
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): June 7, 2019

Hancock Jaffe Laboratories, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38325
(Commission
File Number)

33-0936180
(I.R.S. Employer
Identification No.)

70 Doppler
Irvine, California 92618
(Address of principal executive offices) (Zip Code)

(949) 261-2900
(Registrant's telephone number, including area code)

N/A
(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:

- 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))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.00001 per share	HJLI	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

Item 8.01 Other Events.

On June 7, 2019, Hancock Jaffe Laboratories, Inc. (the “**Company**”) issued a press release announcing early results from the Company’s first-in-human VenoValve study. A copy of the press release issued by the Company is attached as Exhibit 99.1 and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated June 7, 2019

SIGNATURE

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 hereunto duly authorized.

HANCOCK JAFFE LABORATORIES, INC.

Dated: June 7, 2019

/s/ Robert A. Berman

Robert A. Berman
Chief Executive Officer

HANCOCK JAFFE LABORATORIES INC

Hancock Jaffe Reports Early Positive Results from First-In-Human VenoValve Study

Reflux Significantly Reduced in Four out of Five Patients

IRVINE, California., June 7, 2019 – Hancock Jaffe Laboratories, Inc. (Nasdaq: HJLI, HJLIW), a developer of medical devices that restore cardiac and vascular health, today announced early positive results from its first-in-human VenoValve Study in Bogota, Colombia. Deep venous reflux has been significantly reduced in 4 out of the first 5 patients that have received VenoValves. Reflux is the primary end point for HJLI's ongoing VenoValve trial and is the main cause of severe, chronic venous insufficiency ("CVI") of the deep vein system. All patients had severe CVI prior to receiving their VenoValves. In addition, there have been no serious device related adverse events associated with the VenoValves.

HJLI is reporting on the first 5 patients to receive VenoValves, including one patient that is more than 90 days post VenoValve surgery, and 4 patients that are more than 45 days post VenoValve surgery. The reductions in reflux for the 4 patients with working VenoValves, including the patient that received the VenoValve more than 90 days ago, are significant enough to expect to see a substantial improvement in the CVI symptoms and in the patient's quality of life. In 2 of the 4 patients, reflux has been reduced close to levels seen in patients without CVI. The VenoValve is currently not functioning in one patient.

CVI is a condition that occurs when the valves in the veins of the venous system of the leg are injured or destroyed, causing blood to flow backwards. Reflux is the mainstay for evaluating CVI and is measured using a duplex scan, also known as a doppler test with ultrasound, a non-invasive evaluation of blood flow through veins and arteries.

Dr. Marc H. Glickman, Hancock Jaffe's Senior Vice President and Chief Medical Officer stated, "Reflux is the key because it causes increased venous pressure, which leads to the pain, swelling, and venous ulcers that are common in severe cases of CVI. By significantly reducing reflux, we have already seen substantial clinical improvement in our patient that received the VenoValve more than 90 days ago. Equally as important to me is that we have not experienced any serious adverse events related to the device. We still have a lot of work to do but we are thrilled with our early results."

Secondary end points for the first-in-human VenoValve trial include VCSS measurements and VEINES scores, two well known clinical assessments for venous disease, and VAS scores, a common pain assessment used for patient studies. For the first patient in the study, who received the VenoValve more than ninety (90) days ago, the VCSS score, a measurement of venous disease severity tracked by the clinician, improved 57%; the VEINES scores, the patient's assessment of the impact of the disease on the patient's quality of life, improved 25%; and the VAS score, a widely used measurement in clinical research based upon the patient's own assessment for pain, improved 57%. All comparison scoring is based on assessments pre-surgery and 90 days after surgery. It is too soon after surgery to report secondary endpoints for the other patients.

Robert Berman, Hancock Jaffe's CEO stated, "The clinical numbers are certainly impressive, but what is equally as important is that 4 of the 5 VenoValve patients are beginning to feel better. Patients with severe CVI endure a daily struggle and our ultimate goal is to improve the quality of their lives, without doing harm. We really couldn't ask for more at this point of the study."

HJLI will present a case management report on the VenovValve later today at the Expert Venous Management (“EVM”) conference in Englewood, New Jersey. EVM is a teaching forum open to vascular surgeons, interventional radiologists, interventional cardiologists, cardiologists, phlebologists, general surgeons, and other medical professionals currently treating venous disease. The conference faculty includes key opinion leaders in vascular medicine, and features case presentations and case discussions in an informal, interactive format.

The initial phase of the first-in-human Colombian study will include up to ten patients who suffer from severe CVI. HJLI has implanted VenovValves in 5 patients, and has recently announced that 2 additional patients have been enrolled in the study. HJLI will continue to provide updates on patient enrollment and additional VenovValve implantations. The next data on VenovValve patients will be reported in September of 2019 when multiple VenovValve patients will be at least five months post-surgery.

The purpose of the first-in-human study is to provide HJLI with valuable feedback to make any necessary product modifications or adjustments to the surgical implantation procedure for the VenovValve. HJLI expects to use the data from its first-in-human study in Bogota as part of its Investigational Device Exemption (“IDE”) application which would be submitted to the U.S. Food and Drug Administration (“FDA”) in order to begin the VenovValve U.S. pivotal trial. Approximately 2.4 million patients in the U.S. suffer from CVI due to reflux in the deep venous system, and there are currently no FDA approved treatments for the condition.

About Hancock Jaffe Laboratories, Inc.

HJLI specializes in developing and manufacturing bioprosthetic (tissue based) medical devices to establish improved standards of care for treating cardiac and vascular diseases. HJLI currently has two lead product candidates: the VenovValve®, a porcine based valve which is intended to be surgically implanted in the deep venous system of the leg to treat reflux associated with Chronic Venous Insufficiency; and the CoreoGraftÖ, a bovine tissue based off the shelf conduit intended to be used for coronary artery bypass surgery. For more information, please visit HancockJaffe.com.

Cautionary Note on Forward-Looking Statements

This press release and any statements of stockholders, directors, employees, representatives and partners of Hancock Jaffe Laboratories, Inc. (the “Company”) related thereto contain, or may contain, among other things, certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements identified by words such as “projects,” “may,” “will,” “could,” “would,” “should,” “believes,” “expects,” “anticipates,” “estimates,” “intends,” “plans,” “potential” or similar expressions. These statements are based upon the current beliefs and expectations of the Company’s management and are subject to significant risks and uncertainties, including those detailed in the Company’s filings with the Securities and Exchange Commission. Actual results (including, without limitation, with respect to our first-in-human VenovValve study) may differ significantly from those set forth or implied in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company’s control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

HJLI Press Contacts:

Amy Carmer
Tel: 949-261-2900
Email: ACarmer@HancockJaffe.com

Media & Investor Relations Contact:

MZ North America
Chris Tyson
Managing Director
(949) 491-8235
HJLI@mzgroup.us
www.mzgroup.us
