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## Expanding Beyond Service Offering, Metabolon Adds Diagnostics to Business

**NEW YORK** (GenomeWeb News) – Having built up a profitable service business, metabolomics firm Metabolon has turned its attention to the diagnostics market, and in a few weeks, it anticipates the launch of its first test.

Founded in 2000 and headquartered in Research Triangle Park, NC, Metabolon is one of a handful of firms in the metabolomics space, focusing on providing research services. Today, the company has a customer base of about 300, including all the major pharmaceutical and biotechnology firms, as well as nutrition and consumer product firms, and universities, according to its CEO.

But in the process of partnering with its clients on studies, the company discovered that its technology “is a very powerful approach to identifying biomarkers, especially biomarkers of disease,” President and CEO John Ryals told *GenomeWeb Daily News* last week. So, a few years ago, Metabolon decided to leverage its knowledge and experience gained from conducting those studies and start R&D work in “a couple of diseases.”

The first fruit of its efforts is a test for insulin resistance, called Quantose, to be launched in Metabolon's new CLIA laboratory at the end of June, Ryals said. Also in the pipeline are two tests for prostate cancer, and further in the future are tests for determining the aggressiveness of

cancers and for assessing tolerance to chemotherapies, directed at bladder and kidney cancers. The initial chemotherapy diagnostic being developed targets the drug cisplatin.

In developing metabolomics-based diagnostics, Metabolon is entering unmapped terrain. Metabolomics remains a nascent technology and Metabolon faces limited competition, with BG Medicine possibly its biggest challenger, while a young firm called Stemina is combining stem cell and metabolomics technology to develop biomarkers for disease detection and drug screening.

Also, Phenomenome has metabolomic research directed at Alzheimer's disease and colon cancer, and Molecular Biometrics is doing metabolomic-based work in reproductive health, Parkinson's disease, and pulmonary health.

Several drug manufacturers, such as Novartis, Roche, Abbott, Bayer, Bristol-Meyers Squibb, and Pfizer have metabolomics programs, as well.

According to Ryals, one advantage of Metabolon's approach is that it allows “a very accurate assessment of the phenotype of what's happening.” While genetic tests may be useful at evaluating a person's risk and predisposition for cancer, for example, “where we're very good is taking a cancer that's already there and figuring out a lot about it.”

Metabolomics has become a crucial technology for cancer-related research, he added. “The oncogenes and tumor suppressor genes and tumor enhancer genes [have] shown to affect metabolism,” Ryals said.

Even as the company prepares to put more resources into its diagnostics business, Metabolon has no intentions of moving away from its service business, which is doing “really very well,” Ryals said, adding that in 2010,



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Metabolon posted about \$14 million in revenues.

However, he sees the possibility for rapid growth in its diagnostics business. It is not expected to generate significant revenue for 2011, and in 2012 it may post “a couple of million dollars,” Ryals said. But in three to four years, it may be able to match Metabolon's service business in terms of revenues.

“The diagnostics, once we launch it, we believe will be profitable pretty quickly,” he said.

### MULLING MARKETING OPTIONS

Metabolon is “in a number of significant negotiations” with potential sales and marketing partners for its Quantose test, while it intends to sell its prostate cancer tests directly.

The difference in its commercialization strategy is based on what Metabolon believes will be the infrastructure needed for its tests. In the case of Quantose, the company is looking to partner because it doesn't have a big enough sales and marketing operation, and it would be too costly to build one. According to Ryals, upwards of 1,000 marketing and sales representatives across the country would be needed in order to fully cover the 300,000 primary care physicians in the US, all of whom would be potential providers of the insulin-resistance test.

He said that in the US about 30 percent of the total population is at risk for type 2 diabetes, and potentially, between 20 million and 30 million Quantose tests, which will be priced between \$100 and \$125, could be performed each year.

The test is comprised of three analytes and will be initially launched as a mass spec-based test because it was developed on the platform, but in order to hit the potential target market of 30 million tests annually, “we're probably going to have to get off the mass spec,” Ryals said.

Meanwhile, Metabolon is targeting an end of the year launch of CLIA tests for its prostate cancer diagnostics, which is being co-developed with researchers at the University of Michigan.

By selling those tests directly, Metabolon will move toward its vision as a “fully integrated company in the cancer space” and not merely a licensing firm for its technology, Ryals said.

One of its prostate cancer assays is for detecting

tumors in urine sediment. The target patient population is men who have had digital rectal exams that are negative for the disease, but whose PSA levels are between 4 and 10 nanograms/mL, a gray zone in which it is unclear whether a man has prostate cancer.

“With our tests, looking at these urine specimens, we can improve that accuracy of that call greatly,” Ryals said. “We still haven't locked down exactly how much we improve it, but it is a great deal of improvement on that group of patients.”

Currently, men with PSA levels in the gray area are monitored by their doctors and undergo testing every few months to see whether the levels rise or fall or whether a palpable mass can be detected by DRE. Metabolon's test would eliminate this “state of purgatory” by providing physicians an additional tool that allows them to make a better-informed decision about whether a patient needs a prostate biopsy, Ryals said.

The second prostate test from the company targets those patients who have had a biopsy and received a Gleason score — used to assess the prognosis of a patient's prostate cancer — between 5 and 8, a “no-man's land” in terms of how aggressive a physician should be in treating the disease. The test would be used to help guide clinicians in treatment decisions.

Metabolon's tests are being developed not for the initial diagnosis of cancer, but rather to help physicians and patients make treatment decisions to manage the disease.

“Many times a biopsy analysis is not very conclusive as to the course of treatment that the patient should have,” Ryals said. “We have the ability to look at metabolism to make that much clearer.”

No decision has been made yet about pursuing clearance from the US Food and Drug Administration for its tests. On the Quantose test, Ryals said that that decision may depend on its marketing partner, but for broad distribution, the test would have to be available in a kit format, which would require FDA approval.

Whether FDA is equipped to evaluate such a test is another matter. While the agency is relatively well-versed in gene-based tests, that may not be the case with diagnostics that are based on other more exotic 'omics technology.

For example, FDA cleared the first proteomics *in vitro*

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diagnostic multivariate index assay, from Vermillion, less than two years ago. But metabolomics is a more niche technology than proteomics, and the FDA may have even less experience evaluating tests such as those being developed by Metabolon.

Ryals said, however, that the company's tests are not metabolomics tests, per se. Though the technology was used to find the biomarkers, "in the end the test is essentially an analyte-driven test, and it's no different than testing cholesterol," which is a small-molecule metabolite, he said.