



NuGenerex
— FAMILY OF COMPANIES —



Generex BIOTECHNOLOGY™

Building the “New” Generex

Joe Moscato
President & CEO

December 2019

Legal Disclaimer



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Strategy: Focus on High Value Specialty Care for Chronic Complex Patients

GNBT is Reorganized & Transformed as an Integrated Life Science & Healthcare Company

1. Build networks of physicians & patients
2. Provide ancillary health & management services
3. Discover, develop, and manufacture innovative products & services
4. Distribute new products through proprietary market channels
5. Expand sales through synergies & cross-selling of multiple product lines

Disease Focus

- Arthritis & Orthopedic Surgery
- Diabetes & Metabolic Disorders
- Cancer & Immunology

Healthcare Focus

- ✓ Build MSO Partnerships with High Value Specialist Physicians
- ✓ Deliver High Value Products & Services for Complex Patients
- ✓ Acquire & Develop Innovative Products In Target Sectors

3-Step Strategy: Focus on High Value Specialty Care for Complex Patients

- 90% of the \$3.5 Trillion in U.S. Healthcare Costs are Spent on Chronic Diseases and Mental Health (CMS & CDC)
- Specialty medications now account for 44.7% of total drug spending (Express Scripts)

A. Build MSO Partnerships with High Value Specialist Physicians

1. **Orthopedic Surgeons/Podiatrists***
2. **Endocrinologists***
3. Gastroenterologists
4. Cardiologists
5. Oncologists

*Current MSOs

B. Deliver High Value Products & Services for Complex Patients

1. Arthritis & Inflammatory Diseases
 - Surgery
 - Wound management
 - Pain
2. Diabetes & Metabolic Disease
 - Ophthalmology
 - Podiatry
 - Chronic Care Management (CCM)
3. Cancer
 - Immunotherapy

C. Acquire & Develop Innovative Products In High Value Sectors

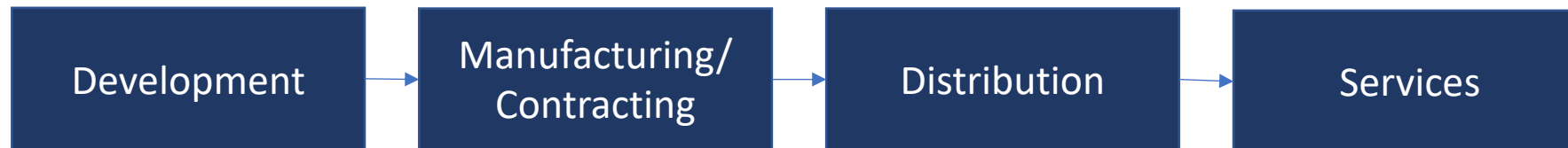
1. Regenerative Medicine
 - Olaregen – Excellagen®
 - Regentys – ECMH
 - AltuCell – Sertoli Cells
 - Biologics
 - Exosomes
2. Surgical Implants & Kits
 - Pantheon & MediSource
3. Immuno-Oncology
 - CAR-T
 - Neo-antigens
 - Immunotherapeutics
4. Artificial Intelligence & Analytics

The NuGenerex Model for Orthopedic Surgeons & Podiatry

GNBT is building an end-to-end solution through acquisitions and partnerships to provide products and services for physicians and patients



End-to-End Solutions From R&D to the Patient



- ❖ Stem Cells & Exosomes
- ❖ Cell & Tissue Therapies
- ❖ Surgical Implants
- ❖ Regenerative Medicine

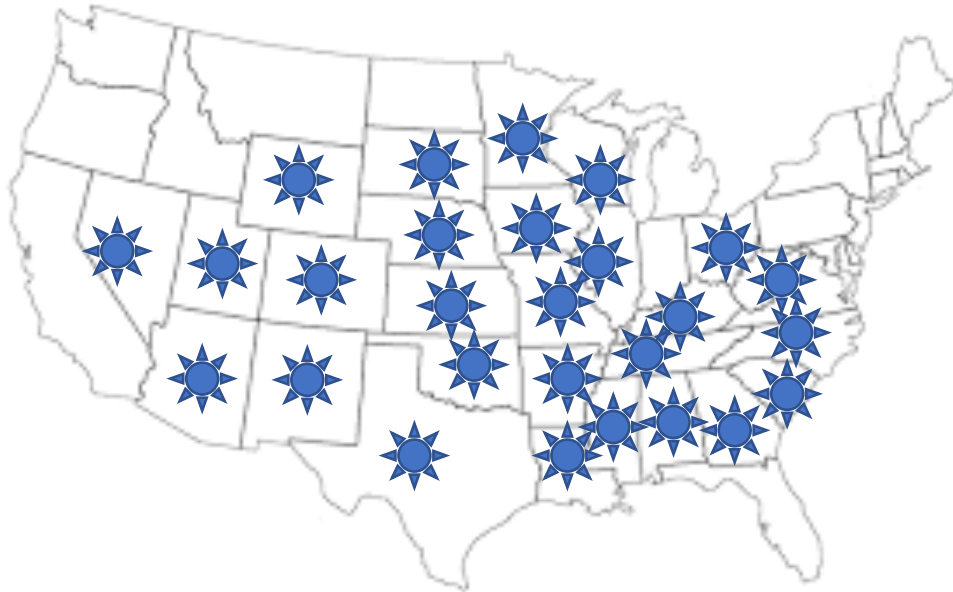
- ❖ Excellagen®
- ❖ Biologics
- ❖ Implants
- ❖ Pantheon Foot & Ankle Kits

- ❖ NuGenerex Distribution Solutions (NDS)
- ❖ MediSource
- ❖ Sales Force(s)

- ❖ NuGenerex Ortho/Pods MSO
- ❖ Group Purchasing
- ❖ Billing & Insurance Adjudication
- ❖ DME-IQ
- ❖ Patient Support Call Center

NuGenerex Distribution Solutions (NDS) Manages the MSO

MSO Growth from 5 to 27 States



Generex Acquisitions: Drug & Device Products for MSO

DME-IQ – Orthopedic Products & Services

Olaregen – Excellagen for Wound Healing

Pantheon – Surgical Kits

MediSource – Implants, Surgical Supplies, Biologics

Growth to New Specialties

- ✓ Podiatrists
- ✓ Orthopedics
- ✓ Diabetology
- Gastroenterology
- Cardiovascular

- Innovative NuGenerex MSO Partnership Model
- Potential expansion into a total of 27 states with the NDS MSO model
- Adding specialty MSOs to expand service offerings
- Group purchasing & specialty product pricing for NuGenerex MSO network physicians
- Expanding product & service offerings



OLAREGEN
THERAPEUTIX INC.

*Innovating
the Science of
Healing*

Excellagen® Commercial Launch

- Commercialization through NuGenerex Distribution Solutions' MSO & pharmacies network of podiatrists & diabetologists
- Clinical Experience Program with the VA
- Contracting with national wound care centers



42 Days Stalled: 4 Excellagen® Applications
49 Days to Closure



240 Days Stalled: 5 Excellagen® Treatments
63 Days to Closure

Excellagen® Pharmaceutically-Formulated Collagen Topical Gel Accelerates Healing Rate Immediately After Application in Patients with Diabetic Neuropathic Foot Ulcers¹

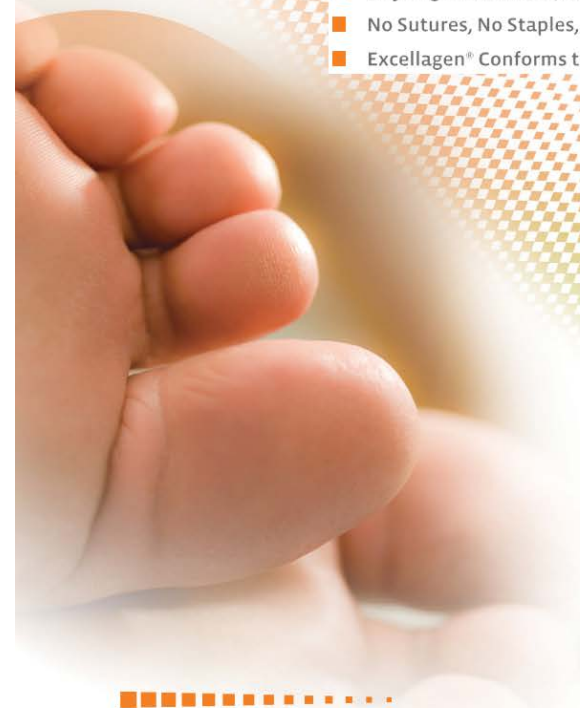
Diabetes Causes ~1.3 Million DFUs Annually in the U.S.
(American Diabetes Association)



Excellagen® is an Advanced, Wound Care Management Platform

Excellagen® for the Management of Diabetic Foot Ulcers

- Randomized Clinical Trial on DFUs Demonstrated a Mean of 1.6 Treatments to Heal the Wound²
- Excellagen®, in its Gel Form, Reduces the Likelihood of Shearing
- Excellagen® was Designed to Reduce Wastage
- 3 Syringe Sizes: 0.5cc, 0.8cc, 3.0cc
- No Sutures, No Staples, No Thawing, No Mixing
- Excellagen® Conforms to the Uneven Wound Bed Surface



Excellagen® is a 3-dimensional wound conforming matrix that immediately activates platelets triggering release of growth factors (PDGF) to accelerate healing in Acute and Chronic Wounds



Pantheon Manufactures FDA-Cleared Products to Provide End-to-End Solutions for Orthopedic Surgeons



Surgical Device Manufacturer of Orthopedic Surgery Products and Tools

The physician friendly “all-in-one,” integrated kit includes plates, screws, and tools required for orthopedic surgeons and podiatrists conducting foot and ankle surgeries.

Pantheon Medical – Foot & Ankle, LLC will be developing the following proprietary systems with the expected release dates:

- Cannulated surgical screw system - December 2019
- Surgical Staples – December 2020
- Proprietary Hammertoe System – December 2021

MediSource Offers a New, Proprietary Market Channel for Surgical Products & Biologics



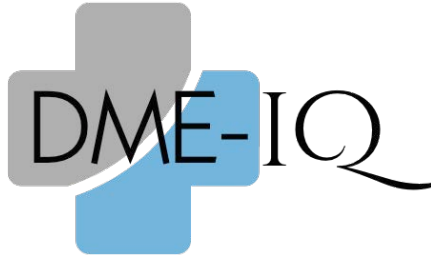
Partnerships and contracts with hospital systems for ordering, billing and inventory management.

FDA Registered Distributor of implants and devices for spine, hips, knees, foot, ankle, hand, and wrist surgeries.

Contracts with over 25 vendors (including Pantheon Medical) for distribution of:

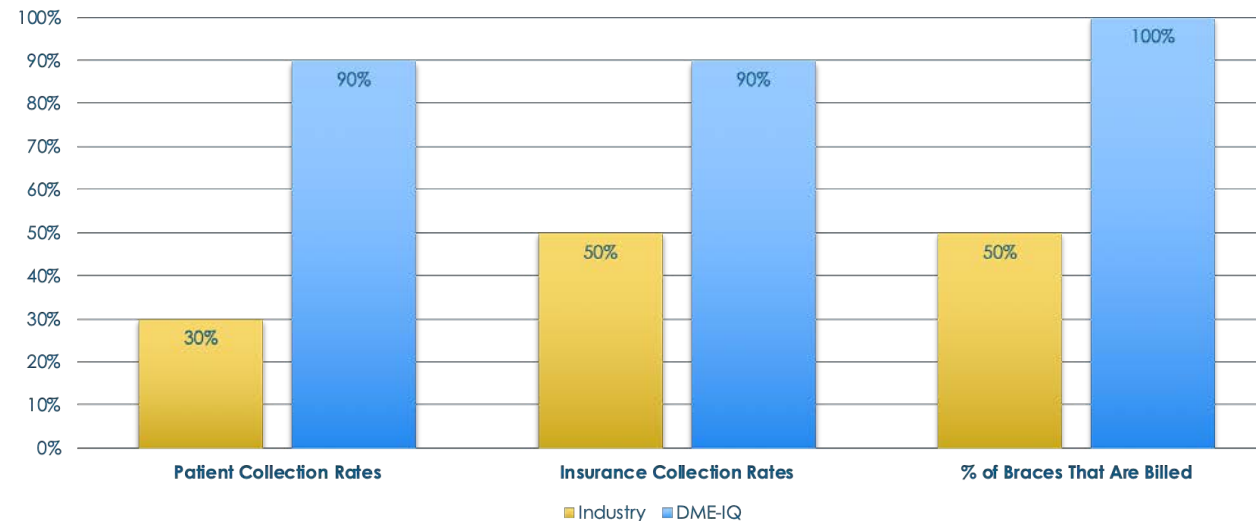
- Implants and devices
- Biologics (blood, bone, tissue, and stem cells)
- Durable medical equipment
- Soft Goods
- Kits to process bone marrow aspirates and platelet rich plasma biologics

DME-IQ Enables Orthopedic Practices to Optimize Office Efficiencies for Maximal Profits



Value Proposition

- Inventory Management Prevents Product Loss
- Billing System Plug-in to Ensure Accurate Accounting
- Patient Presentation of Benefits
- Confirm Eligibility & Prior Authorizations
- Collects Patient Payment Responsibility Using Tablet-based Credit Card Processing
- Purchasing Power for Orthopedic DME
 - Spine, Knee, Shoulder, Ankle Braces





Generex BIOTECHNOLOGY™

Re-Launching the GNBT Diabetes Franchise: Partnerships, Acquisitions, Product Development, Disease Management

- 1. NuGenerex Health MSO: Partnerships with Endocrinology & Internal Medicine Physician Practices focused on Diabetes and Chronic Disease Management in AZ**
- 2. NuGenerex Health HMO – Medicare Advantage Plans for Diabetes care**
- 3. Acquisition of AltuCell – Microencapsulation Technology for Cellular Therapy in Type I Diabetes**
- 4. Development of Second-Generation Oral-Lyn® II Reformulated Buccal Insulin Spray for Type II Diabetes**

NuGenerex Health MSO: Ancillary Care for Diabetes Patients

NuGenerex Health MSO (NGH)

Generex has established NGH in conjunction with physician practices (Arizona Endocrinology and Paradise Valley Family Medicine) who care for a population of ~65,000 patients in Arizona, 25,000 of whom are insulin dependent diabetic patients. NGH employs ophthalmologists, podiatrists, and medical staff to provide ancillary health services for chronic care diabetes patients in support of the medical practices.

Ophthalmology

Medicare Part B (Medical Insurance) covers preventive and diagnostic eye exams as part of a comprehensive diabetes care plan, with reimbursements averaging \$350 per patient per year for standard eye exam with accompanying tests for glaucoma and macular degeneration.

Podiatry

As diabetic foot ulcers (DFUs) are the leading cause of non-traumatic lower extremity amputation costing an estimated \$50 billion annually, CMS promotes preventive and diagnostic foot exams by a podiatrist, with reimbursement rates averaging \$175 for a new patient evaluation, and \$150 for follow up. Under the CMS guidelines, patients are eligible for diabetic foot exams every six months.

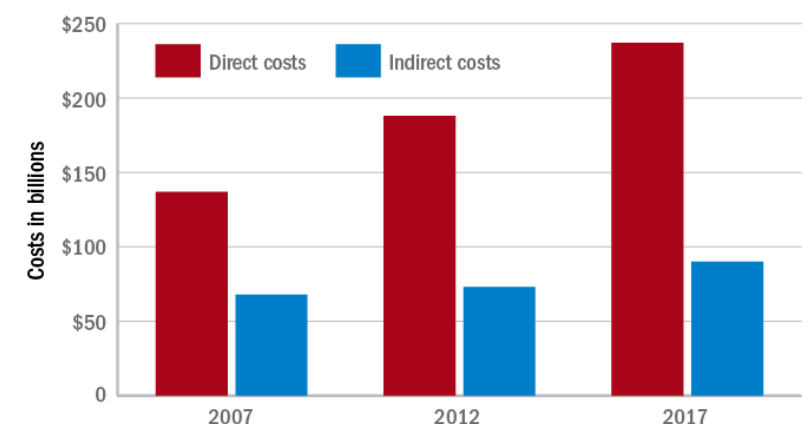
Chronic Care Management (CCM)

An estimated 117 million adults have one or more chronic health conditions, and 2/3 of Medicare patients have 2 or more chronic conditions. The Centers for Medicare & Medicaid Services (CMS) made benefit payments of \$583 billion in 2018, with chronic care patients accounting for 99% of expenditures.

The Diabetes Market

According to a 2017 report by the Centers for Disease Control and Prevention (CDC), more than 100 million U.S. adults are now living with diabetes or prediabetes, and that an estimated 30.3 million Americans – 9.4 percent of the U.S. population – have diabetes. This national epidemic requires new healthcare models to deliver optimal, guideline-directed care to improve outcomes and reduce the costs of this epidemic that costs an estimated \$327 billion.

Total direct and indirect medical costs of diabetes



Note: All cost estimates extrapolated to the 2017 U.S. population and adjusted to 2017 dollars.

Source: Diabetes Care. 2018 Mar 22. doi: 10.2337/dci18-0007

NuGenerex Health MSO is the Foundation for the HMO Business



NuGenerex Health HMO

Generex is Partnering with an Experienced Team of Influential HMO Veterans to form NuGenerex Health HMO

State: Arizona

Infrastructure:

4 Existing Clinics

60 Doctors within Network

65,000 Captive Patients

HMO Plan Administrator:

Beacon Health Solutions

Operational Forecast:

Year 1 - (Setup) 2,000 – 6,000 Enrollees

Year 2 - 6,000 - 14,000 Enrollees

Year 3 - 14,000 to 20,000 Enrollees

Ownership:

GNBT – 51%

HMO Partners – 49%

The Medicare Advantage HMO Market

The number of people eligible for Medicare is projected to reach 72 million by 2025, up from about 63 million at present, with gross spending for Medicare expected to surpass \$1.2 trillion by 2025, up from more than \$800 billion projected for 2019. Medicare Advantage now serves more than one-third of those enrolled in Medicare. **NuGenerex Health** is positioned to emerge as an innovative leader in the delivery of healthcare by combining a multi-specialty MSO and Medicare Advantage HMO supporting contemporary care models to revolutionize how health plans serve their stakeholders.

Product Positioning and Plan Design

Medicare Advantage Prescription Drug Plan (MAPD) HMO for individuals who have both Medicare Part A and Part B.

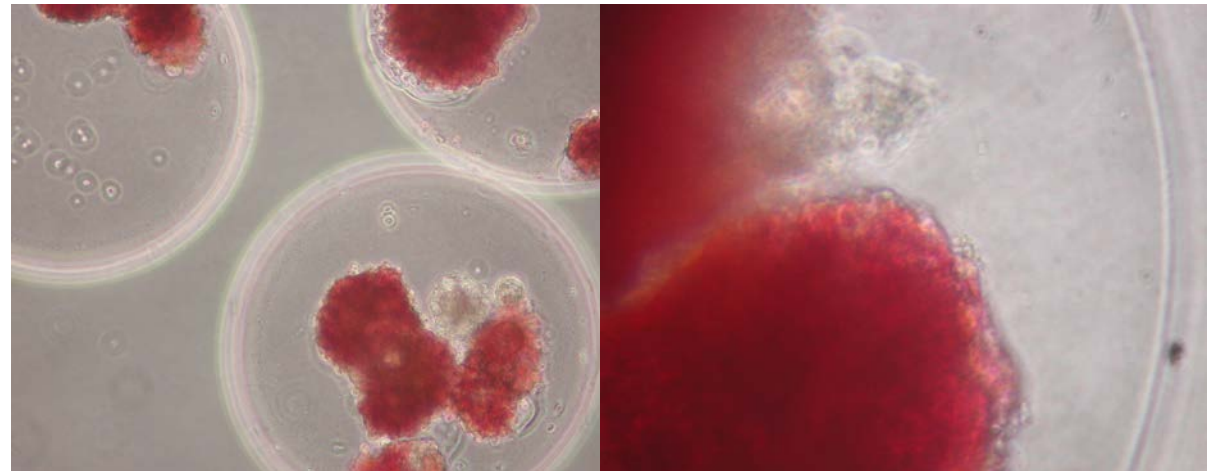
Chronic Special Needs Plan (CSNP) HMO for individuals in addition to having Medicare Part A and Part B are faced with the burden of living with diabetes or a cardiovascular disorder.

Dual Eligible Special Needs Plan (DSNP) HMO for individuals who have both Medicare Part A and Part B and medical assistance through their state of residence.

NuGenerex Health D-SNP HMO Full will cover all Medicare-covered benefits at zero cost-sharing.

❖ **Generex is in the Process of Acquiring AltuCell and the Patents for Microencapsulation Technology**

- Microcapsules formulated with ultra-purified alginates and poly-L-ornithine
- AltuCell Microcapsules Proven Safe After 5 Years of Human Transplantation with No Toxicities
- Microencapsulated Sertoli Cell Transplantation (Altsulin®) for Type I Diabetes: Phase I/II
- Patents for Encapsulation & Transplantation of Regenerative Medicine Therapies
 - Wharton's Jelly
 - Mesenchymal Stem Cells



MICROCAPSULES CONSTITUTE IMMUNOISOLATORY PHYSICAL BARRIERS THAT PREVENT IMMUNE REJECTION OF THE ENVELOPED CELLS UPON GRAFT, WHILE OFFERING A SPECIAL 3D CELL MATRIX-LIKE MICROENVIRONMENT (WHICH GREATLY FAVORS RETENTION OF CELL VIABILITY AND FUNCTION)

4 transplanted patients with long-standing type 1 diabetes have shown evidence of grafted encapsulated islet cell function throughout 5 years of post-transplant follow-up

A New Life for Oral-Lyn

Oral-Lyn® II Buccal-Administered Insulin for Type II Diabetes

- Oral-Lyn evaluated in over 6,000 subjects with Type 1 & 2 diabetes and healthy volunteers
 - Shown to be efficacious and safe
- Collaboration with University Health Network to reformulate Oral-Lyn II for clinical utility
- Reformulated Oral-Lyn II requires only 2-3 puffs to achieve effective prandial metabolic control
- New IP
- Three-year Development & Commercialization Plan



*Oral-Lyn is an investigational drug

Generex Has Acquired Regentys to Develop Regenerative Medicine Products for Gastroenterologists*

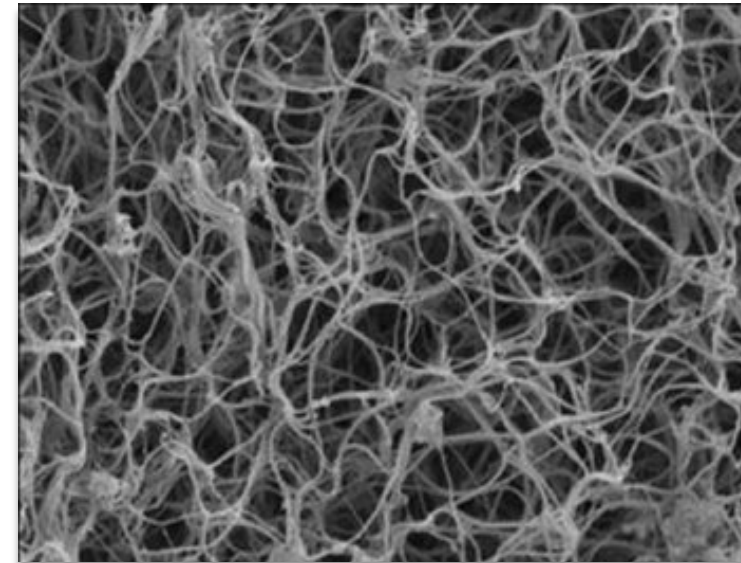
Novel, Patented Extra-Cellular Matrix Hydrogel (ECMH) Designed to Promote
Healing of Inflammatory Bowel Diseases

Billion ECMH Target Markets

- Inflammatory bowel disease
- Ulcerative colitis
- Crohn's disease

Clinical Development Pathway

- 1st indication: ulcerative colitis
- FDA 510K de novo pathway
- Clinical trials starting Q4



*Future MSO for GI Specialists



NuGenerex
IMMUNO-ONCOLOGY

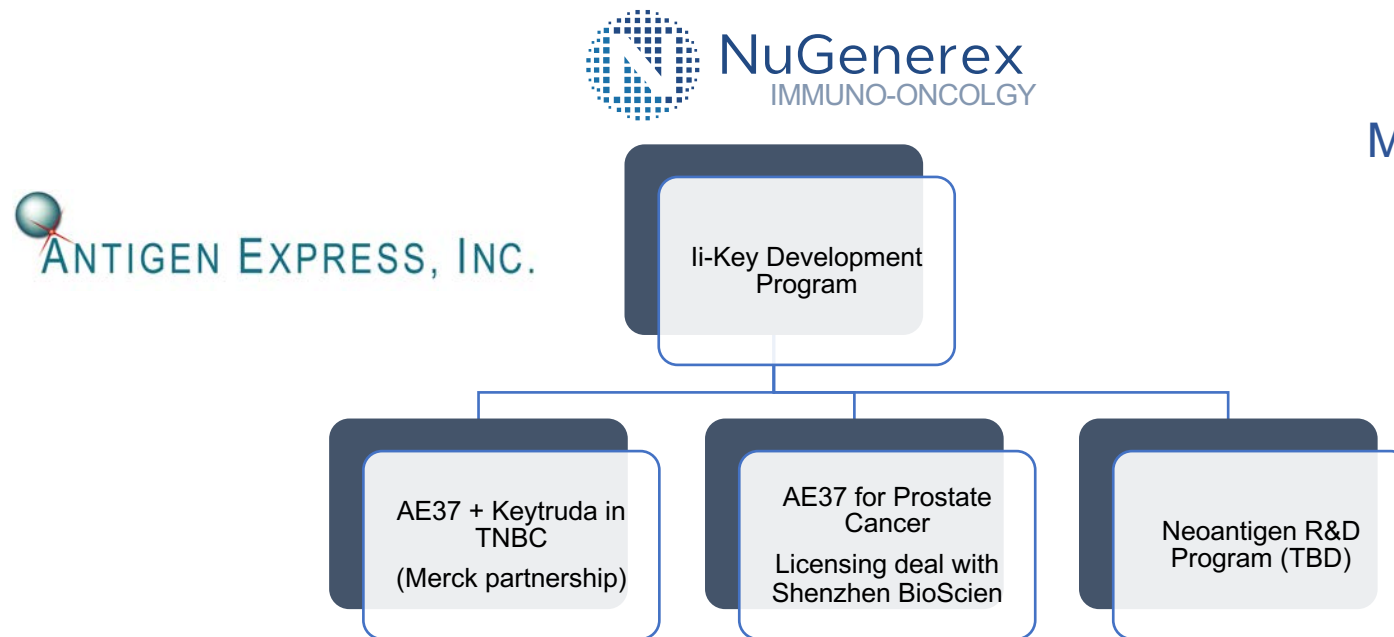


Generex BIOTECHNOLOGY™

**Generex Has Announced Plans to
Launch NuGenerex Immuno-Oncology
(NGIO) as a Separate Public Company**

NuGenerex Immuno-Oncology (Formerly Antigen Express) Capitalizes on the Growth of Cancer Immunotherapy

NuGenerex Immuno-Oncology will be Launched on the Public Markets
With Thousands of Shareholders through Stock Dividends Awarded to Generex Shareholders



NGIO Focus:
Modulation of the Immune
System to Fight Cancer

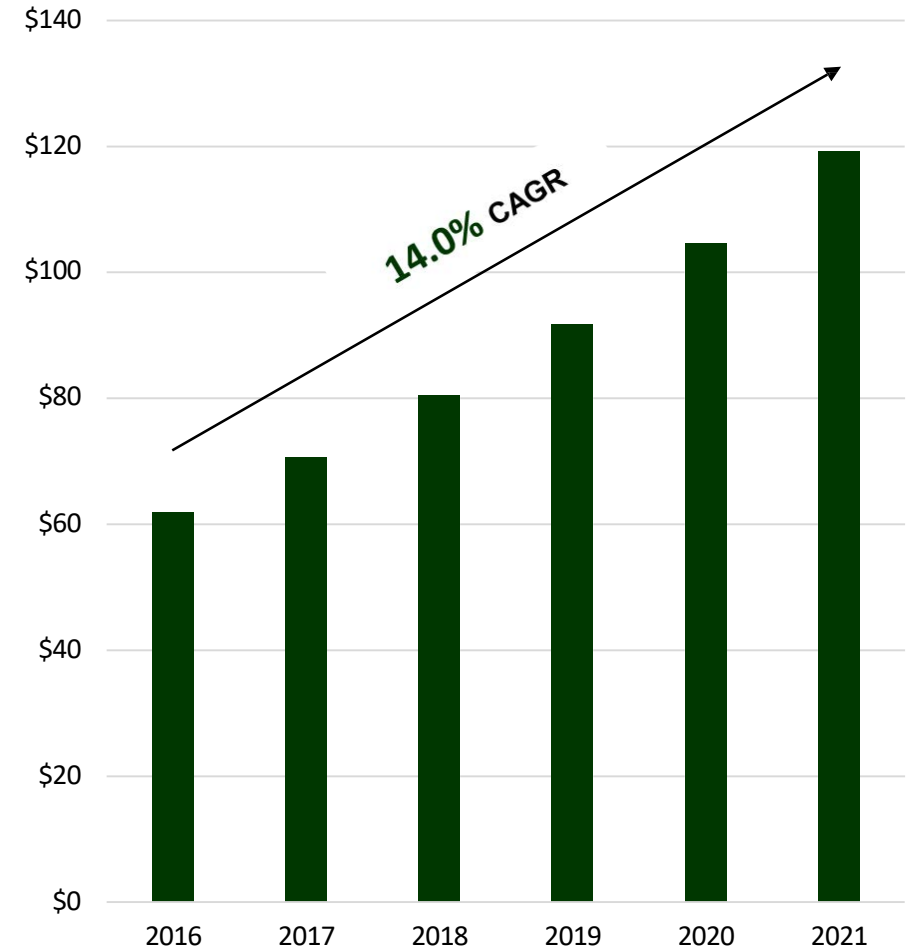
**The Cancer Immunotherapy Market was ~\$40 Billion in 2017, and is
estimated to reach \$170 Billion by 2028 (Research & Markets)**

Market Overview: The Immuno-Oncology Field is Exploding

Cancer Immunotherapy Market

- The global cancer immunotherapy market is expected to reach \$119.39 billion by 2021 from \$61.9 billion in 2016, at a CAGR of 14.0% from 2016 to 2021
 - o Immuno-oncology is one of the fastest growing and promising areas of cancer research
 - o Factors such as increasing incidence of cancer and rising healthcare expenditure are driving the growth of this market
- NuGenerex is well prepared to participate within this fast growing market area with AE37. Product highlights include:
 - o Class-leading specific activation of T cells which has shown long-lasting effect in different patient populations. These two attributes are vital to enable checkpoint inhibitors to achieve long-term remission
 - o Important complement to the success seen with checkpoint inhibitors & CAR-T
 - o li-key platform will drive development of other compounds
 - o Product Line Expansion with li-Key Neo-Antigens for Personalized Cancer Immunotherapy

Cancer Immunotherapy Market Development (\$ in bn)



NGIO R&D Program - Checkpoint Inhibitors Reignite Development of AE37 and li-Key Immunotherapeutic Vaccines

- Phase II will evaluate AE37/Keytruda combination in triple negative breast cancer
 - Collaboration with Merck supplying Keytruda
 - Trial being conducted through the National Surgical Adjuvant Breast and Bowel Project (NSABP) cooperative group
- Licensing agreement with Shenzen BioScien for rights in China
 - Phase II Trial to evaluate AE37 in Prostate Cancer
 - NuGenerex secures data rights & maintains market for ROW
- li-Key Hybrid Peptide Immunotherapeutic Vaccines in Combination with Immune Checkpoint Inhibitors
 - AE37 in Breast, Bladder/Urothelial, Colorectal, Head & Neck
 - GNBT Immunotherapeutic Vaccines: GP100 (48-58); Tyr (370-381) for Melanoma
 - Antigen Identification Program with Data Analytics – Rapid Pipeline Development
 - Multi-Valent epitope combinations



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