

Rani raises \$53M to ramp up pre-trial manufacturing efforts

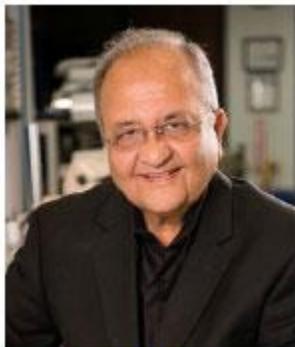
By Michael Fitzhugh
Staff Writer

[Rani Therapeutics Inc.](#), the San Jose, Calif.-based developer of a pill designed to replace injectable drugs for chronic disease, has raised \$53 million to invest in manufacturing and preparation for clinical trials expected to begin within 12 months.

The investment, which follows \$50 million-plus raised two years ago, brings the firm's total raised thus far to \$142 million. New investors in the company include Genescience Pharmaceuticals Co. Ltd., Shire plc, Bossa Ventures and Cathay Venture Inc. They join previous investors GV, the investment arm of Alphabet Inc., Novartis AG, Astrazeneca plc, Ping An Ventures and Virtus Ventures.

The new funds will underwrite the company's construction of largely automated GMP manufacturing process as well as testing of its ability to deliver three internally developed oral delivery programs: one for octreotide, another for parathyroid hormone, and a third for human growth hormone. Success could help the company's intestinal injection technology in the eyes of its partners, Novartis, Astrazeneca and Shire, and lead to licensing of not just the "Ranipill" itself, but the manufacturing process for creating it, enabling more convenient administration of basal insulin, adalimumab, interferon beta-1a, and others therapies, the company said.

Rani spun out from San Jose-based Incube Labs LLC. (See *BioWorld Today*, July 22, 2014, and Feb. 25, 2016.)



Mir Imran, Rani CEO

Patients clearly prefer pills to injections, Rani's CEO Mir Imran told *BioWorld*. Speaking from a colleague's office — he ceded his own to make way for new hires — he said doctors prefer pills, too, because they lead to higher rates of treatment adherence. But

moving into the clinic to prove that Ranipill can deliver on that promise has been challenging. A portion of the manufacturing has to be done in an aseptic environment, a task made easier with automation, but still calling for expensive custom-built machinery. Furthermore, the company has had to look far and wide to find high-quality suppliers for the off-patent drugs it will first put into the pills.

Taking a big step toward tackling those challenges, the company is bringing on Allergan plc's former global head of manufacturing, Ray Diradoorian, as a consultant. It has also hired another Allergan veteran, Wilfredo Ortiz, to lead day-to-day manufacturing operations. For more than 20 years Ortiz has worked in manufacturing operations management, serving as plant manager of Allergan's Fall River, Mass., site and director of operations for the company's Waco, Texas, plant, Allergan's largest aseptic manufacturing site in the U.S. With their help, Imran said he hopes to have production up and running by the first quarter of 2019, if not earlier.

Rani still faces potential competition from multiple companies such as Roseland, N.J.-based Emisphere Technologies Inc., U.K.-based Diabetology Ltd. and Jerusalem-based Oramed Pharmaceuticals Inc., all of which have focused on oral insulin delivery, as well as Chiasma Inc., which is developing octreotide capsules. But Imran is unconcerned, saying that Rani's platform will offer both greater bioavailability and more flexibility to deliver different medicines without costly re-engineering than other platforms.

The many attempts to perfect oral delivery of biologics signify that, "despite the long history of failures, people are willing to try," he said. "If something works, it could be transformative."