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.
MDX Life Sciences, Inc. is a clinical stage biotechnology company developing autologous transplantation for tissue and organ regeneration.
The Problem

Today there is no safe and effective methodology available to perform autologous transplantation for tissue regeneration.
Business Opportunity for Lucrative Medical Treatment

- Unique, revolutionary technology
- Clinical methodology for autologus transplantation methodology for recovery and regeneration of biological tissues
- Clear perceived medical needs
- Huge market potential
- Mature project in an advanced phase (clinical use)
Autologus Transplantation Methodology

Our ability to perform and monitor autologus transplantation gives the point of acceptability for any autologus regeneration

Methodology for monitoring physiological parameters of tissues and organs in vivo was approved by the Food and Drug Administration
Autologus Mitochondrial or Stem Cell Transplantation Methodology
(Typical Example)

1. Tissue Sample Obtained from Patient’s Own Pectoralis Major Muscle
2. Isolate Mitochondria or Stem Cells via Centrifuge
3. Injection via Catheter Into Affected Areas Such as the Heart

Enabled by MDX LIFESCIENCES proprietary method for measuring Tissue Metabolic State
Tissue Metabolic State Detection Methodology

System oriented monitoring is a standard approach used in Operation Rooms (OR) and Intensive Care Units (ICU). Nevertheless, global body monitoring parameters (BP, HR, \( \text{SaO}_2 \), ET-\( \text{CO}_2 \), CT) are not sensitive enough to changes at the tissue level.

MDX LIFESCIENCES Specific Organ-oriented Monitoring can be used to:

- Evaluate the metabolic state of a most vital (brain) or less vital (kidney) organ at the tissue level in ORs and ICUs
- Obtain an early warning signal of changes in body oxygen balance homeostasis by monitoring a less vital organ in adults (urethra) or newborns (skin)
Various Light Sources

When oxygen level in the cell is limited (i.e., Hypoxia) the NADH is accumulated in the mitochondria and the production of ATP will decrease.

The microcirculatory HbO2 level reflects the balance between the supply and demand of oxygen in the capillaries.

When TBF will decrease to a very low-level production of ATP will stop.

This parameter is used in the calculation equation when calculating the corrected NADH fluorescence.
MDX LIFESCIENCES Revolutionary Approach

Real-time evaluation based on monitoring and correlation of the 4 physiological and metabolic parameters at the tissue level using In-vivo Spectroscopy in combination with vital signs measured from the cardiovascular and respiratory systems.

In-vivo Tissue Spectroscopy measures:
- Mitochondrial function level
- Microcirculatory blood flow
- Microcirculatory hemoglobin saturation
- Tissue backscattered light

A Tissue Metabolic Score (TMS) is derived for organ health at the tissue level. The TMS measurement is the key to enabling autologus transplantation methodologies for recovery and regeneration of biological tissues.
Potential Applications
(Human Diseases Associated with Mitochondrial Dysfunction)
Market Potential of Congestive Heart Failure
Autologus Transplantation Procedures
(Only One of Many Markets)

6.1 million admissions/year for heart (MDX-Viewer Fiber-optic Probes/year)
$5,000 per procedure (cost saving base)
$31 billion annual opportunity (for congestive heart failure alone)
History

In 2007 CritiSense received FDA 510(k) clearance for their technology CRV-3 (K062977). A total of $8 million had been invested with TEVA as the lead investor.

- 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’s (20 patients during open heart cardiovascular operations and 6 patients during AAA operations).

After Prof. Mayevsky’s co-founder passed away the company ceased its activities in 2007.

By 2016 Prof. Mayevsky had repurchased all shares of CritiSense, but decided to liquidate the company and start MDX Life Sciences together with the four current partners to develop the new technology, the MDX-Viewer.

All previous patents held by CritiSense were expired by 2017.
Development & Regulatory Status

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’s (20 patients in open heart cardiovascular operations and 6 patients in AAA operations)

Intellectual Property

- 1 Provisional Patent (Diagnosis)
- Tissue Metabolic Score for patient monitoring (Serial No: 62/573,660)
- Additional patents will be filed once MDX-Viewer development has started

Regulatory Status

- Substantial equivalence 501(k) to the Critisense CRV-3 (510k #:K992529) to be filed with FDA once MDX-Viewer is developed.
# Development Plan

## R&D, Regulatory and Marketing pathway

<table>
<thead>
<tr>
<th>Activities</th>
<th>Month 1-3</th>
<th>Month 4-6</th>
<th>Month 7-9</th>
<th>Month 10-12</th>
<th>Month 13-15</th>
<th>Month 16-18</th>
<th>Month 19-21</th>
<th>Month 22-24</th>
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<tbody>
<tr>
<td>MDX-Viewer ICU</td>
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<td>MDX-Viewer NICU</td>
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<td>MDX-Viewer TMS</td>
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<tr>
<td>Marketing/PR</td>
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<td>Initial sales cycle</td>
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</tbody>
</table>

Initial sales cycle
## Use of Funds

Objectives over the next 24 months, with $10 million invested capital

<table>
<thead>
<tr>
<th></th>
<th>year 1</th>
<th>year 2</th>
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</thead>
<tbody>
<tr>
<td><strong>Development &amp; Manufacturing</strong></td>
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<tr>
<td>Hardware Development</td>
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<td>Probe Development</td>
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<td>Software Development</td>
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<td>Certifications</td>
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<td>Manufacturing</td>
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<td><strong>R&amp;D, Regulatory &amp; Clinical Trials</strong></td>
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<td>Laboratory &amp; Research</td>
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<td>Clinical Trials Mitochondrial Transplantation</td>
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<td>Regulatory - 501k certification</td>
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<tr>
<td><strong>Marketing &amp; Sales</strong></td>
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<td><strong>General &amp; Administrative</strong></td>
<td>$1,200,000</td>
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<td><strong>Total expenses over two years</strong></td>
<td>$4,750,000</td>
<td>$5,250,000</td>
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</table>
Management

Prof. Avraham Mayevsky, PhD
CSO
Professor Emeritus at Bar Ilan University in Israel.
The world leader in monitoring of physiological activities in the brain and in tissue.
More than 240 research published articles.

Dr. David Platt, PhD
President
Founder of five public companies.
Author of > 50 patents.
Numerous articles in academic publications.

Ed Goff
CEO
35 years of Executive Leadership in Fortune 50 as well as high-growth Software and High-Tech Startup companies.

Ola Soderquist, CPA, CMA
CFO
30 years of Executive Leadership in public and private organizations.
MBA from Babson College.
Board and Advisors

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.  
> 130 technical publications.

Dr. Dale Conaway, DVM
Chief Veterinary Medical Officer for the Office of Research Oversight in DVA.

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.
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Breakthrough Technologies in Tissue Vitality

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