

**Moderator:**

Good morning and thank you for joining today's conference call to discuss Generex Biotechnology's corporate update.

**<Anthony Crisci - Read Safe Harbor>**

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Forward-looking statements included in this presentation are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as "may," "could," "expect," "intend," "plan," "seek," "anticipate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other comparable terminology. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond our control and that could materially affect actual results, levels of activity, performance, or achievements. A more detailed description of these and other risks and uncertainties may be found in our Annual Report on Form 10-K and other public filings with the Securities and Exchange Commission.

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Now I would like to turn the call over to Joe Moscato, president & chief executive officer of Generex Biotechnology Corporation

**Joe Moscato – Generex Introduction**

Good Morning everyone. On behalf of myself, Generex's executive management team, and the Generex's Board of Directors, I would like to welcome our fellow stockholders and other interested parties to this morning's conference call.

As we continue to execute on our plan to transform Generex into an integrated life science holdings company that offers end-to-end solutions for physicians and patients, I feel that it is important to have these investor calls on a regular basis to communicate our operational progress, our strategic plans, and our M&A activities in order to provide transparency to the market. To that end, we are happy to provide this progress report, starting with our ongoing operations.

### **NuGenerex Distribution Solutions (NDS)**

Since acquiring the Veneto assets in November, Terry Thompson Generex Chief Operating Officer and President of NDS, together with Anthony Crisci, Esq., CPA our General Counsel and Chief Legal Compliance Officer have been working diligently to integrate, reorganize, and streamline the MSO and pharmacy businesses that we acquired. We are happy to report that we have expanded our MSO services from 3 states to 5 states, and we project continued growth through 2019 as we build out a sales and marketing effort and introduce new products and services to support our MSO with end-to-end solutions for patient care. I will now turn the call over to Terry:

### **Terry Thompson**

NuGenerex Distribution Solutions continues to rationalize the Veneto acquisition and is focused on restructuring our sales strategy by streamlining its administrative processes to speed the sales cycle and by adding new products and services to the sales. We are working on expanding our state presences and are close to adding our 6<sup>th</sup> state with a combined MSO and DMEiq sales contract. Meanwhile we have also finished our beta site work on our first DMEiq contract and revenues began to be realized the first week in February. This second product developed to sell to our existing targeted investors and their staff provides a second revenue source opportunity in addition to the MSO Investment in Ancillary services. This product allows for total front to finish management of the Physician's Practice for its DME products with advanced analytical technologies developed to determine the opportunity to pursue a practice as a sales opportunity. It then provides inventory and procurement management, and streamlines the patients experience in the Physician practice ensuring all copays are collected and that the billing takes place and ties into their EMR system utilizing a handheld pad. We have also signed

a second contract for the MSO ancillary services investment which could double our revenue from our Oklahoma base. We are just beginning to embark upon a renewed sales effort. We have also analyzed our delivery platforms and have adopted a pharmacy network management strategy going forward in lieu of bricks and mortar in order to maximize our profits, avoid the regulatory, licensing and contracting bureaucracy also allowing for most of our resources to be focused on sales, marketing and new products and services. We are also in the middle of due diligence on four distribution platform companies in the patient acquisition arena, as well as, surgical and biologic products with a desire to close as soon as complete.

## **OLAREGEN**

As previously reported, Generex has acquired 51% of Olaregen, a regenerative medicine company that is launching our first product, Excellagen™. Additionally, we have been able to obtain an additional 10% of the company from Olaregen investors who are exchanging their shares for Generex shares. Excellagen is FDA-cleared for 17 wound care indications, including post-surgical wounds, diabetic foot ulcers and venous stasis ulcers, post-MOS skin cancer surgery, and cosmetic dermatology applications.

To date, Generex has funded Olaregen with \$1.4 million to support manufacturing and pre-launch activities.

I will now turn the call over to Anthony Dolisi, Generex Head of Commercialization and CEO of Olaregen to comment:

### **Anthony Dolisi**

Launching our first product in April, Olaregen has been extremely active in promoting Excellagen® and growing our business through external relationships, complimentary co-promote partners, Key Opinion Leaders and medical societies and associations. The completion of our comprehensive Sales Training Modules, and with the hiring of a number of experienced specialty sales representatives, we are poised to enter the market with our 0.8cc syringe selling into the VA in-patient and wound care clinics, the DOD, and in-hospital surgical settings. With the supporting data on Excellagen features and benefits, together with our value-based pricing, we anticipate early uptake in these markets.

We are also generating new data on the use of Excellagen in wound care. Dr. Lois Chandler has prepared a subset analysis of the Excellagen Phase 2b Study and developed a manuscript for publication in a peer-reviewed wound care journal. Co-authors include Robert Kirsner, MD,

William Marston, MD, Oscar Alvarez, MD, Peter Blume, DPM and Paul Kim, DPM. Olaregen will participate in the Diabetic Limb Salvage Meeting in Washington, DC, April 4<sup>th</sup>- 6<sup>th</sup> where we plan to meet with the community of Podiatric Surgeons in attendance. Dr. Chandler submitted an abstract on the subset analysis, and she is planning to present the results during the scientific poster sessions. Olaregen will also attend the SAWC Spring Meeting planned for San Antonio, TX, May 7-11, 2019. SAWC is attended by 2,300 wound management professionals including podiatric, vascular, and plastic surgeons all of whom are customers for Excellagen.

Olaregen is engaged in discussions with a specialty dermatologic company to co-promote Excellagen in the derma market. This joint venture will focus on Excellagen in the treatment of post-MOHs surgical wounds, as well as for healing from aesthetic and cosmetic procedures like chemical peels and laser skin resurfacing. Olaregen is finalizing the company's supply chain, initiating contracts with McKesson and 3PL, the primary organizations responsible for product ordering, fulfillment and storage.

If anyone is interested in learning more about our company and Excellagen while attending the aforementioned medical meetings, please stop by our booth to learn more about our activities and plans in the regenerative medicine wound care business.

## **Regentys**

At Regentys, we have just concluded our audit and are finalizing financial disclosures. We have been working on product manufacturing criteria, documenting product development specifications and working with our partners to finalize a protocol and initiate our first-in-human trials in Australia later this year.

To date, Generex has funded Regentys with \$1,050,000 (one million fifty thousand dollars) to support their manufacturing and clinical development efforts.

I now turn the call over to Rick Bulman, CEO of Regentys to comment on our progress:

## **Rick Bulman**

## **FUSE Medical**

Moving on to our M&A activities for NDS, we are finalizing terms to acquire Fuse Medical, a successful and profitable manufacturer and distributor of surgical supplies and biologics for

orthopedic surgery and regenerative medicine. As previously reported, the transaction is structured as an all-stock deal valued at \$34 million of Generex common stock at \$2.50 per share with the potential for earnouts based on certain performance in 2019. Fuse is a publicly-traded company with revenues approaching \$30 million and EBITDA of approximately \$6.5 million – see their SEC filings for details. The deal is not dilutive to our shareholders, as the payment is being made from the Generex pool shares., priced at \$2.50 per share.

We are extremely pleased to bring Fuse into the NuGenerex family of subsidiary companies. Not only does Fuse bring a broad portfolio of specialty surgical products and biologics, but we will also be able to utilize their sales and distribution channels to expedite the launch of Excellagen as well as other products and services from our subsidiary companies in the fields of surgical care and regenerative medicine.

I will now turn the call over to Chris Reeg, CEO of Fuse for comment:

**Chris Reeg**

For detailed information on Fuse Medical, you can visit their website at [www.fusemedical.com](http://www.fusemedical.com).

**Pantheon & Medisource**

To complement the Fuse acquisition, and as previously reported, we are in the final stages of due diligence to acquire Medisource Partners, a specialty distribution company, and Pantheon Medical – Foot & Ankle, a manufacturer of specialty orthopedic surgery products and tools. Under the terms of the deal, Generex will acquire all of the assets of Medisource and Pantheon for a total of \$2.4 Million worth of Generex stock from the pool shares, plus additional cash and stock consideration upon achieving certain sales and profit goals.

With Pantheon and Medisource integrated with Fuse Medical, NuGenerex Distribution Solutions will provide access to a whole new line of products that enhance our current MSO network currently operating in five states, and eventually expanding into 27 states.

Additional details on the Medisource and Pantheon transactions will be disclosed in 8Ks to be filed with the SEC. I will now turn it over to Travis H. Bird for a few words:

**Travis Bird**

## **Nationwide Pharmacy**

After a year of due diligence and a significant amount of accounting effort, we have finally completed our audits of the nationwide pharmacy network, and we are finalizing the terms of the acquisition, which is expected to close in the second quarter. This acquisition will round out our MSO business and enable nationwide direct-to-patient offerings for medication services, disease management, and chronic care solutions to achieve improved outcomes and lower costs. In the coming week to 10 days, we will announce the transaction terms and provide specific details on the acquisition and integration of the pharmacy network, which we plan to close shortly, pending approvals by regulators.

## **Hospital Network**

The new piece of the puzzle for NDS is the acquisition of a multi-hospital network and a hospital billing and management company. We are in the final stages of discussion on acquisition terms, which will enable Generex to acquire the hospitals and management company that generate over \$100 million in revenues and significant EBITDA for \$5 million in cash plus \$5 million in Generex stock from the pool shares. The hospitals are designated by the Centers for Medicare and Medicaid as Critical Access Hospitals, which provide significant financial and operational benefits, including:

- Cost-based reimbursement from Medicare. As of January 1, 2004, CAHs are eligible for allowable cost plus 1% reimbursement. In some states CAHs may also receive cost-based reimbursement from Medicaid.
- Flexible staffing and services, to the extent permitted under state licensure laws.
- Capital improvement costs included in allowable costs for determining Medicare reimbursement.
- Access to Flex Program educational resources, technical assistance, and/or grants.

The CAH hospitals provide networks of physicians and healthcare programs, as well as patient populations with significant medical needs. Generex and our subsidiary companies plan to offer our wide range of drugs, surgical products and biologics, medical devices, and service offerings to not only grow the revenues of Generex, but also to improve the health and wellbeing of rural communities in the network. These hospitals are well positioned to take advantage of the impending allocation of VA services to the private sector, as well as telemedicine initiatives that are reimbursable in these communities. We will provide additional information as this acquisition advances through the due diligence process.

## **NuGenerex Immuno-Oncology**

Congratulations to all of our shareholders. I am happy to announce that the dividend in NuGenerex Immuno-Oncology was paid yesterday, with Generex shareholders receiving 1 share of NuGenerex Immuno-Oncology for every 4 shares of Generex held as of the record date.

Moving forward, we have identified a clinical stage immunotherapy company, and have engaged the management and board in discussion on a merger. Also, we plan to license AI technology and additional immune system activation platforms from a major research institute. Lastly, we are in discussions with several groups on potential co-development agreements.

I will now turn the call over to Eric Von Hofe, President of NuGenerex IO for a clinical operations update on the FB-14 trial of AE37 in combination with Merck's Keytruda for the treatment of triple negative breast cancer:

### **Eric von Hofe**

Clinical Supply for both Merck and Antigen are in the process of secondary packaging and labeling for clinical trial purposes and are expected to be available for site distribution in mid-March 2019. We received IRB approval for the FB-14 study on February 13, 2019 from the central IRB, Advarra, and we have selected the following sites for study participation; these sites were notified by NSABP on February 14, 2019, and include:

University of Pittsburgh, West Virginia University, Allegheny General Hospital, Cancer Care Specialists of Decatur Illinois, and Cleveland Clinic.

NSABP is now working with the aforementioned sites in all aspects of study startup in an effort to get them activated as soon as possible, with a projected first site activated in early April, and a respective First Patient First Visit soon thereafter.

## **NuGenerex Diagnostics**

For a discussion on NuGenerex Diagnostics (NGDx), I will turn the call over to Dr. Hal Haines, President:

### **Hal Haines**

NGDx designed and developed The **NGDx-Express II Rapid Point-of-Care Platform** for Detection of Infectious Diseases, a patent for which has been submitted. The NGDx-Express II Platform

was explicitly designed to be used in professional medical settings, AND for Individual home use without the need for trained personnel to perform. For home use, individuals can accurately perform tests on themselves in privacy, maintaining anonymity, which may be desired, especially for sexually transmitted diseases like syphilis and HIV.

The company applied for and was granted the CE marking by the European Union Regulatory Authority for commercialization of the **NGDx-Express II Test for Syphilis Antibodies** in the European Union and is now canvassing distribution partners. There is currently a worldwide epidemic of syphilis. The treatment and control of this disease depends on accurate and easy-to-use diagnosis. The NGDx Express II Test for Syphilis Antibodies is a rapid point-of-care diagnostic device which allows diagnosis of syphilis in 15 minutes or less and can be self-administered.

The company is preparing to submit a 510k application to the United States FDA for the **NGDx-Express II Test for Syphilis Antibodies** for the eventual commercialization of the product in the United States.

The company has also formulated plans, including development staging, milestones and the selection of commercial partners for the design and development of a proprietary qualitative rapid point-of-care multiplex biomarker assay for the detection and clinical staging of sepsis.

### **Banking**

We are proud to announce that Generex has engaged a top three investment bank, and we are working with several funds to bring in an infusion of non-dilutive capital to complete that projected acquisitions of the pharmacy and hospital networks, the launch of our new products and services, and to advance the mission of Generex as an integrated life science holdings company.

### **Emerging Opportunities in Nutrition**

As we continue to build out our product and services offerings to provide end-to-end healthcare solutions for physicians and patients, we plan to expand our offerings into holistic medicine with the acquisition of two highly successful companies in the medical meal and nutraceutical sectors. Medical meals and nutritional supplements are essential elements of patient centric care, with the clinical data clearly demonstrating improvement in health status and reduction in hospital admission rates for patients who receive home delivery of chronic care meals, including patients with cancer, cardiovascular disease, diabetes, and



rheumatoid arthritis. Medicaid programs in several states cover home delivery of medically approved meals, and the acquisition target has an ongoing business that is projected to grow substantially. Starting in 2020, it is expected that medical meals will be covered under Medicare, as CMS has proposed Medicare Advantage and Part D payment and policy updates to maximize competition and coverage (CMS.gov Jan 30, 2019). These potential acquisitions for the NuGenerex family of companies will add new products and service lines, as well as significant revenues and profits for the Generex holding company. I will provide updates on our progress with acquiring these nutrition-focused organizations.

## **Wrap-up**

Thank you all for your time and attention today. In this exciting time for Generex, we are executing on our strategic goals to build Generex through M&A and operational excellence as an integrated life science holding company with significant revenues and projected profits. We have made significant progress in our plan through the additions of great companies with surgical products, innovative regenerative medicine technologies, and biologics, and two surgical and medical supply companies with proprietary distribution channels and synergies throughout the organization. The target acquisitions of the hospital and pharmacy networks that we expect to complete in the coming weeks will provide the backbone for achieving our corporate goals and business objectives.

As you can see, we've been re-building Generex into a revenue generating and cutting-edge development company with a best in class executive team that has the experience and expertise to lead the new Generex into the future. Management is excited about what the future holds, and though the inherent value of the acquisitions hasn't yet been reflected in our stock price, we are confident, as we continue to execute on our strategy, that the market and new shareholders will recognize our vision to build Generex into a new kind of healthcare company that is more responsive to the needs of different stakeholders in the healthcare value chain with offerings in a variety of services, diagnostics, medical devices, and pharmaceutical development.

Now we'll now open the lines for a few questions from our shareholders.