



Indiana Shop Wins \$2.3M NIH Grant to Validate Protein-Based 'Wellness' Test

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By Tony Fong

Predictive Physiology & Medicine last week announced it has received a two-year, \$2.34 million grant from the National Institutes of Health to validate a proteomics- and metabolomics-based testing platform it is developing.

PPM said the platform is designed to test protein and metabolite biomarkers and other elements in patient blood samples to yield an overall health evaluation. That evaluation is then packaged into a wellness test, made available to patients through their doctors.

PPM CEO Stephen Naylor said the firm will use the funding to pay for the clinical validation, which is being done in collaboration with the Mayo Clinic and is expected to include samples from 1,000 patients.

The study will evaluate the ability of PPM's platform, called NetFit, to determine a patient's cardiovascular health. The study is expected to begin in a few weeks, Naylor told *ProteoMonitor* this week.

At the same time, PPM is working with a small group of physicians and their patients to evaluate the test, called Viveda Cardio Assessment, said Christa Curtis, marketing communications manager for the company. The company expects this week to receive its first blood sample under that agreement, according to Naylor.

PPM also will be doing a similar doctor-patient evaluation for its Viveda Lifestyle Assessment, a more extensive test that gauges cardiovascular, cerebrovascular, and metabolic health, as well as the effect of stress on health.

PPM plans to launch both tests during the first quarter of 2009, Curtis said.

Personal Proteomics?

Personal genomics-services companies, led by 23andMe, Navigenics, and DeCode Genetics, have been garnering buzz in recent months, but Naylor said PPM is the only company about to offer a health evaluation based on a protein and metabolite profile, stressing that its tests will not be marketed as a direct-to-consumer product.

PPM, which abandoned the protein biomarker-discovery market two years ago, may eventually incorporate genomics into its test, but it currently believes genomics will have limited use as a health measure because genomics offers a "blueprint of what is happening with you as an individual as defined at birth," said Naylor.

"As an example, if you have a genetic disposition to Huntington's [disease], there's not an awful lot you can do with that information with regard to your overall health as associated with that disease," Naylor said. "We made a conscious decision that we would look at analytes that really are reflective of your health today and tomorrow."

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However, he stressed that PPM is not in the business of identifying diseases in patients. Rather, the company provides information to help patients and their doctors figure out where the patient is on a continuum between being a healthy individual and one who could be at risk for a particular disease.

The biomarker aspect of NetFit is done to provide PPM a clearer and more precise view of a patient's overall health, Naylor said.

"Clearly the way medicine is structured at the moment, you tend to think about your health and wellness and define it in the context of disease," he said. "We'd like to flip that around and say, 'The reality is that as an individual you really

need to think about the overall health and wellness first and ensure that you don't get caught moving down this pathway ... to disease.'

"As a health and wellness company, we're interested in providing information content back to our clients so that there are actionable items that the client can put into play," Naylor said.

The Viveda tests would be administered by a clinician, who would draw a blood sample and send it to PPM, which is a CLIA-certified laboratory. The company then would use its NetFit platform to analyze the sample and generate data to create a wellness profile.

The report includes a mathematical score of wellness. For the cardiovascular assessment, more than 70 molecules are measured as part of the bioprofile, including C-reactive protein, troponin T, homocysteine, and cholesterol.

Details about how a patient's level for each molecule measures against normal ranges are also included. Using that information, patients and their doctors would decide what steps, if any, would need to be taken, including prophylactic drug therapy, diet, and exercise.

The cardiovascular assessment test will cost \$500, Naylor said, while the lifestyle assessment evaluation will cost \$1,500.

'Spectacular Failure'

A spin-out from Indiana University, PPM was founded in 2005 as a protein biomarker-discovery company to provide services to the pharmaceutical industry. The founders include Naylor, who had been chief technology officer at Beyond Genomics; Fred Regnier, a professor of chemistry at Purdue University; and David Clemmer, a professor of chemistry at IU.

While PPM was able to raise about \$700,000 in seed funding, by the time it opened up shop, biomarker discovery as a business proposition had already lost momentum, and after its first year PPM had not secured a single contract with a pharma firm, Naylor said. It just "wasn't going to fly," he said, and by mid-2006, there were questions whether it made sense for PPM to keep its doors open.

At the same time, though, "it was becoming clearer and clearer and clearer that the public at large was really excited about the advent of what's been called personalized medicine," Naylor said. He recommended to PPM's board that it reinvent itself as a health-and-wellness firm.

Naylor said that while PPM relies on protein and metabolite biomarkers as components of its tests, it is not a biomarker firm in the traditional sense.

"If you think about the biomarker space as it currently exists, we've spent probably the last 15 years in genomic, proteomic, metabolomic analyses doing shotgun comparisons of one cohort population against another," Naylor said. "Biomarker discovery has been epitomized by looking at, for instance, a disease cohort versus a control cohort and hoping to find differences in the genomic, proteomic, or metabolomic levels.

"For the most part, that approach has been a spectacular failure," he said.

Rather than trying to identify protein signatures of disease, "we devised an integrative platform that utilizes informatics and assembly tools [developed in-house] to direct what we should look at in the form of analytes and then we use a suite of analytical tools that include mass spectrometry and affinity platforms ... to do the analysis in a high-throughput manner," he added.

The firm uses mass specs from Leco. In May, Leco and Indiana University provided PPM \$2 million to form its lab and hire staff. PPM is currently trying to raise an additional \$2.3 million to \$2.8 million in Series A funding to help launch the tests, Naylor said.