MDX LIFE SCIENCES INC **Breakthrough Technologies in Tissue Vitality**



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Forward Looking Statement

This report contains forward-looking statements concerning, among other things, possible applications for marketing approval and other regulatory matters, clinical trials, plans for the development of MDX Life Sciences and business strategies.

These forward-looking statements are identified by the use of such terms as "intends," "expects," "plans," "estimates," "anticipates," "should", "can" and "believes.""

These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those predicted by the forward-looking statements because of various factors and possible events. Company risks include lack of FDA or any other regulatory approval for our human product, the difficulty and uncertainty in obtaining regulatory approval, uncertainty about future physician and market acceptance of our product, our limited manufacturing capacity and capital resources and our lack of commercial experience as a medical device company. In addition, we are subject to industry risks such as: our industry is highly regulated, keenly competitive and subject to uncertainty of pricing because of controls on health care spending and uncertainty of third-party reimbursement.

Mission Statement

MDX Life Sciences, Inc. is a Therapeutic Company Developing Technologies for Tissue Regeneration and Real-time Monitoring of Tissue Oxygen Balance

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Innovation - MDXView

MDXView - a revolutionary patient monitoring system providing real-time continuous diagnosis of deviations from organs and body oxygen balance homeostasis.

A calculated Tissue Metabolic Score (TMS) is based on Mitochondrial function and other three physiological parameters, sensed at the tissue level, in combination with systemic vital signs.

The method can apply to any health care patients.





Innovation - Oxygen Carrying Protein

an Oxygen Bridge - Essential to Life

MDX-36 is a licensed sterile, solution consisting of chemically stabilized and modified hemoglobin (the protein that carries oxygen) in a balanced salt solution. Unlike blood, it does not contain red blood cells. Instead it contains crosslinked hemoglobin based molecules (several tetramers bound together) attached with a co-polymer that circulate in plasma and immediately transport oxygen to tissues upon infusion.



enosi (constricted capillary)

Anemic Blood Flow





MDX-36 Enhanced Blood Flow



Objectives over the next 24 months, with \$10 million inve

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Development & Manufacturing		
Hardware Development	\$	7
Probe Development	\$	3
Software Development	\$	4
Certifications	\$	2
Manufacturing	\$	2
R&D, Regulatory & Clinical Trials		
Laboratory & Research	\$	5
Clinical Trials	\$	7
Regulatory - 501k certification	\$	2
Marketing & Sales	\$	2
General & Administrative	\$	1,2
Total expenses over two years	\$	4,7

rested capital				
r 1	year 2			
50,000				
00,000				
00,000	\$	600,000		
00,000	\$	300,000		
50,000	\$	500,000		
00,000	\$	600,000		
50,000	\$	750,000		
00,000	\$	600,000		
00,000	\$	1,000,000		
00,000	\$	800,000		
50,000	\$	5,150,000		

Team

Management





Prof. Avraham Mayevsky, PhD President

Professor Emeritus at Bar Ilan University in Israel. Prof. Mayevsky is the world leader in monitoring In vivo of physiological activities in the brain of experimental animals as well as in human patients. He has published more than 240 research articles.

Ed Goff CEO

35 years in Executive Leadership, Sales and Business Development positions in Fortune 50 as well as high-growth Software and High-Tech Startup companies. Geology Salem State, Computer Engineering Control Data Institute and Executive Management at Babson College.

Ola Soderquist, CPA, CMA, CM&AA CFO

30 years of entrepreneurial management experience. Served in CFO and other capacities in multiple industry sectors and companies such as Industrivarden, Electrolux, Belden. MSA Stockholm School of Economics, MBA Babson College.



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Advisors

Dr. David Platt, PhD

Chairman Ph.D in Chemical Engineering at Weizmann Institute in Jerusalem. Founder of five public. Dr Platt is the author of 50 patents, he has written 2 textbooks, and published 30 scientific articles with about 500 quotes in academic publications.

Dr. Alan Hoberman, PhD

Executive Director of Operations and Toxology, Charles River Labs

Dr. Henry Esber, PhD

Senior Consultant of Business **Development, Charles River Labs**

Dr. Dale Conaway, PhD

Veterinary Medical Officer for the Research Oversight in US DPVA

Dr. Hana Chen-Walden, MD

Specialist Regulatory Affairs in US and Europe for more than 25 years

Prof. David Bell, MB, FACP, FACE

Professor of Medicine, University of Alabama; 320 publications; Director American Diabetes Association



Mitochondria

K H₂O

ATP

CO₂ <

MDX Life Sciences have a unique FDA clearance for a device monitoring NADH in patients



supply of Oxygen originating from the atmospheric air, down the gradient in the body, into Mitochondria

- Mitochondria The Intracellular "Nano" Organelles Providing Energy for Cellular Functions
- The NADH molecule is a control marker in the **Nucleus** energy generation chain in the mitochondria **Glucose** \rightarrow Glucolysis \rightarrow Pyruvic acid **Cell membrane Cytosol of cell** Crista Acetyl coenzyme A Matrix NADH + H⁺ FADH₂ **Electron transport** chain

Human Diseases

Directly Related to Decreased Oxygen Supply and Mitochondrial Dysfunction





Physiological Hypothesis

In emergency metabolic states – the body protects the most vital organs (heart, brain..) by diverting blood flow from less-vital organs (skin, urethra etc.).

The Urethral wall Tissue Metabolic Score in adults (urethra) or newborns (forehead skin), representing the less vital organs, could be used as a real time indicator to the Body Oxygen Balance Homeostasis





Trauma

Increase tissue Perfusion

Better O₂ Supply to Mitochondria

Energy production Preservation



Clinical Unmet Need

In order to save lives and improve outcome of patients, integrated intensive monitoring of systemic and tissue level physiological parameters must be used.

Real time Monitoring of Vitality Parameters in Patients





Solution

A - System oriented monitoring is a standard approach used in ORs and ICUs. Nevertheless, global body monitoring parameters (BP, HR, SaO₂, ET-CO₂, CT) are not sensitive enough to changes at the tissue level

B - Specific Organ Oriented Monitoring is used in order to :

 B_1 - Evaluate the metabolic state of a most vital (brain) or less vital (kidney) organ at the tissue level in ORs and ICUs.

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(urethra) or newborns (skin).



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B₂ - Obtain an early warning signal of changes in body oxygen balance homeostasis by monitoring a less vital organ in adults

In-vivo Tissue Spectroscopy





Current Technology

The MDXView device consists of three components

Main unit: contains the light sources, optical detectors and the main signal processing components

Monitor unit: displays the tissue monitored parameters and contains the MDXView operating user interface.

Probe accessory: contains the optical sensing flexible fiber bundle, connected to the main unit through an optical connector. The probe is integrated into an unique 3 way urinary (Foley) catheter.





Components





Initial Market Potential USA

Intensive Care Units

- 6,000 ICUs •
 - 90,000 beds (MDXView units potential)
 - 6 million admissions/year (MDXView Foley-Probes potential / Year) •
 - \$5,000 per day cost (Cost saving base) •
- \$67.5 billion, 22.8% of total hospital spending •



Disposable Non-Reusable Probes

Per Patient





Capital Equipment



Per Patient Bed

Current Development

The next generations MDXView device will Integrate between monitored parameters and systemic vital signs to present a combined score to serve as an early warning signal of body oxygen homeostasis.





Future Development

CTE monitoring

Monitoring of CTE conditions in youth and professional sports (NFL, NHL, boxing...), and in high risk professionals (pilots, military...).



Tissue Oxygenation - MDX-36

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- Transports oxygen at low pressure



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Delivers oxygen more efficiently than RBCs Carries oxygen where larger RBCs cannot US Navy submission, 2 spices toxicity trial No toxicity from replacing 90% of the blood in dogs https://www.hindawi.com/journals/ccrp/2014/864237/

> **Critical level** of Oxygen Depravation

Day 6



MDX-366 - Organ Preservation

Up to 60% of donated organs go to waste.

MDX-366, indicated to prolong extracorporeal circulation and preservation of organs for transplant during transport or storage from hours to days







Regulatory

Intellectual Property

Proprietary NADH photometric measurement method

- 4 Patents
- Apparatus & methods for monitoring tissue vitality parameters
- Apparatus & methods for monitoring tissue vitality parameters for the diagnosis of body metabolic status
- Patent
- Optical probes for measuring parameters of body tissue (Probe design)

Regulatory Status

A device similar to the MDXView was cleared by FDA for marketing in USA in 2000 (510k #:K992529). A 2nd device was cleared by the FDA in January 18, 2006 (510k #: K051145). Additional FDA Clearance was Received on February 28, 2007 (510k #: K062977).





Opportunity

Business Opportunity

The MDXView - Unique, Unprecedented Technology and Product for early warning signals before clinical deterioration of patients

- **Clear Perceived Medical Needs**
- Huge Market Potential
- Mature Project in an advanced phase (clinical use)

Development Status

Development of technology completed

Pre clinical monitoring of non vital organs in animal models were completed Clinical units were evaluated at the OR's and adults ICU - Sheba Medical Center, Tel Hashomer, Israel Twenty patients were monitored during open heart cardiovascular operations and 6 patients during AAA operations



Development Plan

R&D, Regulatory and Marketing pathway

Activities	Month 1-3	Month 4-6	Month 7-9	Month 10-12	Month 13-15	Month 16-18	Month 19-21	Month 22-24
Engineering		MDXView-1						
Engineering			MDXView	3				
Software				MDXView-2/3	(4+)			
Production				MD	XView-2			
					MDXView-	-3		
R & D				MD	XView-2/3 (4+)			
		M	DXView-1					
Clinical						MDXView-2	MDXView-3	
Regulatory					MDXView-2			
							MDXView-2	
Marketing/PR					MDXView-2/3	(4+)		

MDXView-1 - Urethra

MDXView-2 - Urethra II

MDXView-3 - Skin

MDXView-4+ - Future Projects (Big Data, Wearable, CTE)



Business and Exit Strategy

Strategic Partnering with Market Leaders

- Patient monitoring manufacturers
- Disposable probe manufacturers / distributors ۲

Generate rapid market awareness by providing massive initiation packages to leading institutions in the U.S & Europe







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