

InvivoSciences gearing up for FDA application on heart failure drug

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InvivoSciences, a pre-clinical stage biotech firm based in Madison, is gearing up for a potential FDA application for a heart failure drug and companion diagnostic tool.

But first, company leaders plan to meet with officials at the federal agency to get feedback ahead of making any submission. That's according to Ayla Annac, president and CEO of the startup company.

In an interview yesterday, she highlighted a "severe unmet need" for drugs to effectively treat patients for a specific form of heart failure using precision medicine. She noted this approach, which involves matching disease prevention and treatment to specific patients and populations, is already being successfully applied to cancer treatment.

"Similar things need to happen in the heart failure area," she told WisBusiness.com.

InvivoSciences has developed a drug candidate for this purpose, which was identified using the company's existing drug development platform.

"The FDA meeting will not only go for the drug approval, but also for the companion diagnostic that we are developing for the stratified patient population that matches this drug," she said, adding a meeting is expected to occur later this year.

The business is in the process of putting together its FDA application package before the meeting, Annac said. She explained the meeting with agency officials will help company leaders decide whether the drug and diagnostic tool should be submitted together or separately, and if one should be advanced before the other.

She also noted investors in the past decade or so have shied away from investing in cardiac drugs, while focusing more on cancer treatment. That's because heart disease drugs often involve large clinical trials with more patients, according to Annac.

“So there is a very systematic approach [to] who will come to the clinical trials ... We are picking the groups that will benefit [from] the drug most,” she said. “And that is going to increase efficacy, and also reduce the cost of clinical trials.”

The company has already raised about \$10 million to support the creation of its drug development platform. Meanwhile, the current heart failure drug program has an initial development milestone that will cost between \$3 million and \$5 million, she said. InvivoSciences is seeking strategic partners to help with that effort.

“This is a very useful drug that we are developing, or trying to move forward or advance in Wisconsin,” she said. “It will benefit not only Wisconsin patients, but [the] general population in the United States and beyond.”

See more on the company here: <https://invivosciences.com/>

-By Alex Moe