

# **APELIOTUS**

## **Vision Science**

**Testimony of  
Dr. Gregory Jackson  
Co-Founder and Chief Scientific Officer  
Apeliotus Vision Science**

**Submitted to the PA House Republican Policy Committee**

**November 17, 2010**

Good morning, Representatives. My name is Dr. Gregory Jackson. I am Co-Founder and Chief Scientific Officer of Apeliotus Vision Science. Apeliotus Vision Science is a medical device company. We are commercializing a diagnostic test for an eye disease called age-related macular degeneration.

I thank Representative Payne for the opportunity to tell you about Apeliotus Vision Science. Apeliotus Vision Science is a university spinout based on technology that I invented at the University of Alabama at Birmingham. The company was founded in Hershey because I was recruited to conduct eye research in the Department of Ophthalmology at the Penn State College of Medicine. Penn State allows its faculty to be involved with startup companies, and in turn Apeliotus has conducted essential translational research at the College of Medicine. The relationship has been mutually beneficial because patients in our studies have gained access to cutting edge technology, and Apeliotus Vision Science has been able to validate the concept. The Hershey Center for Applied Research provides us with state-of-the-art space, and its close proximity to the College of Medicine is ideal for university spinouts such as ours.

Age-related macular degeneration is the leading cause of irreversible blindness among adults over 50 years old in the industrialized world. The disease results in the progressive deterioration of the retina, the cells in the back of the eye that enable vision. Once these cells die, vision is permanently lost. The disease destroys central vision that is necessary for reading, driving or simple activities like clearly seeing a face.

An estimated 30 million people are affected worldwide, including approximately 13 million Americans. One in six people over age 65 have the disease, increasing to one in three over age 75. Given the incidence of the disease and the maturation of 76 million baby boomers, almost everyone will know someone with age-related macular degeneration. The market for diagnosis and treatment of age-related macular degeneration is expected to grow to \$7 billion dollars per year.

The key is to diagnose the disease early so that patients with visual symptoms can be directed to an ophthalmologist for immediate treatment. Too many patients discover they have the disease too late,

losing vision in one eye before they know to seek care. Early diagnosis will lead to earlier treatment and reduced vision loss.

I discovered that measuring how well a person adjusts to darkness can quickly determine if that person has age-related macular degeneration. The process of adjusting from day vision to night vision is called dark adaptation, and I have studied the phenomena for the past 14 years. Six years ago, we began the translational research to move from the laboratory to a practical test that would be useful in the clinic. The initial research method required over two hours to make a diagnostic determination. We have reduced that time to 5 minutes. The result is a proprietary instrument to measure dark adaptation called the AdaptDx.

From a business standpoint, Apeliotus Vision Science is following a well-known model for an eye disease diagnostic. Glaucoma is another common eye disease, which leads to irreversible blindness. In clinical practice, optometrists routinely check for glaucoma using an instrument called a visual field analyzer. This test is very sensitive to glaucoma, allowing earlier detection and earlier treatment. Furthermore, it is reimbursed by Medicare and private insurance companies, promoting routine screening and making it a profit center for optometry practices. The market for visual field analyzers to perform glaucoma testing is estimated to be \$200 million per year. Our AdaptDx is very similar to a visual field analyzer and has a similar reimbursement. Thus, we expect optometrists will have a similar incentive to test patients for age-related macular degeneration, to the benefit of patients and the profit of optometrists. Because many more people are at risk of developing age-related macular degeneration, the market is expected to be larger than the glaucoma market and may be as large as \$400 million per year. Apeliotus Vision Science intends to be a dominant player in this market. Our corporate headquarters, research & development and sales & marketing operations are based here in Hershey, and our plan is to manufacture AdaptDx in Pennsylvania.

Ten research centers have conducted clinical studies using AdaptDx over the past six years. These centers include Harvard, Johns Hopkins, University of Melbourne in Australia, University of Copenhagen in Denmark and of course, Penn State. Eighteen translational research projects have been completed or are ongoing, involving more than 1,300 patients. In addition, AdaptDx is being used by three major drug companies to help develop next generation treatments for age-related macular degeneration. Within the next five years there is a good chance that preventative treatments will be developed. Our science has been guided by influential leaders in ophthalmology and optometry, including the Chair of Ophthalmology at Harvard, the founder of Ciba Vision (the company that created the contacts lens industry) and leading clinical scientists from the National Eye Institute and major universities around the world. The validity of the technology has been established, and the scientific risk has been eliminated.

Apeliotus is now in the last stages leading to commercialization. Academics call it translational research. In industry it is referred to as product development. While we are well into the product development phase, final production engineering must be completed, and we still need to learn such things as how optometrists will integrate our test into their practices and how optometrists and patients will use the diagnostic information it provides. For example, will patients decide to see their optometrists more

often for monitoring of their condition? Educational programs need to be developed for clinicians and patients.

To address these issues, Apeliotus has partnered with Edge Product Development in Newtown outside of Philadelphia and Cygnus Manufacturing in Saxonburg, which is northeast of Pittsburgh. Edge Product Design is developing the final commercial instrument and Cygnus Manufacturing is assessing the manufacturability of the design. The commercial instrument will be half the size of the current research prototype and have all the features of a state-of-the art diagnostic test for use in an eye care practice, including a slick touch screen interface for the operator and internet connectivity for electronic medical records and remote servicing.

We have made substantial progress over the past four years despite one of the worst funding environments in memory for a startup company. The basic technology development was bootstrapped with \$1.6 million of grant funding from the National Institutes of Health and private research foundations. Life Sciences Greenhouse of Central Pennsylvania and Ben Franklin Technology Partners then provided \$900,000 to begin translational research, and this critical funding from the Commonwealth has brought us roughly half way through the product development process. To move forward, we need to complete the last stages of product development. Only then can Apeliotus Vision Science attract venture capital for final commercialization.

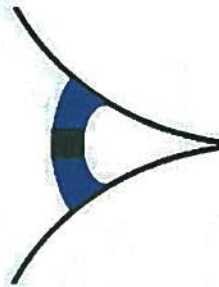
With an additional investment of \$1 million, the company will be able to finish product development, gain regulatory approval from the US Food and Drug Administration and place commercial prototypes at four optometry practices across the Commonwealth for final usability studies. All of this can be completed within one year, putting us in a position to raise venture capital and begin routine commercial sales by the end of 2011.

We are excited about the prospect of helping eye care providers stem the loss of vision from this devastating disease.

Thank you for your time. I would be happy to answer any questions.

# **APELIOTUS**

## **Vision Science**



**Early Detection, Early Treatment**

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Wednesday, November 17, 2010

# Age-Related Macular Degeneration (AMD)



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# AMD Destroys Central Vision



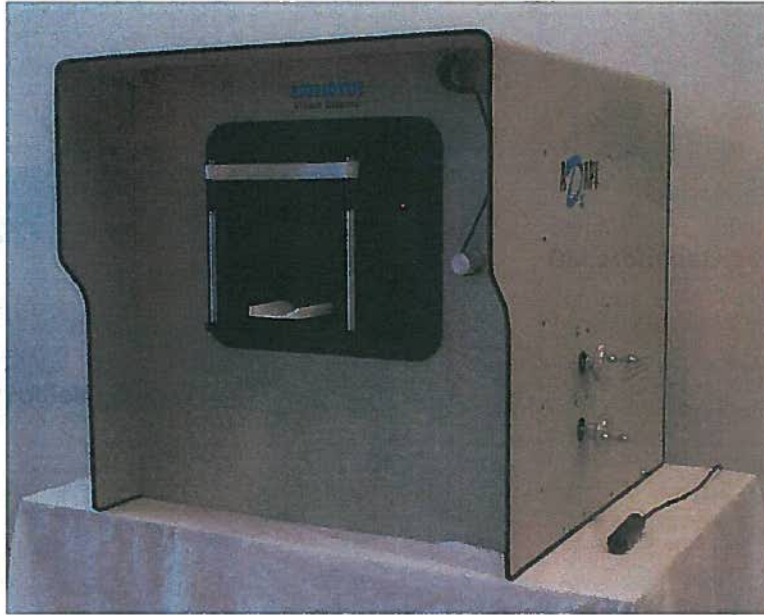
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# AMD: #1 Cause of Adult Blindness

- 30 Million People Affected Worldwide
- 1 in 6 Adults 65+
- 1 in 3 Adults 75+

“Market for diagnosis and treatment of AMD is expected to grow **\$7 billion/year.**”

# AMD Screening



Development Prototype



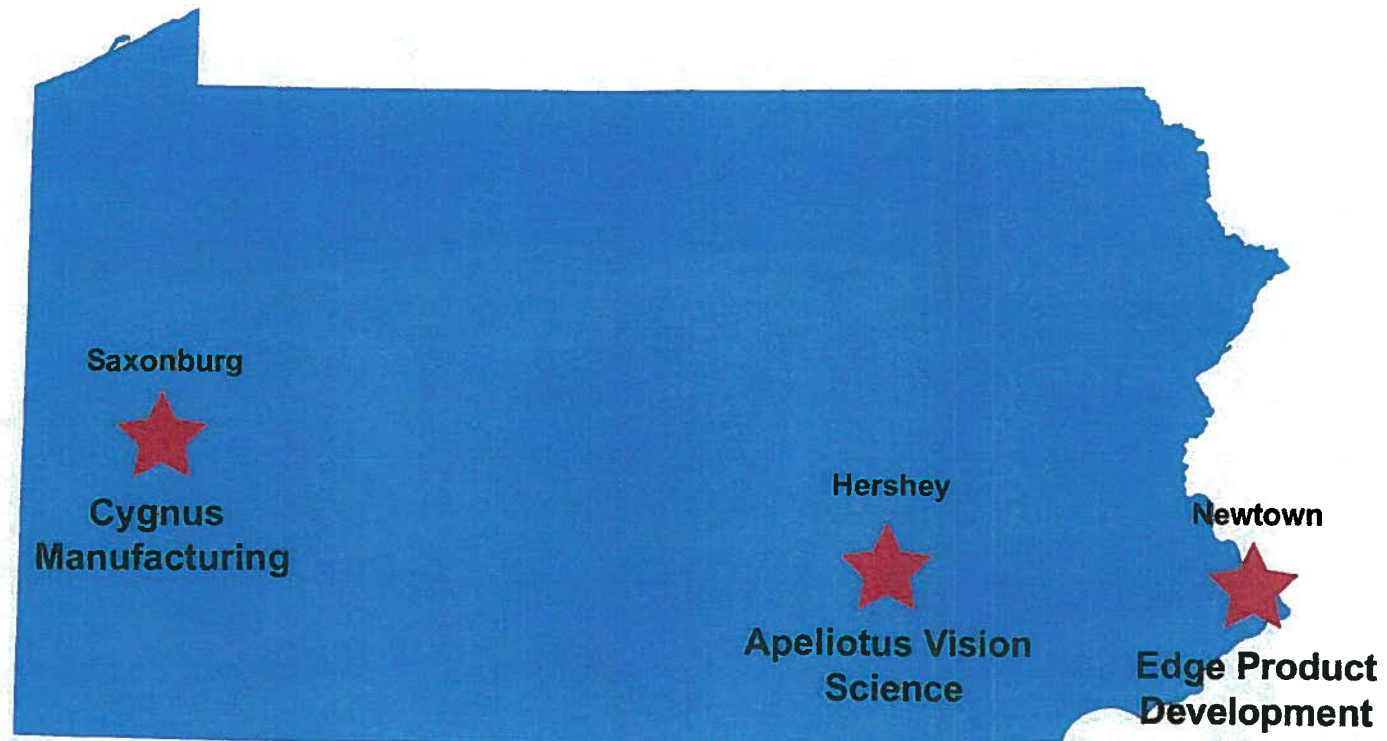
- 5- to 20-Minute Screenings
- \$300-400 Million Market (Annual)
- AdaptDx's Profit Potential is Greater Than Profits Generated from Humphrey Perimeter, a Screening Device for Glaucoma

# Phase I: Technology Development



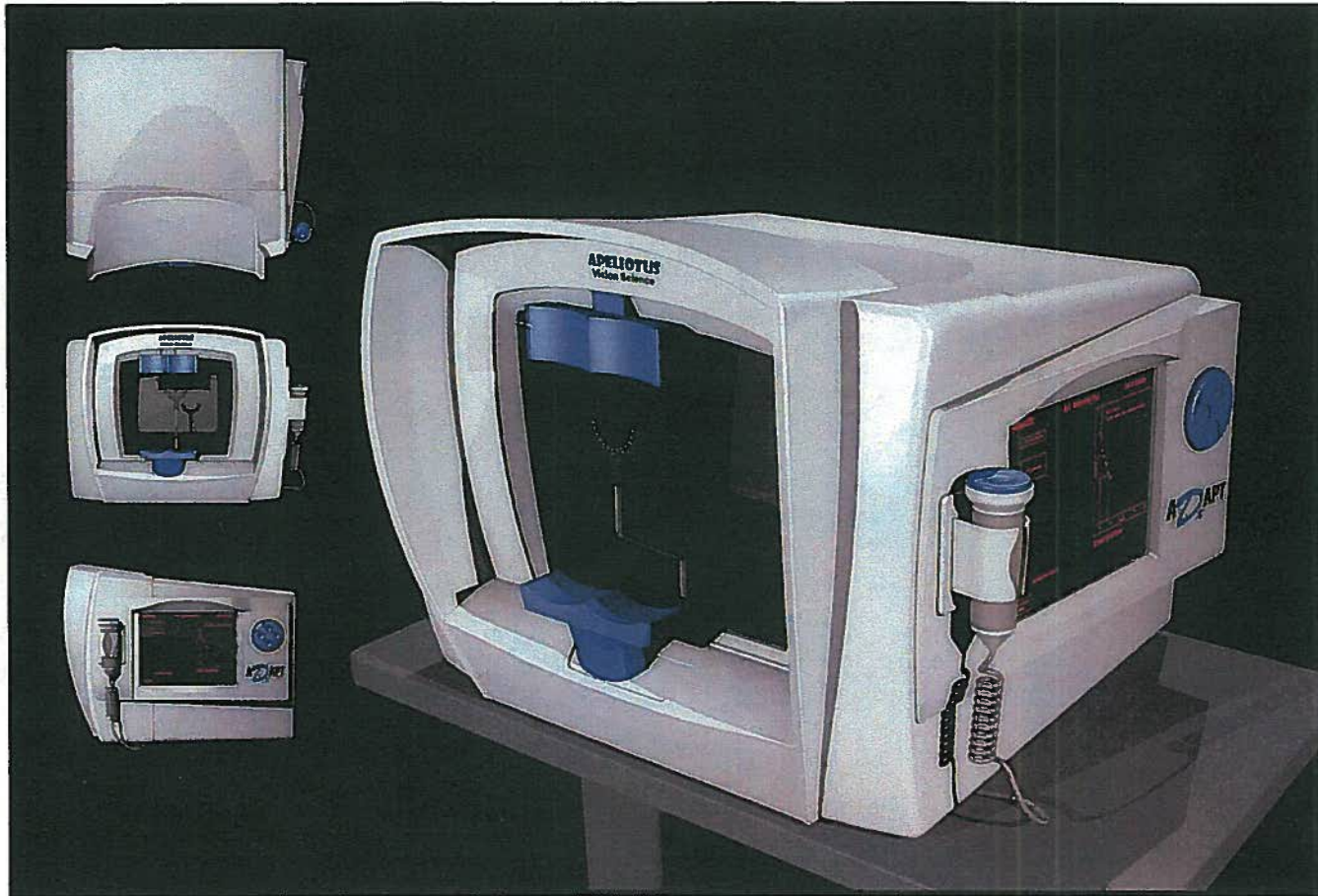
- Established 10 Research Centers Worldwide
- Completed 18 Translational Research Projects
- Tested More than 1,300 Patients

## Phase II: Product Development



Designed and Manufactured in Pennsylvania

# Commercial Product



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# Company History

## Technology Development

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(2004–2008)

Founders' Seed Capital - \$200,000

IRRF Grant - \$112,000

EyeSight Foundation Grant - \$25,000

NIA SBIR Phase I - \$110,000

NIA SBIR Phase II - \$1,120,000

## Product Development

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(2008–2010)

NEI SBIR Phase I - \$138,000

LSGH - \$500,000

Ben Franklin - \$400,000

QTDP (Qualifying Therapeutic Discovery Project) - \$244,000

## Product Demonstration

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(2011)

???? - \$1,000,000

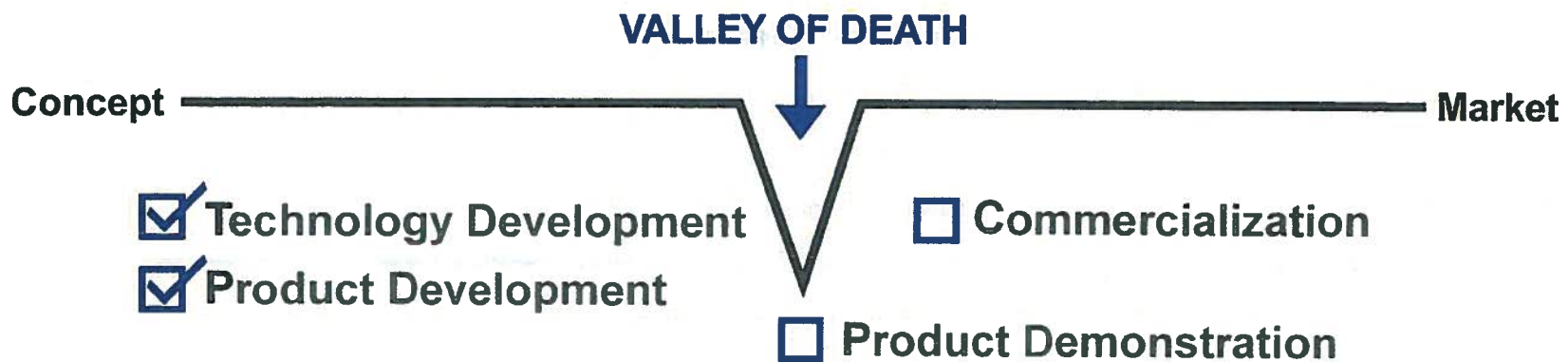
## Commercialization

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(2012)

Venture Capital - \$5,000,000

# Critical Timing



# Critical Need

**VALLEY OF DEATH**



**Market**

**\$1 Million Infusion**

- Production Engineering
- Regulatory Approval
- Product Demonstration Sites

Early Detection, Early Treatment

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