UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021

OR

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: **001-38325**

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

Delaware	**33-0936180**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Title of Each Class:	Name of Each Exchange on Which Registered:	Ticker Symbol
Common Stock, $0.00001 par value	The NASDAQ Stock Market LLC	HJLI
Warrant to Purchase Commons Stock	The NASDAQ Stock Market LLC	HJLW

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes ☐ No ☒

As of August 10, 2021, there were 8,513,662 shares of common stock outstanding.

HANCOCK JAFFE LABORATORIES, INC.
TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

ITEM 1 – Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
CONDENSED BALANCE SHEETS
(unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 41,039,182	$ 9,334,584
Prepaid expenses and other current assets	399,685	234,467
Total Current Assets	41,438,867	9,569,051
Property and equipment, net	490,418	398,967
Operating lease right-of-use assets, net	387,852	539,974
Security deposits and other assets	34,993	29,843
Total Assets	$ 42,352,130	$ 10,537,835
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 308,881	$ 1,390,362
Accrued expenses and other current liabilities	412,466	1,135,969
Note Payable	312,700	312,700
Deferred revenue - related party	33,000	33,000
Current portion of operating lease liabilities	326,265	314,202
Total Current Liabilities	1,393,312	3,186,233
Long-term operating lease liabilities	84,582	253,746
Total Liabilities	1,477,894	3,439,979
Commitments and Contingencies	-	-
Stockholders' Equity:		
Preferred stock, par value $0.00001, 10,000,000 shares authorized: no shares issued or outstanding	-	-
Common stock, par value $0.00001, 250,000,000 shares authorized, 8,513,662 and 2,541,529 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	85	25
Additional paid-in capital	111,348,343	72,421,242
Accumulated deficit	(70,474,192)	(65,323,411)
Total Stockholders' Equity	40,874,236	7,097,856
Total Liabilities and Stockholders' Equity	$ 42,352,130	$ 10,537,835

See Notes to these Unaudited Condensed Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
CONDENSED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Operating Expenses:				
Selling, general and administrative expenses	1,295,747	839,735	2,472,202	1,837,631
Research and development expenses	1,089,716	706,173	2,721,511	1,216,797
Loss from Operations	(2,385,463)	(1,545,908)	(5,193,713)	(3,054,428)
Other (Income) Expense:				
Interest (income) expense, net	(6,701)	(228)	(9,660)	(2,861)
Change in fair value of derivative liabilities	-	81,276	-	(264,853)
Other expense	(867)	-	(33,272)	-
Total Other (Income) Expense	(7,568)	81,048	(42,932)	(267,714)
Net Loss	$ (2,377,895)	$ (1,626,956)	$ (5,150,781)	$ (2,786,714)
Net Loss Per Basic and Diluted Common Share:	$ (0.28)	$ (1.89)	$ (0.72)	$ (3.49)
Weighted Average Number of Common Shares Outstanding:				
Basic and Diluted	8,512,059	858,572	7,159,782	797,875

See Notes to these Unaudited Condensed Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
CONDENSED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
(unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2021	2,541,529	$ 25	$ 72,421,242	$ (65,323,411)	$ 7,097,856
Common stock issued in public offering	5,914,284	59	38,127,717	-	38,127,776
Common stock issued for exercise of warrants	52,077	1	239,999	-	240,000
Shared-Based Compensation	-	-	106,850	-	106,850
Fair Value of Warrants Issued	-	-	211,976	-	211,976
Net loss	-	-	-	(2,772,886)	(2,772,886)
Balance at March 31, 2021	8,507,890	$ 85	$ 111,107,784	$ (68,096,297)	$ 43,011,572
Shared-Based Compensation	-	-	202,983	-	202,983
Shares issued in satisfaction of trade payable	5,772	-	37,576	-	37,576
Net loss	-	-	-	(2,377,895)	(2,377,895)
Balance at June 30, 2021	8,513,662	85	111,348,343	(70,474,192)	40,874,236

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Capital	Deficit	Equity
Balance at January 1, 2020	717,274	$ 7	$ 57,177,858	$ (56,187,925)	$ 989,940
Common stock issued in private placement offering	52,000	1	24,304	-	24,305
Share-based compensation:	-	-	116,820	-	116,820
Warrants granted to consultants	-	-	14,070	-	14,070
Net loss	-	-	-	(1,159,758)	(1,159,758)
Balance at March 31, 2020	769,274	$ 8	$ 57,333,052	$ (57,347,683)	$ (14,623)
Common stock issued in public offering	192,688	2	1,973,306	-	1,973,308
Share-Based Compensation	-	-	37,717	-	37,717
Net loss	-	-	-	(1,626,956)	(1,626,956)
Balance at June 30, 2020	961,962	$ 10	$ 59,344,075	$ (58,974,639)	$ 369,446

See Notes to these Unaudited Condensed Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)

	For the Six Months Ended June 30,	
	2021	2020
Cash Flows from Operating Activities		

Net loss	$ (5,150,781)	$ (2,786,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	331,281	168,607
Depreciation and amortization	59,058	44,961
Amortization of right-of-use assets	152,122	144,494
Change in fair value of derivatives	-	(264,853)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(125,218)	(104,159)
Security deposit and other assets	(5,150)	-
Accounts payable	(1,083,905)	346,167
Accrued expenses	(532,975)	123,971
Payments on lease liabilities	(157,101)	(144,342)
Total adjustments	(1,361,888)	314,846
Net Cash Used in Operating Activities	(6,512,669)	(2,471,868)
Cash Flows from Investing Activities		
Purchase of property and equipment	(150,509)	(127,786)
Net Cash Used in Investing Activities	(150,509)	(127,786)
Cash Flows from Financing Activities		
Proceeds from private placements of common stock and warrants, net	-	570,341
Proceeds from registered direct offerings of common stock with warrants, net	-	1,973,308
Proceeds from public offering, net	38,127,776	-
Proceeds from issuance of note payable	-	312,700
Proceeds from Warrant Exercises	240,000	-
Net Cash Provided by Financing Activities	38,367,776	2,856,349
Net Increase in Cash, Cash Equivalent, and Restricted Cash	31,704,598	256,695
Cash, cash equivalents and restricted cash - Beginning of period	9,334,584	2,117,286
Cash, cash equivalents and restricted cash - End of period	$ 41,039,182	$ 2,373,981

See Notes to these Unaudited Condensed Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

	For the Six Months Ended June 30,	
	2021	2020
Supplemental Disclosures of Cash Flow Information:		
Cash Paid (Received) During the Years For:		
Interest, net	$ (9,660)	$ (2,861)
Non-Cash Financing Activities:		
Fair value of warrants issued in connection with common stock included in derivative liabilities	$ -	$ 513,534
Fair value of placement agent warrants issued in connection with common stock included in derivative liabilities	$ -	$ 32,502
Fair value of common stock issued in satisfaction of trade payable	$ 37,576	-
Fair value of warrants issued	$ (211,976)	$ -

See Notes to these Unaudited Condensed Financial Statements

HANCOCK JAFFE LABORATORIES, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(unaudited)

Note 1 – Business Organization and Nature of Operations

Hancock Jaffe Laboratories, Inc. is a medical device company developing tissue-based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. The Company's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the current standards of care. Our products which we are developing include: the VenoValve®, a porcine based device to be surgically implanted in the deep venous system of the leg to treat a debilitating condition called chronic venous deficiency ("CVI"); and the CoreoGraft®, a bovine based conduit to be used to revascularize the heart during coronary artery bypass graft ("CABG") surgeries. Both of these products are currently being developed for approval by the U.S. Food and Drug Administration ("FDA"). Our current senior management team has been affiliated with more than 50 products that have received FDA approval or CE marking. We currently lease a 14,507 sq. ft. manufacturing facility in Irvine, California, where we manufacture products for our clinical trials and which has previously been FDA certified for commercial manufacturing of product.

Each of our products will be required to successfully complete significant clinical trials to demonstrate the safety and efficacy of the product before it will be able to be approved by the FDA.

Note 2 – Going Concern and Management's Liquidity Plan

The accompanying unaudited condensed financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

Although we expect to continue incurring losses for the foreseeable future, may never earn revenues large enough to support operations, and may need to raise additional capital to sustain operations, pursue product development initiatives, and penetrate markets for the sale of products, Management believes that our capital resources at June 30, 2021, are sufficient to meet our obligations as they become due within one year after the date of this interim filing, and sustain operations.

Note 3 – Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed financial statements of the Company as of June 30, 2021 and December 31, 2020, and for the three and six months ended June 30, 2021 and 2020. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the operating results for the full year. These unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2020 included in the Company's Form 10-K filed with the SEC on March 31, 2021. The condensed balance sheet as of December 31, 2020 has been derived from the Company's audited financial statements.

Concentrations

The Company maintains cash with major financial institutions. Cash held in United States bank institutions is currently insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000 at each institution. There was an aggregate uninsured cash balance of $40,789,182 as of June 30, 2021.

Net Loss per Share

The Company computes basic and diluted loss per share by dividing net loss attributable to common stockholders by the weighted average number of common stock outstanding during the period. Basic and diluted net loss per common share are the same since the inclusion of common stock issuable pursuant to the exercise of warrants and options, would have been anti-dilutive.

Subsequent Events

The Company evaluated events that have occurred after the balance sheet date through the date the financial statements were issued. Based upon the evaluation and transactions, the Company did not identify any other subsequent events that would have required adjustment or disclosure in the financial statements.

Recent Accounting Standards

In December 2019, the FASB issued ASU No. 2019-12, Simplifying the Accounting for Income Taxes, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. There was not a significant impact to the financial statements from the adoption of this standard.

Note 4 – Property and Equipment

As of June 30, 2021 and December 31, 2020, property and equipment consist of the following:

	June 30, 2021	December 31, 2020
Laboratory equipment	$ 412,342	$ 320,830
Furniture and fixtures	124,093	98,392
Computer software and equipment	91,624	65,078

Leasehold improvements	164,842	158,092
Software	244,479	244,479
	1,037,380	886,871
Less: accumulated depreciation	(546,962)	(487,904)
Property and equipment, net	$ 490,418	$ 398,967

Depreciation expense amounted to $59,058 and $44,961 for the six months ended June 30, 2021 and 2020, respectively. Depreciation expense is reflected in general and administrative expenses in the accompanying statements of operations.

Note 5 – Right-of-Use Assets and Lease Liability

On September 20, 2017, the Company renewed its operating lease for its manufacturing facility in Irvine, California, effective October 1, 2017, for five years with an option to extend the lease for an additional five years at the end of the initial lease term. The initial lease rate was $26,838 per month with escalating payments. In connection with the lease, the Company is obligated to pay $7,254 monthly for operating expenses for building repairs and maintenance.The Company has no other operating or financing leases with terms greater than 12 months.

The Company accounts for this lease following the guidance in ASC Topic 842, Leases, and elected to adopt the short-term lease exception and not apply Topic 842 to arrangements with lease terms of 12 months or less. The Company determined the lease liabilities using the Company's estimated incremental borrowing rate of 8.5% to estimate the present value of the monthly lease payments.

Our operating lease cost is as follows:

	For the Three Months Ended June 30, 2021	For the Six Months Ended June 30, 2021
Operating lease cost	$ 85,492	$ 170,983

Supplemental cash flow information related to our operating lease is as follows:

	For the Three Months Ended June 30, 2021	For the Six Months Ended June 30, 2021
Operating Cash Flow Information:		
Cash paid for amounts in the measurement of lease liabilities	$ 87,981	$ 175,962

Remaining lease term and discount rate for our operating lease is as follows:	June 30, 2021
Remaining lease term	1.3 years
Discount rate	8.5%

Maturity of our lease liabilities by fiscal year for our operating lease is as follows:

Six months ended December 31, 2021	$ 178,599
Year ended December 31, 2022	271,854
Total	$ 450,453
Less: Imputed Interest	(13,422)
Present value of our lease liability	$ 437,031

Note 6 – Accrued Expenses and Other Current Liabilities

As of June 30, 2021, and December 31, 2020, accrued expenses consist of the following:

	June 30, 2021	December 31, 2020
Accrued compensation costs	$ 276,718	$ 473,799
Accrued professional fees	92,500	79,650
Accrued franchise taxes	27,832	25,607
Accrued research and development	15,416	368,809
Accrued warrants	-	188,104
Total	$ 412,466	$ 1,135,969

Note 7 – Note Payable

The note payable consists of the following at June 30, 2021 and December 31, 2020:

Carrying value	$ 312,700
Stated maturity date	April 22, 2022
Stated interest rate	1% per annum

Note 8 – Commitments and Contingencies

Litigations Claims and Assessments

In the normal course of business, the Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records legal costs associated with loss contingencies as incurred and accrues for all probable and estimable settlements.

Robert Rankin Complaints

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned his employment on or about March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020.

The complaints assert several causes of action including a cause of action for failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement, defamation, unlawful labor code violations, sex-based discrimination, and unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages and attorney's fees and costs.

The Company intends to vigorously defend the claims, investigate the allegations, and assert counterclaims. As of the date of these financial statements, the amount of loss associated with these complaints, if any, cannot be reasonably estimated. Accordingly, no amounts related to these complaints are accrued as of June 30, 2021.

Note 9 –Stockholders' Equity

Common Stock

On February 11, 2021, the Company raised $41,400,000 in gross proceeds, with cash offering costs of approximately $3,300,000, in a public offering of 5,914,284 shares of its common stock for a purchase price of $7.00 per share and warrants to purchase 2,957,142 shares of its common stock. The exercise price of the warrants is $7.00 per share, subject to customary adjustments and they expire on February 11, 2026. The warrants had grant date fair value of $4.84 per share for an aggregate grant date fair value of $14,312,567, using the Black Scholes method with the following assumptions used: stock price of $7.53, risk-free interest rate of 0.11%, volatility of 113.1%, annual rate of quarterly dividends of 0%, and a contractual term of 2.5 years. We determined that equity classification of the warrants was appropriate. Accordingly, their value is included in additional paid-in capital.

On April 26, 2021, the Company issued 5,772 shares with a value of $6.51 per share, or $37,576, in satisfaction of a trade payable.

Warrants

In November 2020 the Company's Board of Directors approved the issuance of warrants to purchase 6,400 shares of common stock to an advisor and warrants to purchase 20,000 shares of common stock to certain participants in the preferred share exchange. Separately the Company agreed to re-price warrants issued to the placement agent for the Company's February 25, 2020 private placement. These warrants and the re-priced warrant were issued in February 2021. The value of these warrants when they were issued $211,976. The Company determined their value using the Black-Scholes method with the following assumptions: stock price of $8.91 - $9.31, risk-free interest rate of 0.47%, volatility of 113%, annual rate of quarterly dividends of 0%, and an expected term of 2.5 to 3.5 years.

Stock Options

From time to time, the Company issues options for the purchase of its common stock to employees and others. Share-based compensation related to stock options is included in selling, general and administrative expenses on the accompanying statement of operations, and was $0.3 and $0.2 million of during the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, there was $1.5 million of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 2.2 years.

Note 10 – Net Loss per Share

The following table summarizes the number of potentially dilutive common stock equivalents excluded from the calculation of diluted net loss per common share as of June 30, 2021 and 2020:

	June 30,	
	2021	**2020**
Shares of common stock issuable upon exercise of warrants	4,402,032	438,072
Shares of common stock issuable upon exercise of options	386,096	96,689
Potentially dilutive common stock equivalents excluded from diluted net loss per share	4,788,128	534,761

Note 11 – Related Party Transactions

On June 8, 2021, the Company updated its agreement with the vendor affiliated by common ownership and control with a shareholder holding approximately 10% of the Company's outstanding common stock. The Company engaged this vendor to provide support in the VenoValve U.S. pivotal trial. Expenditures to that vendor were approximately $0.4 million during the six months ending June 30, 2021, and are included in in Research and Development expenses in the accompanying statement of

operations.

Item 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our unaudited condensed financial statements and notes thereto included herein. In connection with, and because we desire to take advantage of, the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, we caution readers regarding certain forward-looking statements in the following discussion and elsewhere in this report and in any other statement made by, or on our behalf, whether or not in future filings with the Securities and Exchange Commission. Forward-looking statements are statements not based on historical information and which relate to future operations, strategies, financial results or other developments. Such forward-looking statements involve significant risks and uncertainties. Forward looking statements are necessarily based upon estimates and assumptions that are inherently subject to significant business, economic and competitive uncertainties and contingencies, many of which are beyond our control and many of which, with respect to future business decisions, are subject to change. These uncertainties and contingencies can affect actual results and could cause actual results to differ materially from those expressed in any forward-looking statements made by, or on our behalf. Words such as "anticipate," "estimate," "plan," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions are used to identify forward-looking statements. Such forward-looking statements also involve other factors which may cause our actual results, performance or achievements to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements and to vary significantly from reporting period to reporting period. Although management believes that the assumptions made and expectations reflected in the forward-looking statements are reasonable, there is no assurance that the underlying assumptions will, in fact, prove to be correct or that actual future results will not be different from the expectations expressed in this Quarterly Report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

Unless the context requires otherwise, references in this document to "HJLI", "we", "our", "us" or the "Company" are to Hancock Jaffe Laboratories, Inc.

Overview

Hancock Jaffe Laboratories, Inc. is a medical device company developing tissue-based devices that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. The Company's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the current standards of care. Our products which we are developing include: the VenoValve®, a porcine based device to be surgically implanted in the deep venous system of the leg to treat a debilitating condition called chronic venous insufficiency ("CVI"); and the CoreoGraft®, a bovine based conduit to be used to revascularize the heart during coronary artery bypass graft ("CABG") surgeries. Both of these products are currently being developed for approval by the U.S. Food and Drug Administration ("FDA"). Our current senior management team has been affiliated with more than 50 products that have received FDA approval or CE marking. We currently lease a 14,507 sq. ft. manufacturing facility in Irvine, California, where we manufacture products for our clinical trials and which has previously been FDA certified for commercial manufacturing of devices.

Each of our products will be required to successfully complete significant clinical trials to demonstrate the safety and efficacy of the product before it will be able to be approved by the FDA.

We are in the process of developing the following bioprosthetic implantable devices for peripheral vascular and cardiovascular disease:

VenoValve

The VenoValve is a porcine based valve developed at HJLI to be implanted in the deep venous system of the leg to treat severe CVI. By reducing reflux, and lowering venous hypertension, the VenoValve has the potential to reduce or eliminate the symptoms of deep venous, severe CVI, including venous leg ulcers. The current version of the VenoValve is designed to be surgically implanted into the patient via a 5 to 6 inch incision in the upper thigh.

There are presently no FDA approved medical devices to address valvular incompetence, or effective treatments for deep venous CVI. Current treatment options include compression garments, or constant leg elevation. These treatments are generally ineffective, as they attempt to alleviate the symptoms of CVI without addressing the underlying causes of the disease. In addition, we believe that compliance with compression garments and leg elevation is extremely low, especially among the elderly. Valve transplants from other parts of the body have been attempted, but with very-poor results. Many attempts to create substitute valves have also failed, usually resulting in early thromboses. The premise behind the VenoValve is that by reducing the underlying causes of CVI, reflux and venous hypertension, the debilitating symptoms of CVI will decrease, resulting in improvement in the quality of the lives of CVI sufferers.

We estimate that there are approximately 2.4 million people in the U.S. that suffer from deep venous CVI due to valvular incompetence.

VenoValve Clinical Status

After consultation with the FDA, and as a precursor to the U.S. pivotal trial, we conducted a small first-in-human study for the VenoValve in Colombia. The first-in-human Colombian trial included 11 patients. In addition to providing safety and efficacy data, the purpose of the first-in-human study was to provide proof of concept, and to provide valuable feedback to make any necessary product modifications or adjustments to our surgical implantation procedures for the VenoValve prior to conducting the U.S. pivotal trial. In December of 2018, we received regulatory approval from Instituto Nacional de Vigilancia de Medicamentos y Alimentos ("INVIMA"), the Colombian equivalent of the FDA. On February 19, 2019, we announced that the first VenoValve was successfully implanted in a patient in Colombia. Between April of 2019 and December of 2019, we successfully implanted VenoValves in 10 additional patients, completing the implantations for the Colombian first-in-human study. Overall, VenoValves have been implanted in all 11 patients. Endpoints for the VenoValve first-in-human study include safety (device related adverse events), reflux, measured by doppler, a VCSS score used by the clinician to measure disease severity, and a VAS score used by the patient to measure pain, and a quality of life measurement.

Final results from the first-in-human study were released in December of 2020. Among the 11 patients, reflux improved an average of 54%, Venous Clinical Severity Scores ("VCSSs") improved an average of 56%, and visual analog scale (VAS) scores, which are used by patients to measure pain, improved an average of 76%, when compared to pre-surgery levels. VCSS scores are commonly used by clinicians in practice and in clinical trials to objectively assess outcomes in the treatment of venous disease, and include ten characteristics including pain, inflammation, skin changes such as pigmentation and induration, the number of active ulcers, and ulcer duration. The improvement in VCSS scores is significant and indicates that almost all of the VenoValve patients who had severe CVI pre-surgery, had mild CVI or the complete absence of disease at one-year post surgery. Quality of life measured by a VEINES score showed statistically significant improvement.

VenoValve safety incidences were minor with no reported device related adverse events. Minor non-device related adverse safety issues included one (1) fluid pocket (which was aspirated), intolerance from Coumadin anticoagulation therapy, three (3) minor wound infections (treated with antibiotics), and one occlusion due to patient non-compliance with anti-coagulation therapy.

In preparation for the VenoValve U.S. pivotal trial, we submitted a Pre-IDE filing with the FDA in October of 2020 and had a pre IDE meeting with the FDA on January 11, 2021. Topics presented at the meeting included the background and clinical need for the VenoValve, proposed U.S. pivotal study design, patient monitoring protocols for safety and efficacy, bench testing protocols used to develop the device, and the VenoValve first-in-human results. We received valuable feedback from the FDA in several areas during the Pre-IDE meeting and believe we reached consensus on many important issues.

An investigational device exemption or IDE from the FDA is required before a medical device company can proceed with a pivotal trial for a class III medical device. On March 5, 2021 we filed an IDE application with the FDA for the VenoValve U.S. pivotal trial. On April 1, 2021, twenty-seven days after filing the IDE application, we received notification from the FDA that our IDE application was approved. The U.S. pivotal for the VenoValve will be known at the SAVVE (Surgical Anti-reflux Veno Valve Endoprosthesis) study and is a prospective, non-blinded, single arm, multi-center study of seventy-five (75) CVI patients enrolled at up to 20 U.S. sites.

Endpoints for the SAVVE trial mirror those endpoints used for the first-in-human trial, and include the absence of material adverse safety events (mortality, deep wound infection, major bleeding, ipsilateral deep vein thrombosis, pulmonary embolism) at thirty (30) days post implantation, reductions of reflux at one hundred and eighty days (180) days post VenoValve implantation, VCSS scoring to measure disease manifestations, VAS scores to measure pain, and quality of life measurements. We have significant interest from key opinion leaders and several of the top vascular clinicians in the U.S. who would like to participate in the VenoValve U.S. pivotal trial. We are in the process of qualifying the sites, seeking investigational review board ("IRB") and other necessary approvals, negotiating clinical trial agreements, and preparing for site training and initiations. At this point we expect the first implantation for the SAVVE study to occur during the third quarter of 2021.

On August 3, 2020, we announced that the FDA granted Breakthrough Device Designation status to the VenoValve. The FDA's Breakthrough Devices Program was established to enable priority review for devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions. The goal of the FDA's Breakthrough Devices Program is to provide patients and health care providers with timely access to medical devices by speeding up their development, assessment, and review, while preserving the FDA's mission to protect and promote public health.

CoreoGraft

The CoreoGraft is a bovine based off the shelf conduit that could potentially be used to revascularize the heart, instead of harvesting the saphenous vein from the patient's leg. In addition to avoiding the invasive and painful SVG harvest process, HJLI's CoreoGraft closely matches the size of the coronary arteries, eliminating graft failures that occur due to size mismatch. In addition, with no graft harvest needed, the CoreoGraft could also reduce or eliminate the inner thickening that burdens and leads to failure of the SVGs.

In addition to providing a potential alternative to SVGs, the CoreoGraft could be used when making grafts from the patients' own arteries and veins is not an option. For example, patients with significant arterial and vascular disease often do not have suitable vessels to be used as grafts. For other patients, such as women who have undergone radiation treatment for breast cancer and have a higher incidence of heart disease, using the LIMA may not be an option if it was damaged by the radiation. Another example are patients undergoing a second CABG surgery. Due in large part to early SVG failures, patients may need a second CABG surgery. If the SVG was used for the first CABG surgery, the patient may have insufficient veins to harvest. While the CoreoGraft may start out as a product for patients with no other options, if the CoreoGraft establishes good short term and long term patency rates, it could become the graft of choice for all CABG patients in addition to the LIMA.

CoreoGraft Clinical Status

In January of 2020, we announced the results of a six-month, nine sheep, animal feasibility study for the CoreoGraft. Bypasses were accomplished by attaching the CoreoGrafts from the ascending aorta to the left anterior descending artery, and surgeries were preformed both on-pump and off-pump. Partners for the feasibility study included the Texas Heart Institute, and American Preclinical Services.

Test subjects were evaluated via angiograms and flow monitors during the study, and a full pathology examination of the CoreoGrafts and the surrounding tissue was performed post necropsy.

The results from the feasibility study demonstrated that the CoreoGrafts remained patent (open) and fully functional at 30, 90, and 180 day intervals after implantation. In addition, pathology examinations of the grafts and surrounding tissue at the conclusion of the study showed no signs of thrombosis, infection, aneurysmal degeneration, changes in the lumen, or other problems that are known to plague and lead to failure of SVGs.

In addition to exceptional patency, pathology examinations indicated full endothelialization for grafts implanted for 180 days both throughout the CoreoGrafts and into the left anterior descending arteries. Endothelium is a layer of cells that naturally exist throughout healthy veins and arteries and that act as a barrier between blood and the surrounding tissue, which helps promote the smooth passage of blood. Endothelium are known to produce a variety anti-clotting and other positive characteristics that are essential to healthy veins and arteries. The presence of full endothelialization within the longer term CoreoGrafts indicates that the graft is being accepted and assimilated in a manner similar to natural healthy veins and arteries that exist throughout the vascular system and is an indication of long-term biocompatibility.

In May of 2020, we announced that we had received approval from the Superintendent of Health of the National Health Counsel for the Republic of Paraguay to conduct a first-in-human, feasibility trial for the CoreoGraft. Up to 5 patients that need coronary artery bypass graft surgery were to receive CoreoGraft implants as part of the first-in-human study. In July of 2020, we announced that we had received permission to proceed with the first-in-human study, which had been put on hold due to the COVID-19 pandemic, and in August of 2020 we announced that the first two patients had been enrolled for the first-in-human CoreoGraft trial. Heart bypass surgeries for the first two patients to receive CoreoGraft implants as part of our first-in-human trial were successfully completed in October of 2020. A third bypass surgery using the CoreoGraft was successfully completed in November of 2020 and another surgery was completed in December of 2020. Two CoreoGraft surgical patients have expired due to non-device related adverse events, one in October and one in November of 2020. As a result of these deaths, the feasibility study was put on hold, pending a review by an ethics committee that oversees the feasibility trial. Although the committee has given approval to resume with the feasibility study, due to the recent resurgence of COVID-19 in South America (including in Paraguay), the first-in-human CoreoGraft feasibility trial remains on hold. At this time we have no further information as to when the study might resume.

Comparison of the three months ended June 30, 2021 and 2020

Overview

We reported net losses of $2.4 million and $1.6 million for the three months ended June 30, 2021 and 2020, respectively, representing an increase in net loss of $0.8 million or 50%, due to an increase in operating expenses of $0.9 million, and a decrease in other income and expense of $0.1 million.

Revenues

As a developmental stage Company, our revenue, if any, is expected to be diminutive and dependent on our ability to commercialize our product candidates.

Selling, General and Administrative Expenses

For the three months ended June 30, 2021, selling, general and administrative expenses increased by $0.5 million or 54%, to $1.3 million from $0.8 million for the three months ended June 30, 2020. The increase is primarily due to $0.3 million in higher compensation costs due mainly from share based compensation, $0.1 million in higher Delaware franchise taxes, which increased due to changes in our capital structure, $0.1 million in higher outside services due to recruiting fees and $0.1 million in higher D&O insurance premiums, partially offset by $0.1 million in lower legal fees.

Research and Development Expenses

For the three months ended June 30, 2021, research and development expenses increased by $0.4 million or 54%, to $1.1 million from $0.7 million for the three months ended June 30, 2020. This increase results from our efforts to apply and prepare for the IDE submission and pivotal trial of the VenoValve, and related lab and personnel costs to support those activities, and is primarily due to $0.3 million in compensation due to a larger team, and $0.1 million in other lab costs to support preparation for our pivotal trial.

Change in Fair Value of Derivative Liability

For the quarter ended June 30, 2020, we recorded a gain on the change in fair value of derivative liabilities of $0.1 million. Our derivative liabilities were related to warrants issued in connection with our February 25, 2020 private placement. There were no similar instruments outstanding during the quarter ending June 30, 2021.

Comparison of the six months ended June 30, 2021 and 2020

Overview

We reported net losses of $5.2 million and $2.8 million for the six months ended June 30, 2021 and 2020, respectively, representing an increase in net loss of $2.4 million or 85%, due to an increase in operating expenses of $2.2 million, and a decrease in other income and expense of $0.2 million.

Revenues

As a developmental stage Company, our revenue, if any, is expected to be diminutive and dependent on our ability to commercialize our product candidates.

Selling, General and Administrative Expenses

For the six months ended June 30, 2021, selling, general and administrative expenses increased $0.7 million or 35%, to $2.5 million from $1.8 million for the six months ended June 30, 2020. The increase is primarily due to $0.3 million in higher compensation cost $0.2 million in higher Delaware franchise taxes, which increased due to changes in our capital structure, $0.1 million in higher D&O insurance premiums, and $0.1 million in higher outside services due to recruiting fees.

Research and Development Expenses

For the six months ended June 30, 2021, research and development expenses increased by $1.5 million or 124%, to $2.7 million from $1.2 million for the six months ended June 30, 2020. This increase results from our efforts to apply and prepare for the IDE submission and pivotal trial of the VenoValve, and related lab and personnel costs to support those activities, and is primarily due to $0.5 million in compensation due to a larger team, $0.7 million in costs related to the preparing for VenoValve pivotal trial including regulatory submissions other preparatory work, $0.2 million in costs related to product testing and production, and $0.1 million in other lab costs to support preparation for our pivotal trial.

Change in Fair Value of Derivative Liability

For the six months ended June 30, 2020, we recorded a gain on the change in fair value of derivative liabilities of $0.3 million. Our derivative liabilities were related to warrants issued in connection with our February 25, 2020 private placement. There were no similar instruments outstanding during the period ending June 30, 2021.

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities for the six months ended June 30, 2021. Since inception, we have funded our operations primarily through our IPO, private and public offerings of equity and private placement of convertible debt securities as well as modest revenues from royalties, contract research and sales of the ProCol Vascular Bioprosthesis.

As of August 6, 2021, we had a cash balance of $40.1 million.

We measure our liquidity in a variety of ways, including the following:

	June 30 2021	December 31, 2020
	(unaudited)	
Cash	$ 41,039,182	$ 9,334,584
Working capital	40,045,555	6,382,818

Based upon our cash and working capital as of June 30, 2021, we have sufficient cash to sustain the Company's operations at least one year after the date of this Report.

The COVID-19 pandemic has disrupted the global economy and has negatively impacted large populations including people and businesses that may be directly or indirectly involved with the operation of our Company and the manufacturing, development, and testing of our product candidates. The full scope and economic impact of COVID-19 is still unknown and there are many risks from the COVID-19 that could generally and negatively impact economies and healthcare providers in the countries where we do business, the medical device industry as a whole, and development stage, pre-revenue companies such as HJLI.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

As a smaller reporting company, we are not required to provide the information requested by paragraph (a)(5) of this Item.

Critical Accounting Policies and Estimates

For a description of our critical accounting policies, see Note 3 – Significant Accounting Policies in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item.

Item 4: Controls and Procedures

Disclosure Controls and Procedures

Our management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer (who is our Principal Executive Officer) and our Chief Financial Officer (who is our Principal Financial Officer and Principal Accounting Officer), of the effectiveness of the design of our disclosure controls and procedures (as defined by Exchange Act Rules 13a-15(e) or 15d-15(e)) as of June 30, 2021, pursuant to Exchange Act Rule 13a-15(b). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of June 30, 2021 because of the material weakness in internal control over financial reporting discussed below.

Notwithstanding the material weakness in internal control over financial reporting described below, our management has concluded that our consolidated financial statements included in the Quarterly Report on Form 10-Q are fairly stated in all material respects in accordance with accounting principles generally accepted in the United States of America.

Material Weakness

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We did not maintain effective controls over accounting for warrants issued in connection with our February 25, 2020 financing, and, as a result, did not record an associated derivative liability on a timely basis. At the time of issuance, the Company sought and received technical accounting guidance on the accounting treatment for the derivative liability. However, due to personnel changes, the existence of the guidance was not known to new finance personnel. This deficiency did not result in the revision of any of our previously issued financial statements. However, if not addressed, the deficiency could result in material misstatement in the future. Accordingly, our management has determined that this control deficiency constitutes a material weakness.

Remediation Plan

We are in the process of developing a detailed plan for remediation of the material weakness, including developing and maintaining a transition process for new finance executives to review existing critical accounting policies and judgments. We will continue to assess the effectiveness of our remediation efforts in connection with our future assessments of the effectiveness of internal control over financial reporting and disclosure controls and procedures.

Changes in Internal Control over Financial Reporting

Other than the material weakness discussed above, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control that occurred during the quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. Controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time we may be subject to litigation and arbitration claims incidental to its business. Such claims may not be covered by our insurance coverage, and even if they are, if claims against us are successful, they may exceed the limits of applicable insurance coverage.

On July 9, 2020, the Company was served with a civil complaint filed in the Superior Court for the State of California, County of Orange by a former employee, Robert Rankin, who resigned his employment on or about March 30, 2020. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01146555-CU-WR-CJC and was filed on May 27, 2020. The complaint asserts several causes of action, including a cause of action for failure to timely pay Mr. Rankin's accrued and unused vacation and three months' severance under his July 16, 2018 employment agreement with the Company. Mr. Rankin alleges that he was forced to resign, however, we believe that he did not give the Company notice or an opportunity to cure the allegations. The complaint seeks, inter alia, back pay, unpaid wages, compensatory damages, punitive damages, attorneys' fees, and costs. On September 3, 2020 the Company and its Chief Executive Officer were served with a second complaint filed in the Superior Court for the State of California, County of Orange by Mr. Rankin. The case is entitled Rankin v. Hancock Jaffe Laboratories, Inc. et al., Case No. 30-2020-01157857 and was filed on August 31, 2020. The complaint asserts several causes of action, including defamation, unlawful labor code violations, sex-based discrimination, unfair competition, and seeks damages for lost wages, emotional and mental distress, consequential damages, punitive damages and attorney's fees and costs. The Company intends to vigorously defend the claims, investigate the allegations, and assert counterclaims. Mr. Rankin resigned as the Company's Chief Financial Officer, Secretary and Treasurer on March 30, 2020.

Item 1A. Risk Factors

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide information required by this Item. Our current risk factors are set forth in our Form 10-K, filed with the SEC on March 31, 2021.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On April 26, 2021, the Company issued 5,772 shares with a value of $6.51 per share, or $37,576, in satisfaction of a trade payable.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine and Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The following is a complete list of exhibits filed as part of this Form 10-Q. Exhibit numbers correspond to the numbers in the Exhibit Table of Item 601 of Regulation S-K.

Exhibit	Description
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act. *
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Sarbanes-Oxley Act. *
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act**
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*

* Filed herewith.
** Furnished and not filed herewith.

SIGNATURES

Pursuant to the requirements of Section 12 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: August 10, 2021

HANCOCK JAFFE LABORATORIES, INC.

By: */s/ Robert Berman*
Robert Berman
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Craig Glynn*
Craig Glynn
Chief Financial Officer
(Principal Financing and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Robert Berman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Hancock Jaffe Laboratories, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 10, 2021

/s/ Robert Berman

Name: Robert Berman
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Craig Glynn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Hancock Jaffe Laboratories, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-493313];

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 10, 2021

/s/ Craig Glynn

Name: Craig Glynn
Title: Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Hancock Jaffe Laboratories, Inc. (the "Company's Quarterly Report") on Form 10-Q for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Robert Berman, as Chief Executive Officer and principal executive officer and Craig Glynn, as Chief Financial Officer and principal financial officer of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of the undersigned's knowledge and belief, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

/s/ Robert Berman
Robert Berman
Chief Executive Officer and Principal Executive Officer

Dated: August 10, 2021

/s/ Craig Glynn
Craig Glynn
Chief Financial Officer and Principal Financial Officer

Dated: August 10, 2021

This certification accompanies this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.