

Mobile Health Monitoring and Diagnostics Ventures Thriving in New Haven

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When we think of global healthcare, we tend to think: inefficient, fast growing, costly, MD shortage.

All those things are true, but mobile healthcare (mHealth) is rapidly changing the potential negative outcome of that doleful equation. According to Research 2 Guidance, a specialist firm focused on mobile healthcare, 500 million smartphone users worldwide will be using a health care application by 2015, and by 2018, 50 percent of all smartphone and tablet users will have downloaded mobile health applications. The Roadshow is showcasing New Haven area ventures this month and since there are several local ventures engaged in the mobile monitoring and diagnostic medical devices market it seems fitting to take a look at that vertical.

Transparency Research estimates the mobile health monitoring and diagnostic market was \$650 million in 2012 and forecasts \$8.03 billion revenues in 2019, a CAGR of 43.3%. The market is segmented into 1) diagnostic instruments and 2) monitors for blood pressure, sleep apnea, cardio, glucose, pulse and multi-parameters. Research 2 Guidance projects the monitor or sensor market alone –in 2013 about 200 different devices- will grow to \$5.6 billion globally by 2017 at CAGR of 69% with 61 million sensors shipped. The diagnostic instruments side is smaller but holds enormous promise. The mobile monitoring and diagnostics market contributes the maximum share of revenue, about 85%, to the overall mobile healthcare solutions market, which also includes 100,000 apps in smartphone catalog stores, many free. The majority of all these companies are startups

Venture capital activity in mobile health is soaring. In 2012, \$900 MM was invested, in 2013, nearly \$1.2 billion and in the first quarter of 2014, \$310MM. Mobile strategic investors are also active. Formed in December 2011, Qualcomm Life, Inc. aims to connect medical devices wirelessly via *cloud*-based services to both device users and health care providers. It provides an encrypted, HIPPA-compliant open platform for manufacturers which is registered with the FDA as MDDS. The company has also established a \$100 million fund to invest in [wireless health companies](#). This month Apple announced it will bring third party apps under a common platform called Healthkit, which would enable (as an example) a blood pressure reading app to connect to an MD alert app.

In the New Haven area we have several exemplary young companies in the mobile monitoring and diagnosis market, among them Applivate, whose product ShugaTrak is a glucose monitoring app for diabetics and Tangen BioSciences, a mobile medical instrument for molecular diagnosis.

ShugaTrak's mobile app for both IOS and Android smartphones connects via Bluetooth adaptor to the most widely used glucose meters in the US market. Born out of personal family experience, ShugaTrak has very modest monthly fees (\$4.99 per month) and is actively seeking new customers (www.shugatrak.com). They differentiate their offering with software which provides instant data capture and real time cloud based analytics and alerts for the diabetic end user. Founder John Fitzpatrick shares some good news on the FDA regulation side: "FDA regulation of mobile apps was still evolving when we were building the initial version of ShugaTrak, so, as a small startup without the resources to go through an expensive, time-consuming approval process, we deliberately excluded features that might have drawn regulatory scrutiny. Recently, however, the FDA has been more specific about how it intends to regulate mobile apps, stating just two weeks ago, for example, that it does not intend to regulate 'Mobile apps that allows a user to collect, log, track and trend data such

as blood glucose...' We at Applivate welcome this lighter regulatory touch and believe it will speed the delivery of helpful technologies to patients without posing any undue risk."



ShugaTrak Adaptor (in pouch) with Glucose Meter

A local representative of the fast growing mobile diagnostics segment of the market is Tangen Biosciences of Guilford (www.tangenbio.com). Tangen has developed an instrument capable of delivering cost effective mobile molecular diagnostics at the point of care anywhere in the world. There is today currently no truly portable DNA based diagnostic device in the worldwide in vitro diagnostics market. Tangen fills this gap with a patent pending technology that enables portable, high speed, sample-to-answer diagnostics that are infrastructure independent, requiring neither lab, power grid, refrigeration nor highly skilled medical technicians.

John Nobile and John "JD" Davidson formed Tangen in January 2013 and developed both the technology and the prototype instrument, which successfully performed rapid amplification and detection of DNA in April 2013. Tangen's prototype instrument delivers rapid DNA detection with the same sensitivity of lab-based DNA techniques. Their compact, simple to manufacture, and safely disposable test kit enables cost effective high margin production

The rapidly growing, global in vitro diagnostics industry is projected to reach \$36.5 billion by 2018 and includes opportunities for Tangen in food contamination detection, crop and food identification, water quality assessment, bio-defense, and clinical disease diagnostics. DNA based clinical disease diagnostics alone represented an \$8.3 billion dollar market in 2012 according to Point of Care Diagnostic Testing World Markets (TriMark Publications), of which Tangen's point of care market opportunity for molecular diagnostics is forecast to have a CAGR of 8.7% between 2011 and 2018.



Tangen BioSciences Prototype with Assay Disk

Tangen has initially targeted the diagnosis of active pulmonary tuberculosis (TB). Tuberculosis is a major global health threat. It is estimated that approximately 3% of the global population *will at some point* become infected with contagious pulmonary TB. In spite of being a highly curable disease it has a 50% mortality rate, largely due to poor access to effective diagnosis. The World Health Organization (WHO) estimates that roughly \$1 billion is spent annually on TB testing, with less than 70% of that testing in the developing world where there is limited access to centralized testing laboratories. Earlier detection is critical in stopping this disease. Tangen's point of care solution is well-positioned to have a substantial impact on the quality of care for those thought to be infected with TB, due to the instrument's portability, speed, sensitivity, and ability to detect TB's many strains in a single test.

Unlike the monitoring side of mobile medical devices market, FDA regulations are part of the equation for Tangen in the US market. As a result, like many young companies before them, they will launch the product outside the United States and use their early overseas results to accelerate acceptance of the instrument by the FDA.

Keep your eye on these young ventures and others like them as New Haven continues to leverage its proximity to Yale New Haven and Science Park in the mobile health arena.