SOM), this equals $110,000,000 -- the amount of money that would be saved in the healthcare system by using Edura™. If Flow Pharma receives only ten percent (10%) of that amount, company revenues the first year after FDA approval would be $11 million (for the US market alone).

## About the research


(1) Stall AC, Becker E, Ludwig SC, Gelb D, Poelstra KA. Reduction of postoperative spinal implant infection using gentamicin microspheres. Spine (Phila Pa 1976) . 2009 Mar 1;34(5):479-83. doi: 10.1097/BRS.0b013e318197e96c.