Generex CEO Provides 2017 Year-End Summary to Stakeholders

MIRAMAR, Florida, January 4, 2018 (BUSINESS WIRE) – Generex Biotechnology Corporation (OTCQB:GNBT) (http://www.otcmarkets.com/stock/GNBT/quote) (www.generex.com) today issued the following letter from the Company's President & Chief Executive Officer, Joseph Moscato, providing his fellow stockholders with a summary of the Company's initiatives and achievements over the course of 2017. This letter is being issued in advance of the Company's investor conference call, to be hosted by Mr. Moscato, and his management team, **today** at **10:30 a.m. Eastern time**:

Toll Free: **1-877-888-4291**

Passcode: **35411**

To my fellow shareholders, employees, Board members and partners:

2017 has been year of profound change here at Generex, and we are pleased with our progress and the execution on our strategic plans. Following the successful conclusion of our Company-wide reorganization in November, we are laying the foundation for the implementation of our new business plans to drive growth and shareholder value, enabling our Company to thrive in the coming years.

We are proud of what we have been able to accomplish in 2017, and we are excited to realize our vision of rebuilding our Company as a strategic, diversified life sciences holding company. So, in 2018, we will have a new name - NuGenerex Life Sciences Holdings, Inc. (NuGenerex) - and a new mission to build a modern organizational platform for the financing, development, commercialization, and distribution of promising therapeutic and diagnostic products that will improve human health and return value to our stakeholders.

As we effect the new plans, I'd like to summarize our accomplishments this year, in which we embarked upon an aggressive reorganization of our executive leadership and public securities structure beginning in mid-January of 2017. Throughout the year, we have taken the steps necessary to put the company back on stable financial and operational footings so that we can not only build the value of our underdeveloped asset portfolio, but also add significant value through strategic acquisitions and partnerships, as outlined herein. The Company's accomplishments for the year include:

- repopulated the Company's Board of Directors with a solid mix of proven leaders in finance, drug development and drug delivery, business development, and corporate governance;

- recruited a solid management team with the requisite expertise, knowledge, and experience to execute on our go-forward plans;

- negotiated with certain investors to settle derivative liabilities and securities encumbrances that weighed down our security structure, thereby paving the way to a pristine and transparent capital structure;

- filed the Company's quarterly and year end reports to bring us current and compliant as a fully-reporting company with the SEC, thereby ending lengthy dormant period;

- implemented a shareholder-approved reverse stock split and completed a return up-listing to the OTCQB® Venture Market, with an eye to ultimately returning to a national exchange; and,

- cleared SEC comments on the Company's proxy statement, and conducted our annual meeting of shareholders on November 21, at which our shareholders approved the measures we believe will enable us to complete the reorganization and to implement the planned initiatives that will ultimately lead to the up-listing of the Generex common stock to a national exchange in 2018.

Throughout the year, we have aggressively sought to identify acquisition targets that will offer significant upside value for our shareholders. Our acquisition strategy focuses on identifying companies with promising product development pipelines offering significant revenue and out-licensing opportunities. We invest in great management teams to provide the finances, operational and regulatory guidance, and managerial oversight to achieve product development milestones and ultimately commercial success.

The future of NuGenerex will be defined by the successes of our subsidiaries. The companies we seek to acquire are a reflection of our vision and values. Only those exhibiting the highest standards of scientific and professional integrity are given consideration.

In 2017, we reviewed over one hundred potential candidates for acquisition. Of these, exhaustive due diligence was performed on twenty-five. Eight companies have been identified as ideal targets for acquisition and negotiations are currently underway. These companies are diverse within the biotechnology sectors and include therapeutic, diagnostic, and medical device platforms at all stages of commercialization. Each company is primed with multiple, attainable inflection points to deliver a series of quantifiable value-driving milestones. Each product represents a high-value proposition by addressing unmet clinical needs while supporting responsible healthcare economics. Importantly, each product has a clearly defined development, regulatory, reimbursement, and commercialization pathway that is achievable within a practical, controlled budget. Lastly, each

company targeted for acquisition comes with a strong, robust intellectual property portfolio and experienced management teams of the highest quality.

The key to our strategy is the foundational acquisition of a nation-wide network of pharmacies including integrated data and CRM systems that can generate significant revenue and earnings through distribution of specialty pharmaceuticals across multiple therapeutic indications in such high-value, chronic disease areas as diabetes and metabolic disease, cardiovascular diseases, rheumatoid arthritis, mental health, central nervous system (CNS) disorders, and pain management. For the last eight months, Generex management has worked to identify acquisition targets that will give us a nation-wide infrastructure to provide a direct-to-patient pharmacy solution to meet their chronic medical needs. On December 28, 2017, the Company initiated this strategy to establish itself as a presence in the U.S. direct-to-consumer pharmaceuticals business with the acquisitions of Empire State Pharmacy LLC in New York State and Grainland Pharmacy LLC in Kansas. It is expected that both locations will be fully operational early in 2018. Generex is actively pursuing acquisitions of additional turnkey retail pharmacy operations with multiple product lines in more than a dozen U.S. states, some of which have received accreditation from the Utilization Review Accreditation Commission (URAC®) and the Verified Internet Pharmacy Practices Sites (VIPPS) program of the National Association of Boards of Pharmacy. We are targeting additional pharmacy assets for acquisition and due diligence and audits are currently underway. This Direct-to-Patient (DTP) acquisition strategy includes national marketing, customer service, operations, pharmacy technicians, physician order verification, information technology (including proprietary Data Analytics and Customer Relationship Management (CRM) systems and E-Commerce), warehousing, finance, and human resources. Our go-forward plan is to expand the product portfolio with additional specialty drugs, medical devices, orphan drugs, and other prescription medicines in high value therapeutic areas to achieve significant revenue growth and earnings once the network is fully established.

We believe that by acquiring a highly profitable pharmacy network, we can begin self-funding our own product development initiatives and advancing our acquisition strategy without constantly raising money and diluting shareholders, thereby creating long-term value rather than short-term gains. While we may need to raise additional capital to fund the acquisitions, we expect to reduce dilution through this strategy.

As we have been executing on our acquisition strategy, we have also been extremely active in reinvigorating the existing platform assets of our subsidiary companies, including the Ii-Key cancer immunotherapy platform technology AE37, and our proprietary peptide buccal delivery system, Generex Oral-lyn® for diabetes.

- Through the efforts of Dr. Eric von Hofe, PhD, President of our wholly-owned subsidiary Antigen Express (www.antigenexpress.com), we signed a co-development agreement with Merck to conduct a combination clinical trial of the AE37 immunotherapeutic vaccine with Merck's FDA-approved cancer treatment, Keytruda® for the treatment of triple negative breast cancer. Together with Merck, we are working with the National Surgical Adjuvant Breast & Bowel Project (NSABP), a clinical trials cooperative group supported by the National Cancer Institute (NCI), to conduct the trial. The protocol has been completed and a clinical supply of GMP AE37 manufactured for this Phase II clinical trial. The trial is scheduled to enroll the first patient in mid-2018, with enrollment expected to take roughly 18 months. Note that additional funding will be required 2018 - 2020 to complete the trial.

- Antigen Express also signed a License and Research Agreement with Shenzhen BioScien Pharmaceuticals Co. Ltd, (Shenzhen Overseas - Longgang - Venture Park, People's Republic of China) to develop and commercialize the AE37 immunotherapeutic vaccine for prostate cancer in China (including Taiwan, Hong Kong, and Macau). Shenzhen BioScien has paid Generex a non-refundable, up-front license fee of $700,000 USD (net of applicable Chinese withholding taxes). Under the Agreement, Shenzhen BioScien will make milestone payments to Generex of $1,000,000 USD each upon completion of the Phase II and Phase III clinical studies of the vaccine as well as a milestone payment of $2,000,000 USD upon regulatory approval of the vaccine in the territory. Generex will also receive a 10% royalty on net sales of the product in the territory. Although the license is confined to the prostate cancer indication in China, Shenzhen BioScien plans to conduct the Phase II proof-of-concept trial of AE37 in the treatment of prostate cancer at sites in Europe under the guidelines of the International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). This is an essential element of the licensing deal, as we maintain marketing rights for the rest of the world, and can use the Phase II data to further our own applications with FDA and European Medicines Agency for AE37 in the treatment of prostate cancer.

- NuGenerex is seeking to augment our leadership position in cancer immunotherapy with the Ii-Key technology through acquisitions of new companies, products, and intellectual property in the field. Our leadership team has applied our extensive experience in oncology product development, commercialization, and patient treatment to identify several acquisition targets, which are currently being evaluated through our due diligence process.

- Generex Oral-lyn® is the NuGenerex buccal insulin product that utilizes our patented buccal drug delivery system for the treatment of diabetes.

Through the efforts of Dr. James H. Anderson, Jr., MD, a member of our Board, we have initiated the reformulation of Generex Oral-lyn® with a view to reducing the number of sprays required. With the extensive clinical safety package developed during the Phase III Type I diabetes trial, we are excited about going back to the FDA and requesting a "fast track" pathway through the regulatory process for Type II diabetes.

- Additionally, we have identified patent counsel to aggressively seek legal remuneration from numerous companies that have infringed upon and violated our extensive portfolio of global patents for buccal delivery of drugs and peptides.

The management at NuGenerex has worked diligently through the year to restructure and refocus the Company; we evaluated dozens of companies to identify acquisition targets and commercial opportunities. Some highlights, accomplishments, and outcomes for 2017 are outlined below.

- At the beginning of the year, we completed the acquisition of Hema Diagnostic Systems (HDS) (www.hemadiagnosticsystems.com), which has a complete line of rapid diagnostic point-of-care tests (RDTs), primarily in the infectious disease space, ready for global distribution, with emphasis on use in resource-poor and developing countries.

- HDS currently is on the procurement lists of the World Health Organization (WHO) with rapid diagnostic tests for infectious disease agents including HIV and Malaria. The Company has also developed other rapid assays for distribution throughout the world which include Tuberculosis, Syphilis, Hepatitis B, and Hepatitis C.

- The Company's Tuberculosis assay, the world's first tuberculosis test point-of-care triage diagnostic test, is currently undergoing clinical trials under the auspices of a World Health Organization Tuberculosis and Lung Disease Collaborating Center and The University of Rome.

- NuGenerex Diagnostics plans to introduce select RDT products in the United States, starting with a rapid syphilis assay with the goal of establishing a foothold in the U.S. market to meet the present critical need of rapid sexually-transmitted disease testing. There is a current epidemic of syphilis and other STD's in the Unites States and other developed countries which has resulted in an urgent medical necessity for the rapid diagnosis and treatment of these diseases.

- Infectious sepsis and systemic immune shock syndrome (SIRS) are leading causes of death in the United States, and the most common cause of death among critically ill patients in non-coronary intensive care units. Recent data suggest the annual cost of hospital care for patients with

septicemia is $14 billion in the U.S. Sepsis and SIRS are critical public health problems that NuGenerex Diagnostics intends to ameliorate, with R&D on our proprietary Multiplex Sepsis Assay scheduled in 2018, and commercial enabling clinical trials beginning in 2019.

- Since finalizing the HDS acquisition in January 2017, we reorganized and streamlined the Company's operations, and appointed Dr. Hal Haines, PhD as President to implement our go-forward plans. Dr. Haines has an extensive background in the development of diagnostics, and we are happy to have him shepherding the FDA approval process in 2018 for HDS RDTs, and the research and development of a quantitative Multiplex Sepsis Assay.

- We seek to expand the NuGenerex presence in the diagnostic space with a mission to advance personalized medicine through rapid precision diagnostics. To that end, we are in discussions with select technology companies in the fields of rapid polymerase chain reaction (PCR) and Next-Generation DNA sequencing (NGS) to build an advanced diagnostics business within our subsidiary structure.

- Early in the year, we signed a Letter of Intent to acquire a controlling interest in Emmaus Life Sciences, Inc. well ahead of its FDA PDUFA date for the treatment of sickle cell disease. Unfortunately, due to timing and SEC accounting regulations, we were not able to complete the acquisition ahead of the FDA approval, which Emmaus received on July 5, 2017, as predicted. Though the transaction did not result in a final deal, this case demonstrates NuGenerex management's credibility in identifying "winners" and a "winning platform" in the FDA approval process.

- We would like to congratulate Emmaus CEO Dr. Yutaka Niihara and his team at Emmaus for the approval and wish them the best of everything as they seek to commercialize L-Glutamine to help this underserved patient population. Once the pharmacy network acquisition is complete, we plan to work with Emmaus to implement a distribution and patient access strategy.

- It is important to note that Emmaus repaid $4 million in advance payments to NuGenerex, a portion of which was used to retire a convertible note and the balance of which has been and will be used to support the go-forward operational plans for the Company as we move into 2018.

- In mid-year, we signed another Letter of Intent to acquire a controlling interest in Core Tech Solutions, Inc., a transdermal drug delivery company with patented and differentiating adhesive and film technologies. The company also holds patents in the field of opioid anti-abuse formulations and disposal systems that have significant commercial potential.

- The primary drivers of valuation for the Core Tech acquisition were three licensing and manufacturing agreements that Core Tech had signed with two “Big Pharma” partners for the development of three new prescription pharmaceutical patches. The agreements included 100% payment of the clinical development costs, exclusive manufacturing contracts, and royalties on sales.

- Unfortunately, those Big Pharma partners ultimately elected not to proceed with those arrangements (for reasons unrelated to the quality of the Core Tech technologies). The cancellation of the contracts and associated projected revenues required that we renegotiate the valuation of Core Tech for the purposes of an acquisition transaction. To date, the parties have yet completed renegotiation of a deal structure and price, so the Letter of Intent has been cancelled; we wish Core Tech much future success.

We plan on restructuring NuGenerex into three operating subsidiaries to drive the intrinsic value of the Company’s patented platform technologies in cancer immunotherapy, rapid diagnostic testing, and drug formulation & delivery systems. We are establishing NuGenerex Immuno-Oncology based on AE37 and the Ii-Key immunotherapy platform, NuGenerex Global Diagnostics to develop and market point-of-care diagnostic test kits by HDS, and NuGenerex Drug Delivery Systems to advance Generex Ora-lyn® buccal insulin for the treatment of diabetes. Additionally, the Company is preparing to launch NuGenerex Health Care and Clinical Finance, designed to be a joint venture subsidiary with a healthcare investment fund as a financing partner. We will aim to provide our research and development partners with customized financial instruments designed to support medical customers with health care receivables (HCR) and clinical research institutions with rapid clinical trial advance (RCTA) payments. Through proprietary financing solutions, we plan to strategically partner with global biopharmaceutical companies, hospitals and health systems, and research institutions and investigators to bring financial stability and operational efficiency to clinical research and medical practice.

Each of these NuGenerex divisions will seek to leverage the corporate restructuring through collaborative development and commercialization of our core assets, as well as through strategic acquisitions of companies, technologies, and intellectual properties that meet our regulatory and commercial standards in therapeutic sectors of high medical and economic value. Our core assets are back on track with robust clinical development programs and co-development partners heading into the new year, and we will provide further updates throughout the first quarter of 2018.

Most importantly, we seek to emerge in 2018 as an operational, revenue generating, and profitable Company with the launch of NuGenerex Distribution

Solutions, LLC once the targeted pharmacy acquisitions are completed. The foundational acquisitions of pharmacy assets, operations, databases, and logistics systems will form the backbone for delivery of direct-to-patient solutions in areas of high unmet medical need, including drugs, medical devices, and educational materials that will help chronic disease patient populations achieve optimal clinical outcomes. NuGenerex Distribution Solutions will be designed to provide a managed care platform that generates recurring revenue streams through reimbursements from private health insurance plans and Medicare Parts B, D, and E. As negotiations become definitive, we will announce more details on the plan, as well as our financial and pharmacy partners. We would like to acknowledge Brooks Houghton & Company, a merchant banking firm that we have retained to provide M&A advisory services; the team at Brooks Houghton have been integral in shepherding the pharmacy network acquisition plans through preliminary due diligence efforts, financial analysis & modeling, and deal structures.

In 2018, rebranded as NuGenerex Life Science Holdings, Inc., we will be focused on generating significant revenues and profits, and executing on our acquisition strategy and development programs. Through our continued, dedicated efforts, we are targeting an up-listing for NuGenerex to a national stock exchange this year, further demonstrating our commitment to building shareholder value. We are energized for the new year and look forward to leading NuGenerex into the future.

Sincerely,
Joseph Moscato
President & Chief Executive Officer

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This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or

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Generex Contact:

Joseph Moscato
646-599-6222

Generex Biotechnology Corporation
Todd Falls
800-391-6755
Extension 222
investor@generex.com