

Akston Biosciences raising up to USD 10m to advance COVID-19 vaccine and other products, CEO says

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Akston Biosciences, which is testing a novel COVID-19 vaccine and veterinary diabetes treatments, is looking to raise up to USD 10m in a Series C round to advance product development and gain regulatory approval, said Todd Zion, CEO and co-founder.

Akston is advancing what it calls a “novel fusion protein platform” that can be used in new classes of biologics, including vaccines, long-acting insulins and auto-immune disease. Besides the COVID-19 vaccine and the veterinary insulin products, it is in pre-clinical testing of a novel long-acting therapy for Type 1 diabetes which would be a major advancement in treating the genetic disease if successful, it said.

Beverly, Massachusetts-based Akston’s lead product is AKS-452, a COVID-19 vaccine that is being tested in large Phase 2-3 clinical trials in India and earlier-stage trials in the Netherlands. It is aiming to file for an Emergency Use Authorization in India and Europe this year, which could lead to commercialization in 2024 or earlier, said Zion. It will also target the US market with data from the global trials, he added.

Akston is looking to tap a developing world market that has less access to the COVID-19 vaccines that are sold by the top four vaccine makers – Pfizer/BioNTech, Moderna, Janssen (JNJ) and AstraZeneca. Akston’s vaccine can be stored at room temperature, unlike widely used mRNA COVID-19 vaccines, making distribution less challenging, he said. The vaccine is being developed both as a primary vaccine for developing countries and as a booster vaccine in markets where approved vaccines are in widespread use.

“Because immunity to COVID-19 wanes over time, and because new variants arise, the world will need an ongoing supply of booster vaccines,” Akston said in a press release. “AKS-452 is cost-effective to manufacture at scale and does not require the cold-chain necessary for mRNA vaccines,” calling it “a practical solution to provide necessary protection, especially for difficult-to-reach populations.”

The company has raised USD 55m in previous funding rounds from founders, family offices, wealthy investors and non-dilutive grants from the US National Institutes of Health, the Helmsley Charitable Trust and others. The latest round would likely tap a similar investor base, but it may look for investment by strategics, such as mid-sized drugmakers who may be more interested in a new COVID-19 vaccine than major pharmaceutical companies, said Zion.

“We are always out there talking to strategics, but they are more likely to participate as partners” by licensing products and technology, said Zion.

Akston’s major partnership for its COVID-19 vaccine, branded AmbiVax-C, is with Bengaluru, India-based Strides Group subsidiary Biolexis, which has a licensing, manufacturing and commercialization agreement for over 130 low- and middle-income countries in India, Asia, Latin America and Africa, the company said.

Alston is also partnered with Dechra Pharmaceuticals to commercialize once-a-week canine and feline insulin treatments, dubbed AKS-321d and AS-425c.

Around 160,000 US dogs and cats are diagnosed with diabetes each year, with current therapies including twice-daily injections by owners, a treatment Akston called “onerous and error-prone,” with a significant number of pets being put down within one year of diagnosis, according to Akston’s website.

Zion said the veterinary insulin products are currently in clinical testing and could reach the market by 2024 assuming regulatory approval, a market he estimated at USD 100m-200m a year.

The CEO said an exit strategy is still under consideration while it advances product development and approvals, but would lean towards an initial public offering. A sale to a strategic which is interested in its platform technology and global public health mission could also be considered, he added.

“We want to generate as many opportunities as possible for this engine,” he said, referring to its biologics product technology. “An IPO is probably the best way to do it.”

He said the company has already had initial discussions with investment banks about strategic options, including a public listing through a special purpose acquisition company (SPAC). But he said the company is unlikely to list through a SPAC, given the recent well-publicized fallout in that market.

The company was founded by Zion and a team that developed the world’s first glucose-responsive insulin at SmartCells, a venture-backed company which was sold in 2010 to Merck [NYSE:MRK] for USD 500m.

by Dane Hamilton

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