NY BIOHUD® VALLEY

2013 ANNUAL REVIEW

THE STATE OF THE LIFE SCIENCES INDUSTRY IN THE HUDSON VALLEY

HVEDC
HUDSON VALLEY ECONOMIC DEVELOPMENT CORPORATION

REGENERON

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions.

Regeneron markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition, and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis.

Regeneron has been based in Westchester County since Dr. Leonard Schleifer, founder, president, and CEO, and Dr. George Yancopoulos, founding scientist and now Chief Scientific Officer, opened the first lab at The Landmark at Eastview campus in 1989, one year after the company was founded. Today Regeneron is part of the S&P 500 stock index and employs over 2,400 people.

In addition to the research and development laboratories and administrative offices in Tarrytown, the Company has its industrial operations and product supply operations in Rensselaer, New York. In 2011, Dr. Schleifer was selected as New York Region Entrepreneur of the Year in Healthcare by Ernst & Young and was appointed co-chair of the Mid-Hudson Region Economic Development Council by New York Governor Mario Cuomo. *Scrip Intelligence*, a leading pharmaceutical industry publication, named Regeneron its Biotech Company of the Year in 2012, and in 2013 named Drs. Schleifer and Yancopoulos as its Management Team of the Year and Regeneron's dupilumab product candidate as its Clinical Advance of the Year.

In 2012 and 2013, Regeneron was also voted "Best Company in the Pharmaceutical Industry to Work For" by an annual reader survey conducted by *Science* magazine. For additional information about the company, please visit www.regeneron.com.

2013 ANNUAL REVIEW

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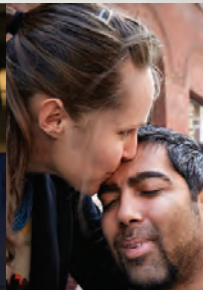
THERAPEUTICS

Our mission
is to develop therapies that provide hope
for people with nervous system disorders.

www.acorda.com



Welcome to the first edition of the State of the Life Sciences Industry in the Hudson Valley Annual Review.

When Hudson Valley Economic Development Corporation (HVEDC) launched the NY BioHud Valley cluster development initiative back in 2010, we brought together leaders from business, government, academia, research institutions, and community organizations, in order to establish the Hudson Valley corridor as a global leader in the life science, pharmaceutical, and medical device industry.

Today, the NY BioHud Valley region is a thriving economic engine fueled by entrepreneurism, and supported by a vast network of the best and brightest minds with access to ample public and private resources, including:

- a highly educated workforce;
- robust transportation and utility infrastructure;
- abundant venture capital;
- world-class research institutions and hospitals.

The Hudson Valley provides an incredible ecosystem for life sciences and health-related companies to grow–whether your company is just starting up, expanding, or relocating from another region.

That is why we hope you enjoy this first Annual Review, and if you want to explore business opportunities within the NY BioHud Valley region, please call HVEDC at 845-220-2244 or visit us at www.nybiohudvalley.com.

Laurence P. Gottlieb
President & CEO
Hudson Valley Economic Development Corporation

CHARLES E. SCHUMER
NEW YORK

COMMITTEES:
BANKING
DEMOCRATIC POLICY & COMMUNICATIONS
FINANCE
JUDICIARY
RULES

United States Senate
WASHINGTON, DC 20510

February 27, 2014

From the Office of Senator Charles E. Schumer

The Hudson Valley Economic Development Corporation's NY BioHud Valley initiative reflects the best of the Hudson Valley's burgeoning life sciences, pharmaceutical and medical device industry corridor by strongly reinforcing the region's position as an epicenter for the development of these technologies across the nation and beyond.

I have been proud to support the efforts of our local businesses and economic development leaders, who are creating sustainable, hi-tech jobs in the Hudson Valley. Whether it be securing federal resources for workforce development and job training, working with leaders like Regeneron to protect patents and innovation, or supporting incubators that create business opportunities, I am always happy to work with BioHud Valley to make it a premier destination for growing and new companies alike.

The NY BioHud Valley's leadership in these critical industries is based upon nurturing an abundance of intellectual capital – the scientists, researchers and all of their supporting personnel – dedicated to advancing the bio-tech and life sciences industry with innovation in their laboratories, research facilities and academic institutions. As well as developing treatments and finding cures for today's most challenging diseases and chronic conditions.

With the inaugural launch of *The State of the Life Sciences Industry in the Hudson Valley*, HVEDC is providing the community-at-large with a thought-provoking snapshot of the conglomeration of entrepreneurial companies and academic institutions that are all paramount to the success of the NY BioHud Valley now, and in the future.

I congratulate HVEDC for the organization's outstanding promotion of the Hudson Valley as fertile ground for the attraction and expansion of life sciences and medical device companies, as well as reaffirm my dedication to helping HVEDC and all of its regional partners in continuing their mission in growing the NY BioHud Valley.

Sincerely,

Charles Schumer

Charles E. Schumer
United States Senator

KIRSTEN E. GILLIBRAND
NEW YORK

UNITED STATES SENATOR

February 21, 2014

Dear Friends,

It is a privilege to continue my support for the Hudson Valley Economic Development Corporation's NY BioHud Valley initiative, which I helped launch in 2010. NY BioHud Valley reinforces and builds on the benefits of more than eighty life sciences companies that employ thousands of Hudson Valley residents and create life changing innovations.

This 2013 Annual Review highlights the collaborations and successes that these companies have experienced over the past year. I am grateful to the Hudson Valley Economic Development Corporation and all its supporters for their outstanding commitment to serving the vibrant life science businesses and health care facilities across the region.

Renowned medical centers and laboratories, as well as some of the most prominent research institutes in the world are located in the Hudson Valley, which has become a headquarters for the life sciences industry. The success of the NY BioHud Valley initiative is made possible by the dedication and cooperation of many of our community's public and private partners.

It is my hope that your efforts inspire others to build and enhance the biotechnology opportunities in this region, and make new discoveries which improve the lives of people all over the world. I look forward to continuing to work together towards these important goals.

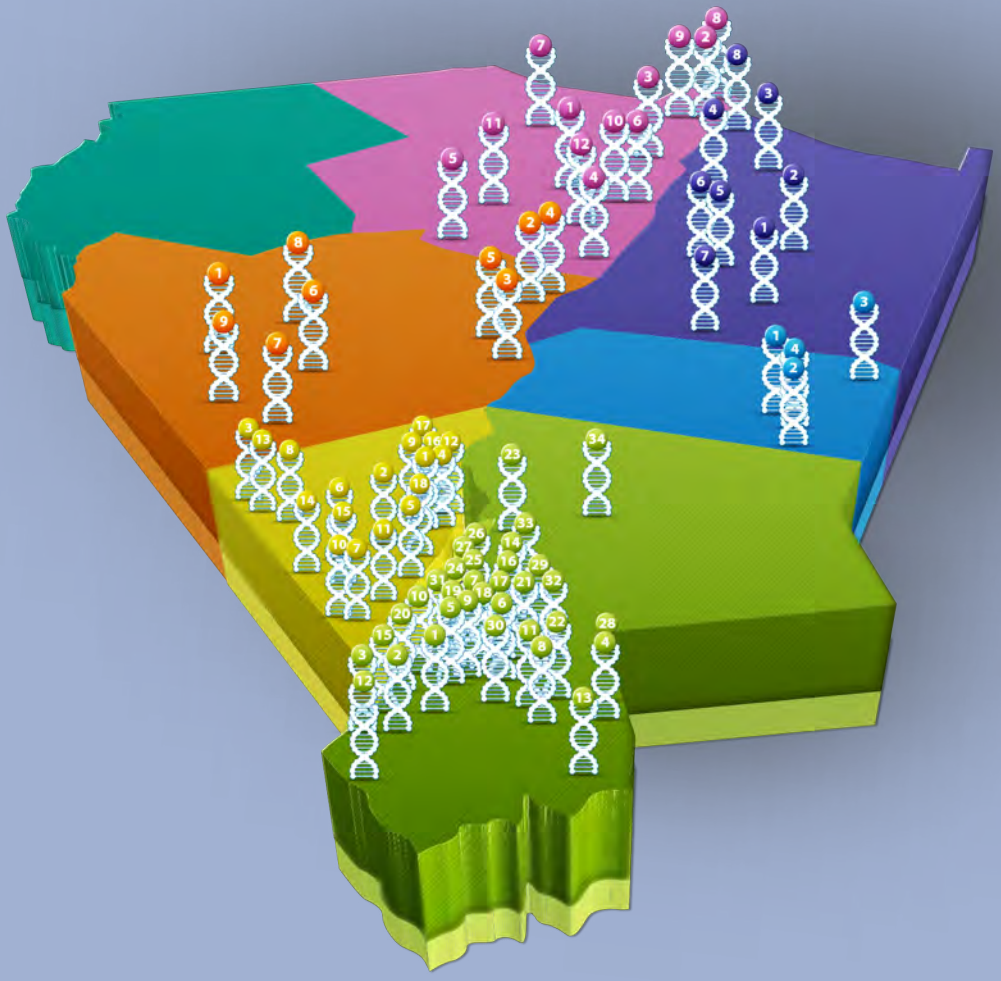
Sincerely,

Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

NOT PRINTED AT GOVERNMENT EXPENSE

Life Sciences Companies



Name of Biopharmaceutical Companies[1-3]

Number of Biopharmaceutical Companies[1-3]

Sullivan	0	
Putnam	4	1 BioDesign Inc. of New York 2 ENVIRO-ZYME International, LLC 3 JRS Pharma LP 4 Silarx Pharmaceuticals, Inc.
Dutchess	8	1 Air Products and Chemicals, Inc. 2 Beech Grove Technology 3 Dermasave Labs 4 Duso Chemical Company, Inc. 5 Flavormatic Industries, Inc. 6 Laerdal Medical Corporation 7 Life Medical Technologies 8 Topical BioMedics
Orange	9	1 Balchem Corporation 2 CymoGen Dx 3 Ondamed Inc. 4 OXYVITA Inc. 5 Randob Laboratories Ltd. 6 Repro-Med Systems, Inc. 7 Rifton Equipment 8 RIJ Pharmaceutical Corporation 9 Stauber Performance Ingredients, Inc.
Ulster	12	1 Charles River Laboratories 2 Electronic Control Concepts 3 Image Technology Laboratories, Inc. 4 Innovative Design Solutions, Inc. 5 Kiss My Face Corporation 6 Millrock Technology, Inc. 7 Model Optics, Inc. 8 Simulaids, Inc. 9 Stainless Design Concepts 10 Stavo Industries Inc. 11 Ultra Seal Corporation 12 Ultra Tab Laboratories Inc.
Rockland	18	1 ADH Health Products, Inc. 2 AMA Laboratories, Inc. 3 Avon Research and Development 4 Bee-Alive, Inc. 5 Biodefen Solutions 6 BioSource Pharm, Inc. 7 Cardiovascular Research Foundation 8 CDx Laboratories Inc. 9 Chartwell Pharmaceuticals 10 EuroMed, Inc. 11 Instrumentation Laboratory 12 Intercos America Inc. 13 Novartis Pharmaceuticals Corporation 14 Par Pharmaceutical 15 Pfizer Inc. 16 Star Kay White, Inc. 17 Valois of America, Inc. 18 XTL Biopharmaceuticals Ltd.
Westchester	34	1 Acorda Therapeutics, Inc. 2 Advanced Viral Research Corp. 3 Ambulatory Pharmaceutical Services 4 Averion International Corp. 5 Bayer Healthcare 6 BioScrip, Inc. 7 BMR-Landmark at Eastview LLC 8 Burke Rehabilitation Center 9 Ciba Specialty Chemical Corp. 10 Clarity Testing Services Inc. 11 ConsumerLab.com, LLC 12 ContraFect Corporation 13 Curemark LLC 14 Gene Link 15 Glycomed Research Inc. 16 Gradipore Inc. 17 IBM Life Sciences 18 Immune Pharmaceuticals, Inc. 19 Nada Jain PC 20 New York-Presbyterian Hospital 21 Nevis Laboratories Columbia University 22 New York Medical College 23 Philips Research 24 Profectus BioSciences Inc. 25 Progenics Pharmaceuticals, Inc. 26 PsychoGenics Inc. 27 Regeneron Pharmaceuticals, Inc. 28 Richardson Consulting Services, LLC. 29 Taro Pharmaceuticals U.S.A., Inc. 30 Tech Air 31 TechnoVax 32 TR Biotech 33 Viro Dynamics 34 Warren Pharmaceuticals, Inc.

Healthcare Jobs in the Hudson Valley

6,500
healthcare jobs added from 2006 to 2009 in the Hudson Valley[4]

Nursing and Residential Care Facilities

Occupational Title	% of Workers	Projected Employment Change (%) by 2016
Registered Nurses[4]	6.1	+ 13.7
Nursing Aides, Orderlies, and Attendants[4]	21.1	+ 11.0
Licensed Practical and Licensed Vocational Nurses[4]	7.0	+ 12.6
Home Health Aides[4]	15.0	+ 33.0

Ambulatory Healthcare Services

Occupational Title	% of Workers	Projected Employment Change (%) by 2016
Registered Nurses[4]	6.7	+ 13.7
Physicians and Surgeons, All Other[4]	4.2	+ 11.5
Licensed Practical and Licensed Vocational Nurses[4]	3.1	+ 12.6
First-Line Supervisors-Managers of Office and Administrative Support Workers[4]	3.4	+ 0.5
Home Health Aides[4]	14.3	+ 33.0
Medical Assistants[4]	4.2	+ 27.7
Personal and Home Care Aides[4]	3.7	+ 36.3

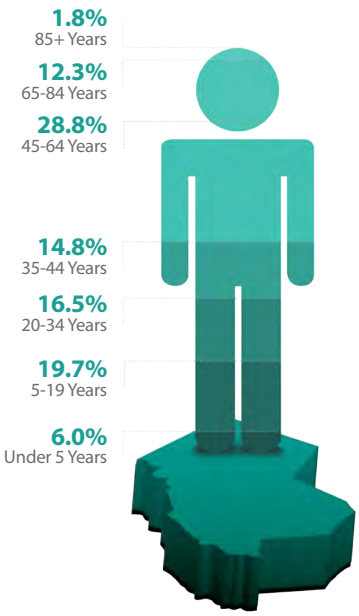
Hospitals

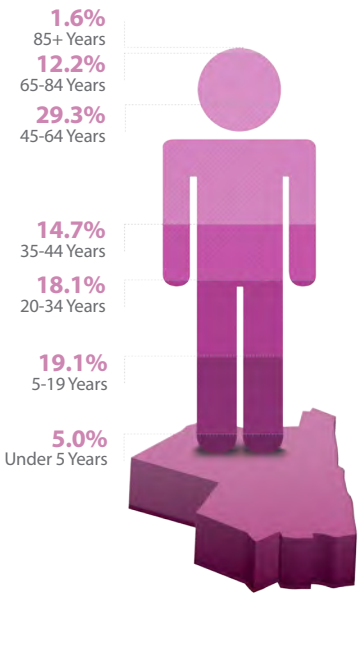
Occupational Title	% of Workers	Projected Employment Change (%) by 2016
Registered Nurses[4]	23.6	+ 13.7
Nursing Aides, Orderlies, and Attendants[4]	8.2	+ 11.0
Physicians and Surgeons, All Other[4]	4.8	+ 11.5
Medical and Health Services Managers[4]	3.7	+ 6.6
Office Clerks, General[4]	3.6	+ 6.3
Licensed Practical and Licensed Vocational Nurses[4]	2.4	+ 12.6
First-Line Supervisors-Managers of Office and Administrative Support Workers[4]	1.9	+ 0.5
Medical and Clinical Laboratory Technologists[4]	1.8	+ 6.6

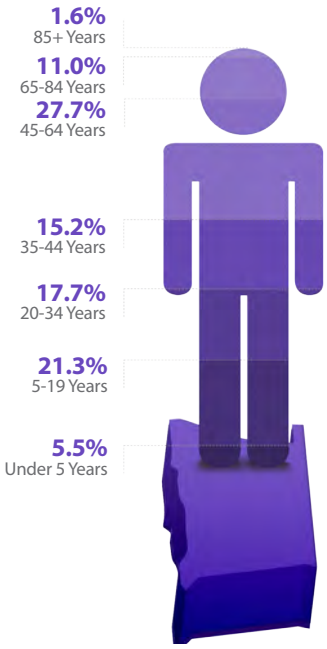
NY BioHud Valley 2013 Annual Review
Healthcare At-A-Glance

Population At-A-Glance[5-11]

	Sullivan	Ulster	Dutchess
Population	75,828	181,440	293,562

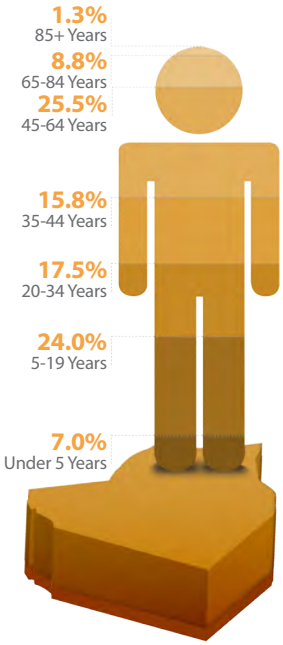


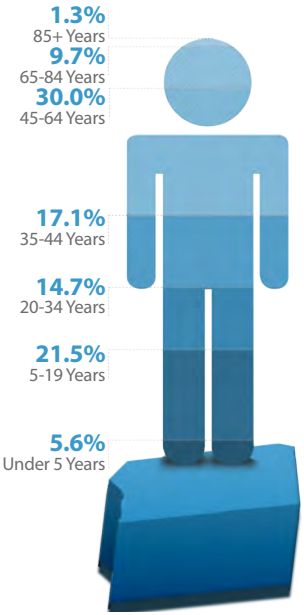


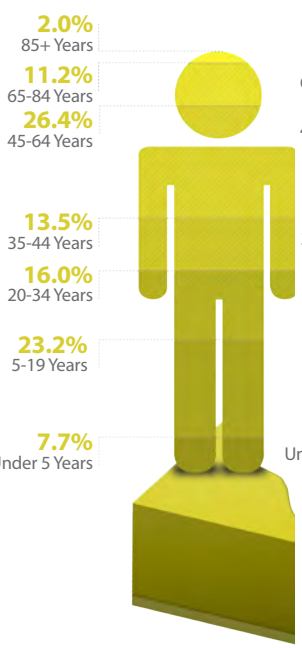


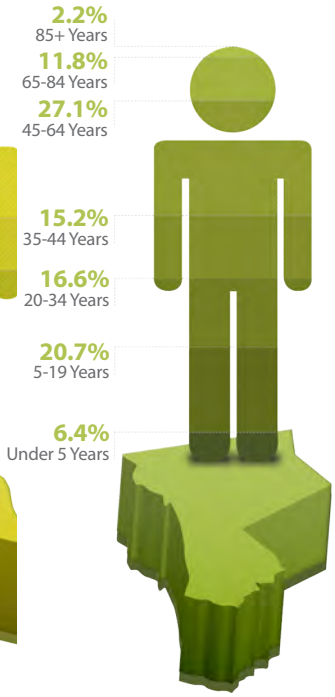
Total Population
2,289,762

Orange	Putnam	Rockland	Westchester
383,532	**99,265**	**300,173**	**955,962**









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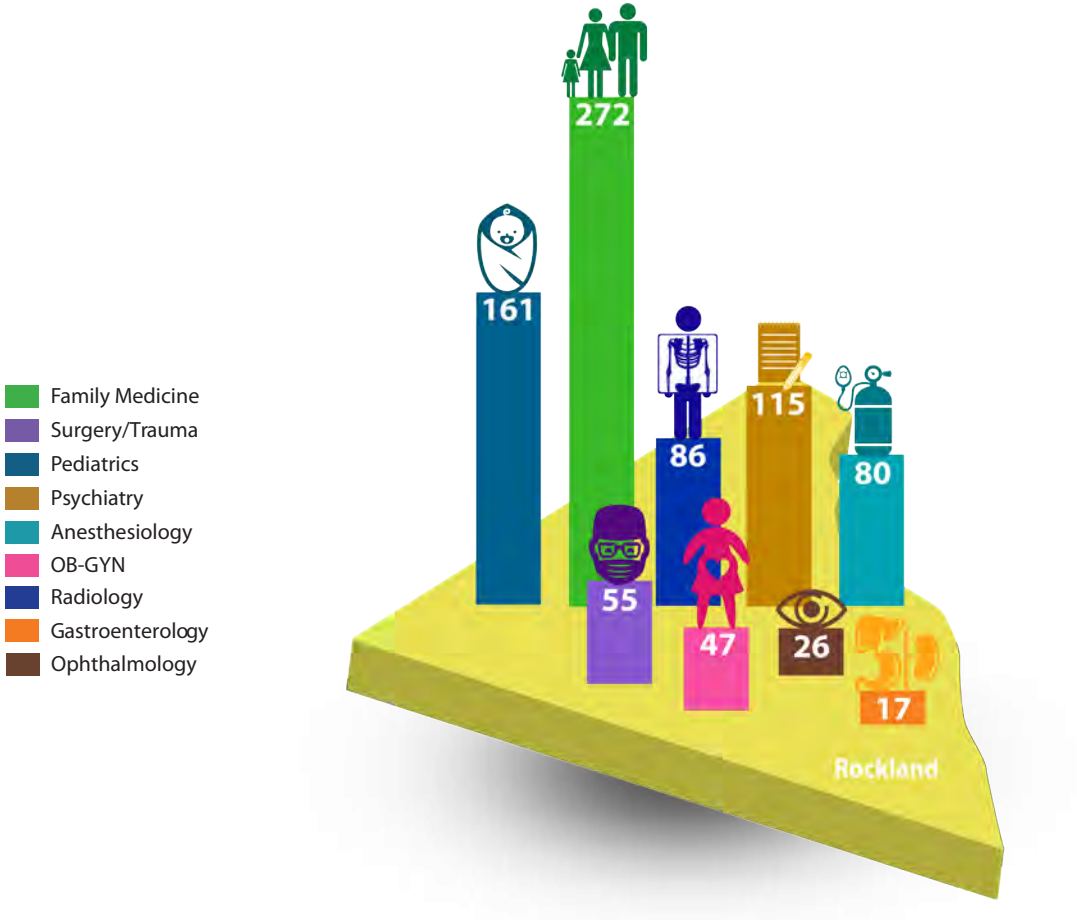
Healthcare At-A-Glance

Top Physician Specialties in the Hudson Valley Region

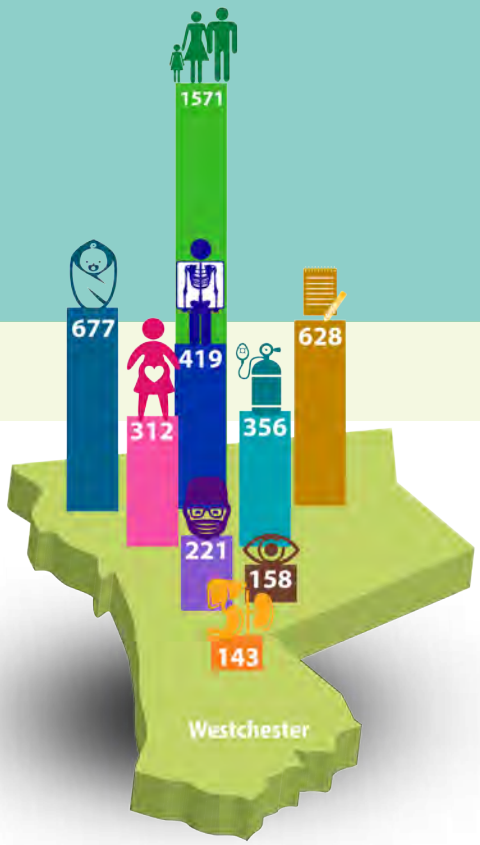
1,165 Total Number of Physicians in Rockland County



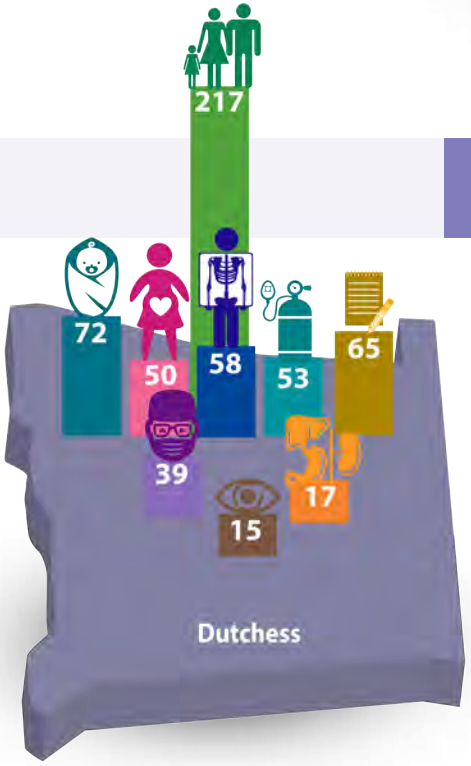
Total Number of Physicians in Hudson Valley

6,248 Total Number of Physicians in Westchester County

- Family Medicine
- Surgery/Trauma
- Pediatrics
- Psychiatry
- Anesthesiology
- OB-GYN
- Radiology
- Gastroenterology
- Ophthalmology



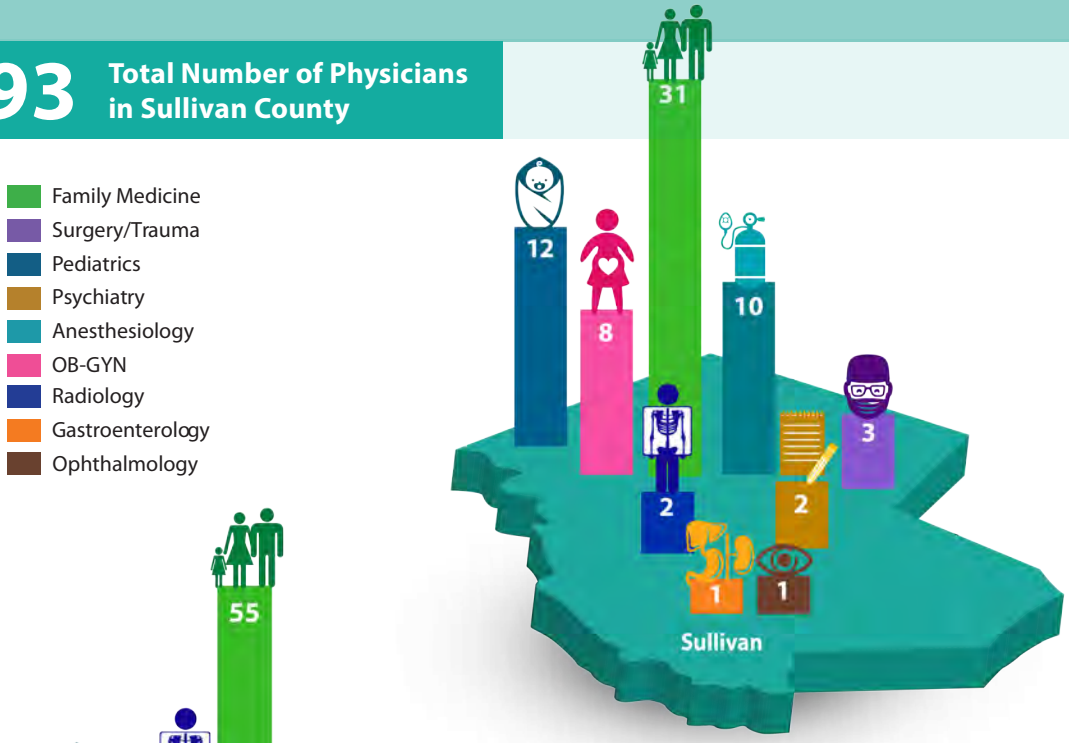
792 Total Number of Physicians in Dutchess County



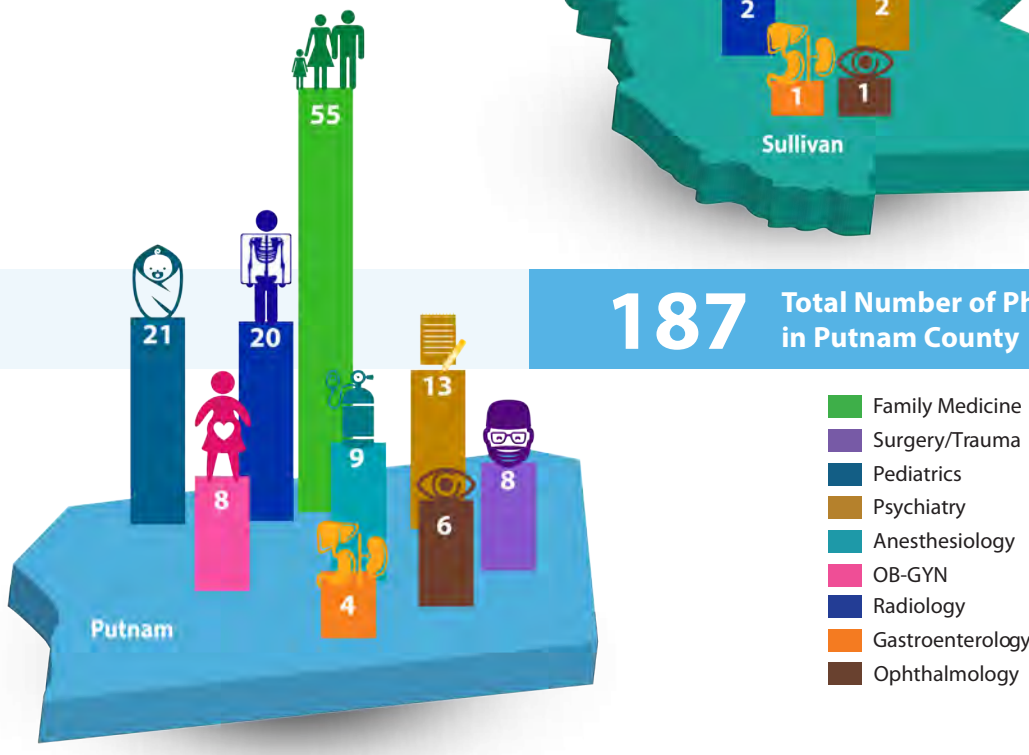
- Family Medicine
- Surgery/Trauma
- Pediatrics
- Psychiatry
- Anesthesiology
- OB-GYN
- Radiology
- Gastroenterology
- Ophthalmology

Top Physician Specialties in the Hudson Valley Region

93 **Total Number of Physicians in Sullivan County**

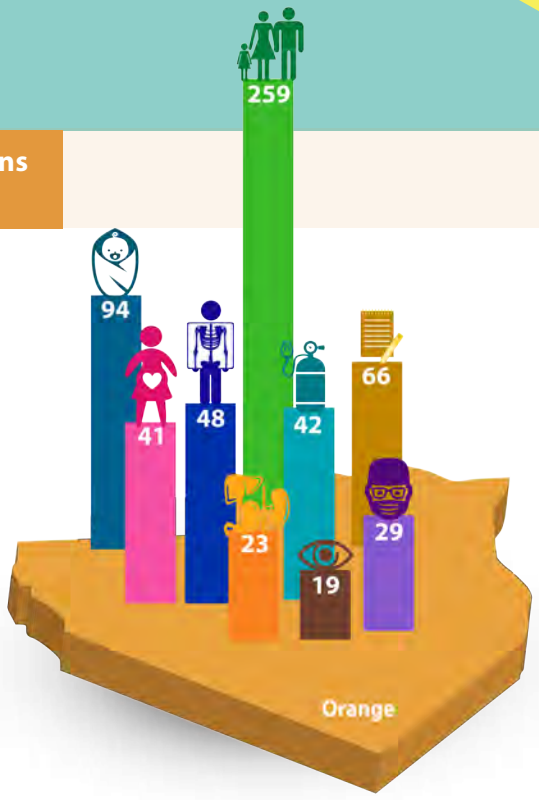


187 **Total Number of Physicians in Putnam County**



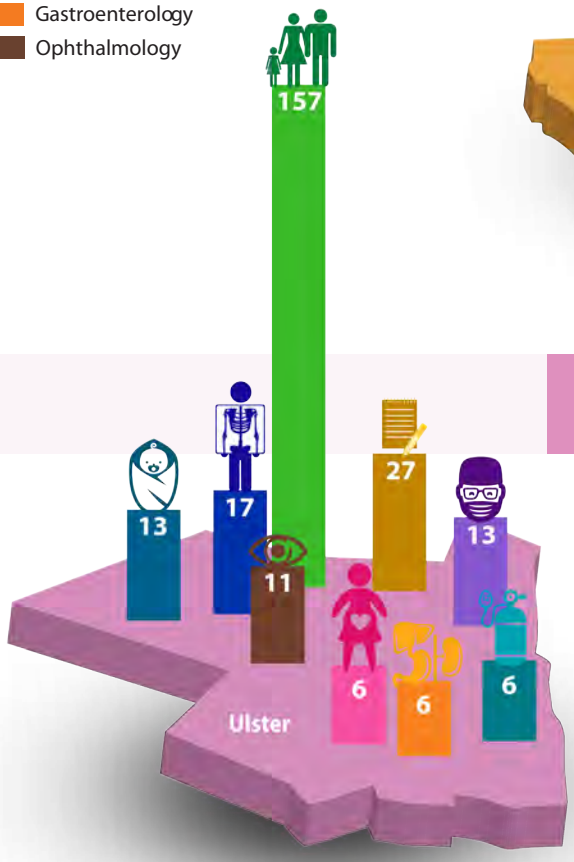
879 Total Number of Physicians in Orange County

- Family Medicine
- Surgery/Trauma
- Pediatrics
- Psychiatry
- Anesthesiology
- OB-GYN
- Radiology
- Gastroenterology
- Ophthalmology



323 Total Number of Physicians in Ulster County

- Family Medicine
- Surgery/Trauma
- Pediatrics
- Psychiatry
- Anesthesiology
- OB-GYN
- Radiology
- Gastroenterology
- Ophthalmology



NY BioHud Valley 2013 Annual Review
Healthcare At-A-Glance

Hospitals[12]

2 Hospitals[12]

1. Catskill Regional Medical Center
2. Catskill Regional Medical Center - G. Hermann Site

# of Medical & Surgical In-Patient Procedures[12]

5,403

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Obstetrical procedures
2. Miscellaneous diagnostic and therapeutic procedures
3. Digestive system operations

Primary care physician to resident ratio[13]

2,279:1

3 Hospitals[12]

1. Ellenville Regional Hospital
2. HealthAlliance Hospital Broadway Campus
3. HealthAlliance Hospital Mary's Avenue Campus

# of Medical & Surgical In-Patient Procedures[12]

14,784

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Miscellaneous diagnostic and therapeutic procedures
2. Obstetrical Procedures
3. Digestive system operations

Primary care physician to resident ratio[13]

1,332:1

3 Hospitals[12]

1. Northern Dutchess Hospital
2. St Francis Hospital
3. Vassar Brothers Medical Center

# of Medical & Surgical In-Patient Procedures[12]

37,091

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Miscellaneous diagnostic and therapeutic procedures
2. Cardiovascular system operations
3. Obstetrical procedures

Primary care physician to resident ratio[13]

1,398:1

1 Hospital[12]

1. Putnam Hospital Center

# of Medical & Surgical In-Patient Procedures[12]

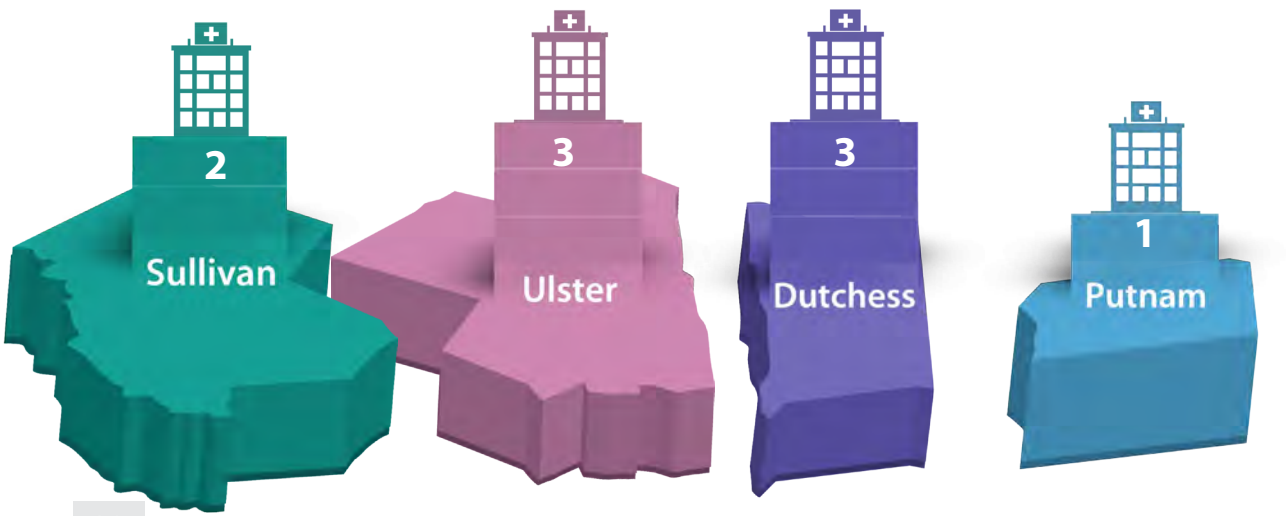
9,917

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Miscellaneous diagnostic and therapeutic procedures
2. Musculoskeletal operations
3. Digestive system operations

Primary care physician to resident ratio[13]

1,749:1



5 Hospitals[12]

1. Bon Secours Community Hospital
2. Orange Regional Medical Center
3. St. Anthony Community Hospital
4. St. Luke's Cornwall Hospital/ Cornwall
5. St. Luke's Cornwall Hospital/ Newburgh

of Medical & Surgical In-Patient Procedures[12]

50,752

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Miscellaneous diagnostic and therapeutic procedures
2. Digestive system operations
3. Obstetrical procedures

Primary care physician to resident ratio[13]

1,465:1

4 Hospitals[12]

1. Good Samaritan Hospital of Suffern
2. Helen Hayes Hospital
3. Nyack Hospital
4. Summit Park Hospital- Rockland County Infirmary

of Medical & Surgical In-Patient Procedures[12]

40,597

Top 3 Medical & Surgical In-Patient Procedures[12]

1. Miscellaneous diagnostic and therapeutic procedures
2. Obstetrical procedures
3. Digestive system operations

Primary care physician to resident ratio[13]

1,042:1

16 Hospitals[12]

1. Blythedale Children's Hospital
2. Hudson Valley Hospital Center
3. Lawrence Hospital Center
4. Mount Vernon Hospital
5. New York-Presbyterian Hospital-Westchester Division
6. Northern Westchester Hospital
7. Phelps Memorial Hospital Center
8. St Joseph's MC-St Vincent's Westchester Division
9. St Joseph's Medical Center
10. St John's Riverside Hospital-Dobbs Ferry Pavilion
11. St John's Riverside Hospital-Park Care Pavilion
12. St John's Riverside Hospital-St Johns Division
13. Sound Shore Medical Center of Westchester
14. Westchester Medical Center
15. White Plains Hospital Center
16. Burke Rehabilitation Center

of Medical & Surgical In-Patient Procedures[12]

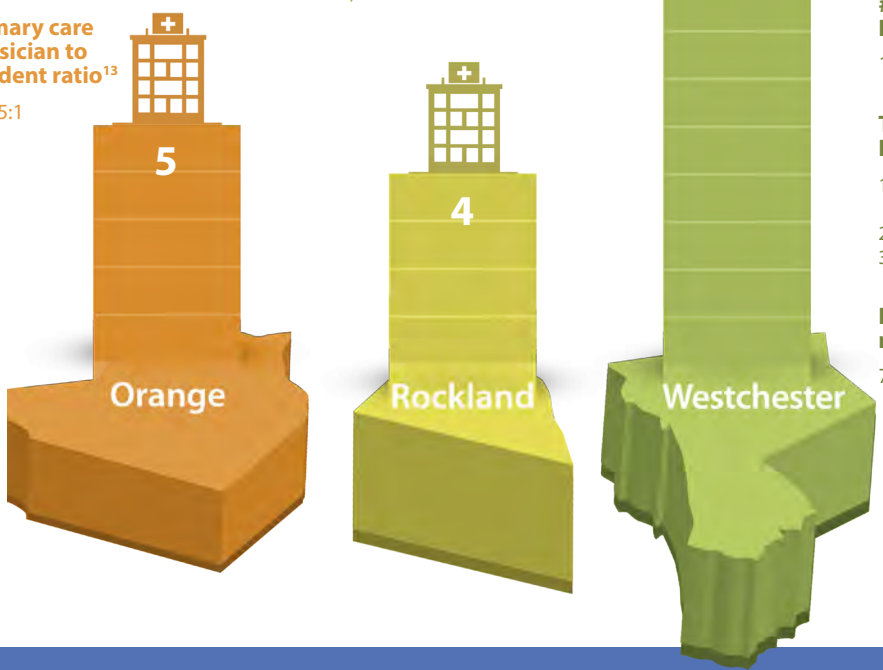
151,372

Top 3 Medical & Surgical In-Patient Procedures[12]

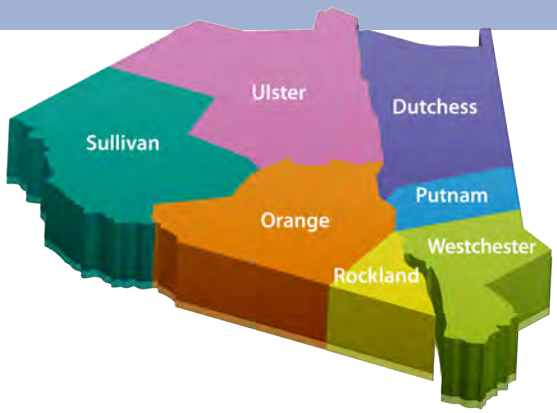
1. Miscellaneous diagnostic and therapeutic procedures
2. Cardiovascular system operations
3. Digestive system operations

Primary care physician to resident ratio[13]

714:1

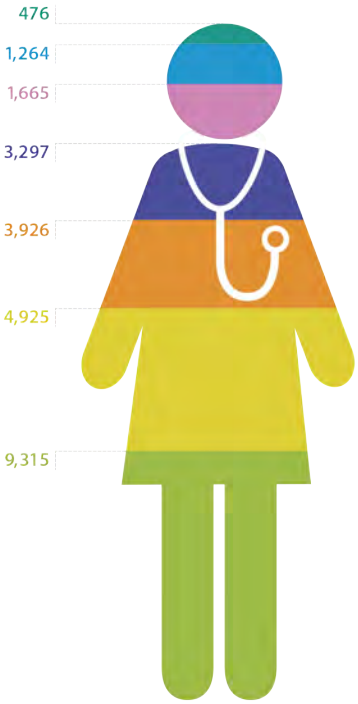


Population At-A-Glance



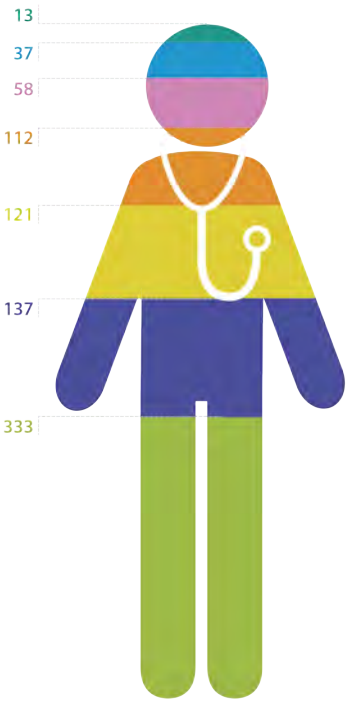
Registered Nurses by County

24,868
Population



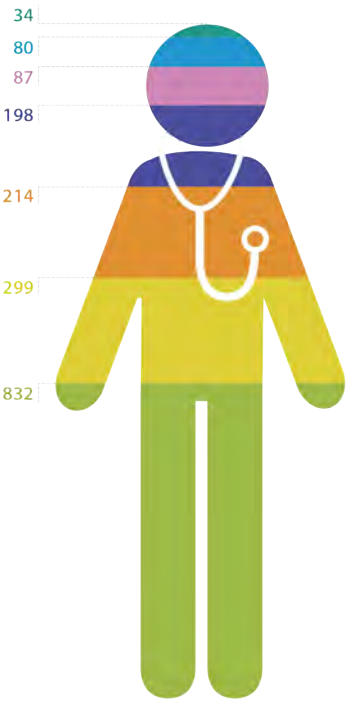
Physician Assistants by County

811
Population

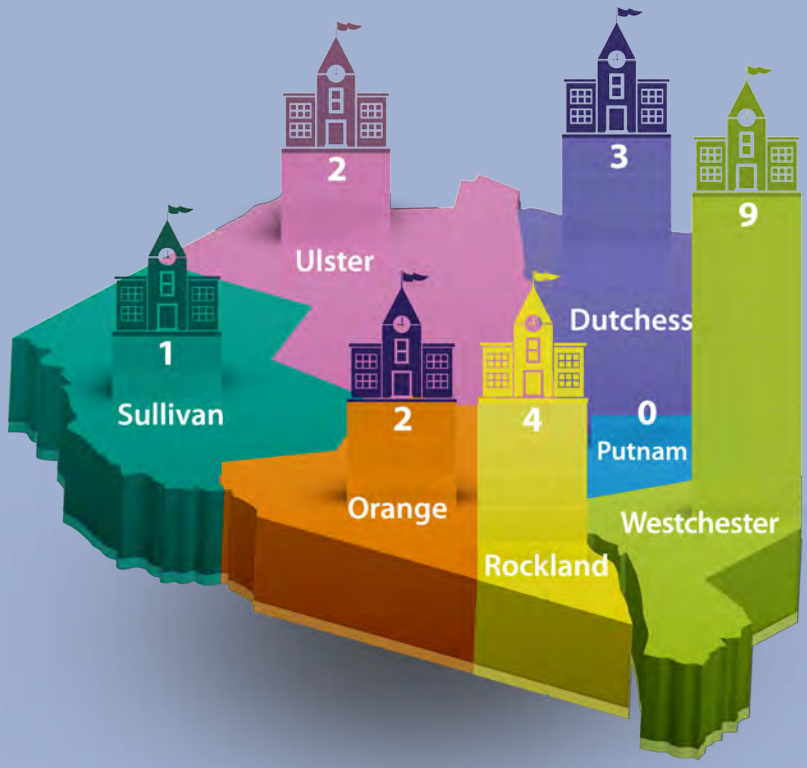


Nurse Practitioners by County

1,744
Population



List of Colleges for Health/Medical Professionals[14-34]



SULLIVAN	ULSTER	DUTCHESS	PUTNAM	ORANGE	ROCKLAND	WESTCHESTER
1. Sullivan County College	1. SUNY New Paltz 2. SUNY Ulster	1. Dutchess Community College 2. Adelphi University 3. Marist College		1. Orange Community College 2. Mount Saint Mary College	1. Rockland Community College 2. St. Thomas Aquinas College 3. Nyack College 4. Dominican College	1. Westchester Community College 2. The College of Westchester 3. Monroe College 4. Berkeley College 5. Manhattanville College 6. Mercy College 7. Concordia 8. Pace University 9. New York Medical College

Philips Research in the Hudson Valley

Dr. Michael D. Pashley
Research Department Head, Ultrasound, Photonics and Bioinformatics, Philips Research NA

Philips Briarcliff Manor Aerial: Aerial view of the Philips site in Briarcliff Manor, the location of Philips Research North America

In North America, Philips is headquartered in Andover, Massachusetts in the U.S. and Markham, Ontario in Canada. The North America Philips companies are affiliates of the Netherlands-based Royal Philips N.V., a diversified health and well-being company, focused on improving people's lives through meaningful innovations. Our long history in North America began in 1933, and today, it is the company's largest single market in the world, with more than 21,500 employees and operations at 57 major facilities in 26 states and across 3 Canadian provinces. Sales for the region in 2013 were more than $9.5 billion, which accounts for more than 30% of Philips' global revenue. For more information, visit www.philips.com.

Philips concentrates its health and well-being focus on professional and consumer markets across three interconnected sectors: Healthcare, Consumer Lifestyle, and Lighting. Philips aims to turn customer insights into meaningful innovation. Our goal is to improve the lives of three billion people a year by 2025.

Philips has a strong track record of acquiring companies and technologies that complement and strengthen its core business areas. Strategic U.S. acquisitions include Color Kinetics (LED lighting systems), Genlyte (indoor and outdoor lighting), Discus (oral health), Lifeline Systems (medical alert service), Burton Medical Products (medical lighting), Stentor (healthcare, now IntelliSpace PACS medical and information management system), and Respironics (healthcare).

Healthcare

A world-wide leader in cardiac care, patient monitoring and home healthcare, Philips Healthcare, headquartered globally in Andover, Massachusetts, employs approximately 15,000 people in North America and is among the top-three global healthcare companies. The strategy for the Healthcare business is grounded in the belief that clinical excellence and continuous innovation around the patient experience can fundamentally change healthcare as we know it. Philips Healthcare reflects Philips' growing portfolio of radiology, oncology and women's health products, world-class services and one of the largest offerings of clinical decision support technology in the industry.

Consumer Lifestyle

Philips Consumer Lifestyle aims to make it easier for people to achieve a healthier and more sustainable lifestyle. The sector has approximately 800 employees across North

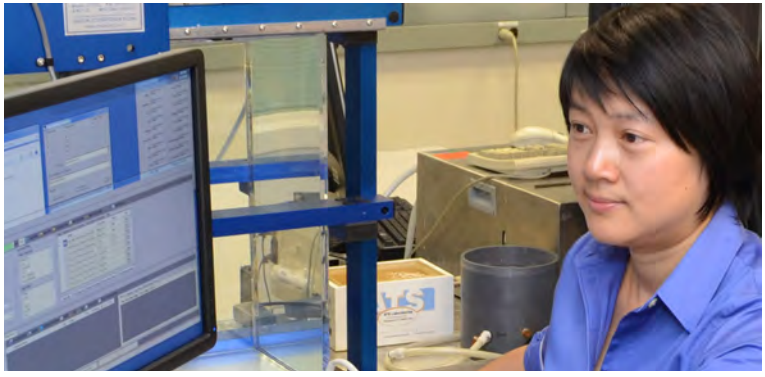
America. Consumer Lifestyle's insight-led research and development process delivers breakthrough, meaningful innovations that meet consumers' most important needs. The sector's rich history of pioneering new technologies has created some of the world's most recognizable brands, including Philips Sonicare, the #1 recommended power toothbrush brand by U.S. dental professionals and Philips AVENT, the baby bottle brand most recommended by moms worldwide. Product categories include Men's Grooming, Beauty, Light Therapy, Oral Healthcare, Mother and Child Care, Coffee and Kitchen Appliances.

Lighting

The Philips Lighting sector, which has been at the core of Philips throughout the company's 120 year-history, has approximately 6,000 employees across North America. Philips Lighting partners with cities, schools, building owners and government to enhance people's lives with light, while protecting the environment. Philips was the first to develop the most advanced lighting technology in the world light emitting diodes (LEDs). This technology has revolutionized the lighting industry and how people look at lighting choices. Philips' Lighting business continues to be at the forefront of revolutionary technologies, working with customers to create solutions with more than 3,000 products, including street and outdoor lighting, office and industrial lighting, acute care and assisted living lighting, hospitality lighting and retail lighting, and home lighting.

Philips Research

Philips Research was started in 1914 and this year celebrates its first 100 years. It is a global organization with laboratories in Europe, North America, India and China, and an emerging laboratory in Brazil. Philips Research provides innovation in support of all the businesses of Philips. Philips Research North America has always been based in the Hudson Valley. The first laboratory opened in Irvington in 1948. In order to allow for expansion



Philips Ultrasound Research: Research scientist working in the ultrasound lab at Philips Research North America

We're making great progress so far:

- 70% of the top 50 U.S. hospitals have chosen Philips solutions for cardiology
- Philips lights 65% of the world's top airports, 30% of offices and hospitals and landmarks such as the Empire State Building, the NYC Times Square New Year's Eve Times Ball, the CN Tower, the Sydney Opera House, and the Great Pyramids
- One of three cars worldwide uses Philips automotive lighting
- Each day more than one million of our consumer lifestyle products are purchased
- Philips owns more than 59,000 patent rights, is one of the world's top-50 most valuable brands, one of the world's top-50 most innovative companies, and ranked one of the Best Global Green Brands by Interbrand
- The company has won numerous awards, including ranking as a National Top Workplace by Workplace Dynamics in 2012; one of the Best Places to Work for Recent Grads by Experience.com in 2013; #7 on "Big Companies with the Best Work-Life" list by Forbes in 2013; one of the World's Most Ethical Companies by Ethisphere in 2011 and 2012; #1 Greenest Company in its sector and #23 in the world by Newsweek in 2012; 7th on Corporate Knights Global 100 Most Sustainable Corporations list; #23 on Forbes/The Reputation Institute's "The World's Most Reputable Companies;" and one of Thomson Reuter's Top 100 Global Innovators in 2012.

it moved to Briarcliff Manor in 1965 and remains there to this day. Today the Briarcliff campus houses Research, Philips Intellectual Property & Standards, and our US Eastern region Healthcare Sales and Services, along with representatives from other Philips businesses across North America. Altogether, Philips employs over 200 people in the Hudson Valley, and is continuously expanding its presence.

Philips Research North America is predominantly working in healthcare with some additional activities in support of our lighting business. Our healthcare research focuses on the following areas: ultrasound, image guided intervention, and informatics.

Our ultrasound research team provides innovation for the Philips Ultrasound business, the 2nd largest ultrasound company globally. We developed the core technology behind the enhanced imaging capabilities of the new EPIQ premium ultrasound platform released by Philips last year. We have a team of experts in ultrasound elastography that has developed new ways of analyzing tissue in order to improve the diagnosis of liver disease and to better identify many types of tumors. This technology has been introduced into our products over the last few years.

Medical imaging enables new minimally invasive procedures that remove the need for open surgery for many patients. In Philips Research North America we have developed electromagnetic and optical tracking technologies and combined them with imaging to provide complete image guided solutions. We are able to register diagnostic images from imaging modalities including magnetic resonance, computed tomography and x-ray with real time imaging with ultrasound that is done during the intervention. The precise location of interventional devices such as needles and catheters can also be shown to the physician. We apply this work to many clinical applications including cardiology and oncology.

In today's practice of medicine we are gathering large amounts of data on patients. This comes from many sources including patient medical history, medical imaging, patient monitors, pathology, and now starts to include genomic data. It is increasingly difficult for doctors to evaluate all this information and provide the best treatment options for the patient. Going forwards clinical informatics is going to be increasingly important to turning large amounts of data into clinically useful information. In our Briarcliff Manor research lab we work on three key areas of clinical informatics: patient monitoring and critical care, radiology reporting, and bioinformatics. In the modern intensive care unit (ICU) a vast array of vital signs are continuously monitored on each patient. Philips is a world leader in these monitoring systems. The challenge is to inform the medical staff which patients really need attention and ultimately to predict ahead of time when the condition of a patient is deteriorating so that intervention can occur ahead of time and so improve outcomes. In the area of radiology we aim to help the physician to more efficiently make a diagnosis from a wealth of medical images and patient history. Analysis of images and comparison with a large database of similar cases can help to improve diagnosis and hence patient outcomes. The dramatic advances over the last few years in the technology that enables sequencing of the human genome is going to have a huge impact in healthcare. The amount of data generated is enormous and the field is moving so fast that it is very difficult for a doctor or even a single hospital to take full advantage of this technology. We are developing a bioinformatics platform that will take the output reads of the sequencer and provide clinically actionable information to the doctor. This can be applied to many areas of medicine including oncology and infectious disease. This is a big challenge, but we are convinced that this is critical to the future of patient care.

In order to bring our healthcare innovation forward it is essential that we work closely with clinical researchers. We therefore collaborate with many clinical research institutions across North America. We actually have a few of our researchers located at key clinical sites so that they can work with clinicians on a daily basis. We need to understand the clinical need and ensure that our innovations solve real clinical problems and that they will make a difference to clinicians and patients. We have recently joined forces with New York Medical College in Valhalla to bring genomic sequencing and bioinformatics applications into clinical practice.

Philips Research is proud to be a part of the BioHud Valley initiative of HVEDC and the opportunities that it brings to enhance the ecosystem of the region. We look forward to engaging with more companies and research institutions to further grow the innovative climate of the Hudson Valley.

State of the Valley Survey

Why stay in the Hudson Valley?

The Location:

- Proximity to academic and research facilities, and to other biopharma companies
- Access to NY Metro Area

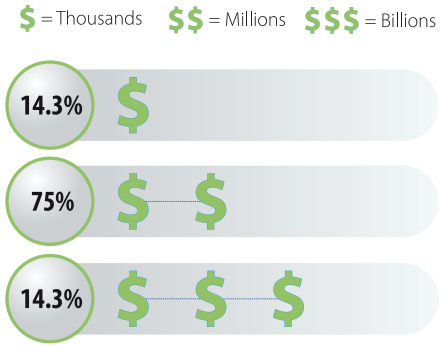
The People:

- Highly educated workforce
- Proximity to NYC and Boston healthcare and bio-medical research universities for recruiting
- Prospective regional industry peers/partners, and enhancing the collaboration and dialogue between all the organizations located in the Hudson Valley.

The Business:

- Affordable business environment
- Own building / property
- Favorable business climate (tax incentives,support for permitting)

Annual Revenue in 2013



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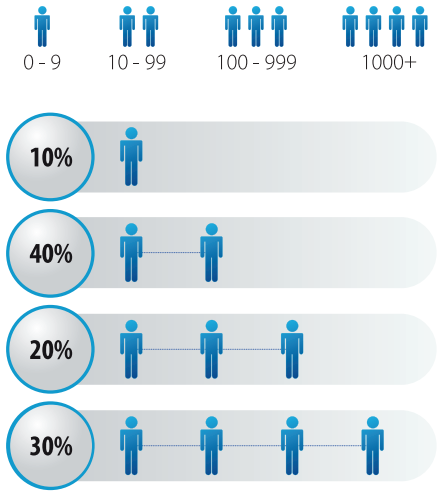
Number of Employees



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Burke Rehabilitation Center: A Pioneer in Rehabilitation

Richard Sgaglio, PhD
Director, Marketing & External Relations
Burke Rehabilitation Hospital & Burke Medical Research Institute

Today, Burke continues to be a leader in rehabilitation medicine and research. Together, its physicians, therapists, and medical research scientists work together to ensure that every patient makes the fullest possible recovery from a debilitating illness or traumatic injury.

Burke Rehabilitation Center: A Pioneer in Rehabilitation

Burke Rehabilitation Center has been on the forefront of rehabilitation medicine since its founding nearly 100 years ago. New York philanthropist John Masterson Burke saw that the medical community was missing a much needed interim place where patients could go and convalesce after being discharged from the hospital, much like Burke.

A Brief History of John Masterson Burke and Burke Foundation

Burke Rehabilitation Center's founder John Masterson Burke was born in New York City to Irish immigrants on July 2, 1812. At 16 years of age, he began his schooling in business and industry that would later lead him to becoming a noted businessman and philanthropist.

Throughout his long 98 years, Mr. Burke engaged in numerous profitable industries including iron foundry and steel construction, cotton, sugar, and railroads. His keen business intellect, wise investments and modest living afforded John Burke the ability to spend as he pleased, including in philanthropic ventures.

For a number of years prior to his death, Mr. Burke wished to do some useful and important work for the benefit of his fellow citizens. Finally, when approaching his 90th year, Mr. Burke chose to create and endow a free convalescent home for New Yorkers. The home was to be a tribute to and bear the name of his mother, and be used temporarily by those who were sick and feeble to convalesce while they were unable to work.

Conscious of his advanced age, Mr. Burke declined to assume the labors connected with the construction and development of the organization. He placed the greater portion of his property as a Trust, accompanied by an endowment of $4,500,000, stating his wishes and fully outlining the proposed procedure; the actual work, however, was to be postponed until after his death.

The Winifred Masterson Burke Foundation

Mr. Burke selected the Honorable Abram R. Hewitt, Edward M. Shepard, William R. White, and Frank K. Sturgis as Trustees to handle to the fulfillment of his wishes, and the Winifred

***Glen Prusky, PhD, Director of the Center of Vision Restoration**, aims to develop treatments for progressive visual decline arising from retinal degenerative disease, diabetic neuropathy, and aging. His lab also is involved in the development of rehabilitative strategies for stroke.*

Masterson Burke Relief Foundation was born.

John Masterson Burke died on Dec. 4, 1909. Two years later, in the autumn of 1911, a 61-acre site in White Plains was secured by the Trustees and the architectural firm of McKim, Mead, and White was hired to create the blueprint for the foundation's buildings. The firm designed 12 neoclassical buildings connected by a series of colonnades and underground tunnels to help minimize patient exposure to the New York's inclement weather. The clock tower, believed to be from the original Madison Square Garden, and Greek revival columns all added to the architectural splendor of the Burke campus.

Construction commenced in July 1912 and was completed nearly three years later on April 7, 1915, and on that day, the doors of the Winifred Masterson Burke Foundation officially opened to patients.

The Winifred Masterson Burke Foundation hired the firm of McKim, Mead and White to design the hospital's facilities. The renowned architectural firm designed 12 neoclassical buildings connected by a series of colonnades and underground tunnels to help minimize patient exposure to bad weather. The clock tower, believe to be from the original Madison Square Garden, and Greek revival columns all added to the architectural splendor of the Burke campus.

Burke Rehabilitation Hospital's Early Years

Prior to being admitted to the White Plains facility, patients went to the receiving department in New York City where they were examined before being transported to White Plains. During these early years, the foundation treated patients with pneumonia, ulcers, fatigue, cardiac problems, and thyroid disease. The program included exercise in all weather, medical supervision, and daily chores.

In 1918, during World War I, Burke served as the only naval hospital in

Burke Rehabilitation Hospital Early Year

HIGHLIGHTS

- Approval by New York State Medicaid as a rehabilitation hospital, initiated clinical internships in physical therapy (1953)
- Initiated clinical internships in occupational therapy (1956)
- Established postgraduate training program for foreign trained occupational therapists and physical therapists, and a medical student fellowship residency training program (1957)
- Created the Nutritional and Metabolic research division and established the Cerebral Palsy Clinic in conjunction with U.C.P.A of Westchester (1959)
- Speech and Hearing Service Medical Rehabilitation program approved as a conservation of hearing center (1960)
- Changed its name to Burke Rehabilitation Center (1962)
- Began offering mental health psychiatric rehabilitation services in conjunction with Westchester County Community Mental Health Board, approved as hospital by Joint Commission on Accreditation of Hospitals, certified by the New York State Department of Health for juvenile amputee rehabilitation, and established Children's Rehabilitation Services (1963)
- Instituted Cardio-Pulmonary Rehabilitation Service, and established Socio-Medical Research program (1965)
- Initiated Stroke Research Study along with Cornell University Medical College and also cemented an affiliation agreement with the Cornell medical community, including Cornell University Medical College, the New York Hospital, the Hospital for Special Surgery, and Memorial Hospital (1968)
- Received full accreditation from American Board of Examiners in Speech Pathology and Audiology of the American Speech and Hearing Association (1970)
- Became affiliated with North Shore University Hospital residency training programs, reestablished residency training programs in physical medicine and rehabilitation with New York Hospital (1971)
- Dedicated a new 150-bed hospital wing (1972)
- Established the Outpatient Division, then known as Day Hospital, as a permanent arm of the center (1975)

Westchester County, caring for more than 2,000 ill and wounded sailors who became known as Burke's Navy. The war also brought on extensive changes to the field of medical rehabilitation. The vast numbers of seriously injured veterans led to an emphasis on physical and occupational therapy, improvements to wheelchairs and prosthetic limbs and the development of needed support services.

Burke continued to focus on physical rehabilitation not only for the veterans but all patients. Burke was among the first institutions to encourage moderate exercise for cardiac patients, and in 1924, the Burke Foundation helped found the American Heart Association. As a convalescent care foundation, Burke served 139,950 patients from 1919 through 1950 when medical rehabilitation came to the forefront of medicine.

As rehabilitation became a greater focus for the medical community, Burke, which had been focusing on rehabilitation since its inception, changed its name to better capture its mission. In 1951, under the direction of then medical director Dr. Edward J. Lorenze, the Burke Foundation changed its name to Burke Rehabilitation Hospital and established inpatient beds for rehabilitation medicine. That same year, the hospital formalized its physical medicine and rehabilitation services, opening a Physical Therapy, Occupational Therapy, Psychology, Speech, and Vocational Services departments.

Also in 1951, Burke's first clinical laboratories also opened; however the Burke Medical Research Institute would not be established until more than two decades later. Until then, the hospital continued to pioneer rehabilitative treatments for its patients.

The year before the creation of the Outpatient Division, Burke Rehabilitation Center officially added rehabilitation medicine research as a focus of the organization with the appointment of Fletcher H. McDowell, MD, as medical director and chief executive officer. Dr. McDowell was also the first Burke professor of rehabilitation medicine at Cornell University Medical College (CUMC).

Birth and Growth of Burke Medical Research Institute

Along with being a professor, Dr. McDowell was also an associate dean at CUMC. Dr. McDowell understood the importance of world-class research for rehabilitation medicine and for training future leaders and established an affiliation with Cornell to study neurological dysfunction, specifically cognitive problems, that limited the ability of a patient to optimally engage and benefit from neurological rehabilitation strategies.

This tie with CUMC was critical for recruiting outstanding scientists and physicians to Burke Rehabilitation Center and for providing the intellectual enrichment necessary to maintain Burke's quality faculty. The Burke/Cornell relationship has laid the groundwork for the creation of an outstanding research and training programs oriented toward patient rehabilitation.

Four years later, in 1978, the Burke Medical Research Institute (BMRI) officially opened to foster the development of new approaches to cognitive and motor rehabilitation in collaboration with Burke Rehabilitation Hospital and CUMC. Since its inception, the breadth and depth of research going on at Burke has dramatically expanded. Fundamental research on molecules critical for brain repair and plasticity are coupled with drug discovery, novel cell transplantation approaches, human biomarker studies, non-invasive brain stimulation trials in humans, and robotics. These studies are providing new knowledge on which the rehabilitation therapies of tomorrow for stroke, spinal cord injury, and traumatic brain injury will be based. New programs in vision restoration, pain, and motor recovery have recently been developed headed by a world class cadre of scientists and clinician-scientists.

To provide the tools necessary to solve problems of neurological disability (the number one cause of disability in the United States), Burke currently has more than 20 Cornell faculty members working synergistically and collaboratively amongst themselves and with clinicians and scientists around the globe. The scientific efforts at Burke are complemented by remarkable infrastructures that exist in Ithaca at the Cornell University undergraduate campus and at the Weill-Cornell Medical College in New York City. Each of BMRI's faculty members is sanctioned by appointment committees at our Ivy League affiliate.

Today, under the leadership of Rajiv R. Ratan, MD, PhD, who was appointed as BMRI's executive director in 2002, the primary, overriding goal of the Burke Medical Research Institute is to develop novel therapeutic approaches that give hope to the acutely and chronically disabled. A second, critical part of the mission of BMRI is to foster and cultivate a pool of talented young scientists, clinicians, and clinician-scientists who will lead the next

generation in studies on repair and rehabilitation of the nervous system.

Also under his guidance, Burke has been able to recruit and retain many top notch scientists that now make up the BMRI staff. Ratan was formally appointed professor of neurology and neuroscience at Weill Cornell Medical College in 2004 and named an associate dean of the medical college in 2011.

In 2012, Burke Medical Research Institute further spread its capabilities while keeping its commitment to solving the problems of brain repair by investing more than $7 million on the renovation of its research laboratories, increasing its regenerative medicine research laboratories to more than 40,000 square feet. Burke officially opened its Regenerative Medicine Laboratories on Sept. 14, 2012.

The following year brought even more exciting additions to BMRI, including the Early Brain Injury Recovery Program, the Restorative Neurology Clinic, and the Burke-Blythedale Hemiplegia Center.

***Argyrios Stampas, MD**, Director of the Spinal Cord Injury Rehabilitation Program, helps a young spinal cord patient work with the MOTOmed cycle for leg training. In conjunction with the cycling motion, the MOTOmed has a functional electrical stimulation (FES) system that provides stimulation to the leg muscles to make up for the missing impulses from the brain. This technology provides an active training option despite paralysis.*

Early Brain Injury Recovery Program

Opened in February 2013, the Early Brain Injury Recovery Program consists of two basic science laboratories that study activity-based therapies for brain repair and one clinical laboratory to study these therapies in children. The labs are linked by two common themes: response of the young brain to injury, and repair of the injured brain using activity; and a common mission: to restore neurological function in children who sustain injury to the developing nervous system by accelerating the incorporation of new neurorehabilitation treatments into clinical practice.

The Motor Recovery Laboratory is led by Jason Carmel, MD, PhD. The lab uses electrical stimulation to promote recovery of movement in rodents with neonatal brain injury. Dr. Carmel is a neurologist and neuroscientist with expertise in recovery of movement using brain electrical stimulation. He has shown that brain stimulation can promote recovery of movement in rodents with brain injury, even when applied long after injury.

The Early Brain Injury Recovery Laboratory is led by Kathleen Friel, PhD. Her lab uses non-invasive brain stimulation to promote recovery of movement in children with weakness on one side of the body. Dr. Friel is a neuroscientist with expertise in techniques to safely stimulate the human brain. She has shown that intensive hand therapy not only restores function but also strengthens brain connections in children with cerebral palsy.

The Vision Rehabilitation Laboratory is led by Glen Prusky, PhD. His lab uses visual experience to enhance recovery of vision in rodents with brain injury. Dr. Prusky is a neuroscientist with expertise in the visual system and the role of visual experience in restoring vision. He created Optomotry, a virtual reality system that tests rodents and enhances visual experience. Remarkably, the visual experience can also restore visual attention in rodents with developmental brain injury.

Restorative Neurology Clinic

In April 2013, BMRI launched a new Restorative Neurology Clinic to assist patients regain movement through robot-assisted therapy under the direction of Dylan Edwards, PhD,

*The laboratory of **Dianna E. Willis, PhD**, (second from the front) director of pain research, is working on understanding neuropathic pain and how it can be treated in various diseases, such as diabetes and amyotrophic lateral sclerosis (ALS) or Lou Gehrig's disease.*

who is also the current director of Burke's Brain Stimulation and Robotics research program. It is appropriate for those with decreased range of motion caused by neurological illness or injury such as stroke, spinal cord injury, or brain injury, and those whose motor recovery has stalled. The new clinic's approach is based on findings from years of study in motor function and through collaboration with other medical rehabilitation experts. Studies have shown that engaging in this form of robotic therapy can lead to significant and meaningful improvements in arm function in patients who have had a stroke.

The two types of robots used in the clinic were custom-designed for Burke by the Massachusetts Institute of Technology. The robots provide customized, goal-directed therapy aimed at building arm function and strength, and re-training of the nerves from the brain to body connection. The first robot is the Planar Robot, which focuses on shoulder and elbow function. The other robot is the Wrist Robot, which helps to regain function and strengthen the wrist and forearm. Both robots gently assist patients with initiation, accuracy and smoothness of natural movement. As patients' actions become more accurate and stronger in their movement patterns, the robots will adjust to require the patient to initiate more movement.

The Restorative Neurology Clinic offers six-week intensive workshops for individuals who do not qualify for current research programs but have arm or hand weakness as a result of a neurological illness or injury.

Burke-Blythedale Hemiplegia Center

Opened in late 2013, the Burke-Blythedale Hemiplegia Center is a multidisciplinary center where children with hemiplegic cerebral palsy receive expert medical care and participate in state-of-the-art rehabilitation research. Young patients with hemiplegia who come to the center are given full assessments and referrals to therapies and treatments, including physical, occupational, speech, and vision therapies.

The children also are given treatments for spasticity and joint contractures, and enrolled in cutting-edge clinical research trials, including robotic therapy, intensive hand therapy, and non-invasive brain stimulation, when appropriate. The opening of this partnership further expands Burke's pediatric services through research, as the hospital generally provides rehabilitation services for patients aged 14 and older.

The pace of research development at BMRI, as evidenced by the most recent expansions, only points to greater advancements in the years to come. Through BMRI, Burke Rehabilitation Center is one of the only free standing rehabilitation facilities with dedicated programs in basic research (understanding how the normal brain functions and how it goes awry in disease), translational research (understanding how to move basic research to the human bedside), and clinical research (testing of new therapies in humans). These programs all enjoy the sanction that comes from intense competition for external support from the National Institutes of Health and from private and public foundations.

Burke Rehabilitation Center Today

With the synergy between Burke Medical Research Institute, Burke Rehabilitation Hospital, and the Burke Outpatient Division, Burke Rehabilitation Center provides a comprehensive approach to rehabilitation grounded in research and medical expertise.

Convenient to Westchester County, New York City, Long Island, and

Connecticut, Burke attracts and welcomes patients from across the country and around the world. It provides inpatient and outpatient care for a broad range of neurological, musculoskeletal, cardiac, and pulmonary disabilities caused by disease or injury. Burke treats patients who have suffered a stroke, spinal cord injury, brain injury, amputation, joint replacement, complicated fracture, arthritis, cardiac and pulmonary disease, and neurological disorders. Patients are most frequently transferred to Burke from acute care hospitals once their condition is stable, and they are able to participate in intense physical, occupational, and speech therapy. On average, Burke treats 3,400 inpatients per year.

Headed by Mary Beth Walsh, MD, who was named CEO and executive medical director in 1995, Burke's doctors, nurses, and therapists provide customized treatment, and this personalized care is the result of expert, interdisciplinary teams, led by a remarkable range of highly respected medical specialists. Burke's full-time physicians include neurologists, physiatrists, internists, rheumatologists, pulmonologists, and neurophysiologists.

The intensive therapy regimens provide a minimum of three hours of one-on-one physical, occupational and speech therapy per weekday, for each of Burke's rehabilitation programs. Group sessions are offered on the weekends. The inpatient hospital follows a program model, meaning each program has dedicated clinicians that work solely on one particular diagnosis. This ensures that each patient will be treated by a professional specially trained for that injury or illness. The rehabilitation programs at Burke Rehabilitation Hospital include:

Amputee Rehabilitation Program

The Amputee Rehabilitation Program is a two-phase program that begins immediately following surgery. In the first phase, focus is on pain control, healing, emotional support, and preparing the limb for prosthesis. Burke's prosthetist then assesses, designs, measures, fabricates, and fits various types of upper and lower extremity prostheses. The prosthetist also may be involved in the education and training in regarding the use, care, and function of the prosthesis during phase II, which can be done on an inpatient or outpatient setting depending on the patient's level of function.

Brain Injury Rehabilitation Program

The intensive Brain Injury Rehabilitation Program strives to return patients to the most active and productive lifestyle possible following a traumatic or acquired brain injury. It serves adolescent through elderly patients with diagnoses such as brain tumor, meningitis, skull fracture, cerebral contusion, encephalitis, intra-cerebral or subarachnoid hemorrhage, and brain abscess.

Cardiopulmonary Rehabilitation Program

The Cardiopulmonary Rehabilitation Program is divided into two parts: the cardiac program and the pulmonary program. The cardiac program is tailored for individuals with heart disease and the post-operative cardiac patient. The pulmonary program serves young-adult through elderly patients with diagnoses such as COPD - emphysema, bronchitis, bronchiectasis, chronic and acute respiratory failure, and pulmonary fibrosis.

Neurological Rehabilitation Program

The Neurological Rehabilitation Program serves adolescent through elderly patients with diagnoses such as multiple sclerosis (MS), Parkinson's disease, Guillain-Barre syndrome, myasthenia gravis, and peripheral nervous system disease.

Orthopedic Rehabilitation Program

The Orthopedic Rehabilitation Program serves patients with diagnoses such as unilateral and bilateral knee replacements, unilateral and bilateral hip replacements, hip resurfacing, lower extremity fracture, and multiple traumas. Most of the patients in this program return home within one to two weeks.

Single Joint Replacement Program

The Single Joint Replacement Program serves post-surgical patients who have had unilateral total knee replacement or unilateral total hip replacement. Most of these patients return home within one week, walking independently with a single cane.

Spinal Cord Injury Rehabilitation Program

The Spinal Cord Injury Rehabilitation Program serves adolescent through elderly patients with diagnoses such as traumatic spinal cord injury, spinal cord hemorrhage and infarction, multiple

sclerosis, transverse myelitis and spinal tumors.

Stroke Rehabilitation Program

The Stroke Rehabilitation Program helps post-stroke patients achieve the highest level of independence possible from the physical, visual, cognitive, and psychological impairments caused by stroke. The stroke team uses evidence-based practices and comprehensive services to prevent secondary complications, minimize impairment, and reduce limitations to the patient's pre-stroke activities.

The program clinicians also take advantage of the full range of technological advances to provide the best care for patients.

These technologies and others, plus specialized medical professionals, such as respiratory therapists, social workers, audiologists, psychologists, pharmacists, and dietitians round out the services offered at Burke. Recreational therapy, chaplain visits, patient green house activities, intergenerational therapy, and family support groups are also available. These resources explain Burke's national reputation for excellence and its consistent success helping patients achieve their maximum recovery.

In addition to being a leader in the field of medical rehabilitation, as mentioned, Burke is a leader in rehabilitation research. Patients admitted to Burke Rehabilitation Hospital may have the opportunity to participate in cutting-edge medical research for ongoing studies at Burke Medical Research Institute. Current studies being conducted at the Institute include stroke, brain injury, spinal cord injury, robotics, and pharmacological studies to name just a few.

Former inpatients who need further physical, occupational, and speech therapy can also access these services on an outpatient basis through the Outpatient Division. These programs are also open to community members who haven't had prior affiliation with Burke. In 2013, the Outpatient Division provided nearly 75,000 visits, a number that continues to rise each year.

To address the growing demand, Burke opened two new outpatient facilities in Yonkers and Somers in 2013, bringing the total number of outpatient satellite clinics to six. The other locations are the White Plains clinic on the main Burke campus, and the clinics in the Bronx, Mamaroneck, and Purchase, New York.

As an acute in-rehabilitation hospital, outpatient service provider, and research center, our medical staff, therapists and research scientists share the mission to ensure that every patient at Burke makes the fullest possible recovery from a debilitating illness or traumatic injury.

Technological Advances Include:

- The **InMotion ARM™** interactive robot that uses state of the art robotics technology to help patients with reduced arm mobility due to stroke, brain injury, or other neurological conditions gain increased arm movement. The robot can assist and guide patients to move with greater initiation, control, and coordination

- The **ZeroG Lite**, that when used in combination with a comprehensive rehabilitation program, helps treat gait impairments in individuals after stroke, traumatic brain injury, incomplete spinal cord injury, cerebral palsy, amputation, orthopedic injuries, and others, by allowing patients to safely practice intensive gait and balance activities

- The **SaeboFlex** is a custom-fabricated orthosis that allows individuals suffering from neurological impairments, such as stroke, the ability to incorporate their hand functionally in therapy and at home by supporting the weakened wrist, hand, and fingers

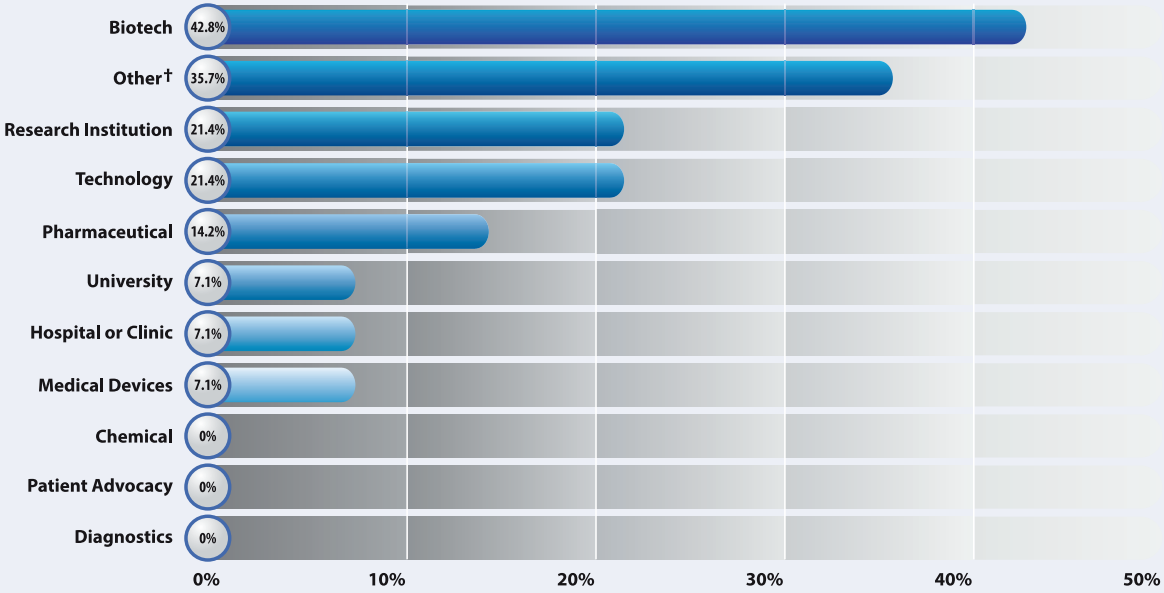
- The **VitalStim® Therapy System** is a safe, non-invasive, external, electrical stimulation therapy used to help treat patients with difficulty swallowing or dysphagia. It unites the power of electrical stimulation with the benefits of swallowing exercises to accelerate muscle strengthening and restore swallowing function

- The **Nintendo Wii Fit** helps patients work on their balance and build strength through various Wii games that help develop a person's sense of balance, build muscle strength and stamina. It also provides feedback and tracks the patient's progress

State of the Valley Survey

Types of Organizations Completing the Survey*

The following results are from a survey distributed to medical device, technology, hospital or clinic, patient advocacy, chemical, research institution, diagnostics, consultancy firms, and intellectual property companies.



(n=14)

Multiple responses permitted.

†Other: "Contract research organization," "Intellectual property legal services," "An intellectual property law firm serving the healthcare, biotech, pharmaceutical and medical device industry," "Consultancy firm," and "Legal."

China's Zongyi Group Invests in Yonkers-based Biotech ContraFect

Barry Kappel, PhD, MBA
Vice President,
Business Development

Press Conference coverage of Zongyi's $9.5 million investment in Contrafect Corporation. Watch a video summary of this announcement on YouTube: http://goo.gl/8Jglr0.

ContraFect Corporation, a biotechnology company spearheading the use of lysins and monoclonal antibodies to treat life-threatening infectious diseases, announced in 2012 that the Zongyi Group invested $8.6 million in the company. Zongyi Group is a leading diversified business group of China. Its business scope covers new energy, information technology, investment, and asset management.

The funding from Zongyi Group is more than an investment for ContraFect. It is the beginning of a relationship that will provide ContraFect unique access to China, the world's fastest and most important emerging market. The infusion of funds from Zongyi Group will advance ContraFect's ability to bring new pharmaceutical products to market with benefits for people all over the world.

ContraFect is pioneering the use of lysins and monoclonal antibodies to address the growing challenge of pathogen drug resistance and treat life-threatening infections. ContraFect's initial products include new agents to treat diseases such as MRSA (drug resistant staphylococcus bacteria) and influenza. Its scientific strategy focuses on the use of combination therapies, where it believes that the company's products will overcome high rates of mutation and resistance observed in microbes.

Yonkers Mayor Mike Spano was thrilled to hear of the good news and said, "As Yonkers continues to attract businesses and to revitalize its waterfront and downtown, I am so pleased that ContraFect is prospering and attracting vital new investors. The infusion of funds from an important Chinese investor will advance its ability to bring new pharmaceutical products to market with benefits for people all over the world. I'm so pleased that Steven Rockefeller, working with Hudson Valley Economic Development Corporation and Scenic Hudson, has helped our new friends from China recognize that the Hudson Valley, and specifically Yonkers, are great places to invest. I offer our friendship and thanks to all."

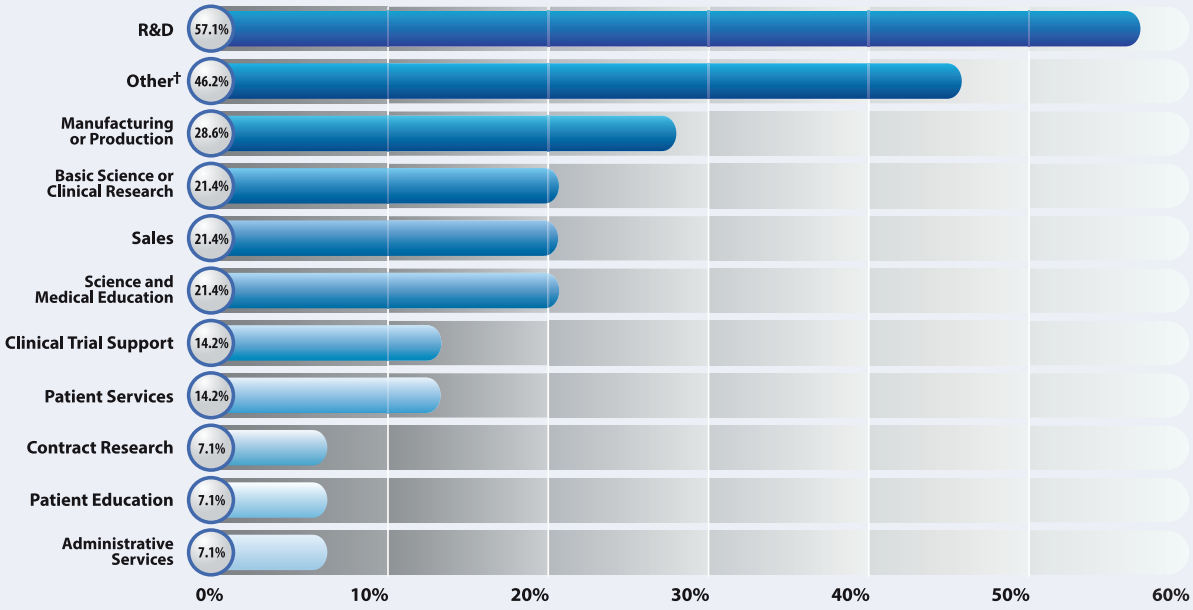
Steven Rockefeller Jr. said, "I am very excited that my friends and colleagues from China understand that the Hudson Valley represents an exciting place to invest funds in a setting that offers beauty, opportunities for win-win environmental and economic benefits, and lasting partnerships."

Laurence P. Gottlieb, president of the Hudson Valley Economic Development Corporation, also said, "This investment builds on the Hudson Valley Economic Development Corporation's longstanding commitment to the biopharmaceutical industry in the Hudson Valley and is the culmination of our BioHud Valley initiative that promotes this important growing regional industry. I want to thank my predecessor, Mike Oates, for his role in promoting Yonkers and the Hudson Valley as an ideal location for this investment."

The growth of ContraFect is expected to help downtown Yonkers develop more jobs in existing buildings and will build on the success of the "daylighted" Saw Mill River. Hudson Valley Economic Development Corporation (HVEDC) along with the BioHud Valley Initiative share a commitment to fostering and growing the biopharmaceutical industry in the Hudson Valley. With the help of the Zongyi Group, ContraFect hopes to be able to contribute to HVEDC's longstanding mission to enhancing the Hudson Valley region.

State of the Valley Survey

Main Types of Services Responding Companies Offer*



(n=14)

***Multiple responses permitted.**

†Other: "The Philips site in Briarcliff Manor includes Philips Corporate Research, Philips Healthcare Sales and Service, Philips Intellectual Property & Standards,""Installation services,""Our professionals handle a broad variety of technologies and a diverse, yet interrelated spectrum of intellectual property issues including intellectual property portfolio development, patent prosecution, licensing, trademark clearance and registration, copyrights, freedom to operate, strategic assessments of competitors' infringements, domain names, cybersquatting, trade secrets, unfair competition, advertising, privacy policies, content usage agreements, rights of publicity, web site terms and conditions, and other related commercial issues. We apply our interdisciplinary experience and creativity to each of our projects, whether it is for the benefit of corporate clients trying to operate in competitive industries or for independent inventors who want to extract all that can be had from their ideas. We help our clients develop comprehensive plans that address their short- and long-term needs,""Direct inpatient and outpatient care,""Intellectual property legal services," and "Legal services."

Changing the Pharmaceutical Paradigm

Ken Nanus

Business Challenges in Drug Development

Each year, the Food and Drug Administration (FDA) approves dozens of new medicines. From low testosterone to high cholesterol treatments, patients are receiving new weapons in the fight against disease.

Many of these new drugs combat diseases that never before had treatments. However, there are still many conditions for which there are no FDA-approved treatments.

Given the state of today's pharmaceutical industry, it's no wonder more new drugs are not available. Taking a new drug from laboratory discovery through rigorous FDA trials and all the way to approval can require ten years or more. The trials alone can cost hundreds of millions of dollars. According to the Pharmaceutical Research and Manufacturers of America, on average it takes 10-15 years and $1.2B to get a drug from discovery to approval. Only one in every 5,000 new drugs successfully completes the process.

With stratospheric development and clinical costs, and a development success rate languishing around .02%, it's easy to understand, why major pharmaceutical companies have dramatically scaled back their research and development budgets. For many companies, the perceived risk is simply too high and they've eliminated their research and development efforts altogether. Other companies have adopted a strategy of acquiring startup or small biotech companies that have a new drug in process, overpaying if necessary to mitigate their risk.

For years pharmaceutical companies have used their libraries of novel compounds to retrofit them into potential candidates for new drugs to treat disease. But when pharmaceutical R&D departments are shuttered or downsized, fewer new drugs enter the pipeline. Patients' unmet medical needs continue unabated.

As major drug companies back away from new development, startup and small biotechnology companies have stepped into the breach and have made an enormous impact by thinking outside of traditional boxes.

One such company, Curemark, LLC in Rye, has not only begun changing the traditional development paradigm but is making an impact with the largest unmet medical need among American children today–autism. Curemark is providing a template for future startup and small biotechnology companies to follow by developing new strategies for raising large amounts of capital, employing a "virtual" organizational structure and workplace and dramatically changing the approach to scientific research.

The central tenet of Curemark's new approach to science is translational medicine.

The Role of Translational Medicine

Irrespective of a company's size or resources, startup or small drug new drug compounds are most often uncovered in the laboratory. That's why, to consumers, the phrase "pharmaceutical drug development" conjures up images of white-coated lab technicians poring over microscopes slides while beakers of colored liquids cook in the background.

Once discovered, these new compounds are then rigorously tested on groups of patients under strict FDA guidelines before they're delivered to patients.

Dr. Joan Fallon, Curemark's Founder and CEO, believes that the current drug development model works backwards. She believes that translational medicine, using insights gleaned from patients and clinical research to solve existing patient problems, is the future of drug development.

"Pharmaceutical companies make new drugs in the lab and then take them to patients," she said. "I believe it makes more sense to listen to patients' needs first and take that information back to the laboratory to try and solve their specific problems. New treatments and tests to determine who may benefit from them are likely are to come from patients, not from the traditional basic science laboratory," she said.

"What's more, experience tells us that disruptive, breakthrough technology and discoveries that disrupt

Curemark Founder and CEO, Joan Fallon

the status quo are more likely to come from start-ups. Innovation simply isn't in 'big pharma's' DNA. Their sheer size and their self-created silos restrict it."

Those "silos" refer to the rigid departmental structure of major pharmaceutical companies. When new discoveries are made, approval for research and development resources relies on specialists in a particular medical area. For example, development of a new medication for ulcers would require approval by a company's gastrointestinal experts. If a new drug impacts multiple organs or systems in the body all departments must agree, leading to a slower and more cumbersome process.

Dr. Matthew Heil, Curemark's Chief Scientific Officer, agrees. "When I meet with scientists to discuss translational medicine, I find that they view it as a large conveyor belt with the scientist on one end and patients on the other. From their point of view, the belt runs in one direction– from scientist to patient. They see their goal as simply making the belt move faster. It doesn't work," he said.

"For true translational medicine to work, the belt has to work in a circle, starting at the patient, moving toward the scientist who now better understands what's needed and finally making it's way back to the patient. That's why my Curemark experience is a truly novel explanation of what translational medicine could be," Dr. Heil continued.

Curemark's New Understanding of Autism

As a clinician, Dr. Fallon built a thriving practice from the two beliefs that 1) patients will tell you what's really wrong with them if you listen to them and 2) the body's systems work together and impact each other. Her confidence in translational medicine led to a breakthrough diagnosis and treatment for autism while creating a company that is changing the way new drug development is accomplished.

"Sometimes," she said, "new drug development just begins with one person talking to one doctor. When a practitioner listens – really listens – to patients, patterns will emerge that can lead you to something new."

Dr. Fallon's autism discovery began by listening to patients and their families that were dealing with autism. She knew the difficulties of dealing with a disease for which there was no medical treatment. She had seen hundreds of children with the condition over more than 25 years of practice and while parents' reactions were largely the same, it never ceased to move her. For example, one afternoon Dr. Fallon was talking with a father in her office on Central Park Avenue in Yonkers. His child had been recently diagnosed with autism.

"Autism is a very scary word," the father said. "My wife and I feel guilty all the time. It impacts every facet of our life. I began working two jobs so that we can get him the help he needs, but that means my wife is constantly home alone with our children."

That father isn't alone. Autism impacts many American families. Experts agree with the Center for Disease Control that autism ranks as the fastest growing childhood developmental disorder. That growth continues to accelerate.

The Center for Disease Control says a new case of autism is diagnosed every 20 minutes. Currently there are approximately 560,000 autism cases nationwide, a tally that grows at 10% or more annually, with an estimated 3-5 million cases worldwide. According to the Center for Disease Control, autism is more prevalent in children

than childhood cancer, hearing loss, vision impairment, or cerebral palsy.

In America, one in 110 children lives with the condition, according to the latest statistics. Far more boys (one in 70) are afflicted than girls. The condition, which is hereditary, impacts one family in every 62. Those are just the cases that have been definitively diagnosed.

It's also likely there are families with children who could benefit from evaluation and treatment, but either insurance or qualified professional care is not available. Other parents might believe that, though they suspect a problem, a thorough evaluation of their child would subject him/her to the stigma of being labeled "different" in school or with their friends.

Typically evidenced by the age of three, autism impacts communication skills, social interactions, and cognitive functioning while disrupting the lives of all members of the sufferer's family. Some children with autism can't speak. Others cannot make eye contact or be toilet trained. Family finances and relationships experience severe stress.

Three symptoms are required for a diagnosis of autism as stated in the DSM-V:

1. Socialization (i.e. how your child interacts with other people)
2. Restricted repertoire of interests, behaviors, and/or activities
3. Impaired speech and communication

Autism can present differently in different children, which is why it's characterized as a "matrix" condition and a "spectrum disorder." The severity of symptoms in each child can vary; with one more pronounced than the other two, two more pronounced than the third, etc.

Psychiatric specialists currently diagnose autism through observation, based on the presence of at least 6 of 12 abnormal behaviors during a 3-5 hour interview.

Once diagnosed, parents' options are limited to unproven therapies and a daunting array of psychotropic drugs, many of which are rarely tested on children with autism before being prescribed. These drugs typically have substantial side effects. Other than drugs, insurance rarely covers costs of care.

Since there is no standard of care or accepted medical protocol, parents and doctors choose from among a combination of physical, speech, and/or occupational therapy, depending on the child's age. For parents, creating a "normal" life for children with autism and their siblings is impossible in today's medical environment, which largely explains why divorce rates for couples raising children with autism are estimated at over 75%.

There are tests for diabetes, prostate cancer, and many other conditions, but in today's science there's no definitive medical test for autism. There's no medical treatment for autism's core symptoms, either.

Finding a New Path to Treating Autism

Dr. Fallon's expertise working with her patients and families dealing with autism did not open the door to her discovery. Listening to her patients did.

As Dr. Fallon said recently during a Fox Business News Interview (http://video.foxbusiness.com/v/2873126616001/how-to-find-alternative-funding-for-small-businesses/#sp=show-clips), "The longer I continued to see these children, the more one particular thing began to stick out to me–they had very unusual diets."

"Many children eat unusual diets. They can eat peanut butter and jelly sandwiches for two weeks then suddenly switch to hamburgers. But the children with autism were different. And while not every child with autism eats an unusual diet, what I saw was that more than half of these children ate what their parents called white foods, tan foods, soft foods, and crunchy foods.

"After awhile I named it the 10-thing diet, because it largely consisted of bagels, waffles, cereals, chips, pastas without sauce, etc. It made me wonder if they eat this way for a reason, perhaps because something is wrong inside their body."

Now Dr. Fallon was determined. "I needed to find out why," she said.

By the time she began to answer her question, Dr. Fallon had formed a scientific research company and named it Curemark. Using a business model heretofore unknown in clinical research, Curemark's research determined that approximately two thirds of children with autism appear to have a

gastrointestinal deficiency-–an inherent inability to digest protein properly because they lack key digestive enzymes.

Dr. Fallon and her team determined that children with autism may eat the same way as other children, but the proteins they ingest are not fully broken down into their amino acid components. In turn, those amino acids never make it to their brains and other parts of the body. When the brain does not receive the nutrition it needs to develop properly, it leads to a series of severe behavioral and cognitive disabilities. Their brains are literally starving.

We also know now that the amino acids which are not being broken down due to the enzyme deficiency are necessary to make new proteins and exert epigenetic effects on specific genes.

Some of these epigenetic effects, as expressed by a deficiency in the amino acid methionine, could help turn on and off the CHOP gene, which has already been implicated in a defective mechanism found in the brains of children with autism (neural pruning).

Curemark's ongoing research examines the role of a deficiency of the enzyme chymotrypsin and its role in the dearth of the important essential amino acids tryptophan and phenylalanine, which are needed to make serotonin and dopamine in the body.

Curemark followed up on its finding by securing patents for a biomarker to determine the presence or absence of these key digestive enzymes.

While raising $50MM in operating capital, Curemark developed the first investigational drug to address the core symptoms of autism and conducted successful FDA double-blind, placebo-controlled Phase III trials. Curemark's new drug, CM-AT, received "Fast-Track" designation from the FDA. Fast Track facilitates the development and expedites the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to meet unmet medical needs.

Curemark has now taken the final step down the road toward bringing this discovery to the children and their families by beginning to file its Novel Drug Application, or NDA, for final FDA approval. Upon approval, Curemark's biomarker will be the first medical treatment for the core and non-core symptoms of autism.

The Challenges of Drug Development

At a time when digital technology innovation is as visible as your watch or kitchen, pharmaceutical innovation–particularly in giant pharmaceutical companies–has become stifled. Digital technology innovation moves at the speed of light, largely because new products reach markets quickly with only two significant metrics to meet–Does it work? Is it needed?

By contrast, drug makers need to jump over 5 hurdles–Does it work? Is it safe? Does it stand up to scientific scrutiny? Does it pass regulatory muster? Is it needed?

Upon making the discovery and filing initial patents, Curemark quickly realized that complete success would require the creation of a new business and financial model for startup biotechnology companies, too.

Typically, drug development requires two different groups of people, both whom are highly paid and highly skilled. Scientists that test new compounds in the laboratory may need years and thousands of person-hours to work through the hits and misses of laboratory research.

When a new compound gets past the laboratory, scientists who administer and run FDA trials take over. From enrollment to randomization to completion, each subject in an FDA trial can cost the sponsoring company as much as $25,000. Trials typically require hundreds (sometimes thousands) of subjects and the FDA will often require multiple trials before it approves a company's NDA.

Legal costs can skyrocket, too. Regulatory lawyers help navigate FDA concerns and issues. Intellectual property attorneys protect a biotech's most valuable asset. Financial attorneys guide a nascent company toward stability and enable it to maintain shareholder confidence.

While they only receive publicity when there's a problem, manufacturing and processing of new drug discoveries are essential elements of this process. Factories and laboratories that manufacture drugs must undergo frequent FDA testing in order to continue operating. The finished drug product must pass FDA requirements for stability. Will the product stay equally efficacious on the shelf over time? Will its effectiveness wane?

Then there's the FDA itself. Prior to beginning a clinical trial, pharmaceutical companies must submit their

protocol, a specific roadmap for how the trial will be run and subsequently analyzed for success or failure. The protocol's specificity and thoroughness can determine a trial's success or failure before it starts, so it's meticulously planned, written, and reexamined before FDA submission.

Before a company can get approval to run a clinical trial, it must first file an application for an Investigational New Drug. Clinical trials are often run at sites across the country, and it is against the law to transport unapproved (or illegal) drugs across state lines without governmental approval. Filing fees can run into the millions of dollars.

Pharmaceutical companies must bear the cost of fees and testing. A new drug's failure can occur at virtually any point in this process.

While startup or small drug companies have become a shopping destination for big pharma, they have significant obstacles of their own. The money required for clinical trials can come at the cost of losing operational control to a venture capitalist or private equity firm. Protecting the intellectual property around a new discovery, navigating the FDA regulatory process, and ensuring quality and stability for a new drug all contribute to the urgency of constant fund-raising.

Curemark Changes the Pharmaceutical Business Paradigm

To this point, Dr. Fallon had spent her professional career in her practice. She gave up that practice to start Curemark. While learning to run a company, Dr. Fallon utilized a previously unrecognized skill–she became a salesperson.

Startup companies often secure angel or early funding from private equity or venture capital forms. When meeting with them, Dr. Fallon ran into a brick wall. "There's simply no venture or private money available for autism," she said. "VCs and private equity prefer situations with no barriers to market entry. The failure rates of clinical trials and the regulatory bodies involved make them gun-shy about pharma."

So she met with friends and family to secure the capital that opened Curemark's doors. Dozens of other friends and families invested through a belief in Dr. Fallon and the strength of her early testing.

As CM-AT's development has continued, Dr. Fallon remains a one-woman fundraising machine, closing $50MM to date.

Those resources have been maximized through a "virtual" organization that minimizes headcount and total overhead. Curemark employs an extremely small fulltime staff, utilizing dozens of consultants across a wide swath of specialties.

Senator Kirsten Gillibrand speaking at Curemark in Feb 2011 to announce her proposal to expand, simplify, and make permanent R&D tax credits

"Outsourcing provides a tremendous amount of flexibility, Dr. Heil said. "For example, if I want analytical chemistry done, I can go to some of the best around; people with decades of experience. It's like being able to choose what I need, when I need it and get the best of everything, within budget constraints of course, without being committed to one specific vendor."

"Curemark's small headcount gives it agility and focus that larger companies envy," Dr. Gannon said. "The company is extremely thorough about its decision–making process and the steps they take when they take them. Every decision is well thought out. In addition, they've been extremely thorough and smart at developing their portfolio and protecting it from a patent and growth standpoint. The small staff has also allowed them to

develop strong working relationships with both their contractors/suppliers and the regulatory bodies involved in this the process.

The Impact of Curemark's Discovery

When Curemark's autism treatment enters the market, Hudson Valley businesses and residents stand to reap an enormous group of benefits, including:

Job Creation: Manufacturing, agriculture, packaging, marketing, and sales will generate a host of new jobs. Since it embodies the entrepreneurial spirit she wants to expand, Senator Kristin Gillebrand (D, NY) chose Curemark's conference room as the place to announce her proposed Research and Development Tax Credit.

"My number one focus is on creating good-paying, family-supporting jobs," she said. "By supporting research and development, we can help our businesses become more competitive and create the high tech jobs of tomorrow. Our state is already home to the universities, businesses, laboratories, researchers, and the bright minds we need for long-term economic strength. This proposal would leverage more private investment in our high-tech sector, creating good paying jobs right here in Westchester."

Medical research: Autism has been perceived as a mental health disorder, which is largely responsible for the absence of insurance coverage. For the first time, autism will be acknowledged to have a physiological origin. Discussion of the gastrointestinal origin of autism will spur substantial new medical research and embolden biotech startups, while heightening awareness of the Hudson Valley as an emerging center of biotechnology.

Healthcare cost reduction: The staggering out-of-pocket financial costs of autism care for families can be as much as $15,000 per month. Approval of this medication could substantially reduce that burden, as well as reimbursement outflow from Medicare and Medicaid.

The National Institute of Health estimates that the care of a child with autism will average $3.2 million over their lifetime. There are currently about 560,000 reported cases of autism in America. If 50% of autism cases could be treated –or even eliminated–the total savings to the economy could approach one trillion dollars.

Additional benefits will accrue to the Hudson Valley. For example, local municipalities will find other uses for a portion of the special education monies currently allocated for children with autism. Two parent families can become two income families again, if they wish, because the demands on the parent-caregiver's time will substantially decrease.

What began as one doctor listening to one patient demonstrates that small and startup biotechnology companies can fill the huge space left in the wake of major pharmaceutical's reduction of research and development efforts.

SUCCESS LEAVES CLUES. CUREMARK'S USE OF A NOVEL BUSINESS MODEL IS AS GROUNDBREAKING AS ITS APPROACH TO SCIENCE.

Seven years ago, Curemark started because one doctor employed what she calls a "zero-based" strategy for diagnosis and treatment. By approaching each situation with a blank slate, asking many questions and listening carefully without any expectation, Dr. Fallon gained insight into children with autism that promises to improve these childrens' lives for many generations to come. And, in the process, her company is showing the pharmaceutical industry that when it comes to drug development, David is just as strong as Goliath.

Intellectual Property and the Life Sciences Industry

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Intellectual property rights provide a vehicle through which innovators and creators can realize the economic value of their contributions to society. Historically, the opportunities to obtain valuable intellectual property rights in the life sciences industry resided primarily in bringing to market either broad based medical treatments that were tied to small molecules or pioneering medical devices. However, focusing oneself on those limited models is very twentieth century.

Due to recent advances in molecular and cellular biology, the accelerating importance of information processing technologies to the life sciences industry, and an aging population that has developed an increased demand for a greater number of solutions to more conditions, the brass ring in the life sciences industry no longer resides primarily in the silos of Big Pharma or well-established medical device companies as it once did. This paradigmatic shift has brought with it new and numerous opportunities.

The value of these opportunities at any point in time is impacted by a rapidly changing landscape of intellectual property positions and what is at times a somewhat slow to respond legal framework that is responsible for both awarding intellectual property rights and deciding between or among parties who dispute the existence and/or appropriate allocation of those rights. This dynamic and the often unpredictable intellectual property system within which the life sciences industry operates pose risks for the unwary. However, it also offers great potential rewards for the innovator who pays attention to changes in the competitive marketplace and the rules that define this system. For example, as Forbes recently reported, in 2013 the American Stock Exchange's Biotechnology Index rose 50.6%, and there were 65 IPOs that collectively raised $7.5 billion, which is 254% more than in 2012. Thus, the marketplace has recently demonstrated that it places a premium on contributions in the life sciences.

The following sections present half of a dozen noteworthy developments that occurred in 2013 that both illustrate important trends within the life sciences industry and provide insight into the intellectual property framework for this industry. With this information inventors and investors can look to 2014 with a better appreciation of the environment in which they must now operate in order to grow.

First, 2013 marked another year in which well-known and very profitable pharmaceuticals went off patent, and pharmaceutical companies were left with the ramifications of the albatross of the patent cliff. This patent cliff, which some measures spans the years 2010 -2016, and by other measures as extending even beyond 2016, refers to the step losses in revenue faced by pharmaceutical companies due to the expiration of patents. The cause of the patent cliff is two-fold.

One of the causes is a reflection of the unprecedented number of genuine scientific breakthroughs made during the 1980s. A number of new pharmaceuticals were discovered during that time period, and there is, at least the perception that the current pipeline of pharmaceuticals is much drier.

The other cause is an artifact of a grandfathered way for determining when patents expire. Currently, the term of a utility patent is typically measured as ending twenty-years from the date that the application or any priority application of it other than a provisional or foreign patent application was filed. This term can be extended due to certain administrative agency delays; however, any of those extensions that are due to United States Patent and Trademark Office ("USPTO") delays will be offset by delays caused by an applicant. Because a patent is not enforceable until it issues, i.e., one cannot enforce a patent application, and one does not want to lose patent term extension due to one's own delays, applicants have an incentive to move their applications through the USPTO as rapidly as possible. However, for any patent that issues off of an application that was filed prior to June 8, 1995, the term ends the later of seventeen years from its issuance or twenty-years from its filing (or the filing of any non-provisional or foreign applications to which it claims priority). Under this legacy framework, particularly when manufacturers of pioneering pharmaceuticals were facing delays for approval by the FDA, there was an incentive to delay processing at the USPTO, thereby pushing back the expiration of the patent. Thus, if an application were filed, e.g., in 1992 and took four years to issue, it would have issued in 1996, and the expiration date would be seventeen years later in 2013.

The continuation of pharmaceuticals going off of the patent cliff was not unexpected, but it nonetheless has significant ramifications for the life sciences industry. Most notably, it affects the profitability of pharmaceutical companies, which

in turn affects and continues to affect their ability to invest in research and development. However, it also has left the industry and the public clamoring for new inventions, thereby inspiring innovative researchers to find new treatments to bring to market.

Second, 2013 witnessed the reporting of at least three dozen partnering deals in the healthcare arena that were valued at $500 million or more. The value of the deals usually rests in large part in the value of the intellectual property that is at issue, and many of America's most well-known pharmaceutical companies participated in these transactions, including but not limited to Johnson & Johnson, Astrazenca, Bristol-Myers Squibb, GlaxoSmithKline, Eli Lilly, and Roche. Many of the transactions focused on collaborations and the development of new products. These types of agreements and the willingness of renowned players to participate in them demonstrate a need to look outside of one's organization to bring products to market. Entrepreneurs should be cognizant of this trend and think carefully about how rights should be allocated in any deals in which they participate.

Third, the United States Supreme Court changed the rules for what is patentable subject matter. In the well-publicized recent decision of Association for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013), the Supreme Court drew a clear line between isolated genomic DNA and cDNA with respect to the issue patentable subject matter, holding that the former is not patentable subject matter while the latter is. Although the line is clear, it was drawn late. The decision came approximately four decades after the technologies for sequencing DNA went into effect. Additionally, with respect to isolated genomic DNA, the decision resolves the issue of its patent eligibility in a way that almost universally had been answered differently by lower courts, the United States Patent and Trademark Office ("USPTO") and foreign Patent Offices. More importantly, the decision may have the unintended consequence of deterring valuable dollars from certain types of biotechnology research.

By requiring one to focus on the similarity between what is claimed and what exists in nature, the Supreme Court has set the stage for the USPTO to reject claims that are directed to molecules that exist in nature in forms that are less pure than what is claimed, and for accused infringers to challenge the patentability of claims directed to these types of molecules. Thus, there is now a cloud over some patents and potentially a decreased value of new discoveries of naturally occurring molecules. Time will tell the extent to which this chills certain direction for research and development.

Fourth, the Supreme Court addressed the issue of whether pay-for-delay settlement agreements violate antitrust laws. Because of the potential value of exclusivity in the field of pharmaceuticals, there have been a number of instances in which innovator pharmaceutical companies have paid generic companies not to come to market. These payments are referred to as "reverse payments" because they flow from the patent holder to the accused infringer rather than in the more typical direction of from the accused infringer to the patent holder. Critics of these arrangements refer to them as "pay for delay" and according to the Federal Trade Commission ("FTC"), these types of agreements have cost consumers $3.5 billion annually. On June 17, 2013, in FTC v. Actavis, 133 S. Ct. 2223 (2013), the United States Supreme Court held that reverse payments, even in the absence of allegations of fraud on the Patent Office or sham litigation, can be the subject of antitrust scrutiny. This may have a chilling effect on the settlement of Hatch-Waxman cases and usher in more antitrust challenges to these types of settlements.

Fifth, the FDA released its final guidelines on mobile medical applications and signaled that for a significant number of types of applications that touch upon the healthcare industry, the FDA is going to impose no burdens. Thus, there are apps that are not deemed to be devices and thus not within the FDA's jurisdiction, including mobile apps that: (1) are intended to provide access to electronic copies of medical textbooks or other reference materials; (2) are intended for healthcare providers to use as education tools for medical training or to reinforce training previously received; (3) are intended for general patient education and facilitate patient access to commonly used reference information; (4) automate general office operations in a healthcare setting and are not intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation treatment or prevention of disease; or (5) are generic aids or general purpose products.

More importantly, the report also provided examples of mobile apps that are within the FDA's discretion to regulate, but because the FDA deems them to be of low-risk to consumers, the FDA will not actively regulate them. Examples include apps that: (1) help patients/users self-manage their disease or condition without providing specific treatment suggestions; (2) provide patients with simple tools to organize and track their health information; (3) provide easy access to information related to health conditions or treatments; (4) help patients document, show or communicate potential medical conditions to healthcare providers; (5) automate simple tasks for healthcare providers; and (6) enable patients or providers to interact with Personal Health Records (PHR) or Electronic

Health Record (EHR) systems. The consequence of this clarification is that many life sciences inventors who focus on new computer software will be largely free from FDA oversight.

Sixth, on March 16, 2013, the United States moved from a first to invent to a first inventor to file patent system. Particularly for the start-up company, this change can lead to increased burdens. As has always been the case for anyone who sought to obtain intellectual property rights outside of the United States, there was a race to the Patent Office and, in a competition between two parties that were seeking patent protection for the same invention, the first to arrive would prevail. However, until last March, the later filer could in many circumstances still prevail in the U.S. if he or she could prove being the first to invent.

Particularly for start-up and small companies this change in the law is an added pressure. It will push many of these companies that have focused primarily or exclusively on U.S. markets both to file patent application sooner than they previously would have done and to increase the number of provisional patent applications that they file, which will in turn increase their costs. However, by establishing procedures by which to get to the USPTO earlier many of these companies will increase the urgency with which they conduct research and better position themselves with respect to foreign rights.

With these developments in mind one should keep an eye on six developments that will occur in 2014.

First, this Supreme Court will again speak to the issue of patentable subject matter. Whereas last year the Supreme Court addressed the issue of whether molecules that are the same as those that exist in nature are patent eligible, this year it will confront the issue of the extent to which computer implemented inventions are patent eligible.

Over the past fifteen years, the USPTO has been inundated with patent applications for inventions that are directed to the implementation of methods on computers, i.e., that are software inventions. During this time period, the Human Genome Project was completed and many life sciences related companies developed new and non-obvious ways to analyze and to process data. Some of these companies sought and obtained patent protection for their inventions. However, there is ambiguity in the law as to the standard for allowing patent claims directed to these types of inventions and large amounts of resources have been spent over the past few years fighting over the standard to apply in any particular case and how to apply it.

Doctrinally, the challenge for determining whether software related inventions are patentable rests in the principle that abstract ideas are not patent eligible. In December of 2013, the Supreme Court agreed to hear CLS Bank International v. Alice Corp., a case that, although not routed in the life sciences space, will hopefully provide more guidance on how to determine the validity of these types of claims. If the Supreme Court reads the exception broadly, as it is expected to do, particularly in view of Justice Kagan's comment last year that the USPTO is "patent happy," the decision may bring into question the validity of thousands of existing patents and cause the USPTO to be more stringent when analyzing these types of claims.

In the short run, this may put more inventions into the public domain. However, a potential ramification is that many innovators will keep their invention confidential. The case is scheduled to be heard on March 31, 2014, and a decision is expected in June of this year.

Second, the Supreme Court has agreed, in Nautilus, Inc. v. Biosig Instruments, Inc., to address whether patent claims with multiple reasonable interpretations are valid if the ambiguity is not insoluble by a court. The patent-in-suit is directed to a heart rate monitor for use in association with exercise equipment. As is common in medical devices patents, certain elements were described in relationship to each other. Within the independent claim at issue was the following limitation: "a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other; a second live electrode and a second common electrode mounted on said second half in spaced relationship with each other."

If the Supreme Court sets a standard that restricts how and under what circumstance a court can determine which of multiple constructions of a claim is appropriate, the decision may lead to an increase in challenges to claims based on patent validity. Additionally, for growing companies, particularly those in the medical devices field, it may send a signal to be more precise in how they draft their patent claims, which may in turn lead to narrower patents but more predictability for competitors when conducting freedom to operate analyses.

Third, in President Obama's most recent State of the Union address, he called upon Congress to "pass a patent reform bill that allows our businesses to stay focused on innovation, not costly, needless litigation," noting "[t]here are entire industries to be built based on vaccines that stay ahead of drug-resistant bacteria." The President's comments reflect a growing concern that patent litigation is too burdensome for America's innovators.

The most common targets of this type of criticism are the non-patent entities, which are pejoratively referred to as patent trolls. These are entities that owns patent rights but do not practice any technology. At the beginning of this year, there were eleven bills in Congress to reduce what are perceived as abuses by these entities. Patent trolls are portrayed as villains on both sides of the aisle, and one can expect this to be one of the few areas where bipartisan legislation may emerge. For the life sciences community, any reduction in the likelihood and/or cost of litigation is a good thing

because it frees funds for other research and development.

Fourth, one should expect to see acceleration in the growth of incubators. As noted above, we are in the middle of a period in which significant assets of big pharmaceutical companies are going over the patent cliff, and the press frequently reports that the pipeline for many of these companies has been drying up. At the same time, the public has been clamoring for faster development of more and better pharmaceuticals.

In a response to these pressures, as well as for many other reasons, a number of the best and brightest in the healthcare industry have started their own companies or joined start-ups or recently started companies rather than to join any of the large pharmaceutical companies. In order both to accommodate these entrepreneurs and to render their endeavors more economically feasible, biotechnology incubators have been and continue to spring up across the region. One can expect both investors and established pharmaceutical, biotechnology and medical companies to compete for alliance with these newer companies or acquisition of the best of the intellectual property that comes out of these endeavors.

Fifth, one should expect more focus of the investment community on orphan diseases, and an eye should be kept on who is developing intellectual property rights in this area. Orphan diseases and disorders are those that affect fewer than 200,000 persons in the United States. Because a large number of them trace their causes to genetic issues, the current state of scientific knowledge, including being more than a decade past the completion of the Human Genome Project and the further elucidation of cellular biologic mechanisms such as RNA Interference, make them valuable targets for continued research and scientific advancements.

Furthermore, although orphan diseases and disorders by definition, affect a finite number of persons, regardless of patent rights, the economics of working in these areas can be particularly attractive, because pharmaceuticals for these conditions receive a seven year period of FDA exclusivity, which is larger than for non-orphan conditions. Thus, the risk of unpredictable patent positions is mitigated. Additionally, the FDA provides incentives to entities that conduct research and development in this area.

Sixth, one can expect to see increased activity at the FDA in providing a roadmap for companies to obtain regulatory approval for biosimilar products and an increased investment by the private sector in ways by which to develop biosimilar products and to test for biosimilarity. By at least one estimate, the market for biosimilars is predicted to increase twenty-fold between 2013 and 2019. This potential market provides significant opportunities for innovative companies that are looking to partake in the global biosimilar bounty, and one can expect there to be increased competition in the contest to stake out strong intellectual property positions related to biosimilar products. This competition will likely take the form of increased filings of patent applications and battles over patent rights both at the USPTO and in the courts.

The year 2014 coincides with an upswing in market conditions that will be conducive to large investment into the life sciences industry. Where these investments go will likely be a reflection of the predicted value of the intellectual property rights of inventors and companies around the globe. In order to maximize the likelihood of understanding this value and how it will change over time, one cannot underestimate the developments in the intellectual property landscape that were seen in 2013 and both the foreseeable and unpredictable ones that have yet to arrive.

Scott D. Locke, Esq.
Partner & Chair of the Intellectual Property Department
Dorf & Nelson LLP

Bio:
Scott D. Locke is the Chair of Dorf & Nelson's Intellectual Property Department and oversees the Life Sciences practice area. Mr. Locke provides individual inventors, start-up businesses and well-established companies in diverse industries with strategies and tools for maximizing the return on their ingenuity, creativity and goodwill. Mr. Locke counsels clients in industries on the cutting edge of many scientific disciplines, including biotechnology, genetics, pharmaceuticals, bioinformatics, fuel cells, automobile catalysts and eco-friendly technologies. He also counsels clients in the following industries: coatings and pigments, luxury goods, cosmetics, medical devices, data processing and storage, e-commerce, and mobile devices.

Experience in Life Sciences:
Mr. Locke provides legal services to innovative clients in the life sciences industry with respect to RNA synthesis; DNA synthesis; RNA interference, including siRNA and miRNA; SNP technologies; gene therapy; cosmetic formulations; detection of diseases and disorders; pharmaceuticals; and delivery systems. Mr. Locke provides counsel regarding positioning and prosecuting patent portfolios, as well as litigating and licensing valuable intelligent property rights to these clients.

BioHud Anticipates Birth of Incubator at New York Medical College

Robert W. Amler, MD, New York Medical College, Vice President, Government Affairs, Dean of the School of Health Sciences and Practice, and Institute of Public Health Professor of Public Health, Pediatrics, and Environmental Health Science

The Dana Road Building on the New York Medical College's campus.

The biotechnology incubator at New York Medical College, renamed **BioInc@NYMC**, is approaching the end of its closely watched gestation and will open for business in 2014.

Strategically situated in the midst of the bioscience and educational environment of the New York Medical College campus in Westchester, the incubator was identified as a regional initiative by New York BioHud Valley and highlighted as a top priority for two consecutive years by the Mid-Hudson Regional Economic Development Council. Construction was funded by Empire State Development in two successive rounds, by private philanthropy and institutional resources, and by several other New York State programs. In addition, the facility includes a business-science training facility funded in part by the US Department of Commerce, Economic Development Administration (EDA), as a partnership with Hudson Valley Economic Development Corporation and Westchester Community College's Professional Development Center.

BioInc@NYMC is designed to create a supportive idea-rich community for small start-up entrepreneurs developing their concepts for potential new drugs, vaccine strains, medical devices, and health-related apps. Initially built in a secure 4,500 square-foot lab-equipped wing with expansion options to 10,000 square feet or more, the facility has small private labs and offices for individual client-firms as well as shared core facilities (cold room, equipment storage, etc). A key differentiating feature is ready access to the milieu of a health sciences university campus with bioscience infrastructure, accomplished faculty-scientists, health sciences library, and some 1,500 medical students, graduate students and research fellows. Moreover, its strategic location close to the I-287 corridor and Tappan Zee Bridge, is seen by many as a vital regional hub for a biotech-driven economy.

The university has a growing list of prospective occupants and has retained an experienced consultant team to refine the selection criteria and establish administrative policies. An advisory board will be composed of experienced leaders in biotech, incubation, commercialization as well as clinical and bioscience faculty. In addition, entrepreneurs operating off campus can qualify to participate in incubator activities as virtual client-firms. Provision will be made to support the incubator community with privately sourced business services such

as accounting, finance, intellectual property protection, growth management, and commercialization strategy.

The project has enjoyed strong support from US Senator Chuck Schumer, Congresswoman Nita Lowey, State Senator Andrea Stewart-Cousins, County Executive Rob Astorino, and numerous agencies and other elected officials from New York State, Westchester, and Town of Mount Pleasant, as well as many business leaders in biotechnology and related sectors. Additional partnerships are forming with the Westchester Industrial Development Agency, Business Council of Westchester, and the "Blueprint for Westchester" Accelerator of the Westchester County Association.

Laboratory on New York Medical College campus.

"Successful life science corridors provide nurturing environments for start-up firms in order to cultivate the next Regeneron or Acorda Therapeutics," noted NY BioHud Valley Co-founder and Hudson Valley Economic Development Corporation President & CEO, Laurence Gottlieb. "With their stellar reputation and outstanding research pedigree, New York Medical College's BioInc@NYMC is the perfect ecosystem for developing the Hudson Valley's next generation of life sciences superstars."

The Future of Medicine:
How Genome Sequencing & Informatics are Changing the World

Jeffrey Reid, PhD,
Director & Head of Genome Informatics at Regeneron Pharmaceuticals

Introduction

You are defined by your genome. More so than anything else about you, the sequence of roughly three-billion deoxyribonucleic acids (conveniently represented by A, T, C, and G–the chemicals adenine, thymine, cytosine, and guanine) that make up your DNA is the blueprint of you. Of course, there is a lot more to it, environmental factors in particular play a very important role in your health, but like the blueprint of a building, your genome is literally the plan for you.

Over the last decade, the cost of genome sequencing has plummeted at an astoundingly fast rate. The digital imaging technology that makes digital cameras and phones ubiquitous has also transformed the economics of identifying the DNA sequence of an individual. According to the National Human Genome Research Institute, the cost of sequencing a whole human genome was roughly $100 million in 2001; today that cost is approaching $1,000.

To sequence an individual's genome, genomic DNA is extracted from blood or tissue, biochemically prepared for sequencing, and processed in such a way as to create homogeneous clusters of small fragments of DNA on a DNA sequencing instrument. This allows a very high-resolution digital camera to take pictures of these clusters which are chemically excited to emit light indicating the DNA sequence of that particular DNA fragment or "read".

These processes have been tuned and optimized over time so that while technical experts are still needed to perform DNA sequencing, it is possible for DNA sequence to be reliably and reproducibly generated. This is where "genome informatics" comes into the picture. The analysis of those DNA sequence fragments involving the comparison of sequence reads to the reference genome, the identification of sequence variation (differences between an individual and the genome reference), and the annotation and understanding of that variation in the context of health and disease has become the most costly and time-consuming aspect of genome sequencing.

It is this analysis and interpretation of an individual's "personal" genome that promises to define the future of medicine. Currently we have a real clinical understanding of only a small fraction of the exome (the roughly 1% of the whole genome that contains protein coding genes and the network of gene regulation elements). By sequencing a large number of people and working to understand correlations between their health and disease status (what geneticists refer to as "phenotype") and specific regions of the genome (known as "genotype"), scientists will develop the knowledge that physicians will use to individualize medical treatments (as described by the slogan, "the right treatment for the right patient at the right time and at the right dose") and to eventually predict and improve a baby's medical future from birth.

Large-scale Genome Sequencing Projects

With the rapidly decreasing cost of genome sequence, scientists around the world have engaged in a variety of large-scale genome sequencing projects to provide insights into and support for a much deeper understanding of the genome, its function, and the impact of genetic variation on disease and health.

Among the first key large-scale genome sequencing projects was the Thousand Genomes Project sponsored by the National Institutes of Health (NIH). Because the reference genome represents a very narrow view of human genetic variation (the Human Genome Project that generated the reference genome sequenced DNA from 13 anonymous volunteers to produce a single genome reference sequence), and before whole genome sequencing was economically feasible, only small, specific regions of the genome could be interrogated in a large number of individuals. This meant that the full spectrum of normal variation was not known. This was a big gap, because it is extremely important to understand a personal genome in the context of normal genomic variation. Common sequence variations, those present in hundreds of healthy people, are unlikely to be significant contributors to serious genetic disease, but before unhealthy genomic variants could be identified and understood, healthy variants needed to be cataloged.

Thus, the Thousand Genomes Project set out to sequence a thousand people (to varying accuracy in varying

regions of the genome). This produced a key resource now used by nearly every genome sequencing effort in the world – a list of the most common variants in various populations and sub-populations. Now when a variant is seen in an individual it can be classified by the frequency seen within the Thousand Genomes Project, providing insight into the likelihood of that particular variant contributing to serious genetic disease in that individual.

Cancer was an obvious goal for early large-scale genome sequencing efforts. Cancer is, by its very definition, a disease of the genome. At some point, genetic factors,

whether inherited or induced (by environmental exposures such as tobacco smoke) cause a cell or a collection of cells to lose their normal growth regulation mechanisms. The cancerous cells begin to replicate in an uncontrolled way leading to tumors and, unfortunately all too often, very serious medical consequences.

The Cancer Genome Atlas Project was initiated by the NIH to sequence tumor-normal pairs to compare the DNA sequence of a cancer patient's normal genome to the DNA sequence of their tumor to provide insight into the drivers of cancerous growth, insights that are redefining the way medicine defines and understands cancer.

Another important project (among many others that won't be mentioned here) is the Cohorts for Heart and Aging Research in Genetic Epidemiology (CHARGE). The CHARGE project is a consortium of large "cohort" studies where many individuals (upwards of 50,000) have contributed their DNA and medical record information. Using a case/controls approach, disease state cases (such as people with very high LDL cholesterol) can be compared to control groups (people with normal cholesterol) to look for genetic associations with disease states. By collecting very large numbers of people and asking the right questions in the right way, associations between disease phenotypes and genotypes (determined by sequencing) can be found. Once genotype and phenotype correlations are found and validated, genetic risks for disease, and possible targets for therapeutics, can be identified.

Clinical Genomics and Early Genomic Medicine Efforts

The large-scale projects mentioned above all have great utility for the medical community in general, but as these projects were purely done for research purposes, none of the data from individuals contributing DNA to the research could be used to improve their health. The research community relies on people like this willing to selflessly give their DNA and health care information into research projects to move forward our understanding of the genome, but ultimately we must be able to use the genome to help improve outcomes for patients.

Using the data resources built by the research community, there are now many clinical sequencing efforts where a patient's DNA can be sequenced and analyzed with the singular goal of understanding that individual's biology and using that understanding to improve their health.

One such effort in which I participated before joining Regeneron in 2013 was a collaboration at The Baylor College of Medicine between the college's Human Genome Sequencing Center – one of the largest in the world – and the college's clinical medical genetics lab. This effort was among the very first to offer clinical exome sequencing to children with severe genetic disease who could not be helped by conventional genetic testing that can only access a very limited number of small genomic regions. Children born with unsolved genetic disease cannot be treated as effectively as those whose disease genotypes are identified, and their parents are left without any knowledge of the likelihood of their future progeny being affected by the same or similar conditions.

Currently, high-throughput genome sequencing has enabled BCM to deliver clinical reports to more than 200 families per month (tests ordered by a physician and paid for by insurance), providing one of the first examples of high-throughput DNA sequencing directly impacting the care of patients.

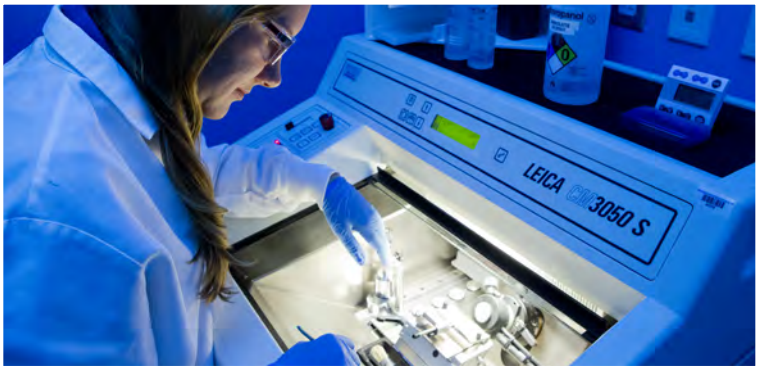
As heartening as it is to see sequencing technology providing a better understanding of disease to patients

and physicians, most genetic answers don't come with obvious treatments. Famous genes such as BRCA (shown to be strongly associated with breast cancer) and APOE (which has variants that are associated with extremely high risk of Alzheimer's disease) have made headlines, but treatment options remain poor. Angelina Jolie famously underwent a prophylactic double mastectomy because of her BRCA status and breast cancer family history, and APOE status is often redacted from genetic reports, as the knowledge that one is more likely to face Alzheimer's disease is of little value without any preventative or palliative treatments to go with it.

It is these kinds of genetic risk associations that make the interpretation of healthy genomes very problematic – without a course of action or effective medical intervention, information of increased disease risk is often more worrisome than helpful. Even in cases where there is a serious genetic disease in a child, understanding the causative genetic variant and identifying the pattern of inheritance often carries with it no real treatment or cure. Without better understanding of the genome and a pipeline for bringing those discoveries into the drug development process, many (perhaps even most) clinical genetic reports will do little to actually improve the health outcomes of the afflicted.

The Regeneron and Geisinger Partnership – Making Genome Medicine Real

Against this backdrop of hope and ambition for improving the lives of patients, in January 2014, Regeneron Pharmaceuticals announced a



partnership with the Geisinger Health System (GHS) of Pennsylvania to sequence 100,000 patient volunteers over a five-year period to provide data that can be used for research to better understand the genome, provide genetic data back to Geisinger where it can be clinically validated and actionable, and ultimately bring hope to currently insolvable genetic disease by finding candidate drug targets to bring into the drug development pipeline.

The Geisinger Health System treats more than three million patients and is nationally renowned for innovation and quality patient care. Due to its early adoption of sophisticated electronic medical records (EMRs) and its stable and, in some cases, multi-generational patient population, Geisinger is uniquely positioned to bring genetics into its clinical practice. Bringing together the detail of a medical record with large-scale genome sequencing has never been done before on the scale planned by Regeneron and Geisinger. Many feel that this can be a goldmine for genetic discovery. The Regeneron-Geisinger collaboration provides a unique opportunity for genetic discovery because of the richness of patient EMRs and the ability to ask important questions as has been done with the case/cohort studies of the past but with access to much larger patient cohorts and much richer phenotype data than ever before. By bringing patient volunteers from a health system like Geisinger, with a very mature EMR and a commitment to keep their patient care on the leading edge of healthcare technology, the Regeneron-Geisinger collaboration will be one of the first examples of sequencing patient genomes at a large scale in a healthcare setting. We hope the collaboration will be a milestone toward a future when every patient will have his or her genome sequenced before birth, and the genomic sequence will become an important part of his or her electronic medical record.

Because of the important equirements for the distinction between medical research and clinical care, all DNA sequencing done by Regeneron for GHS will be done under strict observation by the internal review board at GHS, and will be only used for research purposes. However, where patient sequence data indicates a way to change or improve care, GHS will clinically validate the relevant sequence data identified under the research protocol.

For Regeneron, the collaboration with Geisinger and related new research programs in human genetics – to be managed by a new entity called the Regeneron Genetics Center – are long-term investments to find new indications for therapeutics, and new targets for drug development. The hope is that this new approach to drug discovery will yield a new generation of drugs capable of improving outcomes for patients for whom currently available treatments are inadequate.

The Informatics Challenge

Among the most significant challenges of large-scale genome sequencing is the scale of the data storage and analysis. The read and alignment data for 100,000 exomes is on the order of petabytes (a petabyte is one thousand million million (1015) bytes) of data, and the raw data and analysis intermediates are significantly larger. This can make the construction of a large-scale sequencing facility a very expensive proposition simply from the perspective of the informatics. The acquisition and support of millions of dollars in analysis and storage hardware, along with the cost of software licenses and tools to analyze and understand the data, and the team of experts necessary to build and maintain a high-performance computing facility, is a major barrier to building genome sequencing capacity.

This makes cloud computing – the per-use purchase of commodity computational and storage infrastructure – a logical solution for newly initiated sequencing efforts.

The confluence of the emergence of sequencing and cloud-computing technologies, plus the commitment to scientific innovation at Regeneron, has led us to a novel solution. The Regeneron Genetics Center is the first large-scale genome sequencing effort that is committed to building its analysis infrastructure entirely in a commercial cloud environment. After looking at the costs of building and supporting the local infrastructure necessary for the RGC, it was clear that the cloud is not only the most logical business solution today, but the best solution as the cloud continues to evolve as the most effective platform for data distribution, because it provides the RGC with the unique ability to partner with sequencing and analysis efforts all over the world in a secure environment that provides unmatched analysis and storage scalability.

CONCLUSIONS

Genome sequencing technology has developed at a staggering pace since the human genome was first sequenced at the dawn of the 21st century. There are signs that further technological advances may yet provide even better data faster and cheaper than we can imagine today. The detection of DNA sequence using digital cameras is already giving way to the use of solid-state devices, and many people are working on sequencing DNA by pulling individual long strands of DNA through nanopores that can read off the sequence at a rate and cost that are orders of magnitude less than the current optical detection technologies.

With sequencing becoming ever cheaper, faster, and more accurate, the field of medicine will undergo a phase transition, from the pre-genomic medicine of today to the not-too-distant future where the single most important piece of healthcare information is the genome. Cancer treatment will involve tumor sequencing, already being offered at some medical centers in the United States and by a few innovative new clinical sequencing companies, and a lifetime of surveillance sequencing post-remission – remission that will be achieved in part through cancer therapeutics targeted at the specific drivers of tumor growth and mutation instead of the coarse treatments of today that are mostly defined by tumor location and not genetics. Treatment of lethal and incapacitating diseases other than cancer will also be transformed by genomics, as new generations of drugs and perhaps even effective gene-repair/gene-replacement technologies are developed to modulate newly discovered genetic drivers of disease.

The practice of medicine in 2020 or 2030 will look so different from the practice of medicine in 2000 that the best analogy is likely the experience of computer users 20-30 years ago and the experience of computer users today. Although great challenges remain and although the pace of future progress cannot be known, the unquestionable transition of medicine to a fundamentally genomic science will stand as one of the most important scientific revolutions in human history, and this is just the beginning.

Thermopraxis in the Hudson Valley

Tony Finley
President of the Thermopraxis-Stratego Alliance

Thermopraxis (www.Thermopraxis.com) is a new medical device developer and the first occupant of New York Medical College's biotechnology incubator, BioInc@ NYMC, located on the New York Medical College campus in Valhalla, New York. Thermopraxis along with its sister company, Stratego, based in Rio de Janeiro, is working to advance the commercialization of its proprietary emergency medical device for treatment of traumatic brain injuries.

Using the well-known therapeutic benefits of hypothermia or cooling to alleviate the after-effects of trauma to the brain, the device named "Thermocrown" harnesses thermodynamic principles to confer neuroprotection in a unique way, which is simultaneously simple in its overall concept yet robust in its effectiveness. Because it does not employ power, batteries, or any other external force to be activated when needed and is designed to be initiated easily by anyone without special training, it is expected that Thermocrown will change the landscape in the treatment of head injuries and become the emergency treatment that is used whenever head injuries occur.

Dr. Renato Rozental, MD, PhD, Co- Founder of Thermopraxis and Stratego, is receiving significant initial funding from the Ministry of Health of the Brazilian Federal Government to assist in Thermocrown's development, and is also gaining strong support from the Brazilian Ministry of Health and the State of Rio de Janeiro Military Police. Along with Co-Founder, New York attorney Tony Finley, Dr. Rozental has committed to continue to move the Thermocrown technology forward under the flag of the BioHud Valley.

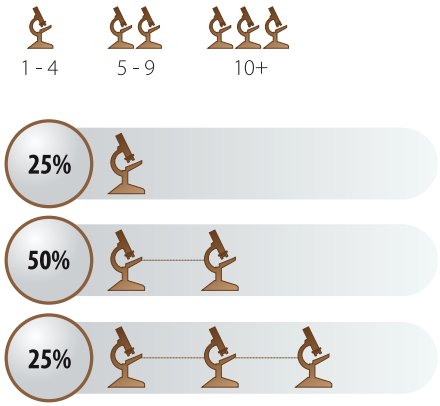
After agreeing to install its office on the NYMC Campus, Dr. Rozental was quoted in a July 2013 Marketwatch press release saying, "We are excited to retain our headquarters in New York and leverage the abundant resources in the growing cluster in and around the Hudson Valley. We are equally excited about our ongoing developments with Thermocrown, the first device that will enable emergency thermotherapy care out in the field to confer brain protection post-traumatic injury. At current, there are no other devices or treatments available anywhere in the world which promise similar efficacy or that can be activated under pre-clinical conditions, such as the battlefield or during catastrophic events. The Hudson Valley will be home to one of the most important emerging technologies of this generation as we make preparation to begin production of Thermocrown for our soldiers and ultimately to benefit society."

Thermopraxis is planning to create commercially available versions of Thermocrown for military, sports, and general use within the next one to two years in response to the constantly growing demand for such a device and to put an end to the concussion crisis that is highlighted virtually every day in the news.

To find out more about Thermocrown contact Tony Finley, President of the Thermopraxis- Stratego Alliance at TFinley@thermopraxis.com .

State of the Valley Survey

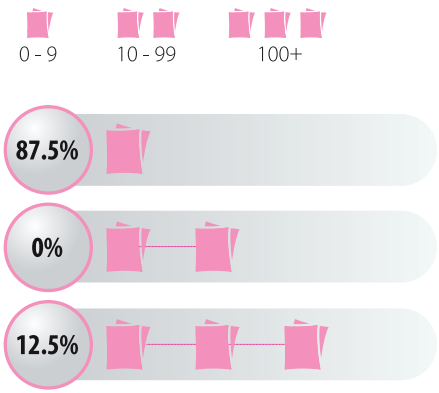
Products in Clinical Development Stage



(n=4)

Most new job opportunities in 2014 will be in Research and Development.

Jobs Lost in 2013



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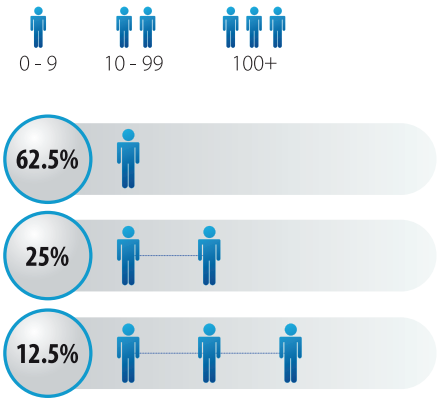
New Jobs Created in 2013



(n=8)

<10% Turnover Rate (n=5)

AXON currently supports over 60 pharmaceutical, biotechnology, diagnostics and medical device companies, as well as world-class medical universities, research institutes and leading non-profit organizations across the globe.

The AXON team brings together a diverse blend of experience. Our backgrounds include academia, clinical research, consulting, drug discovery, medical publishing, journalism, public relations, advocacy/non-governmental organizations, medical communications, social media, clinical trial services, and pharmaceutical sales and marketing. This ensures we know who to talk to, what they should know, when it is best to talk to them, how to reach them, and how they communicate with each other. We bring the right combination of expertise to every project we undertake to ensure that our client partners have the right people working with them.

As AXON is a founding member of NY BioHud Valley, and as our US Managing Partner, Mario Nacinovich, MSc is also a board member of the Hudson Valley Economic Development Council (HVEDC), we pride ourselves on being involved in the community and continue to increase our external relations and outreach since our move from NYC to Rye Brook in January 2012.

In early 2013, our team provided support through donations of provisions and volunteering our time to the Community Services Associates (CSA) Soup Kitchen in Mount Vernon, NY, to help the less fortunate and make a "meal for a night", preparing and serving dinner for over 100 people. We have continued to support the American Heart Association (Purchase, NY) as Mario is also a founding member of their Red Tie Society, and separately have supported the American Cancer Society through their Relay For Life events over the past two years in both Dutchess and Putnam Counties.

Separately, our work with the National Hemophilia Foundation continues to expand beyond the strategic consulting and review of their foundation website, including media training their National Youth Leadership Initiative where we trained over 20 NHF youth leaders from across the country. Director of Education at the National Hemophilia Foundation praised AXON for our help with their website redesign, "I just wanted to let you know and thank you for all of your amazing work. This site redesign is going to have a wonderful impact on NHF and help us to better serve our constituents. Kudos on a job well done!!!"

Additionally, it was our honor to support onsite media relations and management of fellow NY BioHud Valley members at Contrafect Corporation, which announced in April 2013 that the Zongyi Group of China had invested in the company as part of a $9.5-million financing.

Roche Pharma Research and Early Development Scientific Symposium designed and developed by AXON Communications.

"Thank you so much to you and your team for stepping up to the plate and handling the media for this incredibly important event. The room was packed, the coverage was phenomenal, and we got some great video footage for post-publicity and promotion.

Most importantly, the message we delivered yesterday–loud and

clear–was that this success came, not by chance, but rather through an unlikely partnership of government representatives, private enterprise, an environmental group, and a regional business organization who collectively activated a group of creative partners to make this major investment happen for the benefit of the region. That's phenomenal and a great model for collaboration moving forward. When I started NY BioHud Valley with Mike Oates, we always hoped we could bring together a cross-section of players to help grow the Hudson Valley biotech industry beyond just the industry itself. We achieved that and more on this day. Thank you again for a phenomenal job and on behalf of HVEDC."

Mark Khan (VP, Client Services and Business Development) and Mario Nacinovich (Managing Partner) posing with special guests of honor, Craig Marzullo and brain cancer survivor, Ben Marzullo.

As many of our clients are global we have AXON operations in North America and Europe as well as a global affiliate network, we believe we are now even more strategically located in the Hudson Valley, home to leading research institutions, renowned medical centers, and a thriving life science cluster in and around New York, New Jersey, and Connecticut.

At AXON, we consider ourselves an extension of our clients and, with that in mind, we strive to be clients' trusted partner. Two of our more notable client initiatives this past year include, the coordination, management and production for the Inauguration of the Roche Translational and Clinical Research Center (TCRC) and Pharma Research and Early Development (pRED) Scientific Symposium, both of which occurred on October 1, 2013 in New York City. In a testimonial of AXON's efforts, one of our clients shared, "Congratulations to all for a job well done yesterday, with the TCRC inauguration and pRED Symposium. From the inauguration speeches to the scientific symposium, the event was flawless and I heard a lot of positive feedback during the day, especially regarding the patient aspects. It was a great venue and program from start to finish -- the staff was well organized and handled everything so professionally."

AXON strives to build the healthcare leaders of tomorrow through engaging and educational intern rotations. Pictured here (L-R) AXON's Nicholas DeLillo, PhD, Evita Sanchez, Manhattan College student/intern Marisa Kroger, and Mario Nacinovich.

We have the privilege of working on products and devices at every stage of their lifecycle. Some of the most exciting work takes place around the pre-launch and launch of emerging and new brands. We continue to support a wide spectrum of medical communications (e.g. multimedia/digital activities; speaker training; content development; webinars; faculty management; etc.) in association with the new treatment launch of a fixed combination indicated in the reduction

ABOUT AXON

Hudson Valley Location:
800 Westchester Ave, Suite S-540
Rye, NY 10573

Web Site Address:
www.axon-com.com

AXON is an international leader in medical communications, clinical trial management, and healthcare education, composed of specialized medical communications experts. AXON's professional team provides highly specialized services as: interactive investigator education; facilitation and presentation skills training; key opinion leader development; clinical trial patient recruitment and retention; advisory boards and steering committees; editorial support; strategic publications planning; continuing medical education; and congress support.

AXON is wholly owned by NATIONAL Public Relations, but our relationship is more than just business; we collaborate every day on many levels. NATIONAL is the largest PR consultancy in Canada, with offices in Victoria, Vancouver, Calgary, Toronto, Ottawa, Montreal, Quebec City, Saint John, Halifax, St. John's, New York, Copenhagen, and London. The Firm serves leading corporate, government, and institutional clients, and offers the full range of communications services, including corporate communications, investor relations, public affairs, employee engagement, public consultation, and participation, marketing, technology, and healthcare communications. NATIONAL is a subsidiary of RES PUBLICA Consulting Group.

The AXON team posing with family members after a successful day helping to raise over $7,000 for the 2013 Relay for Life event.

of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Since our Firm's entrance into the US market, we have support both the US and global marketing efforts and were recently rewarded with the following praise for our work, "Team, thank you. I value the partnership and your continued efforts to support us at the highest level."

As we look to the future in 2014 and beyond, we hope to build even stronger partnerships amongst all existing and new members of NY BioHud Valley, in addition to increasing our exposure and brand recognition within the healthcare community. Our capabilities will expand in 2014 with dedicated resources added in support of payor communications (ie, managed care/reimbursement), expansion of our practice areas into scientific services, and in analytics and insights. AXON is focused on greater strategic support and research services for our existing and potential healthcare client partners.

KEY FACTS ABOUT AXON

What is your company's mission statement?
We're a specialist healthcare consultancy firm, supporting clients in clinical trial services, medical communications, public relations, and market access.

How do you classify your company?
AXON Communications, G.P. Inc. is a privately held corporation.

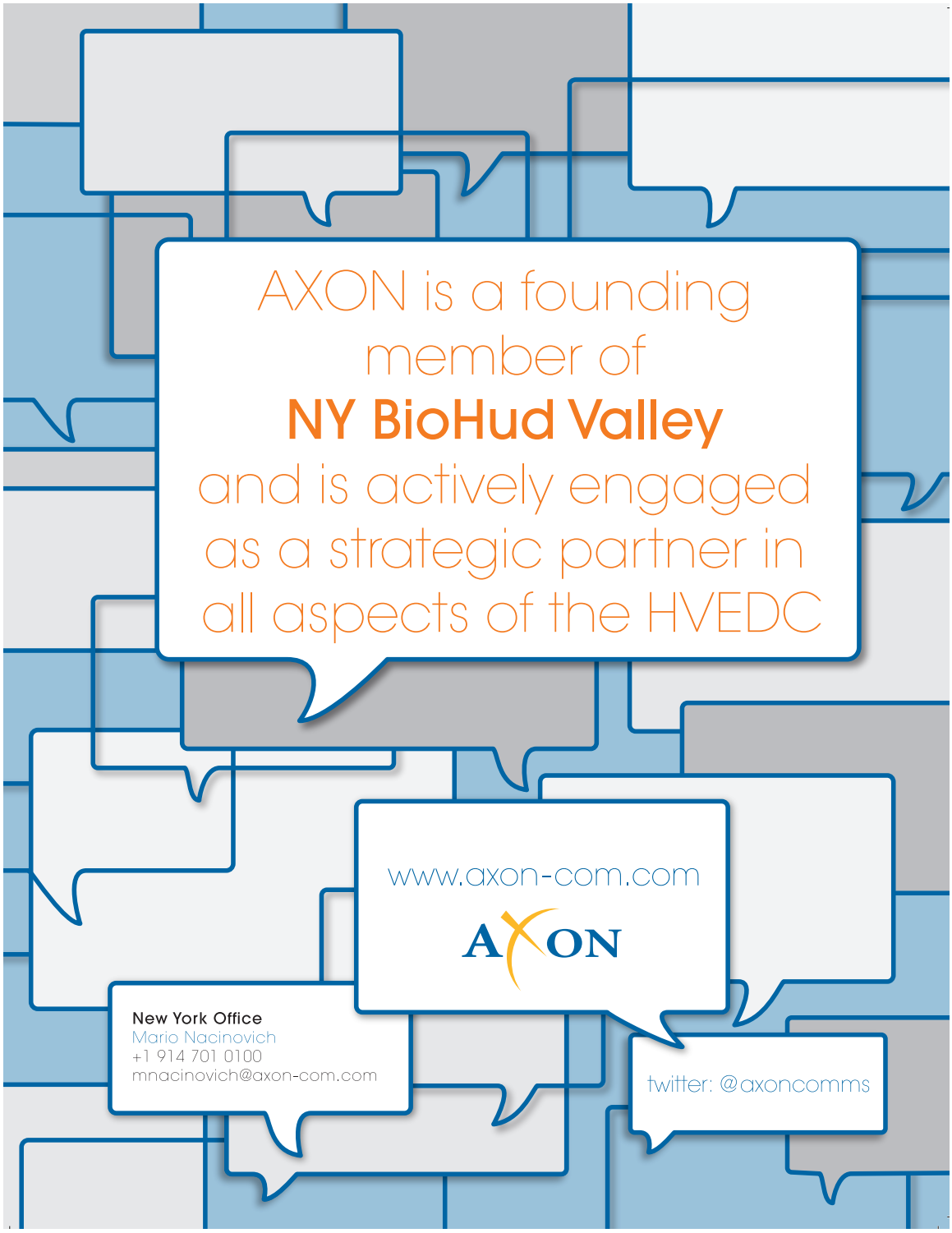
What is your executive's name?
Mario R. Nacinovich Jr., MSc, Managing Partner, AXON, US

How many years has your company been located in the Hudson Valley?
AXON's US operations opened in January 2010 in New York, NY, before moving to Rye Brook, NY (Westchester County) in January 2012.

What is your company's net worth?
AXON is a private limited company and as such does not disclose this information in the public domain.

How many employees work for your company?
AXON has approximately 365 employees worldwide, with 15 dedicated consultants located in our US office (Rye Brook, NY).

List an interesting fact about your company.
AXON US collaborates with LIU Arnold and Marie Schwartz College of Pharmacy by hosting pharmacy students during their APPE rotations. This rotation provides LIU pharmacy students the opportunity to learn more about healthcare communications through a 5-week rotation. It was originally established in 2012 as AXON has enjoyed the six student participants who have rotated through our offices during this time.


AXON is a founding
member of
NY BioHud Valley
and is actively engaged
as a strategic partner in
all aspects of the HVEDC
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