

# GeneEx, Inc.

Medical Diagnostics

GeneEx is a medical diagnostics company developing rapid, point-of-care diagnostic tests for infectious diseases capable of detecting virulence markers produced ONLY during active infections. GeneEx will focus its initial commercialization effort on periodontal disease, group A strep (strep throat) and systemic fungal infections. The Company has significantly de-risked its operations by patent-protecting its core technology and engaging a leading point of care test developer and manufacturer for production of its tests.

## Technology

The GeneEx infectious disease diagnostics are based on virulence proteins produced by pathogens exclusively during infection and disease. Since these virulence proteins are disease-specific and are not made when the pathogen is grown in the lab or when it is a harmless colonizer, they are highly sensitive markers to detect pathogens in action.

The Company's first product, the Rapid Periodontal Test (RPT), is an inexpensive, chair-side saliva test for use during routine dental examination to: 1) screen patients for periodontal disease, 2) measure treatment efficacy and 3) aid in patient compliance. Since GeneEx's test detects only virulence markers produced during active infections, the RPT is the only test capable of diagnosing active periodontitis today. The RPT requires only a drop of saliva, and is complete in less than 10 minutes, like any easy-to-use, home-based kits such as pregnancy tests.

GeneEx's second product is a saliva based, rapid antigen detection test for group A streptococcus (GAS), the cause of strep throat, to both professional and consumer (over the counter) markets. Like the RPT, this test will detect only the virulence markers produced by active GAS pathogenesis, not just the presence of GAS, and the test will reduce unnecessary prescription of antibiotics. Strep A infections are also a known risk factor for heart disease and rheumatic fever.

## Market Potential

- GeneEx projects delivery of its saliva-based RPT to dentists for \$15-\$20, including distributor fees. Market surveys have shown that more than 95% of responding dentists would use the test routinely at this price-point. Based on incidence of periodontal disease, the total dental market potential for GeneEx RPT test is projected to reach \$1.6 billion.
- Approximately 500 million cases of pharyngitis (sore throat) occur annually in the U.S. resulting in 15 million physician office visits.

The current market size is about \$125 million, comprised mostly of professional use tests. A saliva-based rapid antigen detection test for active GAS for over the counter use does not currently exist, but the U.S. market for such a test is in excess of \$500 million.

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## Strategy

To reach general practicing dentists, GeneEx plans to use traditional dental distributors such as Patterson Dental, Benco and Henry Schein supplemented by an established and experienced network of 40 manufacturer's representatives. In addition, GeneEx will use a small direct sales force to proactively market the RPT to large group dental practices, those with over 30 dental practices under management and 200,000+ annual patient visits.

For the professional medical market, GeneEx plans to use traditional medical distributors, supported by medical manufacturers' representatives and a small direct sales force, as well, to distribute the RPT to office and clinic based physicians (OB-GYNs, cardiologists, etc) throughout the US.

## Management Team

### **Jack B. Wilkens, MBA – CEO**

Mr. Wilkens has over 35 years of executive management experience and is the former Chief Operating Officer and Executive Vice President of Consumer Diagnostics for Inverness Medical Innovations, Inc., (NYSE: IMA), the leading point of care rapid diagnostic company worldwide with an annual revenue of \$1.9 billion. Mr. Wilkens has a BS in Chemical Engineering from Michigan State University and an MBA from Western New England College.

### **Mead M. McCabe, Ph.D. – Founder and Chief Scientific Officer**

Dr. McCabe has extensive expertise in executive management, medical technologies and product development. He was Chairman and Chief Scientific Officer of genomics company Genetic Vectors, Inc., served as consultant for the U.S. National Institutes of Health and was a faculty member of the University Of Miami School Of Medicine. Dr. McCabe received a B.S. in Zoology from Pennsylvania State University and an M.S. and Ph.D. in Biology from the University of Miami, Florida.

### **Mead M. McCabe, Jr., MBA – President and CFO**

Mr. McCabe has over 16 years experience in finance, start-up and technology oriented companies. He was CEO and CFO of Genetic Vectors, Inc., a genomics company in Miami, Florida. He has a BS in international business from Auburn University and a dual MBA in both International Business and Finance from the University of Miami, Florida.

### **Robert W. Harrington – Vice President, Sales and Marketing**

Mr. Harrington has several years experience in marketing, product management, and sales within the dental, medical, and electronic industries. He was President & CEO of Amerimed Corporation, Darton Group, Vernitron Medical Products and Ultra Care Products. Mr. Harrington is a graduate of the University of Maryland.

## Contact Information

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