

Life in a Post-Automotive Cleveland, The Medical Device Industry, and Growing 21st Century Companies

IRIS SHOW

September 15, 2009

Robert N. Schmidt, Chairman
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Orbital Research Inc.

NeuroWave Systems Inc. /Flocel Inc.

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A Dynamic In Vitro Blood-Brain Barrier Model

CleveMed

Cleveland Medical Devices Inc.

NE Ohio, Where we are.

- The economic impact of the steel and automotive industries is waning in northern Ohio,
- New industries and companies are required to provide 21st century jobs for the region.
- This requires a significant cultural change, with new entrepreneurial thinking, and new funding sources.
- With a 20-40 year horizon to develop new industries and products, a sustained effort over multiple administrations needs to be made, despite the changing economic environment.
- Engineers, with experience in one type of work place, need to adapt to new requirements, specifications, testing environments, timelines, team sizes and capabilities, and other parameters which push individual comfort zones.



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Agenda

- The Megatrends
- A look at Automotive and Iron & Steel Industries
- Cleveland's Economy and the Role New Bio Companies can Play
- How CleveMed and Orbital Research Plan on Participating in New Job Development



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First, The Megatrends

- Unemployment is up and employment is down.
- Credit is hard to get.
- The dollar is sinking fast.
- Will inflation be far behind?



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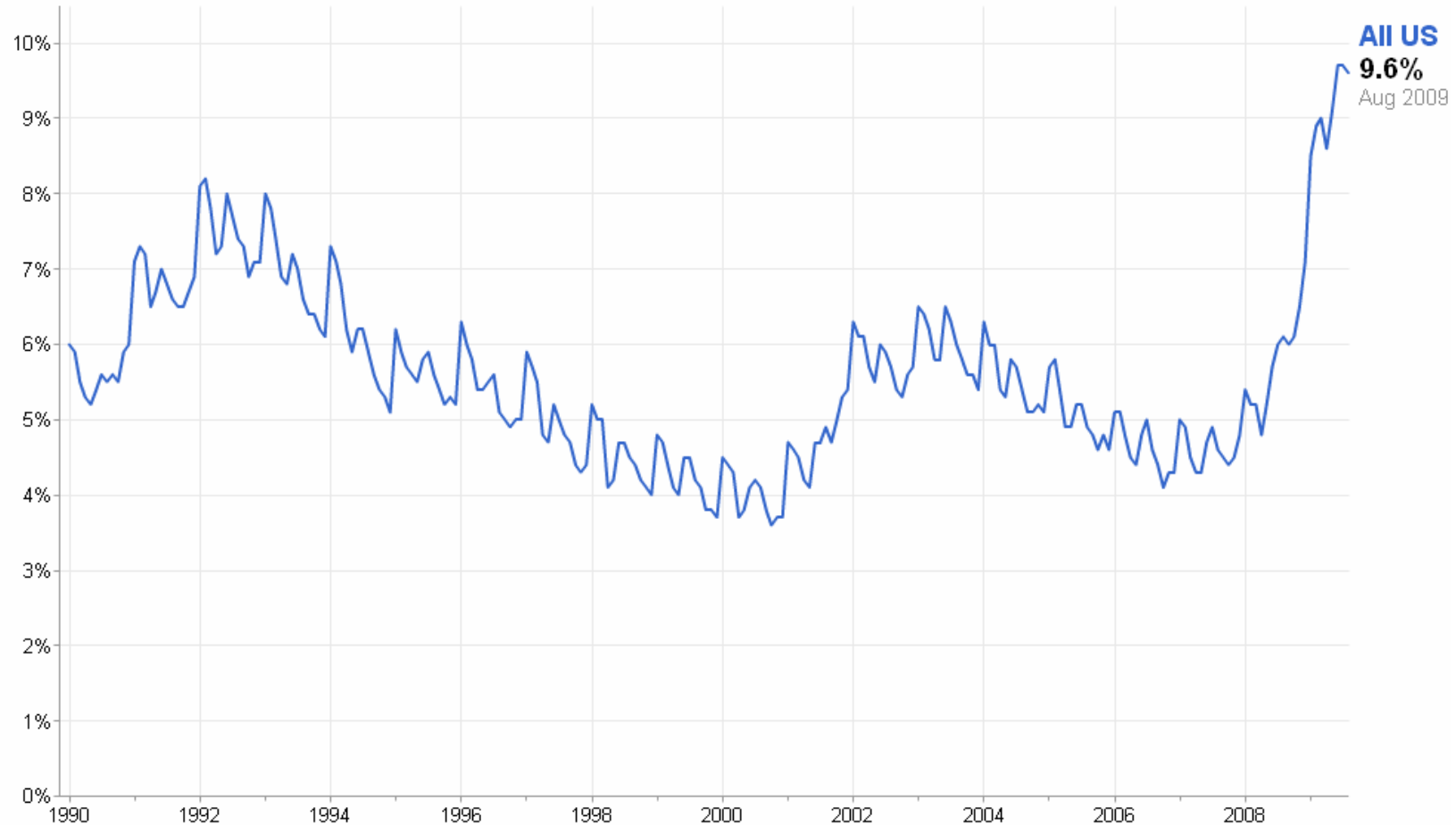
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US Unemployment Rate up to 9.6% (August 2009)

Unemployment rate

The percent of the labor force that is unemployed, not seasonally adjusted. [More info >](#)



Data source: [U.S. Bureau of Labor Statistics](#) - Last updated September 9, 2009



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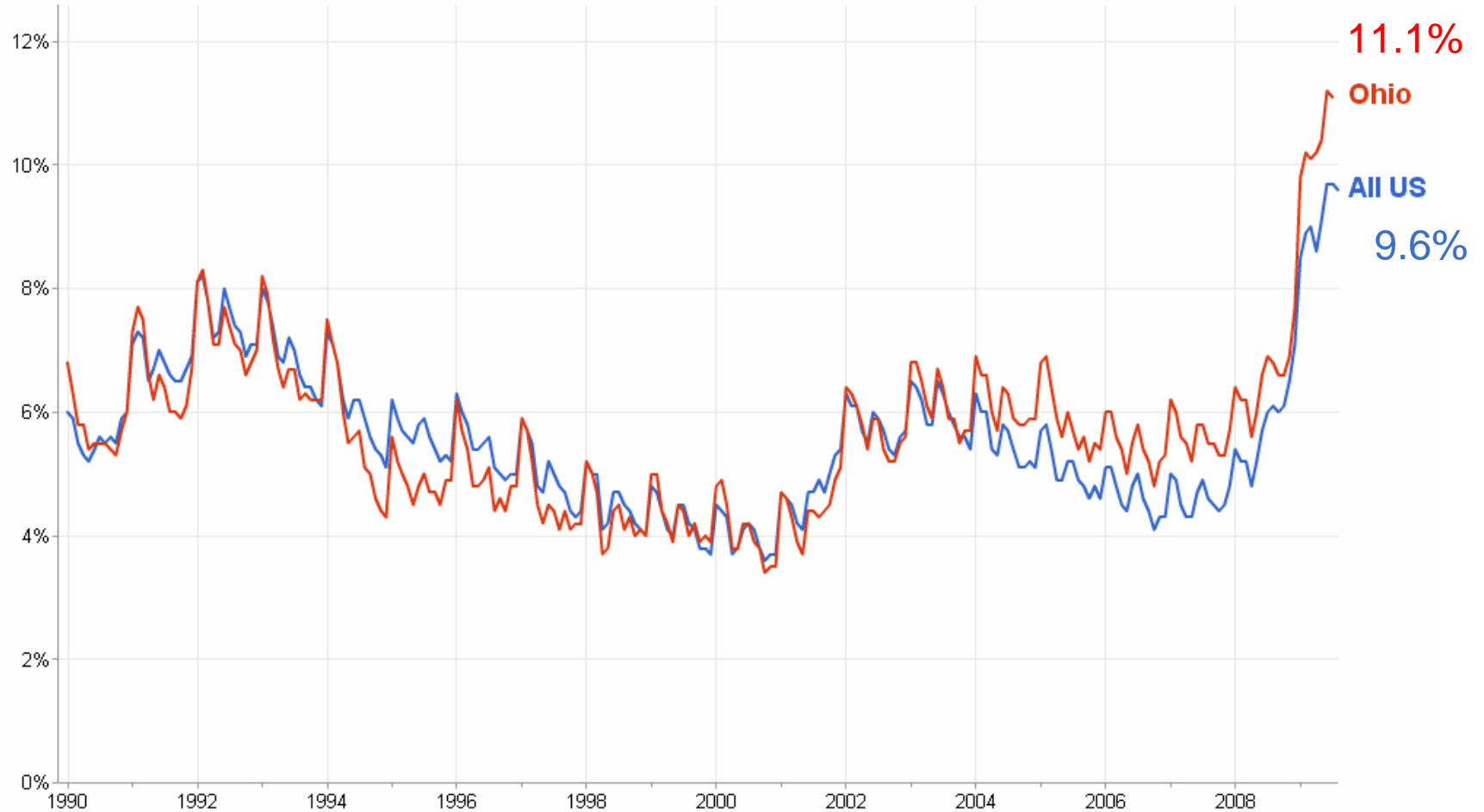


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Ohio's Unemployment Rate is 11.1% (July 2009)

Unemployment rate

The percent of the labor force that is unemployed, not seasonally adjusted. [More info »](#)

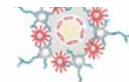


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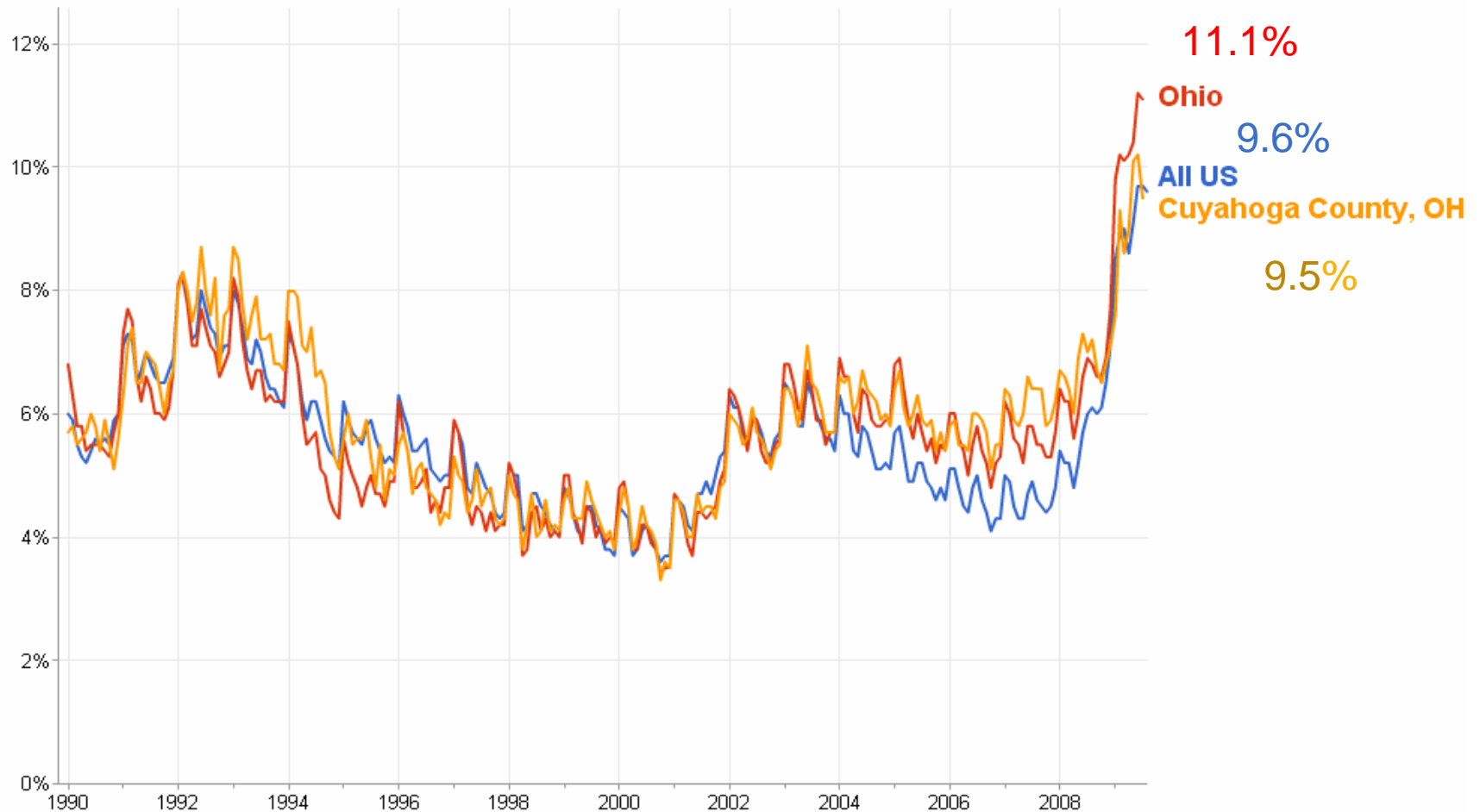
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Cuyahoga County's Unemployment Rate is 9.5% (July 09)

Unemployment rate

The percent of the labor force that is unemployed, not seasonally adjusted. [More info »](#)

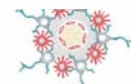


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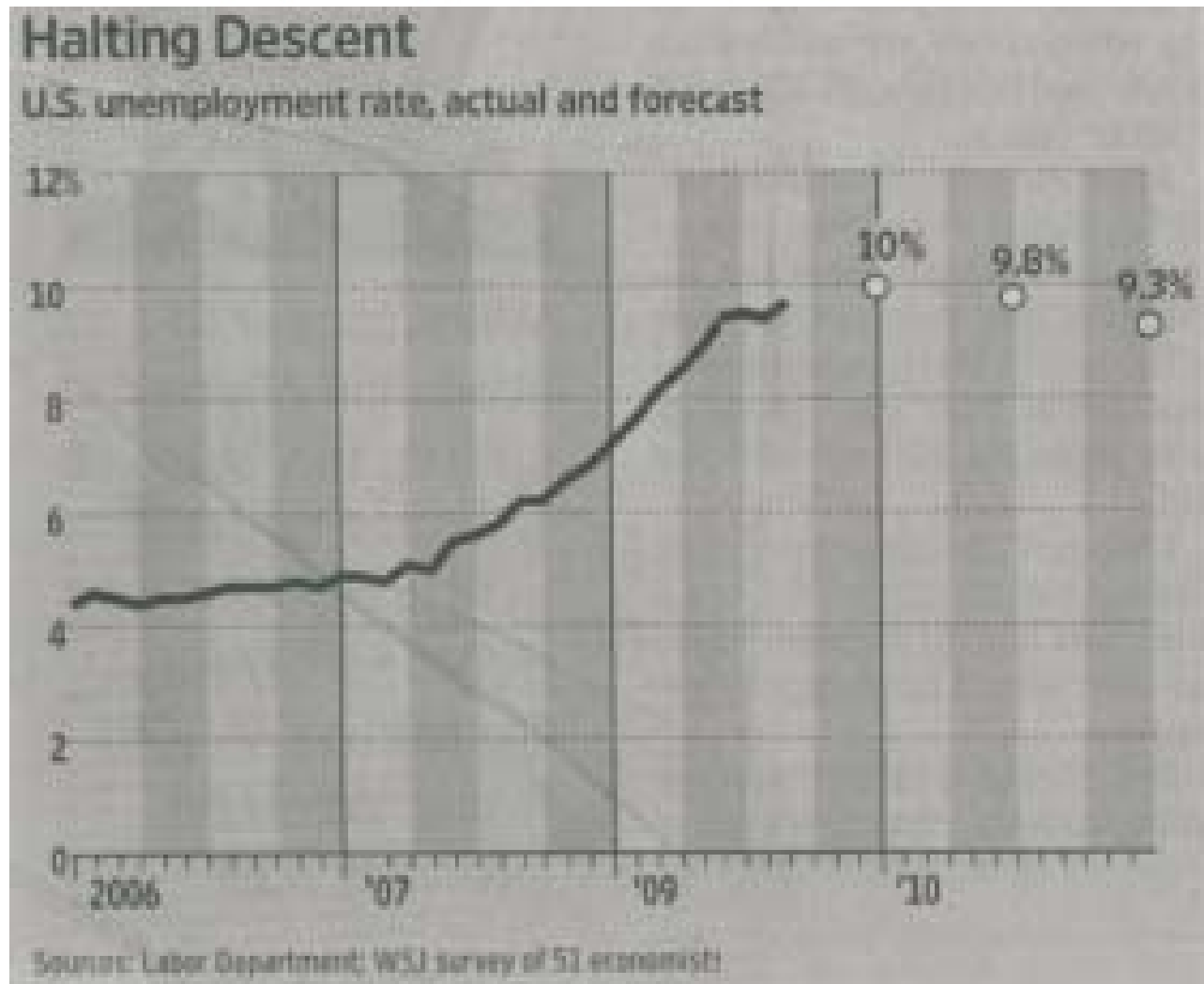
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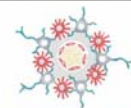
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Economists Think the Unemployment Rate will Come Down in 2010 (August 2009)



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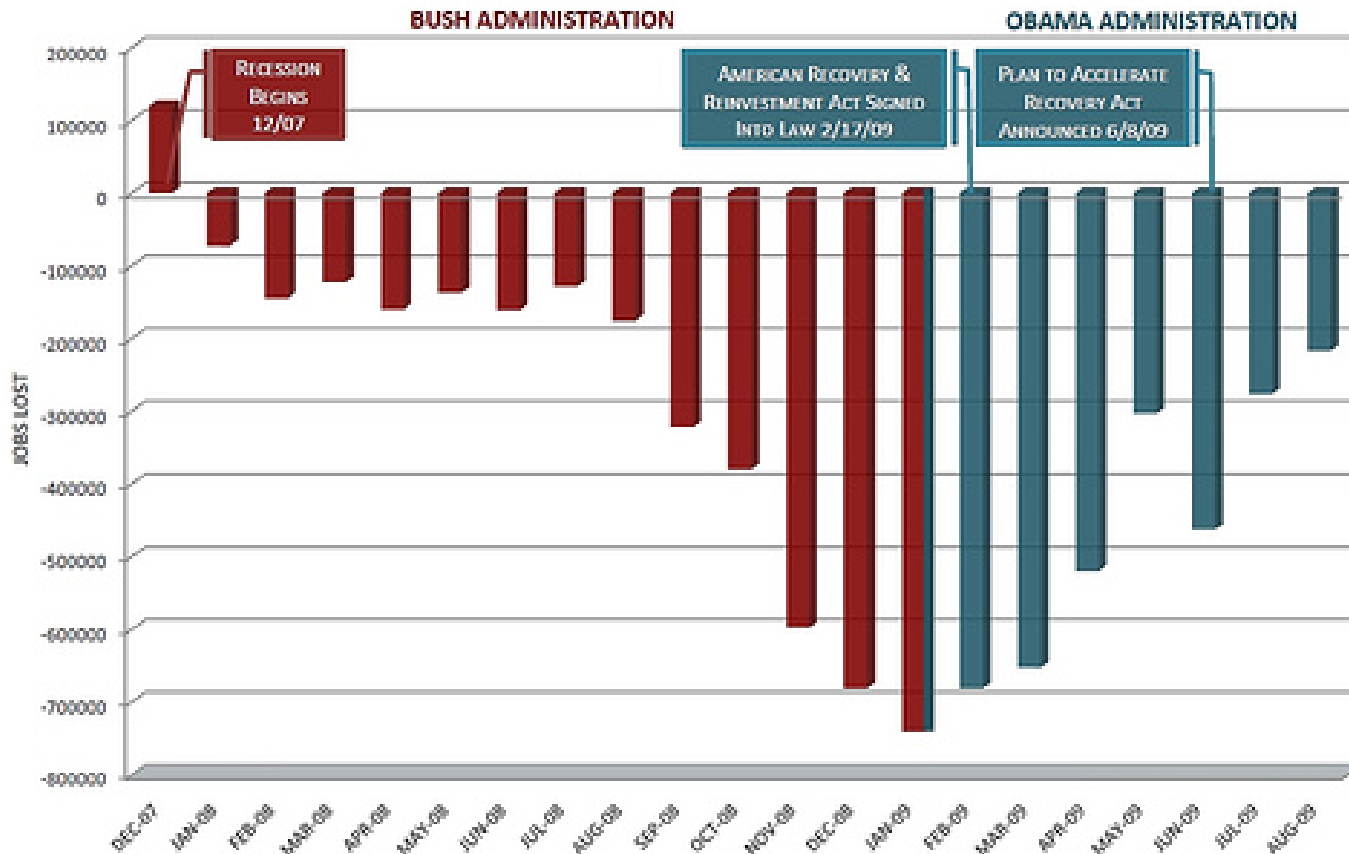
A Dynamic In Vitro Blood-Brain Barrier Model

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Pelosi Says we are on the Road to Recovery

AUGUST SHOWS FEWEST JOB LOSSES IN A YEAR:
AMERICA IS ON A PATH TO ECONOMIC RECOVERY



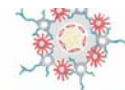
OFFICE OF SPEAKER NANCY PELOSI

SOURCE: BUREAU OF LABOR STATISTICS



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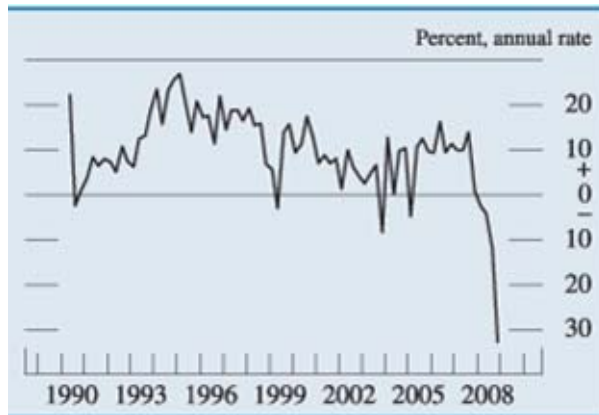
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Credit is hard to get

8. Change in Unused Bank Loan Commitments to Businesses and Households, 1990:Q2–2008:Q4



NOTE: The data, which are not seasonally adjusted, are quarterly and extend through 2008:Q4.

SOURCE: Federal Financial Institutions Examination Council, Consolidated Reports of Condition and Income (Call Report).

<http://www.federalreserve.gov/boarddocs/RptCongress/annual08/sec1/c1.htm>

- Nearly **33 percent drop (annual rate) in total unused loan commitments** reported in fourth-quarter. Many banks indicated in the January survey that they had cut the size of existing credit lines to businesses and households
- **Relationships** between U.S. companies and their banks **are becoming strained** as small and mid-size businesses feel that they are being made to pay for the banking industry's past mistakes.
- More than a third of the 670 small and mid-sized companies participating in the latest Greenwich Market Pulse say they are paying more in interest rates or banking fees than they were six to 12 months ago. Among **small businesses** that have been hit with higher rates or fees, **55% feel they are being taken advantage of by their banks and cite increases as "unacceptable"** as do **44% of mid-sized companies that have experienced increased banking costs.**
- Looking ahead, **three-quarters of small and mid-sized companies** surveyed by Greenwich Associates say they are **concerned about their ability to secure the financing** needed to run their businesses in the coming year.
- http://www.greenwich.com/WMA/in_the_news/news_details/1,1637,1804,00.html?vgnvisit-or=eKKVlqWOnpc=



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Because Banks have Clamped Down on Credit

15. Net Percentage of Domestic Banks Tightening Standards and Increasing Spreads on Commercial and Industrial Loans to Large and Medium-Sized Borrowers, 1993-2009



NOTE: The data are drawn from a survey generally conducted four times per year; the last observation is from the January 2009 survey, which covers 2008:Q4. Net percentage is the percentage of banks reporting a tightening of standards or an increase in spreads less the percentage reporting an easing or a decrease. Spreads are measured as the loan rate less the bank's cost of funds. The definition for firm size suggested for, and generally used by, survey respondents is that large and medium-sized firms have annual sales of \$50 million or more.

SOURCE: Federal Reserve Board, Senior Loan Officer Opinion Survey on Bank Lending Practices.

- Virtually every bank made it more expensive for companies to borrow money, even for their best customers
- More than 80% of the banks made it harder to get a loan, no matter what your credit rating.



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The dollar is sinking fast



- The dollar has continued to decline over the last several quarters.



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Will inflation be far behind?

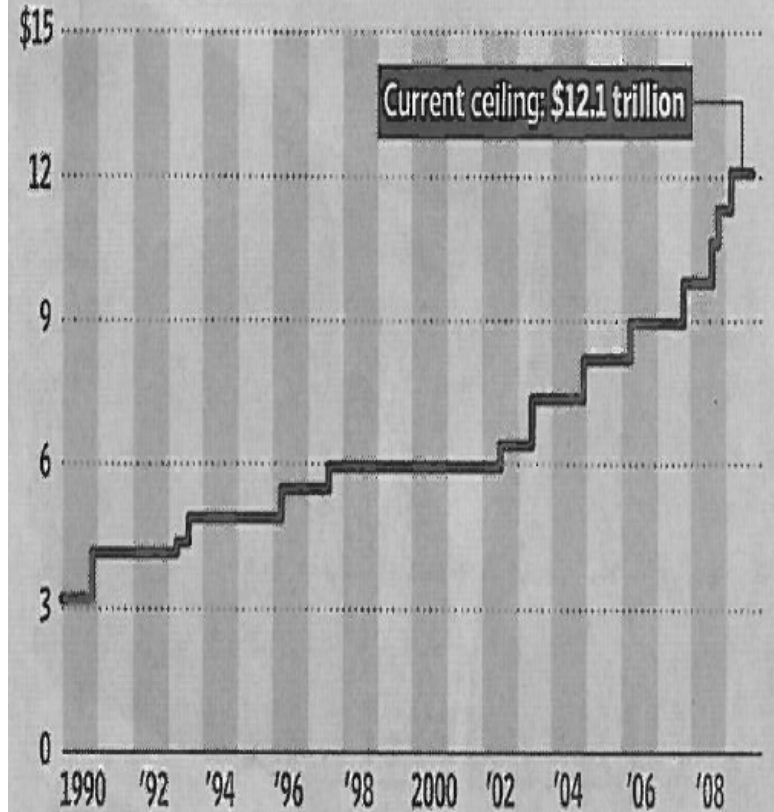
U.S. revenues and spending, in trillions



Source: Congressional Budget Office

Pushing the Limit

The federal debt ceiling, in trillions

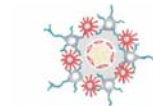


Source: Office of Management and Budget



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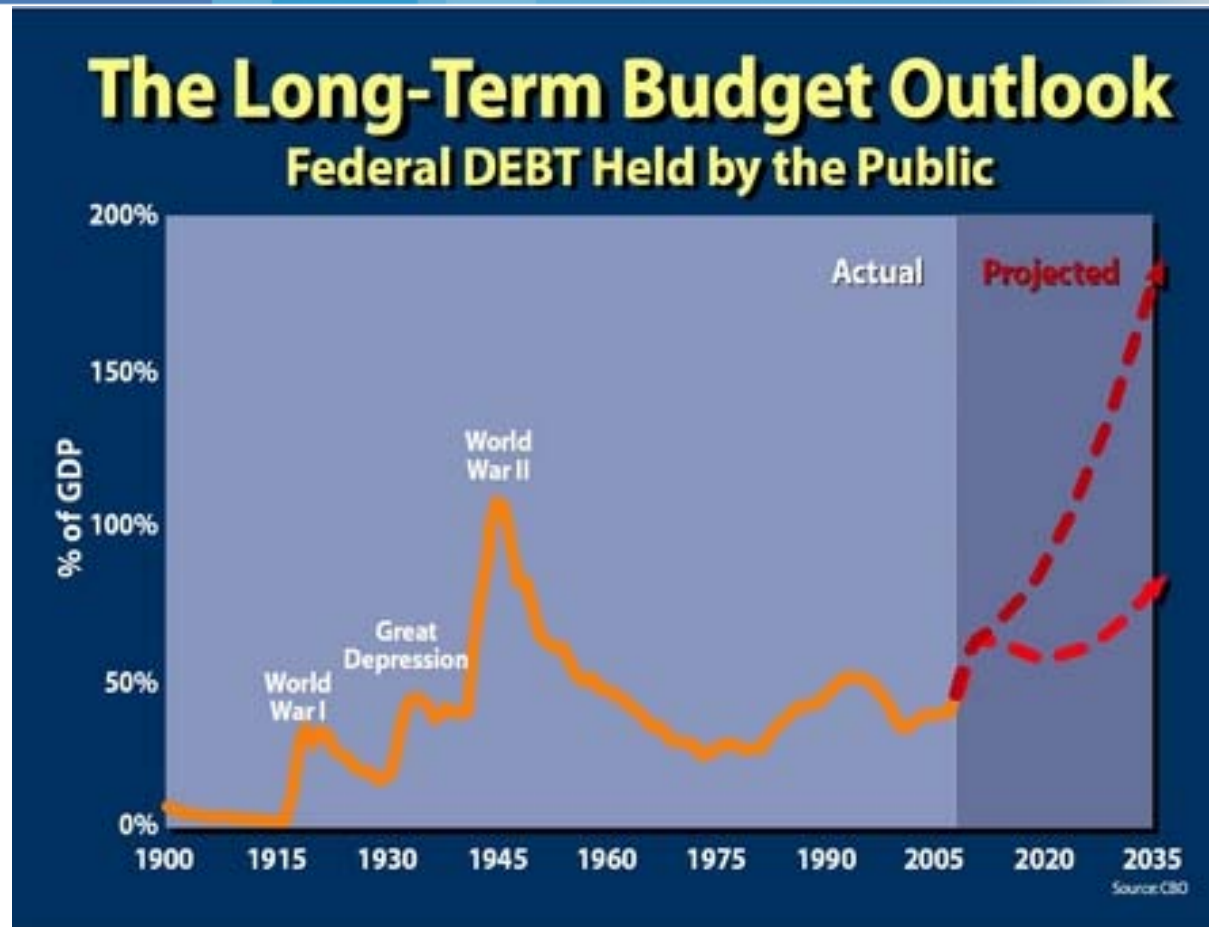
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Interest Rates are Affected by the Debt

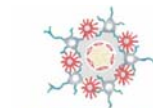


- Increasing debt will likely increase interest rates



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Megatrend Lessons

- **New Jobs will come primarily from Local Companies.**
- **Less money will be available from governments and banks.**
- **Companies will mostly have to self-finance.**
- **Look globally for sales.**



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A look at Automotive and Iron & Steel Industries



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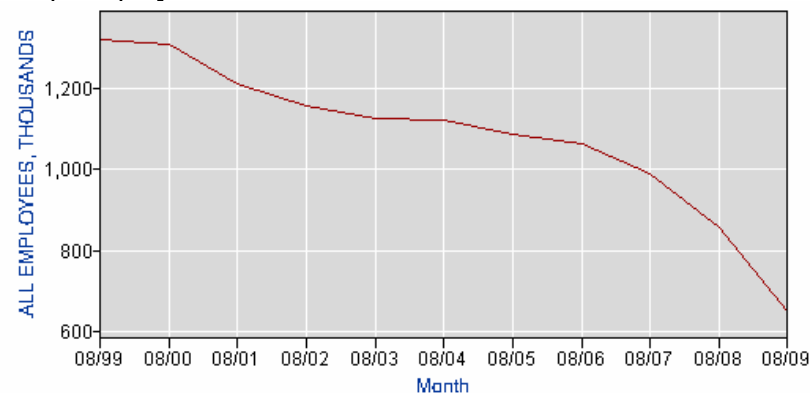
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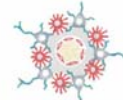
Motor Vehicles & Parts Manufacturing, US Employment

August	Employees, Thousands	% Decrease Since 1999		
1999	1321.5	-		
2000	1309.6	0.9%		
2001	1210.5	8.4%		
2002	1156.8	12.5%		
2003	1123.9	15.0%		
2004	1120.1	15.3%		
2005	1086.5	17.8%		
2006	1064.1	19.5%		
2007	989.7	25.1%		
2008	856.7	35.2%		
2009	653.3 (prelim.)	50.6%		



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Steel Manufacturing, US Employment

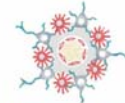
- 2006 Steel Industry Employment 154,000 jobs
 - Iron & Steel Mills 94,000
 - Steel Products & Purchased Steel 60,000
- The industry is projected to shrink by 25.1% from 2006-2016 by BLS

<http://www.bls.gov/oco/cg/cgs014.htm>



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Cleveland's Economy and the Role New Bio Companies can Play



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HARNESSING THE POWER OF EEG



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Cuyahoga County, 2006 Census Estimates

Population:	1,314,241
Businesses	36,990
Employees	698,597
Percent over 65 yrs old	15.1%
Households Retired (OH)	18.9%

Source: <http://quickfacts.census.gov/qfd/states/39/39035.html>

2002 Cuyahoga County Economy

Manufacturers shipments	\$19,827 Million
Wholesale trade sales	\$23,055 Million
Retail sales	\$15,483 Million
Accommodations & food serv.	\$ 2,132 Million
Federal spending, 2004	\$10,166 Million

Cuyahoga County Economy ~ \$70.663 Billion
Gross Regional Economy ~\$171 Billion



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What Does Cuyahoga County Need?

The County had ~93,173 Manufacturing Jobs in 2003
~22,000 Auto & Parts Mfgr. Jobs in Cuyahoga County

Source: http://www.riderta.com/pdf/transit2025/Transit_2025_March_2006_Final_ch2.pdf
<http://www.clevelandfed.org/bsr/Conditions/v7n1/autos.cfm>

With a \$70+ Billion Economy, and ~700,000 Jobs

To be significant, we need to create about 5% of the economy, or:

- \$3.5 Billion of Sales
- 35,000 jobs

This will more than replace the auto & steel industries



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Medical Device Industry in Ohio and NE Ohio



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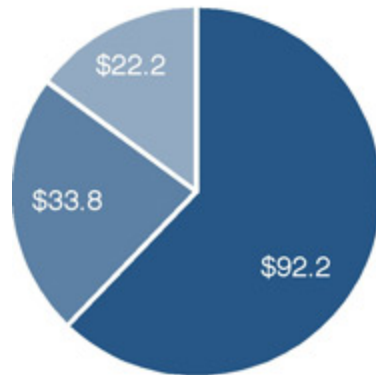
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Biosciences are Already a Significant Part of the Ohio Economy

\$33.8 Billion in
Bioscience
Company Sales

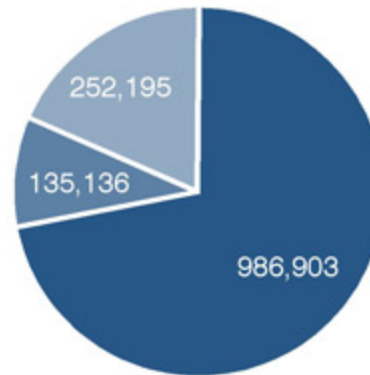
2007 Statewide
Economic Impact



In billions

- Hospitals & Healthcare
- Commercial Bioscience Industry
- Medical Colleges

2007 Statewide
Employment Impact



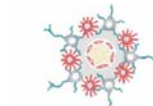
135,136
Bioscience
Company Jobs

The total economic impact of Ohio based bioscience is **\$148.2 billion**, representing **15.7%** of Ohio's total economic output. Bioscience also directly and indirectly generates **1.4 million jobs** in Ohio.



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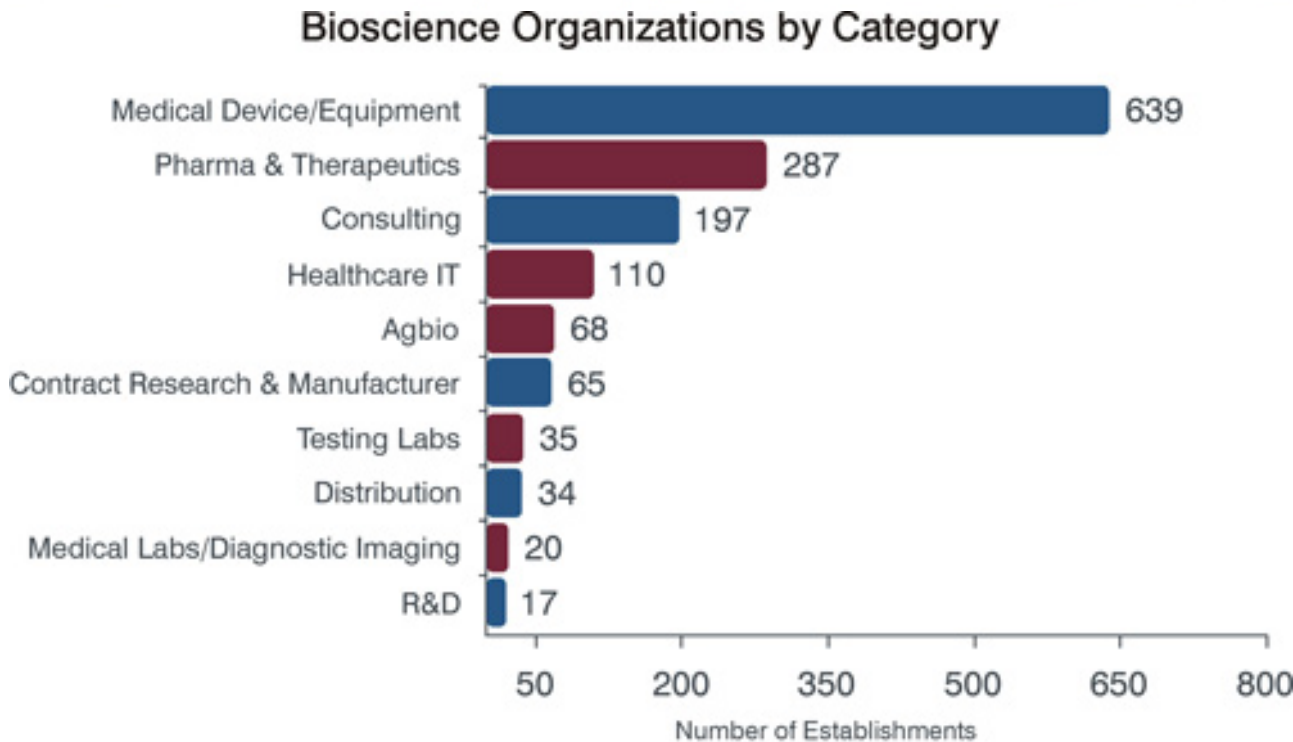
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~1,100 bioscience-related organizations in Ohio



~58% of the bioscience firms are Biomed (medical device companies)

**One company may be categorized within more than one area
Source: BioOhio database*

- More than **\$2.5 billion** were invested across Ohio to accelerate Ohio's bioscience growth in 2007, a jump of more than \$1.4 billion since 2004. The sources of funding include venture capital, angel funds, IPOs, acquisitions, SBIR/STTR, state biomedical R&D grants, and NSF and NIH grants. Most of this is to hospitals and universities.



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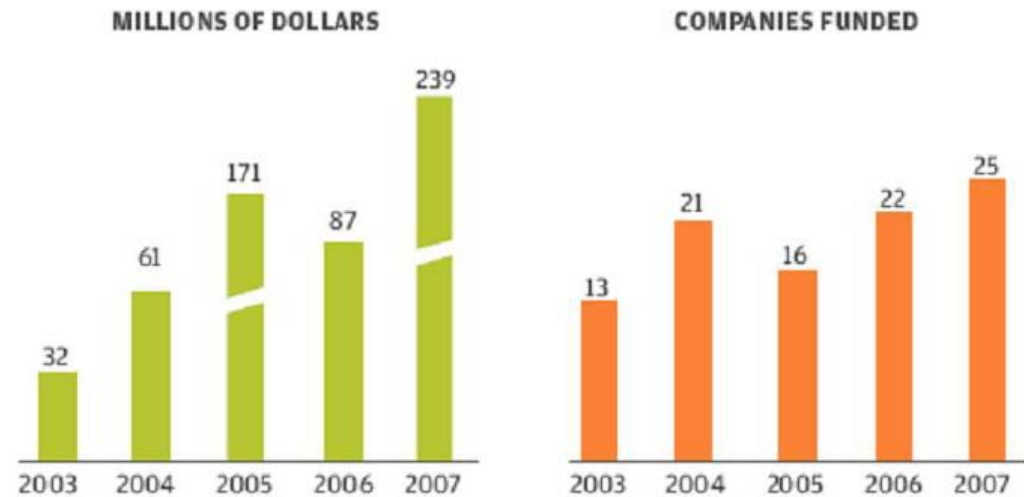
Where is the Medical Device Industry in 2008?

From 2003-2007, 70 health care start-ups in Greater Cleveland have attracted over \$600 million in new equity funding and another 35 have attracted \$70 million in NIH SBIR grants.

Nearly 500 firms that produce goods or provide services into the health care industry exist in the region. These include large companies such as Philips Medical, Hitachi, Invacare, Steris, and Boehringer Ingelheim (Ben Venue) as well as an array of smaller firms. Medical device firms represent more than half of the companies.

Source: Cleveland: The Nation's New Bioscience Innovation Destination: BioEnterprise Report 2008

HEALTH CARE EQUITY INVESTMENT



Source: Midwest Health Care Investment Report

There are about 300 Medical Device firms in the NE Ohio

I Estimate about 175 in Cuyahoga County



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Rules of Thumb for Company Start-Up

<u>Product or Service</u>	<u>Cost to Launch</u>	<u>Time* (Years)</u>
Simple Service	\$100K to \$1M	1-3
Simple Product	\$5M+	2-10
BioMed Products	\$5 M to \$50 M	10-20
Drug	\$1 billion +	15-20+

Time to Profitability (self sustaining)



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NE Ohio Needs More Angel and VC Funds

- Ohio has some of the better Angel Funds.
 - North Coast Angel Fund
 - Jumpstart
 - Ohio Tech Angel Fund, Columbus
 - Toledo, Cincinnati, Akron
- BioEnterprise assists with VC funding.
- We need to increase early stage funding by an order of magnitude.



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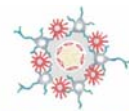
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How CleveMed and Orbital Research Plan on Participating in New Job Development



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My Goals—Grow 3 New Industries in NE Ohio

- **Brain Industry** (Medical Devices)
- **Aerionics** (Aerodynamic Flow Control)
- **MEMS**



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Introduction to Cleveland Medical Devices Inc. and Orbital Research Inc.



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Cleveland Medical Devices Inc. (CleveMed)

- Founded in December, 1990
- Use the Thomas Edison Model, Invention Factory
- Stock owned by employees
- Awards
 - **Inc. 500**, 2000, 812% five year growth
 - **Inc. Inner City 100**, 2000 (34), 2001 (15), 2002 (27)
 - **Weatherhead 100**, (NE Ohio), 1999, 2000/01/03/04/05/06
 - **Ohio Emerging Technology Award**
 - **Tibbetts Award**, Best SBIR Companies (2002/2006)
 - **NIH Success Story** (NIH Website)
 - **Stevie**, Best Product Designer-2007 (NY Post-America's Business Oscars)
 - **Best Neuro Product-Kinesia** Neurotech Business Reports, 2007
 - **Best Product in North America-Kinesia**, Frost & Sullivan 2008



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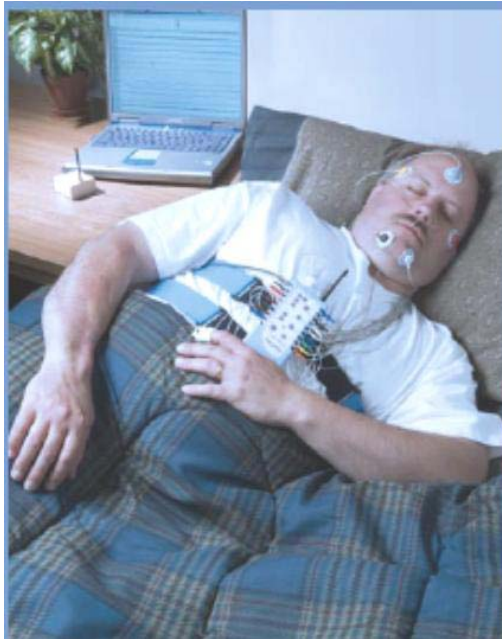
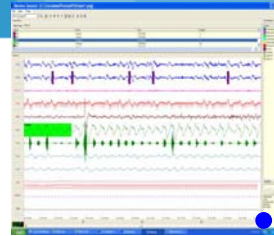
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CleveMed's Medical Products

Sleep Disorders –

Crystal 20-S/B, SleepScout, Sapphire, iPSG, DreamPort, SleepView



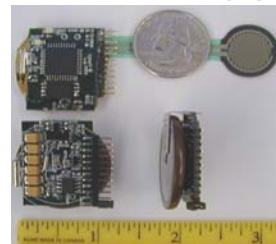
- Diagnoses sleep apnea, insomnia, narcolepsy,.....
- Easy and simple setup. Small, sophisticated circuitry, wireless capability
- Complete software review and analysis package

Movement Disorders - Kinesia

Wireless monitor to quantify the symptoms of Parkinson's disease at home / office

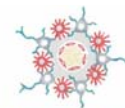


Pressure Ulcer Mgmt - PressoreStep



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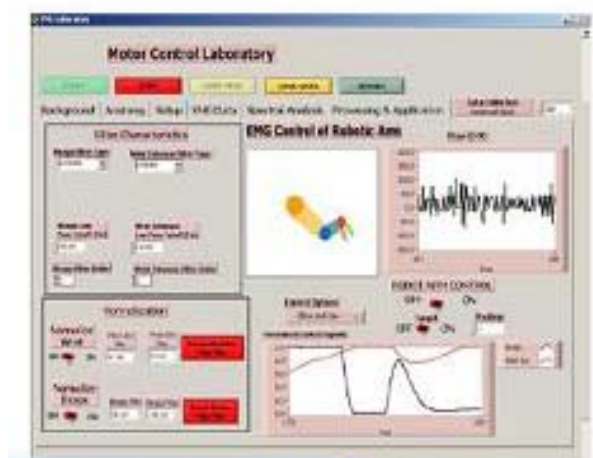
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CleveMed's Research and Teaching Products

CleveLabs™ Laboratory Course System

BioCapture™ RESEARCH SYSTEM



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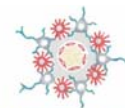
When you learn on CleveLabs, you enhance your Career

BioRadio Crystal Monitor SleepScout Sapphire



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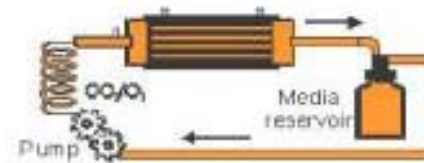
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CleveMed's Spin-offs



Flocel
www.flocel.com

Dynamic In Vitro
 Blood Brain Barrier Model



DIV- BBB System



Cross Section of
 A single lumen



NeuroCAP™
 An objective assessment of sleepiness based on the integrated analysis of EEG and task performance.



NeuroSENSE™ Monitor
 Peri-operative monitoring of the Central Nervous System (CNS) during Anesthesia



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NEUROWAVE
 HARNESSING THE POWER OF EEG



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 - **Inc. 500**, 2001,
 - **Inc. Inner City 100**, 2001/2/3/4
 - **Weatherhead 100**, (NE Ohio), 1999, 2000/01/02/03/04/05/06
 - **Tibbetts Award**, Best SBIR Companies (2007)



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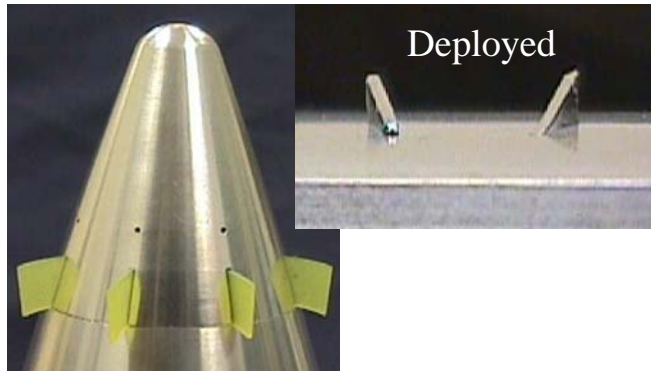
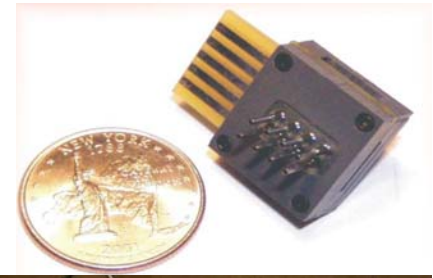


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Orbital Research's MEMS* Developments

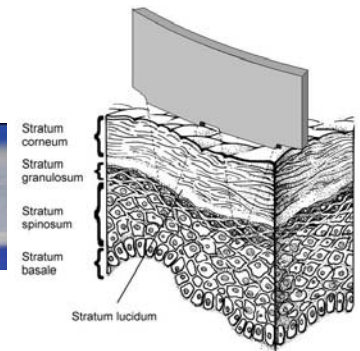
- Micro Valves

- Braille Arrays (Computer Monitors for the Blind)
- Deployable Micro Vortex Generators Flight Actuators for
 - Aircraft
 - Missiles
 - Projectiles



- Dry Electrodes

- Neurology and Cardiology Electrodes that don't require preparation or pastes/gels that dry out



- High Temperature Pressure Sensors

- Pressure sensors for Diesel, Gasoline, and Turbine Engines



*MEMS-Microelectromechanical Systems



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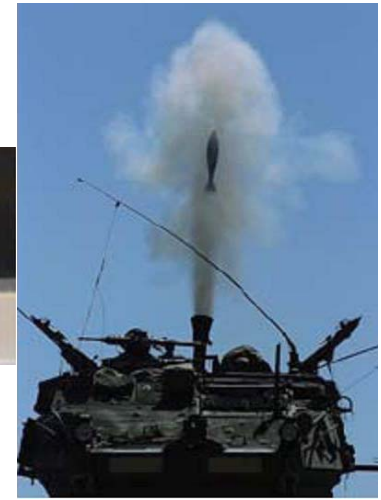
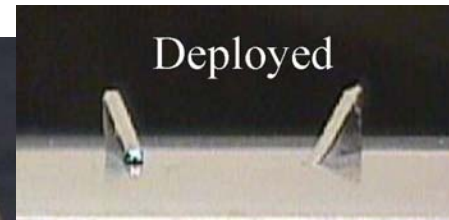
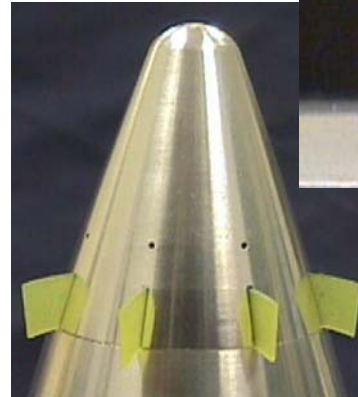
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Orbital Research's Aero Controls - Aerionics

- Deployable Flow Effectors

- Aircraft
- Missiles
- Guided Projectiles



- Plasma Controls



- Micro Air Vehicles



- Aircraft Protection



*MEMS-Microelectromechanical Systems

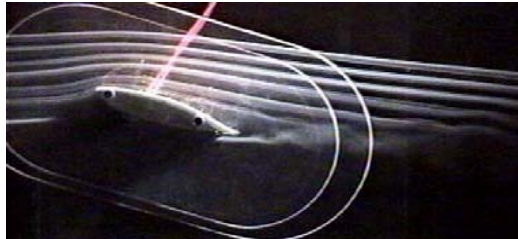
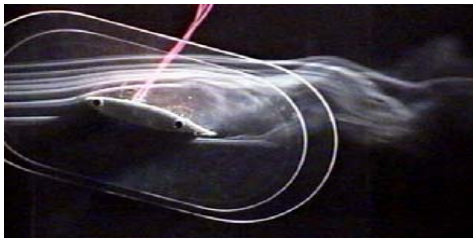
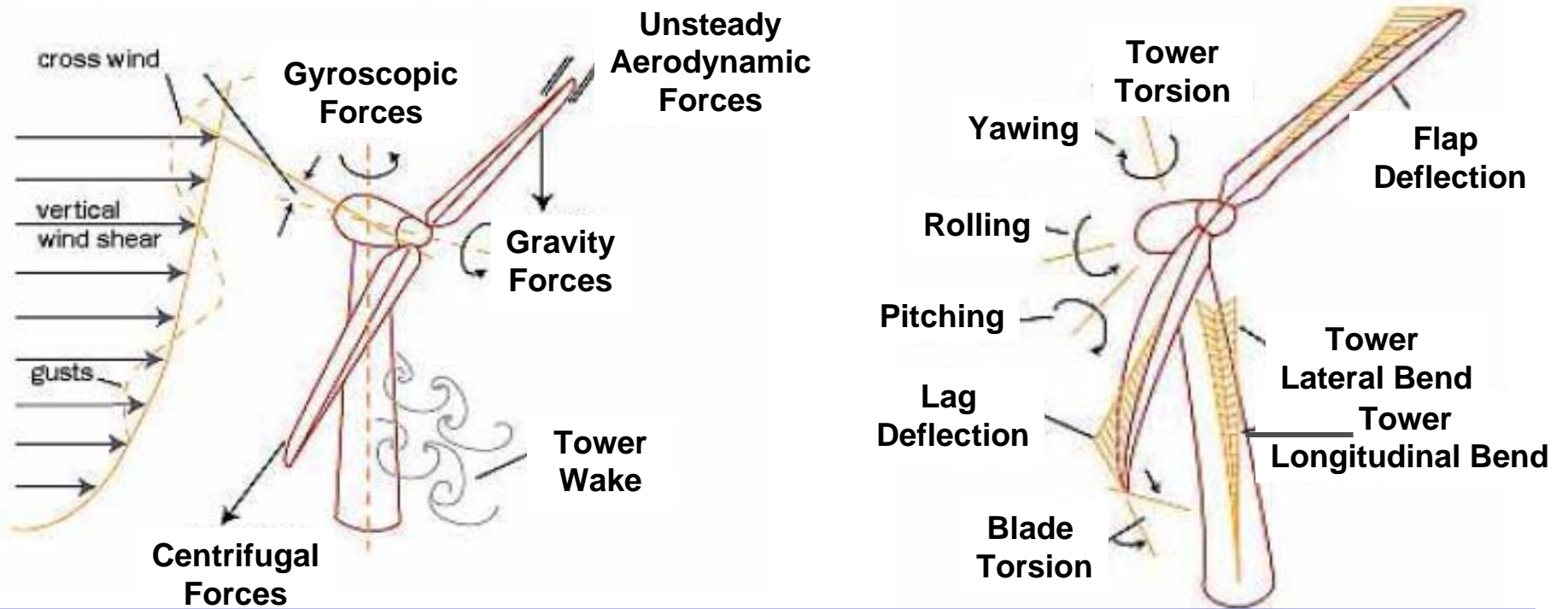


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Aerionics for Wind Turbines



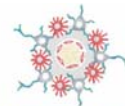
Reduce payback period & Increase Capacity Factor

- Increase net energy output
- Extend wind turbine life
- Reduce Maintenance



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Flocel

A Dynamic In Vitro Blood-Brain Barrier Model

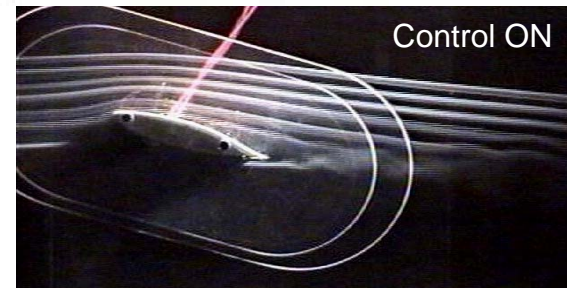
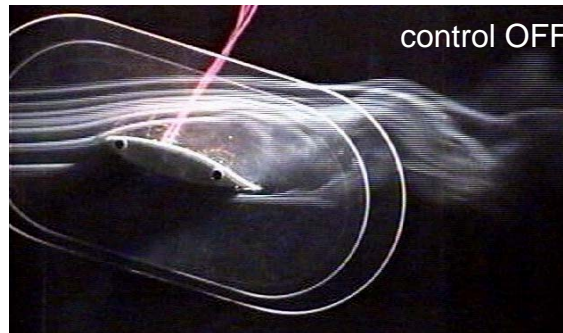
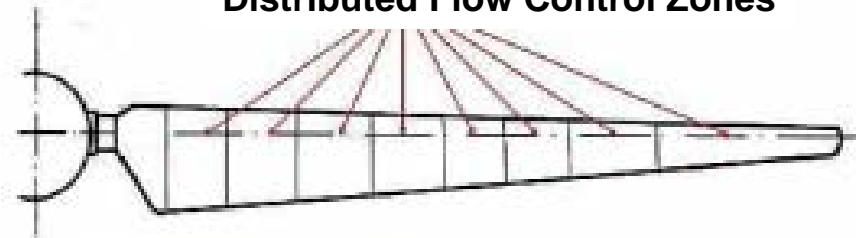
CleveMed

Cleveland Medical Devices Inc.

Plasma Flow Control on Wind Turbine Blades



Distributed Flow Control Zones



30-50% Increase in power generation through greater range of operation



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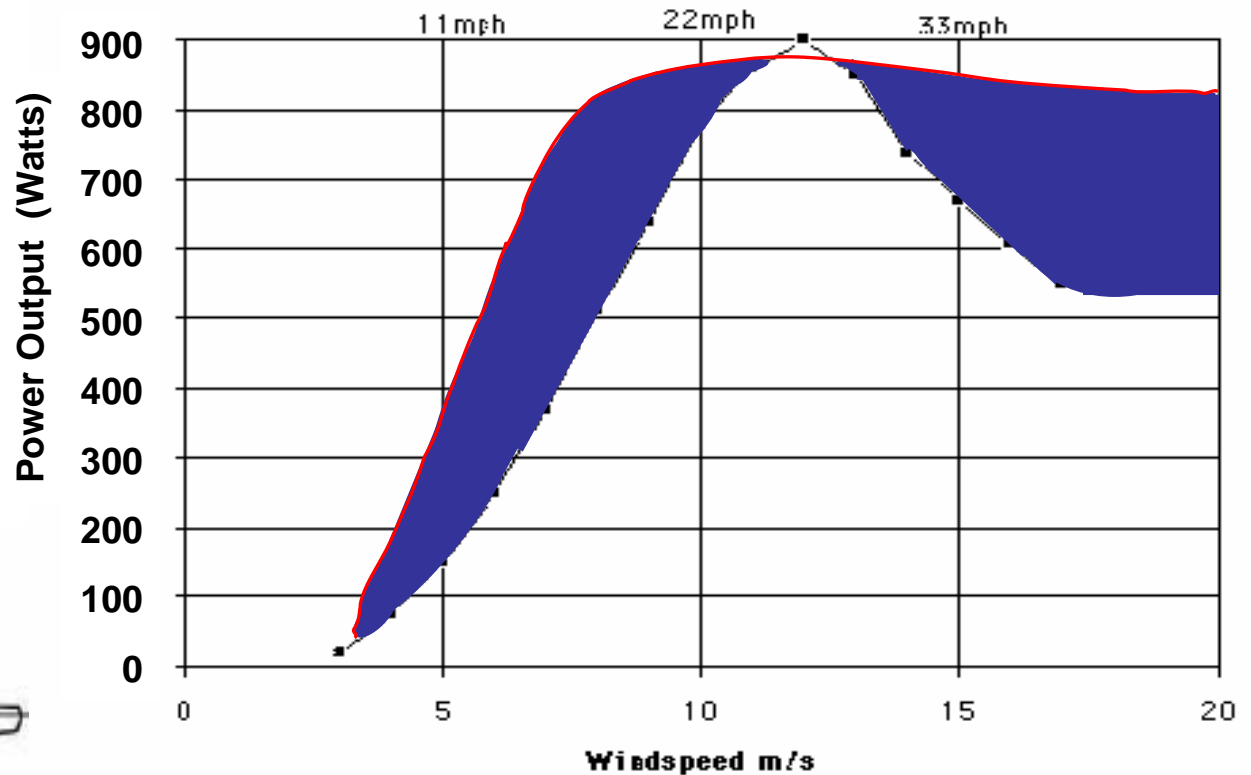
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Increased Power at Low and High Speeds



Increase net energy output
by 30-50%

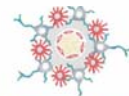


Distributed Flow Control Zones



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CleveMed

Cleveland Medical Devices Inc.

Summary

- NE Ohio needs to support the early stage capital formation and tech transfer for new companies
- We need a bigger vision for the economic future of NE Ohio
- We will attempt to do our part with:
 - CleveMed expanding in Sleep Diagnostics
 - Orbital Research expanding in weapons control and wind turbines
 - NeuroWave expanding with brain monitoring products



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CleveMed
Cleveland Medical Devices Inc.

QUESTIONS?



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