Iowa Startup FBB Biomed Pursues RNA Blood Test to Predict COVID-19 Disease Severity

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NEW YORK – Coralville, Iowa-based FBB Biomed is developing a COVID-19 blood test for RNA biomarkers that it says will be able to predict how severely ill someone infected with SARS-CoV-2 will become from the disease.

The test would "provide physicians an answer to whether the patient is going to proceed to severe disease," CEO and Cofounder Howard Urnovitz said.

"We're not interested in coming up with coronavirus primers, we're interested in being value-added to screening," he said, such as providing information on whether a patient is at high risk for severe disease or even likely to be an asymptomatic carrier. The firm is developing both PCR- and next-generation sequencing-based tests and plans to develop the assays for other indications, as well, including neurologic diseases.

The qPCR and NGS versions will amplify RNA that has been enriched for intronic and intergenic sequences as part of sample preparation. "By doing enrichment we're able to look at critical events associated with acute and chronic disease," Urnovitz said. The firm is targeting 1,600 patient samples for a clinical study now. The study will look at COVID-19 patients, patients who tested positive for SARS-CoV-2 but who did not show COVID-19 symptoms, patients who showed respiratory symptoms but did not test positive for SARS-CoV-2, and healthy controls, including family members. FBB Biomed expects the study to take two months to complete.

Urnovitz suggested that coinfections of other pathogens may be a factor in which patients develop more severe COVID-19, an idea he has held since working on urine-based HIV diagnostics in the 1990s. He is a cofounder of Calypte Biomedical, which offers rapid diagnostic tests for HIV, and is the former CEO of Chronix Biomedical, a California-based firm pursuing NGS-based liquid biopsy tests.

"We're worried about reports of people developing chronic fatigue-like syndromes" after COVID-19, Urnovitz said. "We think that's as important as the initial infection. We want to use NGS to monitor whether someone is going into that."

FBB Biomed launched in 2019 with a focus on developing a blood-based NGS test for RNA biomarkers for neurological disease status. Specifically, the firm is sequencing RNA enriched for intronic and intragenic regions and looking for differential expression that is

associated with multiple sclerosis (MS) flares. The firm pivoted to COVID-19 testing once the pandemic hit the US.

Cofounded with Steven Urnovitz, a clinical lab industry veteran and Howard's brother, and Julien Rey, a business development executive, the company is based in Iowa but operated in a distributed manner. "You've heard of 'other people's money,' we're now pioneers of 'other people's garages,'" Urnovitz said. "I was able to find samples at one site, have labs run them at another site, and do bioinformatics at a third site.

"You couldn't do this 10 years ago," he said. "Capital expenditure [for sequencing] was a high bar. Now you can go over to any university, give them your samples and a Mastercard number, and for $90, you have a whole dataset."

The firm has raised over $400,000 from the founders as well as a friends-and-family funding round, Urnovitz said, and is in talks with undisclosed investors to raise the funds needed to bring the tests to market.

Urnovitz said the firm has not yet obtained patents for its RNA amplification method from whole blood and declined to provide more details. The firm is using Illumina's NextSeq platform but he suggested the method could also be tailored to the Thermo Fisher Scienfic Ion Torrent platform.

In a poster presented at the 2020 Americas Committee for Treatment and Research in Multiple Sclerosis Forum in February, the firm noted its sample preparation method led to about a fivefold reduction in exonic RNA sequences, compared to non-exonic sequences, and in a proof-of-concept study led to the identification of six genes differentially expressed in patients with clinically reported MS flares, compared to stable status. For the study, the firm used Qiagen's Paxgene blood RNA kit.

FBB Biomed has filed for patents on PCR primers, Urnovitz said, and plans to license those, rather than run the PCR test in house and pursue Emergency Use Authorization from the US Food and Drug Administration. However, the firm plans to build a CLIA lab for its NGS test and is preparing a clinical trial to generate data to submit for *de novo* 510k clearance from the FDA, with a test potentially available a year from now. The FDA application could potentially cover non-COVID-19 indications for the NGS-based test, including MS, Alzheimer's disease, Parkinson's disease, amyotrophic lateral sclerosis (ALS), or another virus, which Urnovitz declined to disclose.