

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): May 28, 2019

BIONIK LABORATORIES CORP.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or
Organization)

000-54717

(Commission File Number)

27-1340346

(IRS Employer Identification No.)

483 Bay Street, N105
Toronto, ON

(Address of Principal Executive Offices)

M5G 2C9

(Zip Code)

Registrant's Telephone Number, Including Area Code: (416) 640-7887

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions *see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Not applicable

Trading Symbol
Not applicable

Name of each exchange on which registered
Not applicable

Item 8.01 Other Events.

Bionik Laboratories Corp. (the "Company") issued a press release on May 28, 2019, announcing the completion of a landmark Robot Assisted Training for the Upper Limb after Stroke (RATULS) trial utilizing the Company's InMotion Robotic Therapy Systems. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

| Exhibit | Description |
|----------------|---|
| <u>99.1</u> | <u>Press Release dated May 28, 2019</u> |

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.

Date: May 28, 2019

BIONIK LABORATORIES CORP.

By: /s/ Leslie Markow

Name: Leslie Markow

Title: Chief Financial Officer



Landmark RATULS Research Trial of Robot-Assisted Stroke Therapy Utilizes BIONIK's InMotion Robotic Therapy Systems

Outcomes of trial, funded by The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Program, presented at 5th European Stroke Organisation Conference (ESOC) in Milan

TORONTO and BOSTON (May 28, 2019)– **BIONIK Laboratories Corp. (OTCQB: BNKL)** ("BIONIK" or the "Company"), a robotics company focused on providing rehabilitation and assistive technology solutions to individuals with neurological and mobility challenges from hospital to home, today announced the completion of a landmark [Robot Assisted Training for the Upper Limb after Stroke \(RATULS\)](#) trial utilizing the Company's InMotion Robotic Therapy Systems.

Results of the RATULS trial were presented at the European Stroke Organisation Conference (ESOC) in Milan, Italy on May 22, 2019 and published in the Lancet Online Journal on the same day. The study's purpose was to compare clinical effectiveness of robot assisted training, enhanced upper limb therapy, and usual care for patients with moderate or severe upper limb functional limitation. The RATULS trial began in 2014 and was completed end of 2018.

"We are pleased that the RATULS trial confirmed the finding of previous research studies which demonstrated that robot-assisted therapy improved upper limb impairment when compared with conventional care methods for stroke victims. The trial's finding that robotic therapy is the only therapy to statistically maintain a significant impairment advantage at six months after treatment is a strong signal that robotic therapy is critical for achieving positive patient outcomes," said Dr. Eric Dusseux, CEO, BIONIK Laboratories. "BIONIK's InMotion Robotic Therapy Systems have been selected for some of the largest interventional research studies over the past 10 years, including the Veterans Affairs Robotics Trial which confirmed robot-assisted therapy improvement in upper limb impairment using the Fugl-Meyer Assessment (FMA), a stroke-specific, performance-based impairment index. In the VA study, the impairment advantage achieved through robot-assisted therapy translated into significant upper limb function improvements using the Wolf Motor Function Test."

For the RATULS trial, the primary outcome for upper limb success was determined by Action Research Arm Test (ARAT), with four distinct success criteria that varied according to baseline severity, not used previously and developed by the RATULS trial team. Although the findings demonstrated that robot-assisted therapy improved upper limb impairment, using this ARAT measurement, the trial was unable to conclude that robot-assisted therapy or enhanced upper limb therapy resulted in improved upper limb functionality after stroke compared with usual care provided to patients with stroke-related upper limb functional limitation. The attrition rate was also drastically reduced in patient population following either robotic therapy or enhanced upper limb therapy versus usual care only, and most of the withdrawals before 3 months in usual care were due to disappointment with treatment allocation.

BIONIK

BIONIK recognizes the difficulty of creating a level playing field for comparing technology-assisted therapy to conventional methods and commends Professor Helen Rogers and her UK research team for their diligent undertaking and extensive study of 770 patients over a four-year time period.

“We appreciate the ongoing medical study of innovative technology designed to improve patient recovery from stroke. We are also grateful for the extensive feedback provided by patients and clinical practitioners over the past three years as we have actively researched and developed improved capabilities for our robotic rehabilitation systems,” said Dr. Dusseux. “The combination of evidenced-based medicine and real-world clinical feedback have led to the release of substantially improved versions of the InMotion ARM™ Robotic Therapy System announced in early 2018, and the InMotion ARM/HAND™ Robotic Therapy System announced beginning of 2019. These versions of our products include enhanced software applications with patient-centric configurable protocols to assist the therapist in providing specialized treatment of stroke and traumatic brain injury. BIONIK looks forward to providing the most advanced solutions to allow clinicians to develop the appropriate rehabilitation methods to address upper limb impairment and reduced arm function. We have seen robotic therapy utilized effectively due to its inherent repeatability and predictability which facilitates the standardization of treatment protocols and consistent measurement of patient progress, another great way to reinforce the patient’s motivation.”

BIONIK’s InMotion Robotic Systems have now been utilized in two of the largest interventional trials completed for upper limb evaluation in the past 10 years. The Company’s robotic-assisted rehabilitation technologies were previously utilized in a trial led by the Providence Veteran Affairs Medical Center, involving 127 patients with moderate-to-severe upper-limb impairments six months or more after stroke. The results of that study were published in [The New England Journal of Medicine](#) in April of 2010.

To read the complete RATULS study, please visit the [Lancet Online Journal](#).

About BIONIK Laboratories Corp.

BIONIK Laboratories is a robotics company focused on providing rehabilitation and mobility solutions to individuals with neurological and mobility challenges from hospital to home. The Company has a portfolio of products focused on upper and lower extremity rehabilitation for stroke and other mobility-impaired patients, including three products on the market and four products in varying stages of development.

For more information, please visit www.BIONIKlabs.com and connect with us on [Twitter](#), [LinkedIn](#), and [Facebook](#).



Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "should," "would," "will," "could," "scheduled," "expect," "anticipate," "estimate," "believe," "intend," "seek," or "project" or the negative of these words or other variations on these words or comparable terminology. Forward-looking statements may include, without limitation, statements regarding (i) the plans and objectives of management for future operations, including plans or objectives relating to the design, development and commercialization of human exoskeletons and other robotic rehabilitation products, (ii) a projection of income (including income/loss), earnings (including earnings/loss) per share, capital expenditures, dividends, pipeline of potential sales, capital structure or other financial items, (iii) the Company's future financial performance, (iv) the market and projected market for our existing and planned products and (v) the assumptions underlying or relating to any statement described in points (i), (ii), (iii) or (iv) above. Such forward-looking statements are not meant to predict or guarantee actual results, performance, events or circumstances, and may not be realized because they are based upon the Company's current projections, plans, objectives, beliefs, expectations, estimates and assumptions, and are subject to a number of risks and uncertainties and other influences, many of which the Company has no control. Actual results and the timing of certain events and circumstances may differ materially from those described by the forward-looking statements as a result of these risks and uncertainties. Factors that may influence or contribute to the inaccuracy of the forward-looking statements or cause actual results to differ materially from expected or desired results may include, without limitation, the Company's inability to obtain additional financing, the significant length of time and resources associated with the development of our products and related insufficient cash flows and resulting illiquidity, the Company's inability to expand the Company's business, significant government regulation of medical devices and the healthcare industry, lack of product diversification, volatility in the price of the Company's raw materials, and the Company's failure to implement the Company's business plans or strategies. These and other factors are identified and described in more detail in the Company's filings with the SEC. The Company does not undertake to update these forward-looking statements.

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