

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 1.01 Entry into a Material Definitive Agreement.

As previously reported, on November 28, 2018, Generex Biotechnology Corporation (the “Company”) and Regentys Corporation. (“Regentys”) entered into a binding letter of intent (“LOI”) contemplating the Company’s acquisition of 51% of the outstanding capital stock of Regentys for a total consideration of fifteen million dollars (\$15,000,000). On January 7, 2019 the Company completed a definitive Stock Purchase Agreement and related documents effecting the transactions contemplated by the LOI.

Consideration for Proposed Acquisition

Pursuant to a Stock Purchase Agreement between the Company and Regentys (the “Purchase Agreement”) the Company purchased 12,048,161 newly issued shares of the Regentys common stock representing 51% percent of the issued and outstanding capital stock of Regentys (“Regentys Shares”).

In addition to \$400,000 paid to Regentys upon signing of the LOI, the purchase price for the Regentys Shares will consist of the following cash payments, with the proceeds intended to be used for specific purposes, as noted:

- \$3,450,000 to initiate pre-clinical activities on or before January 15, 2018.
- \$2,000,000 to initiate patient recruitment activities on or before May 1, 2019.
- \$3,000,000 to initiate a first-in-human pilot study on or before September 1, 2019.
- \$5,000,000 to initiate a human pivotal study on or before February 1, 2020.
- \$1,150,000 to submit a 510(k) de novo submission to the FDA on or about February 1, 2021.

The Company issued its Promissory Note in the amount of \$14,600,000 (the “Note”) representing its obligation to pay the above amounts. The Note is secured by a pledge of the Regentys pursuant to a Pledge and Security Agreement. In the event that Generex does not make any of the first three payments listed above, at Regentys’ option either:

- Generex will forfeit all of the Regentys shares issued with no refund of amounts paid; or
- Generex will issue shares of its common stock to Regentys equivalent to 110% of the value of the missing payment, which shares will be registered for resale.

In the event Generex does not make either or both of the fourth and fifth payments, its share ownership of Regentys will be proportionately reduced.

Financial Statement Condition

- Regentys is required to deliver, within sixty (60) calendar days of the Closing Date, its audited financial statements required by SEC regulations. In the event that the financial statements are not timely delivered, Generex will have the option to rescind the transaction, in which event all payments made prior to such rescission will be repaid by Regentys to Generex.

Shareholders Agreement

Pursuant to an Amended and Restated Shareholders Agreement (the “Shareholders Agreement”) among Regentys, Generex, and shareholders of Regentys holding a majority of the shares not owned by Generex:

No shareholder, including Generex, may sell its shares of Regentys without first offering the shares to Regentys and to the other shareholders.

- The Regentys Board of Directors will consist of
 - The CEO of Regentys and one other Regentys officer nominated by the holders of Generex Common Stock For so long as Generex owns at least fifty-one percent (51%) of the issued and outstanding common stock of Regentys, the CEO of Generex or another officer of Generex nominated by the Generex Board and reasonably acceptable to the other directors of Regentys
 - A designee of the holders of Regentys Series A Convertible Preferred Stock
 - Three Independent Directors elected by the holders of Regentys’ common stock, voting a separate class.

Management Services Agreement

In connection with the Purchase Agreement, Regentys entered into a Management Services Agreement with its founders and officers, Richard C. Bulman, Jr., Gerard S. Coombs and Gary Ramphal. The Management Services Agreement contains provisions which could require Generex to take certain actions to provide liquidity for the other Regentys shareholders. Provided Regentys revenues or value meets certain milestones, the Founders can require Generex to undertake an initial public offering of Regentys stock or seek to sell Regentys to a third party. In the event Joseph Moscato is no longer the CEO of Generex, the Founders can require this without Regentys meeting to the revenue and value milestones. In addition, beginning one year after the date of the Management Services Agreement, each Founder shall have the right to request that Generex assist such Founder with obtaining a loan from a third party lender secured by the Regentys stock owned by such Founder and/or the Generex stock issued to such Founder under a Generex stock plan. This assistance would include agreeing with a lender to exchange Generex stock for Regentys stock in the event of a default by the Founder.

The foregoing descriptions of the Purchase Agreement, Note, Shareholders Agreement, Pledge and Security Agreement and Management Agreement are not complete and are qualified in its entirety by reference to the documents is filed as Exhibits 10.1-10.5 to this report and incorporated herein by reference. .

Forward-Looking Statements

Statements in this report may contain certain forward-looking statements. All statements included concerning activities, events or developments that the Generex expects, believes or anticipates will or may occur in the future are forward-looking statements. Actual results could differ materially from the results discussed in the forward-looking statements. Forward-looking statements are based on current expectations and projections about future events and involve known and unknown risks, uncertainties and other factors that may cause actual results and performance to be materially different from any future results or performance expressed or implied by forward-looking statements. Known risks and uncertainties also 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 events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex cannot be sure when or if it will be permitted by regulatory agencies to undertake additional clinical trials or to commence any particular phase of clinical trials. Because of this, statements regarding the expected timing of clinical trials or ultimate regulatory approval cannot be regarded as actual predictions of when Generex will obtain regulatory approval for any “phase” of clinical trials or when it will obtain ultimate regulatory approval by a particular regulatory agency. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act. Additional information on these and other risks, uncertainties and factors is included in the Company’s Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed with the SEC.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of a Business Acquired.

In accordance with Item 9.01(a), the Consolidated Financial Statements of Regentys Corporation required by Item 8-04 of regulation S-X will be filed by amendment to this Current Report within 71 days after the date of this Current Report.

(c) Pro forma financial information.

Pro Forma financial information required by Item 9.01(c) will be filed by amendment to this Current Report within 71 days after the date of GenereX's this Current Report .

(d) Exhibits.

The list of exhibits called included in this Current Report is incorporated by reference to the Exhibit Index filed with this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GENEREX BIOTECHNOLOGY CORPORATION.

Date: January 11, 2019 /s/ Joseph Moscato
Joseph Moscato
President and CEO

Exhibit Index

Exhibit No.	Description
10.1	Stock Purchase Agreement between Regentys Corporation and Generex Biotechnology Corporation as of January 7, 2019.
10.2	Promissory Note issued by Generex Biotechnology Corporation to Regentys Corporation.
10.3	Pledge and Security Agreement between Generex Biotechnology Corporation and Regentys Corporation.
10.4	Amended and Restated Shareholders Agreement of Regentys Corporation.
10.5	Management Services Agreement among Regentys Corporation and its officers.

