



South West
England



LECLAIR RYAN

The South West of England
and the State of New Jersey

Adding an International Shelf to the
World's Medicine Cabinet



LECLAIR RYAN

**SCIENCES CONVERGE TO CREATE NEW
PLATFORM TECHNOLOGIES AND WITH
EVOLVING COLLABORATIVE NETWORKS,
CREATE NEW PRODUCT PIPELINE MODELS TO
GENERATE LEADING INNOVATION**

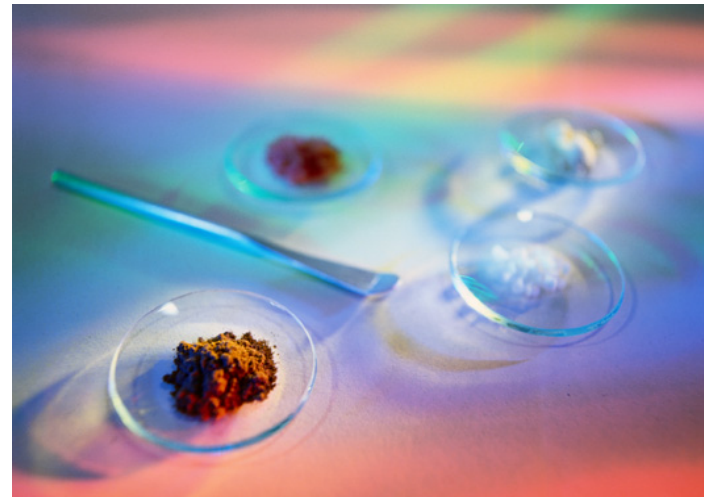
**March 17th to 20th, 2008
Regional Cluster Network
Stanley Underwood North, III
Partner LeClair Ryan Law Firm**

Proud to be Part of the Launch of IBST, an Innovator in a Network Collaboration of International Regions



Speaker: Stanley Underwood North III, International Trade & Investment from LeClairRyan Law Firm

Focus: Academic development and Collaboration for the Super Life Science Cluster networking the Eastern Seaboard USA centered in New Jersey with the South West of England from early stage research, development through to licensing and commercialisation





STANLEY UNDERWOOD NORTH, III, Partner



Mr. North is a Partner in the Firm's Corporate Group and Chair of the International Trade and Investment Committee of the New Jersey State Bar Association. He focuses his practice on international trade and investment, securities law, corporate and commercial transactions, mergers, acquisitions and business combinations and other issues encompassing the full range of commercial transactions. He represents foreign and domestic companies, public and private, in their ongoing operations as well as in complex domestic and international business transactions including deals involving businesses in biotechnology, medical devices, high-technology, health care and environmental remediation industries, among others.

Mr. North advises foreign companies in successfully establishing their presence in North America in accordance with applicable corporate, immigration, intellectual property and other regulatory requirements. On July 4, 2007, Mr. North presented at the administrative launch of Institute of Bio-Sensing Technology by the University of the West of England proposing to collaboratively network the life science clusters of the South West of England and of the State of New Jersey and has subsequently been seeking to make such a collaboration a success.



LeClairRyan

- Attorneys in LeClairRyan's Pharmaceutical and Life Sciences represent a number of companies in a variety of industries segments, ranging from start ups to publicly traded U.S. and foreign companies. Clients include developers and manufacturers of API and finished dosage pharmaceuticals and other specialized life sciences technologies, including both innovator and generic pharmaceutical companies.

Introduction

Stanley North III, LeClairRyan PC Law Firm, International Trade & Investment

- Technology Areas: Pharmaceuticals (CNS; Cardio Vascular and Metabolic) Diagnostics,
- Target Markets: Drug Development, Biotechnology; Medical devices; Clinical trials; Knowledge transfer
- Partnership Type Sought: Strategic Alliances, Technology Licensing, Commercialization opportunities
- Type of Partners Sought: Academic links with SW England academic research and industry organisations; Clinical Research Organisations; International Clinical Trials; Technology innovators (its not just life science anymore)

Introduction of New Jersey

- The Cluster map
- Resource Guide
- Web Site is on its way



Academic Opportunities with Key New Jersey Players

- Industry: 15 of the top 25 Big Pharma (IBST and other SWE innovators to fill pipelines)
- Research/Academics: NJIT; Rutgers; Princeton, Hackensack University Medical Center [4th largest patient intake; 5th largest cancer intake in USA]; UMDNJ [largest teaching hospital in USA]; Public Health Research Institute [infectious disease] together with 50 more

Longer term & Immediate opportunities

- \$270M to Build Biomedical and Stem Cell Research



International Clinical Trials of Innovations

- Diagnostics Phase Zero
- Spinal Cord, Phase I
- Diabetes, Phase III
- Non invasive Cardiovascular, Phase III



Entering the US Market – dipping your toe across the pond!

- Collaborations; Licensing
- An academic model for collaboration and further funding

Where Have We Met Before

- SWE Life Science Trade Mission to New Jersey November 2006
- New Jersey Life Science Coalition Tour of SWE Feb 2007
- SWE Dinner with New Jersey at Bio 2007, May 5th, Boston, MA
- IBST Tour of New Jersey April 2007
- New Jersey Life Science Coalition Return Mission of July 2007
- IBST Tour of New Jersey Life Science and Environment Oct 2007
- IBST BioMarker and Diagnostics NJTC Presentation Dec 2007
- Lord Digby Jones, TI Minister Tour New Jersey Cluster Dec 2007
- IBST/UWE Sponsor of BioMedical Engineering Showcase March 14, 2008



When Will We Meet Again?

- NJTC BioMarker Sophic Demo April 2nd
at Hackensack University Medical Center 4PM
- Open invitation to Bio 2008 San Diego, California
- 9th New Jersey Symposium on Biomaterials
Science and Regenerative Medicine, New
Brunswick, New Jersey October 29-31, 2008

Introduction of New Jersey

- Gov. Jon Corzine (former CEO of Goldman Sachs and US Senator)
- The Cluster map

- 20 Years Ago Pharma pipeline was Robust
Want to do it ourselves under one roof: [Not Invented Here syndrome]
- Later Buy in resources/ move them to New Jersey
- Later Move non-critical areas to lower cost regions
- Now Pipeline has dried up; costs are high

- Focus on drug, device and therapy development
- Outsource Much of the rest to others
- License Third party innovation - Energise pipeline thru collaboration with Innovators

Where do I find these opportunities?

- Map
- Resource Guide
- Web Site on its way

Key New Jersey Players

Academic opportunities with Key New Jersey Players

The Industry is:

- 800 core R&D organisations (1300 related to the industry)
- Employing 184,000 science scientists in over 700 labs
- \$ 7.5 billion in R&D expenditure (half of the US total)
- 6 million square feet of R&D space
- \$150 billion in sales
- 57 universities, colleges and technical schools

Industry: 15 of the top 25 Big Pharma (SWE innovations to help fill pipelines)

15 of the world's largest 25 pharmaceutical companies – including:

- Abbott
- Bayer Healthcare
- Bristol-Myers Squibb
- Becton & Dickinson (900 SWE employees in Plymouth)
- Eli Lilly & Company (Cardio-Analytics - Best Global Service Provider)
- GE Healthcare
- Hoffmann-LA Roche (George Abercrombie, CEO)
- Johnson & Johnson (Welsh, CEO)
- Merck & Company Inc.
- Novartis (Terry Barnett, CEO)
- Pfizer
- Reckitt Benckiser (operations in US and UK)
- Sanofi-Aventis Pharmaceuticals
- Schering Plough (Fred Hassan, CEO – former CEO of Pharmacia)
- University Manchester and Imperial College)
- Stryker
- Wyeth
- + several of the largest generic organisations, Barr, Ranbaxy and TEVA

...**325 Biotechnology companies**



Innovation through to proof of concept and finally commercialisations

Research/Academics	\$Annual R&D
New Jersey's Institute of Technology	\$ 80M
Princeton	\$148M
Rutgers	\$259M
University of Medicine and Dentistry of New Jersey	\$305M
Total (Academics 6,940; Graduates 71,368)	\$793M

New Jersey's Institute of Technology

- **Newark Institute of Regenerative Medicine (New build 100sqft).** Stem-cell pioneer Treena Arinze – Presidential Award Winner
- **Sensor & Device Technology**
- **Advanced Material Processing**
- **Biomedical Engineering**
- **Medical Device Concept Lab**
- **New Jersey Centre for Biomaterials (NJIT; Rutgers; Princeton)**
- **Centre for Applied Genomics**
- **Electronic imaging Centre**
- **Centre for membrane technology.** Kamalesh Sirkar – Transdermal drug delivery based on porous membranes
- **NJ Centre for Engineered Particles.** Rajesh Dave – biopolymer coating
- **Polymer Processing Institute**
- **Centre for Manufacturing systems**

Princeton

Environmental & Earth Science

- Princeton Environmental Institute (PEI)
- Carbon Mitigation Initiative
- Centre for Biocomplexity
- Centre for Environmental Bioinorganic Chemistry

Princeton

Life Science

- Lewis-Sigler Institute for Integrative Genomics
- Program in Neuroscience

Princeton

Materials Science

- Imaging and Analysis Centre
- Princeton Institute for the Science & Technology of Materials (PRISM)

Princeton

Psychology & Neuroscience

- Centre for the Study of Brain, Mind and Behaviour
- Program in Neuroscience

Princeton

MIRTHE

- Goal is to develop mid-infrared (1 - 3-30 μm) optical trace gas sensing systems based on new technologies such as quantum cascade lasers or quartz enhanced photo-acoustic spectroscopy, with the ability to detect minute amounts of chemicals found in the environment or atmosphere, emitted from spills, combustion, or natural sources, or exhaled.

Rutgers and Biomaterials Centre

Research Center Profiles and Contacts (Listed in alphabetical order)

- **Center for Advanced Biotechnology and Medicine (CABM)** - Director Aaron Shatkin
- **Centre for Advanced Food Technology (CAFT)** –Director Jozef L. Kokini
- **The CounterACT Research Centre of Excellence** – Director Jeffrey D. Laskin
- **The Engineering Research Centre for Structured Organic Composites (ERC)** - Director Fernando Muzzio
- **The Institute for Advanced Materials and Devices (IAMD)** Centre for Ceramics Research and the Laboratory for Surface Modification, and will help coordinate the following four new areas :
 - Multifunctional materials and devices
 - Nanoscience and technology
 - Sensors and sensor networks
 - Theory, computation and design - Director Nancy Pamula
- **Institute for Marine and Coastal Sciences** - Director Susan Keller
- **The New Jersey Centre for Biomaterials** - Director Joachim Kohn



Rutgers and Biomaterials Centre

- **The New Jersey Stem Cell Institute** is a joint endeavor with the University of Medicine and Dentistry of New Jersey – Director Dr. Kenneth J. Breslauer
- **Rutgers University is leading the Northeast Structural Genomics Consortium**, - Director Gaetano T. Montelione
- **Nutraceuticals Institute** – Director Paulette Arico
- **The Protein Data Bank**, based at Rutgers, - Director Frank Henrikson
- **The Rutgers Cell and DNA Repository** – Director Jay A. Tischfield
- **Susan L. Cullman Laboratory for Cancer Research** - Director: Allan H. Conney
- **W.M. Keck Centre for Collaborative Neuroscience** - Director: Martin Grumet

For a complete list of all research centers see: <http://centers.rutgers.edu/>



University of Medicine and Dentistry of New Jersey

- The nations largest public university and teaching hospital
- Public Health Research Institute – National Centre of infectious Disease
- New Jersey Medical School
- Robert Wood Johnson Medical School – very strong linkages with J&J
- School of Osteopathic medicine
- New Jersey Dental School
- Graduate School of Biomedical Sciences – Initiating clinical and translational research programme
- School of Health related Professions
- School of Nursing
- School of Public Health
- More than 170 specialised centres and institutes
- More than 200 education and healthcare affiliations throughout New Jersey

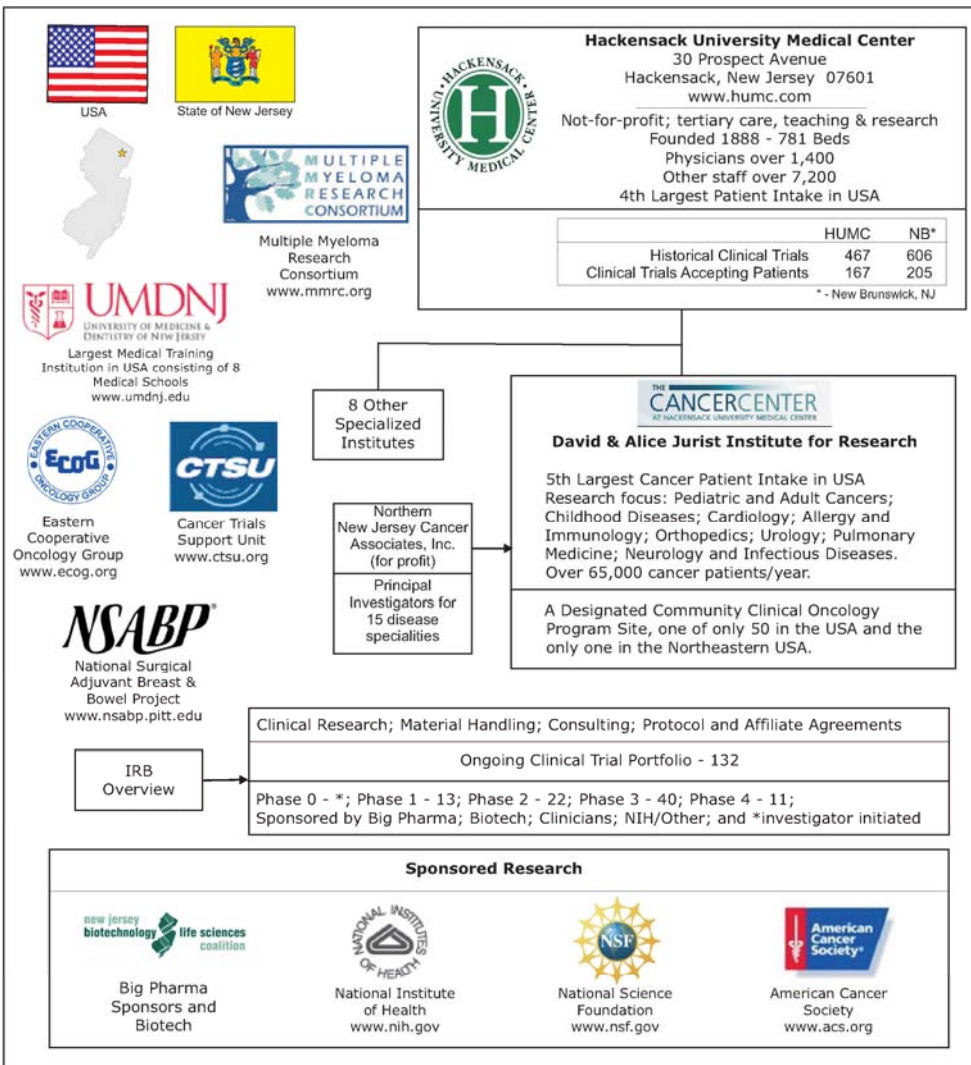


Preliminary Draft for Discussion Purposes Only



LECLAIRRYAN
Two Penn Plaza East - Newark, New Jersey 07105
www.leclairryan.com
Stanley Underwood North, III, Esq.





Entering the US Market

Entering the US Market - dipping your toe across the pond!

- Collaborations; JVs; Mergers; Acquisitions
- A model towards soft landing

When will we meet again?

Opportunity to meet all the regional research VP operatives:

- Kathi Scotto ,VP UMDNJ
- Michale Ritter, VP Research Princeton
- Don Sebastian, VP Research NJIT
- Carole Kantor, Associate Director BioMaterials Institute, Rutgers University
- Dr David Perlin, Executive Director, Public Health Research Institute

When will we meet again?

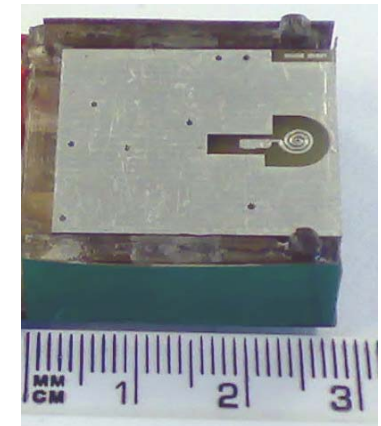
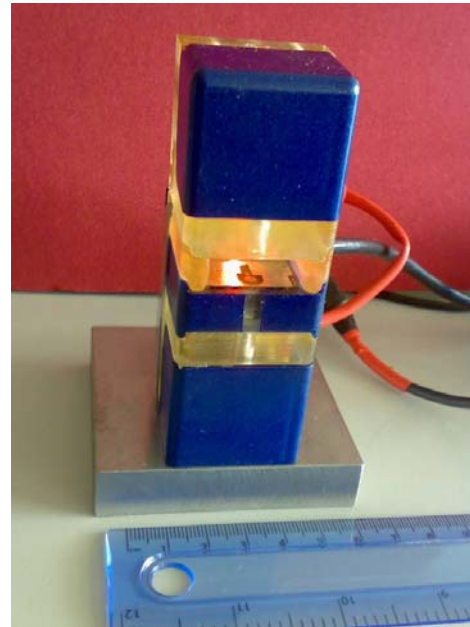
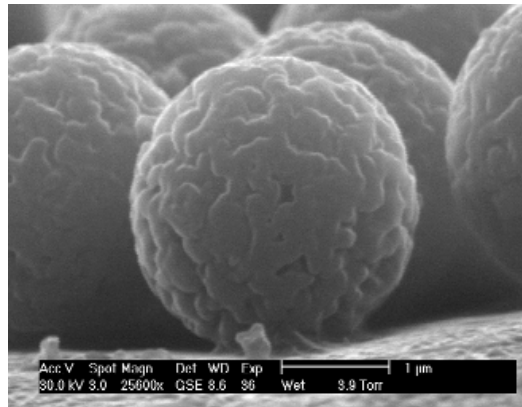
NJTC BioMarker Sophic Demo April 2nd
at Hackensack University Medical Center
4PM

- Open invitation to New Jersey Pavilion Bio 2008 San Diego, California
- 9th New Jersey Symposium on Biomaterials Science and Regenerative Medicine, New Brunswick, New Jersey October 29-31, 2008

IBST Rapid PSA Test

Technology benefits

- Homogenous assay
- Rapid assay (1 to 5 min)
- High sensitivity (ppt)
- Easy to use with minimal manipulation
- Compact, portable detection system
- Low power consumption
- Inexpensive instrument (cost \$200)
- Inexpensive assay (cost \$10-25)



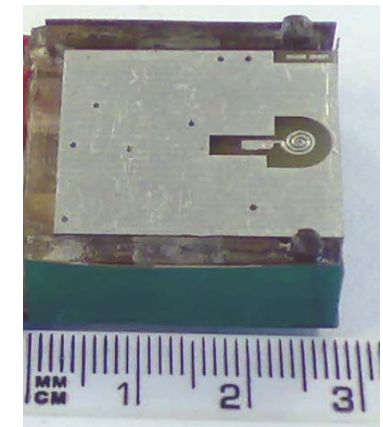
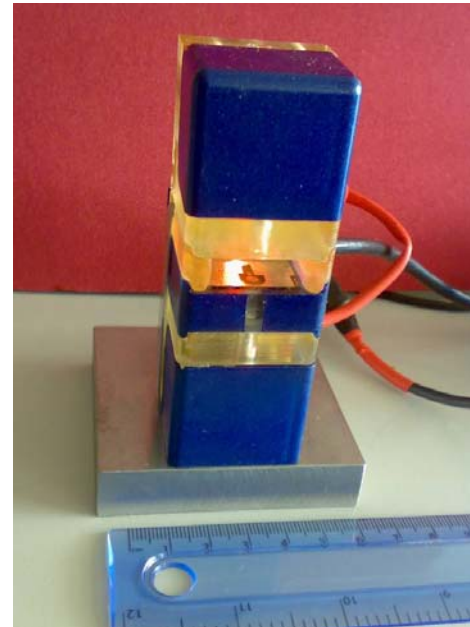
Application areas

- Rapid diagnostics
- Point-of-care testing

IBST Rapid *E.Coli* Bacteria Test

Technology benefits

- Homogenous assay
- Rapid assay (1 to 5 min)
- High sensitivity (ppt)
- Easy to use with minimal manipulation
- Compact, portable detection system
- Low power consumption
- Inexpensive instrument (cost \$200)
- Inexpensive assay (cost \$10-25)



Application areas

- Rapid diagnostics
- Point-of-care testing
- Can simultaneously test up to 5 pathogens at a time



Two Penn Plaza East
Newark, New Jersey 07105
www.leclairryan.com
Stanley Underwood North, Ill, Esq.



University of the West of England
Frenchay Campus Building 605
Coldharbour Lane
Bristol, BS16 1QY England

Launch of Innovative Start-up

Innovative start-up company launch into North America through the Eastern Seaboard

PROPOSED NORTH AMERICAN STRUCTURE

In the last several years, many Innovative Start-up companies have used the Eastern Seaboard to introduce their technologies, products or services into North America



Step 4A— Collaborate and Cross License with US Partners/Customers

[Cross] License Agreement

- Innovator exclusively licenses Collaborator to use Innovator technology in a specified field of use;
- Collaborator to use commercially reasonable efforts to commercialize the Products and cross license improvements;
- Innovator paid \$5X upon execution as an initial license fee and is owed \$25X more milestones up to FDA approval with royalties thereafter at [21% to 50%]

Development Agreement for Innovator and Collaborator

- Sets forth \$80X R&D Budget to develop product through Phase III trials [and FDA approval] subject to meeting periodic product performance criteria throughout the Development Phase;
- Innovator provides product for R&D [at no cost]

Equity Purchase Agreement

- Collaborator purchases of Innovator Equity for \$10X for [unrestricted] working capital subject to customary terms and conditions.

Manufacturers Agreement

- Collaborator purchases FDA approved product from Innovator at 21% to 30% of Average Sale Price ("ASP");
- [Collaborator entitled to build back up manufacturing facility but must cross license improvements]

Security Agreement

- Collaborator is granted a security interest in Innovator equipment pertaining to the Products; the license agreement; books and records; and collateral proceeds as collateral to secure the loan agreement;
- Innovator obliged to insure equipment naming Collaborator as an insured party and not permit liens to be applied thereto.

Loan Agreement

- Collaborator to make \$50X to Innovator of which \$5X advanced for unrestricted working capital; Remaining \$45X intended to fund R&D ED&E under
- Development Agreement;
- [Innovator agrees not to create lien on Product equipment];
- Innovator can prepay advance upon 2 business day notice and must prepay upon issuing equity for \$30X cash or more at any share price lower than Collaborator's investment;
- Otherwise advances repaid @ 2.5% Product sales or if no Product sales as of [7 years from now] then Innovator shares at FMV

Joint Steering Committee

- Innovator has 1 member with tie break vote during Pre-Clinical Phase;
- Collaborator has 1 member with tie break vote during Clinical Phase

R&D Budget Pre-Clinical

Animal Studies	\$4X
Phase I	<u>\$4X</u>
Subtotal	\$8X
Phase II	\$20X
Phase III	<u>\$52X</u>
Total	\$80X

Innovator's Source & Use of Funds from Collaborator

Equity	\$10X
License	5X
Loan	5X
R&D	80X
Royalties	<u>TBD</u>
	\$100X



SCIENCES CONVERGE TO CREATE NEW PLATFORM TECHNOLOGIES AND WITH EVOLVING COLLABORATIVE NETWORKS, CREATE NEW PRODUCT PIPELINE MODELS TO GENERATE LEADING INNOVATION

- Abstract: New platform technologies are converging across the fields of healthcare and the environment. During the past century, academic and industrial institutions ever increasingly specialized in ever narrower and narrower fields of science and technology, however this trend appears to be reversing itself as new platform technologies emerge which require the collaboration of multiple scientific disciplines from multiple regional clusters. These new platform technologies in turn can have a broad application into many fields and industries. This trend is presently unfolding in New Jersey, where regional collaborative networks with the South West of England are demonstrating successful results in breakthrough products and solutions for healthcare and the environment with global collaborations across multiple scientific disciplines and institutions.

Abstract cont.

- These evolving initiatives are a back drop to a larger challenge facing our two respective regions. It is suggested that our current century will be the century of the emergence of China and India as the dominating innovative forces in the world's economy. Undoubtedly technology is spreading to emerging markets faster than it has ever done before, however I believe that such a suggestion is premature. Emerging markets should not be ignored but
- our willingness to invest in the infrastructure necessary to conduct research and development on a regional networked collaborative basis, licensing our innovations back and forth to our areas of respective strengths at ever higher levels puts us on the path of inventing new industries, new cures, and bodes well for maintaining our current lead in generating innovative ideas to make both of our regions and the world as a whole a better place to live in by 2100.

Thank You



LECLAIR RYAN