



THE NEXT GENERATION OF MOLECULAR DIAGNOSTICS

**2019**

**ANNUAL SHAREHOLDER UPDATE**



## About Us

- Tangen Biosciences has developed a rapid molecular diagnostic platform capable of revolutionizing the \$8B infectious disease market
- Platform offers easily integrated sample preparation, rapid time to result, and sensitivity over current diagnostic platforms
- A fungal assay and Anthrax 510(k) pre-submission has been reviewed by the FDA with positive feedback and is planned for commercialization in 2020
- \$ 11.3 million BARDA grant (2017-21)
- Developing an antimicrobial resistant and COVID-19 test utilizing BARDA funding
- Established a GMP Manufacturing facility and completing validation



Dear Shareholders,

I would like to take the opportunity today to bring all of you up to date with the excellent progress we have been making over the past year.

The year started off with Richard Birkmeyer, PhD being brought on as the CEO of the company. Throughout the year the management team was formed, and by year-end, we had the following team:

**Richard Birkmeyer, PhD - CEO.** Rick is a seasoned executive and an accomplished entrepreneur with a proven track record. Before joining Tangen Biosciences, Rick was CEO at CD Diagnostics, Inc. At CD and SDIX, Rick established and implemented highly successful strategic corporate partnerships with Fortune 100 companies, raised venture capital financing, and completed six acquisitions including utilizing a financial reverse merger in 1996 to create a publicly traded company NASDAQ: (SDIX) and liquidity for SDI's venture capital investors. Rick received his B.S. in Biology from the State University of New York, Plattsburgh and his Ph.D. in biochemistry and immunology from the State University of New York, Binghamton. Rick also completed post-doctoral research in immunogenetics at Iowa State University

**John Davidson, PhD - Vice President of Research, Chief Scientific Officer, and Co-founder.** John co-founded Tangen Biosciences in 2013 with John Nobile. John has focused on TangenDx System, a highly sensitive molecular platform for rapid diagnosis of infectious disease from the laboratory to a commercial product. John received his PhD from Harvard University in 2000 and followed up with a post-doctoral research fellowship in Cancer Biology at the University of Washington, where he developed processive DNA polymerase proteins to reduce error rates during PCR.

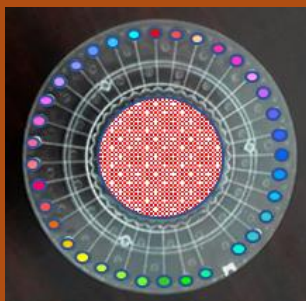
**Brian Chirico - Vice President, Operations.** Brian has over 30 years of Life Sciences Operations experience for both analytical and diagnostic instrumentation and reagents at Perkin Elmer, 454 Life Sciences, and Roche Diagnostics. As part of the 454 team, he spearheaded the scale up of manufacturing for next generation sequencing systems including MRP, Quality Systems, Documentation Control, and Supplier Qualification. Brian has a BSEE from the University of Bridgeport and is 6Sigma Black Belt Certified.

**Keith Kardos, PhD, Vice President, Clinical Affairs.** Keith has over 25 years of experience managing R&D programs. As the leader of our R&D team at CD Diagnostics, Keith executed a comprehensive R&D plan for the company's proprietary synovial fluid assays, including development, validation, and regulatory approval. Additionally, he managed collaborations and relationships with strategic partner and lead efforts to transition CD's joint fluid tests to their CLIA laboratory. Keith has a PhD in Organic Chemistry from Lehigh University.

**Bob McNamee - Vice President, Quality Affairs.** Bob has over 25 years' Quality Management expertise in early phase development, implementation, and management of FDA 21 CFR part 820 and ISO 13485 compliant Quality Management Systems. Bob is a respected leader in areas of Quality Assurance, Compliance, Risk Management, Deviation Management, Corrective and Preventive Action, Continuous Quality Improvement, Key Performance Indicators, Analysis of

## RAMP Amplification

- Sample enters at the center from the LVC
- Mixes with dried enzymes in next radius
- Spins up to send out to 35 wells total at perimeter, back-sealing with wax
- Wells are monitored with light sensors for reactions
- Wells are monitored with light sensors for reactions
- Loop mediated isothermal DNA amplification (LAMP) with tight temperature controlled Hot Start
- Demonstrated sensitivity 1 CFU/ml Blood



Quality Metrics, Clinical Site Monitoring, Process Validation, Supplier Qualification, and Internal Audit

**Anne Cavanaugh - Director, Finance.** Anne is a successful businessperson and entrepreneur who co-founded Strategic Diagnostics Inc. (SDI), a biotechnology company specializing in diagnostic products for agricultural and environmental applications. At SDI, Anne was a key member of a team that raised \$10 million in funding from corporate partners and venture capital funds, completed numerous acquisitions, and created a public company that traded on Nasdaq.

A financing was initiated after a valuation of the common stock by Trout, Ebersole, and Groff. On March 13<sup>th</sup>, Tangen had a first close of the Series A preferred of over \$6 million with \$3.6 million being new money. The Preferred A round was closed in April with a total of \$9 million with approximately \$5.5 million of new money.

### FINANCIALS

We changed Tangen's accounting from cash basis to accrual accounting. Internal controls were established including separation of accounts payable, data entry, bank signing and bank reconciliation. We selected Deloitte and Touche as our auditors who currently are auditing the 2019 year.

For the fourth quarter of 2019 revenue from the BARDA contract was \$1,554,159 versus budget of \$798,000. Total income for the quarter was 102% of budget. Operating expenses for Q4 were 82% of budget, \$1,394,015 compared to budget of \$1,695,110. Net operating income of \$191,240 versus budget of (\$147,110) resulted from the expanded BARDA contract for the second half of the year.

The P&L for 2019 shows BARDA revenue of \$2.888 million versus budget of \$2.926 million, this is 99% of budget. Operating expense for 2019 totaled \$5.046 million versus budget of \$6.046 million; resulting in \$1 million less expense than was budgeted for the year. Net operating income for the year was (\$2.115 million) versus budget of (\$1.569 million).

The December 31 balance sheet remains strong with \$3.7 million in cash. Total Assets were \$4.2 million, and Liabilities totaled \$933k, resulting in equity of \$4.418 million.

The year over year Balance Sheet shows \$4.167 million in 2019 in cash and A/R versus \$558k in 2018. The balance sheet also shows increased inventory and fixed assets, with total assets coming in at \$5.35 million compared to \$1.47 million in 2018. Total Liabilities were \$932k on December 31, 2019 compared to \$3.45 million in 2018; this decrease in liabilities is primarily due to the conversion of the Convertible Notes.

Webster Bank has issued Tangen an \$800,000 credit arrangement consisting of a \$300,000 term loan (payable over 4 years) which was finalized and deposited into Tangen's bank account the end of December. \$500,000 is a revolving line of credit. Conditional to the loan Tangen issued Webster a 7-year warrant to purchase stock based on 5% of the committed debt (\$40,000). The warrant provides for the purchase of Series A preferred stock at a strike price equal to the \$1.50 Series A per share price. The warrant includes a cashless exercise option and customary recapitalization protections.

## Patented Technology

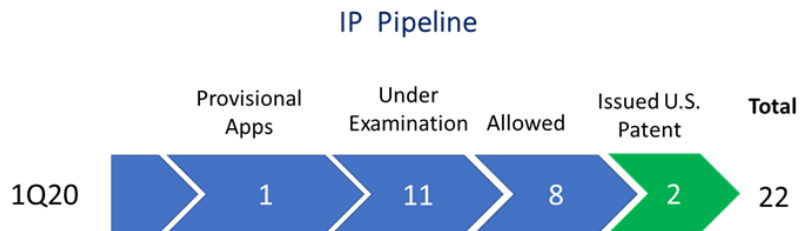
- “Apparatus and method for cell, spore, or virus capture and disruption” - Sonic apparatus for cellular disruption -  
US20170333891A1  
Allowed in Europe 2019-08-14
- “Apparatus and method for extracting pathogens from biological samples” - Sample processing apparatus -  
15/471154  
Issued USPTO 2019-12-11
- “A method for suppressing non-specific Amplification products in nucleic acid amplification technologies” - Suppression of primer artifacts during isothermal amplification  
U.S. Application Serial No. 62/792,613  
USPTO/PCT Filing  
Date: 2019 -11 -21
- “Isothermal methods for amplifying nucleic acid samples” - Two-stage amplification process to improve assay sensitivity and detect SNPs  
US20170204456A1  
Issued 2019 – 07 – 20
- STEM License - In-licensed from Lumora Ltd -Stem accelerated isothermal nucleic acid amplification technology  
US9410190B2 issued 2010

## BARDA

Due to various government delays, the Anthrax contract was not delivered to Tangen until July 2019. Revenue was lower than budget in the 2<sup>nd</sup> quarter due to the delay of the new BARDA contract; however, BARDA did surprise us with an additional \$2.1 million in funding.

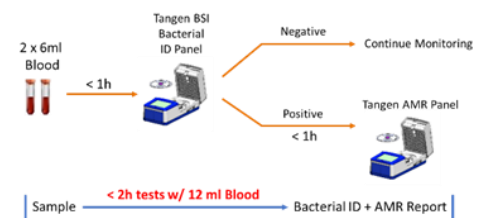
## RESEARCH

Tangen filed a new patent in 2019 covering the novel technology to suppress false positive reactions in isothermal primer based nucleic acid amplification methodologies and is actively seeking licensing agreements. Two patents were issued in the US with associated 8 application allowed or in review in the national phase. These patents cover aspects of the Instrument cell disruption technology, the sample preparation for blood filtration and multiplexing and real time comparison in the Assay disk.



Technology development to enhance the sensitivity of the system was created as part of the Antimicrobial Resistance project funded by BARDA. This technology utilizes Tangen’s multiplexing IP as well as additional novel aspects to create a universal preamplification reaction that multiplies the incoming DNA or RNA allowing the full 30 wells of the Tangen Assay disk to detect different AMR genes or organisms without loss of sensitivity. Tangen demonstrated detection with a panel of 7 divergent AMR genes and organisms including MRSA, E. coli and Mycobacteria pathogens and showed feasibility to detect up to 30 independent targets with high sensitivity. When combined with the Tangen Blood Processing system, Tangen is able to apply the AMR technology to a whole blood specimen to deliver a highly accurate genotyping test for the most prevalent blood stream infections as well as the status of key AMR genes within an hour. BARDA were very interested in this test and have split it out from the single feasibility task embedded in the existing Anthrax contract into a new contract to be reviewed and expanded in 2020.

### AMR PRODUCT USAGE FLOW – REFLEXIVE TEST



The Tangen Blood Processing system was developed as part of the technology to support an Anthrax assay funded through BARDA. The Anthrax project delivered a rapid assay for the detection of Anthrax from a blood sample in less than an hour with an unparalleled sensitivity of  $< 10$  CFU/ml (the Limit of Detection derived from live

## TangenDx™ Platform

### “Sensitive, Simple & Fast”

- Best in class sensitivity for bacterial and fungal testing directly from whole blood
- Rapid testing (<1 hour) for sample to result with no need for accessory lab equipment

### Remote, Handheld Use

- No accessory equipment or measuring required
- Small portable size (Battery pack capable)
- No cold chain for reagents
- Exploring CLIA Waiver

### Versatile

- Testing of up to 30 targets per sample
- Ability to detect antibiotic resistance
- Universal Platform with customizable sample prep kits



anthrax cells spiked into whole blood samples). The final option of the Contract is to bring the Tangen GeneSpark instrument and TangenDx Anthrax Blood stream infection assay to the FDA with a 510k submission in 2020.

### MANUFACTURING

As we did a critical evaluation of our product at the start of the year, we quickly determined that the cost to manufacture a test was too high when we were not taking advantage of all 32 wells as separate tests. The cost to manufacture a rotor was \$105.16, the cost to produce an LVC was \$8.07 with costs for Lyse syringe, wash syringe, finished cap and final kitting costs totaling \$43.09 for a total cost of \$156.32 / kit. If 32 analytes were being evaluated, this was only 156.32/32 test. However, if we were looking at a single analyte, this was way too high.

Our OEM manufacturer had an extremely high overhead structure. After evaluating both them and numerous other 3<sup>rd</sup> party vendors, we concluded that to enhance flexibility and costs, it was necessary to bring production in-house.

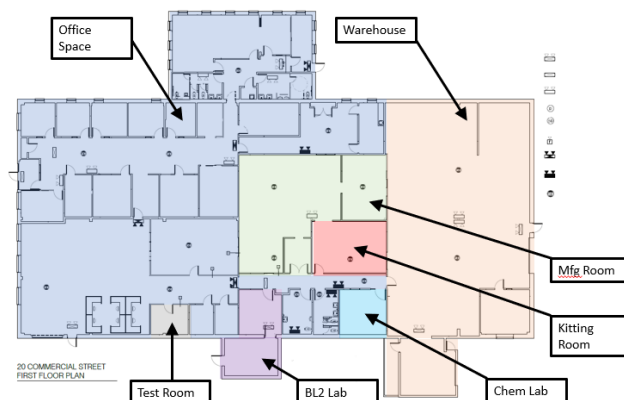
We identified a 16,000 square foot facility that could be modified to accommodate current and future needs. We initially are occupying 12,000 sq. feet, and the landlord covered general build-out costs. On August 29<sup>th</sup> we had our open house to celebrate the opening of Tangen’s new facility. Governor Ned Lamont as well as Senator Richard Blumenthal attended. The new building project was on time and near budget (\$310k vs. \$300k budget).

With manufacturing being moved within Tangen, with simplification of processes and some automation, we have been able to reduce the COGs to \$35.00 for Anthrax which includes the sample extraction kit and \$21.00 for COVID-19, a substantial decrease than we started out in the beginning of the year.

### New Tangen Building



### Tangen Building Floor Plan



## ECCMID 2019



*ECCMID (Amsterdam – April 2019)*

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## CLINICAL / REGULATORY

Tangen presented a 510(k) pre-submission to the FDA for an anthrax test. The FDA met with Tangen to review the pre-submission and provide feedback in February 2019. The clinical team prepared a supplement to the pre-submission and met with the FDA a second time in October 2019 to review the updated testing proposal. FDA feedback has been used to inform coordination and planning of a clinical trial to start in 2020.

Significant progress has been made toward the start of the anthrax clinical trial. Preliminary studies were initiated at Battelle Memorial Laboratories testing the limit of detection, required filter size, and safety of the blood processing system. In addition to the pre-studies, procedure documents were prepared for analytical studies required for 510(k) submission. The clinical team established a relationship with Toolbox Medical Innovations as the CRO for the anthrax study. Toolbox worked to create a protocol for obtaining prospective samples from various clinical locations for the trial.

In addition to the addition of Keith Kardos – VP, Clinical Affairs, the Tangen clinical and regulatory group was expanded to include Grace Peters – Regulatory Specialist and Elliot Cowan who is providing regulatory consulting. Jeff Gibbs and McKenzie Cato (Hyman, Phelps, & McNamara) are providing regulatory legal counsel to Tangen.

## BUSINESS DEVELOPMENT

Tangen exhibited at the 29th European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in Amsterdam in April and garnered a lot of interest. We attended BioPhilly in June and participated at the American Society for Microbiology (ASM) also in June in San Francisco as well as the AACC in August.

These events coupled with other corporate outreach strategies we have implemented, will further our goal of attaining corporate partnerships and ultimately increasing shareholder value.

As we continue in yet another pivotal year for Tangen, we look forward to updating our shareholders on our continuous achievements and completion of critical milestones that will further enhance Tangen's footprint in the molecular diagnostic market, increasing shareholder value, and ultimately saving lives.

Regards,

Richard C. Birkmeyer, PhD  
President and CEO