

## EMERGING COMPANY PROFILE

# miR Scientific: spotting aggression with RNA in urine

BY ELIZABETH S. EATON, STAFF WRITER

miR has paired its panel of urine-based RNAs with a statistical algorithm for accurate diagnosis of aggressive bladder and prostate cancers, sparing patients with lower-grade tumors from invasive biopsies and unnecessary drug treatments.

The company's technology, which was spun out of the State University of New York University at Albany, is based on work by co-founder and CSO Martin Tenniswood that ties expression level of specific small non-coding RNA (sncRNA) sequences to cancer biology. Tenniswood is the director of the Cancer Research Center at SUNY Albany.

CEO Sam Salman wanted to focus Tenniswood's work on urological cancers for two reasons: standard-of-care biopsies are invasive, and are often incorrect or inconclusive in detecting aggressive cancers, pushing patients into drug therapies they don't need. "Most patients diagnosed with prostate cancer opt for treatment, even though 70-75% of patients could safely avoid treatment altogether," Tenniswood told BioCentury.

The goal of miR's Sentinel Score diagnostics is to distinguish patients with progressive or aggressive disease who require treatment from patients with stable, early stage disease who require only active surveillance. In addition, patients on surveillance could receive miR's urine-based test every few months instead of being subjected to repeat biopsies, Salman said.

The Sentinel Score tests screen exosomes in urine for levels of about 280 microRNAs and small nucleolar RNAs (snoRNAs) -- two types of sncRNA -- that paint a picture of the biology of the tumor.

Tenniswood said that compared with mRNA, sncRNAs are more stable, making them easier to extract, purify and sequence.

The sncRNAs' stability, and the large number that the company screens, contribute to the tests' accuracy, Tenniswood said.

By comparing sncRNA sequence patterns to its bank of samples from thousands of patients and healthy volunteers, miR's computational methods need only a urine sample to determine

### MIR SCIENTIFIC LLC

New York, N.Y.

**Technology:** Diagnostics and prognostics based on short non-coding RNAs (sncRNAs) in urine

**Disease focus:** Cancer

**Clinical status:** Registration

**Founded:** 2015 by Impact NRS LLC, Martin Tenniswood, Rob Tenniswood and the Research Foundation for the State University of New York

**University collaborators:** State University of New York at Albany

**Corporate partners:** Undisclosed

**Number of employees:** 10

**Funds raised:** Undisclosed

**Investors:** Impact NRS LLC

**CEO:** Sam Salman

**Patents:** None issued

whether prostate or bladder cancer is present, and if so, whether it is stable or progressing.

Salman said because the algorithm doesn't need other information to build its predictions, it could avoid the biases of two common analysis methods: area under the curve (AUC) measurements that use an arbitrary cutoff to determine significance; and machine learning, which assumes there's enough data to find a pattern and therefore involves the risk of over-fitting data to produce a false result.

He added, "virtually every other major application that we're aware of that uses biostatistics or machine learning requires prior information," such as patient history.

miR presented data for its bladder cancer diagnostic at the American Society of Clinical Oncology (ASCO) meeting last year, showing that in 82 patients, the miR Sentinel Score detected recurring cancer with 100% sensitivity and 96% specificity.

This year, the company presented data for its prostate cancer diagnostic at the European Association of Urology (EAU) meeting, showing that the Sentinel Score detected clinically significant disease in 235 patients with 93% sensitivity and 98% specificity.

Beyond diagnosis and surveillance, miR plans to develop a companion test that would match patients with a precision therapy. The company is working with undisclosed partners to gather response data and plans to announce initial findings in about six months.

miR expects to receive Lab Developed Test approval for both its bladder and prostate Sentinel Score diagnostics within a year, after which it will also seek FDA approval.

miR is a subsidiary of Impact NRS LLC, which in-licenses technology to address health and aging problems. Salman, who is also chairman and CEO of the parent company, said the plan is to spin out miR from NRS within the next year and a half.

According to BioCentury's BCIQ database, at least three companies market urine-based cancer diagnostics. Pacific Edge Ltd. and the Cepheid Inc. unit of Danaher Corp. have bladder cancer tests based on detection of five mRNAs; and the Exosome Diagnostics Inc. unit of Bio-Techne Corp. markets a high-grade prostate cancer diagnostic that detects three biomarkers in exosomal RNA.

Salman declined to compare miR's tests to its competitors. ■

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#### COMPANIES AND INSTITUTIONS MENTIONED

**American Society of Clinical Oncology** (ASCO), Alexandria, Va.  
**Bio-Techne Corp.** (NASDAQ:TECH), Minneapolis, Minn.  
**Danaher Corp.** (NYSE:DHR), Washington, D.C.  
**European Association of Urology** (EAU), Arnhem, the Netherlands  
**Impact NRS LLC**, New York, N.Y.  
**Pacific Edge Ltd.** (NZX:PEB), Dunedin, New Zealand  
**State University of New York University at Albany**, Albany, N.Y.

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### NEWSROOM

pressreleases@biocentury.com

### SAN CARLOS, CA

+1 650-595-5333; Fax: +1 650-595-5589

### CHICAGO

+1 312-755-0798; Fax: +1 650-595-5589

### WASHINGTON, DC

+1 202-462-9582; Fax: +1 202-667-2922

### UNITED KINGDOM

+44 (0)1865-512184; Fax: +1 650-595-5589

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