

**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 September 30, 2020

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**

(State or other jurisdiction of  
incorporation or organization)

**33-0936180**

(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:

<b>Title of Each Class:</b>	<b>Name of Each Exchange on Which Registered:</b>	<b>Ticker Symbol</b>
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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 November 16, 2020, there were 49,775,443 shares of common stock outstanding.

**HANCOCK JAFFE LABORATORIES, INC.**  
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PART I – FINANCIAL INFORMATION

ITEM 1 – Financial Statements

HANCOCK JAFFE LABORATORIES, INC.  
CONDENSED BALANCE SHEETS

	September 30, 2020 (unaudited)	December 31, 2019
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 5,629,003	\$ 1,307,231
Prepaid expenses and other current assets	348,653	116,647
Total Current Assets	5,977,656	1,423,878
Property and equipment, net	425,526	344,027
Restricted Cash	-	810,055
Operating lease right-of-use assets, net	609,656	826,397
Security deposits and other assets	29,843	29,843
Total Assets	<u>\$ 7,042,681</u>	<u>\$ 3,434,200</u>
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 974,229	\$ 1,221,189
Accrued expenses and other current liabilities	287,672	333,438
Note Payable	312,700	-
Deferred revenue - related party	33,000	33,000
Current portion of operating lease liabilities	307,823	288,685
Total Current Liabilities	1,915,424	1,876,312
Long-term operating lease liabilities	332,296	567,948
Total Liabilities	<u>2,247,720</u>	<u>2,444,260</u>
Commitments and Contingencies	-	-
Stockholders' Equity:		
Convertible preferred stock, par value \$0.00001, 10,000,000 shares authorized: 4,205,406 and 0 shares issued or outstanding as of September 30, 2020 and December 31, 2019, respectively	42	-
Common stock, par value \$0.00001, 250,000,000 shares authorized, 40,242,734 and 17,931,857 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	403	179
Additional paid-in capital	65,743,924	57,177,686
Accumulated deficit	(60,949,408)	(56,187,925)
Total Stockholders' Equity	<u>4,794,961</u>	<u>989,940</u>
Total Liabilities and Stockholders' Equity	<u>\$ 7,042,681</u>	<u>\$ 3,434,200</u>

See Notes to these Unaudited Condensed Financial Statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Revenues:</b>				
Royalty income	\$ -	\$ -	\$ -	\$ 31,243
Total Revenues	<u>-</u>	<u>-</u>	<u>-</u>	<u>31,243</u>
Selling, general and administrative expenses	1,164,089	1,157,064	3,001,720	3,989,274
Research and development expenses	758,198	676,970	1,974,995	1,418,293
Loss from Operations	<u>(1,922,287)</u>	<u>(1,834,034)</u>	<u>(4,976,715)</u>	<u>(5,376,324)</u>
<b>Other (Income) Expense:</b>				
Interest (income) expense, net	(564)	(19,139)	(3,425)	(41,680)
Change in fair value of derivative liabilities	53,046	-	(211,807)	-
Total Other (Income) Expense	<u>52,482</u>	<u>(19,139)</u>	<u>(215,232)</u>	<u>(41,680)</u>
Net Loss	(1,974,769)	(1,814,895)	(4,761,483)	(5,334,644)
Deemed dividend to Series C Preferred Stockholders	(23,859)	-	(23,859)	-
Net Loss Attributable to Common Stockholders	<u>\$ (1,998,628)</u>	<u>\$ (1,814,895)</u>	<u>\$ (4,785,342)</u>	<u>\$ (5,334,644)</u>
Net Loss Per Basic and Diluted Common Share:	<u>\$ (0.06)</u>	<u>\$ (0.10)</u>	<u>\$ (0.19)</u>	<u>\$ (0.35)</u>
<b>Weighted Average Number of Common Shares Outstanding:</b>				
Basic and Diluted	<u>36,145,494</u>	<u>17,922,129</u>	<u>25,460,490</u>	<u>15,029,969</u>

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 Capital	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount			
Balance at January 1, 2019	11,722,647	\$ 117	\$ 50,598,854	\$ (48,562,528)	\$ 2,036,443
Common stock issued in private placement offering <sup>[1]</sup>	2,347,997	24	2,317,252	-	2,317,276
Stock-based compensation:					
Amortization of stock options	-	-	82,720	-	82,720
Common stock issued to consultants	85,000	-	-	-	-
Warrants granted to consultants	-	-	2,334	-	2,334
Net loss	-	-	-	(1,573,726)	(1,573,726)
Balance at March 31, 2019	14,155,644	\$ 141	\$ 53,001,160	\$ (50,136,254)	\$ 2,865,047
Common stock issued in public offering <sup>[2]</sup>	3,615,622	36	3,319,620	-	3,319,656
Stock-based compensation:					
Amortization of stock options	-	-	86,870	-	86,870
Common stock issued to consultants/settlement, net <sup>[3]</sup>	150,863	2	298,298	-	298,300
Warrants granted to consultants/settlement	-	-	28,165	-	28,165
Net loss	-	-	-	(1,946,023)	(1,946,023)
Balance at June 30, 2019	17,922,129	\$ 179	\$ 56,734,113	\$ (52,082,277)	\$ 4,652,015
Stock-based compensation:					
Amortization of stock options	-	-	159,864	-	159,864
Common stock issued to consultants	-	-	87,014	-	87,014
Net loss	-	-	-	(1,814,895)	(1,814,895)
Balance at September 30, 2019	17,922,129	\$ 179	\$ 56,980,991	\$ (53,897,172)	\$ 3,083,998

[1] net of offering costs of \$386,724.

[2] net of offering costs of \$549,060.

[3] net of forfeiture of 6,137 shares.

	Series C Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount	Shares	Amount			
Balance at January 1, 2020	-	-	17,931,857	\$ 179	\$ 57,177,686	\$ (56,187,925)	\$ 989,940
Common stock issued in private placement offering <sup>[4]</sup>	-	-	1,300,000	13	24,292	-	24,305
Stock-based compensation:							
Amortization of stock options	-	-	-	-	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	-	-	19,231,857	\$ 192	\$ 57,332,868	\$ (57,347,683)	\$ (14,623)
Common stock issued in public offering <sup>[5]</sup>	-	-	4,817,195	48	1,973,260	-	1,973,308
Stock-based compensation:							
Amortization of stock options	-	-	-	-	37,717	-	37,717
Net loss	-	-	-	-	-	(1,626,956)	(1,626,956)
Balance at June 30, 2020	-	-	24,049,052	\$ 240	\$ 59,343,845	\$ (58,974,639)	\$ 369,446
Common stock issued in public offering <sup>[6]</sup>	-	-	14,375,000	144	3,881,763	-	3,881,907
Preferred stock issued in private placement <sup>[7]</sup>	4,205,406	42	-	-	1,358,060	-	1,358,102
Common stock issued for exercise of warrants	-	-	1,818,682	19	631,607	-	631,626
Reclassification of Warrant Derivatives to Equity	-	-	-	-	334,229	-	334,229
Stock-based compensation:							
Amortization of stock options	-	-	-	-	194,420	-	194,420
Net loss	-	-	-	-	-	(1,974,769)	(1,974,769)
Balance at September 30, 2020	4,205,406	\$ 42	40,242,734	\$ 403	\$ 65,743,924	\$ (60,949,408)	\$ 4,794,961

[4] net of offering costs of \$79,658.

[5] net of offering costs of \$360,026.

[6] net of offering costs of \$718,093.

[7] net of offering costs of \$197,901.

See Notes to these Unaudited Condensed Financial Statements

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

	<b>For the Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash Flows from Operating Activities</b>		
Net loss	\$ (4,761,483)	\$ (5,334,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	363,027	745,269
Depreciation and amortization	71,252	85,060
Amortization of right-of-use assets	216,741	206,618
Change in fair value of derivatives	(211,807)	-
Changes in operating assets and liabilities:		
Accounts receivable	-	32,022
Prepaid expenses and other current assets	(232,006)	(52,547)
Accounts payable	(246,960)	134,205
Accrued expenses	(45,766)	109,768
Payments on lease liabilities	(216,514)	(198,930)
Total adjustments	(302,033)	1,061,465
Net Cash Used in Operating Activities	(5,063,516)	(4,273,179)
<b>Cash Flows from Investing Activities</b>		
Purchase of property and equipment	(152,751)	(350,934)
Net Cash Used in Investing Activities	(152,751)	(350,934)
<b>Cash Flows from Financing Activities</b>		
Proceeds from private placements of common stock and warrants, net <sup>[1]</sup>	570,341	2,317,276
Preferred stock issued in private placement <sup>[2]</sup>	1,358,102	-
Proceeds from public offerings, net <sup>[3]</sup>	5,855,215	3,319,656
Proceeds from issuance of note payable	312,700	-
Proceeds from Warrant Exercises	631,626	-
Net Cash Provided by Financing Activities	8,727,984	5,636,932
<b>Net Increase in Cash, Cash Equivalent, and Restricted Cash</b>	3,511,717	1,012,819
Cash, cash equivalents and restricted cash - Beginning of period	2,117,286	2,740,645
Cash, cash equivalents and restricted cash - End of period	\$ 5,629,003	\$ 3,753,464

[1] Net of cash offering costs of \$79,568 and \$386,724 in 2020 and 2019, respectively.

[2] Net of cash offering costs of \$197,901.

[3] Net of cash offering costs of \$1,078,119 and \$549,060 in 2020 and 2019, respectively.

See Notes to these Unaudited Condensed Financial Statements

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

	For the Nine Months Ended September 30,	
	2020	2019
<b>Supplemental Disclosures of Cash Flow Information:</b>		
<b>Cash Paid (Received) During the Years For:</b>		
Interest, net	\$ (3,425)	\$ 933
<b>Non-Cash Financing Activities:</b>		
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	\$ -
Reclassification of warrant derivatives to equity	\$ (334,229)	\$ -

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. (“we”, “us”, “our”, “HJLI” or the “Company”) 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 two lead products which we are developing are: 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 our current products are being developed for approval by the U.S. Food and Drug Administration (“FDA”). We currently receive tissue for development of our products from one domestic suppliers and one international supplier. Our current business model is to license, sell, or enter into strategic alliances with large medical device companies with respect to our products, either prior to or after FDA approval. 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 product candidates will be required to successfully complete clinical trials and other testing to demonstrate the safety and efficacy of the product candidate before it will be approved by the FDA. The completion of these clinical trials and testing will require a significant amount of capital and the hiring of additional personnel.

On September 15, 2020, at a special stockholders meeting, the Company’s stockholders approved the increase of its authorized common shares to 250,000,000 for a sufficient authorized number to settle all outstanding stock options, warrants and convertible preferred stock.



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

**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. The unaudited condensed financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern for the next twelve months from the filing of this Form 10-Q. The Company incurred a net loss of \$4,761,483 and \$5,334,644 for the nine months ended September 30, 2020 and 2019, respectively, and had an accumulated deficit of \$60,949,408 at September 30, 2020. Cash used in operating activities was \$5,063,516 and \$4,273,179 for the nine months ended September 30, 2020 and 2019, respectively. The aforementioned factors raise substantial doubt about the Company’s ability to continue as a going concern within one year after the issuance date of the financial statements.

The Company expects to continue incurring losses for the foreseeable future and recognizes the need to raise additional capital to sustain its operations, pursue its product development initiatives and penetrate markets for the sale of its products. Toward that end, the Company has completed five separate equity sales in 2020 through the filing date of this report raising aggregate net proceeds of approximately \$12,200,000 (see Notes 10 and 11). As of September 30, 2020, the Company had cash balances of \$5,629,003 and working capital of \$4,062,232. Management believes the proceeds from these transactions should provide sufficient cash to sustain the Company’s operations at least one year after the issuance date of these financial statements.

If necessary, after one year, management believes that the Company could have access to additional capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means. However, there is a material risk that the Company will be unable to raise additional capital or obtain new financing when needed on commercially acceptable terms, if at all, or if it will be successful in implementing its business plan and developing its medical devices. Further, the COVID-19 pandemic has disrupted the global economy and eroded capital markets which makes it more difficult to obtain the financing that we need to fund and continue our operations. The inability of the Company to raise needed capital would have a material adverse effect on the Company’s business, financial condition and results of operations, and ultimately the Company could be forced to curtail or discontinue its operations, liquidate and/or seek reorganization in bankruptcy. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

**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 September 30, 2020 and December 31, 2019, and for the three and nine months ended September 30, 2020 and 2019. The results of operations for the three and nine months ended September 30, 2020 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, 2019 included in the Company’s Form 10-K filed with the SEC on March 18, 2020. The condensed balance sheet as of December 31, 2019 has been derived from the Company’s audited financial statements.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from these estimates. Significant estimates and assumptions include the valuation allowance related to the Company’s deferred tax assets, and the valuation of warrants and derivative liabilities.

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

*Fair Value of Financial Instruments*

The Company measures the fair value of financial assets and liabilities based on the guidance of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) ASC 820 “Fair Value Measurements and Disclosures” (“ASC 820”) which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

FASB ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

- Level 1            Quoted prices available in active markets for identical assets or liabilities trading in active markets.
- Level 2            Observable inputs other than quoted prices included in Level 1, such as quotable prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3            Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

Financial instruments, including accounts receivable and accounts payable are carried at cost, which management believes approximates fair value due to the short-term nature of these instruments. The Company’s other financial instruments include notes payable, the carrying value of which approximates fair value, as the notes bear terms and conditions comparable to market for obligations with similar terms and maturities. Derivative liabilities are accounted for at fair value on a recurring basis.

On September 15, 2020, the fair value of derivative liabilities was reclassified to equity when the Company’s stockholders approved the increase of its authorized shares of capital stock. (See Note 10 –Stockholders’ Equity (Deficiency) *Common Stock*). Accordingly, there is no fair value of derivative liabilities as of September 30, 2020.

The following table sets forth a summary of the changes in the fair value of Level 3 derivative liabilities that are measured at fair value on a recurring basis:

	<b>Derivative Liabilities</b>
Balance – January 1, 2020	\$ -
Derivative liabilities associated with the issuance of common stock warrants	513,534
Derivative liabilities associated with the issuance of placement agent warrants	32,502
Change in fair value of derivative liabilities	(346,129)
Balance – March 31, 2020	199,907
Change in fair value of derivative liabilities	81,276
Balance June 30, 2020	281,183
Change in fair value of derivative liabilities	53,046
Reclassification of warrant derivatives to equity	(334,229)
Balance – September 30, 2020	\$ -

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

*Derivative Liabilities*

On February 25, 2020 in connection with a private placement of its securities (Note 10), the Company issued warrants to purchase 1,430,000 shares of its common stock. The Company determined these warrants were derivative financial instruments when issued.

Derivative financial instruments are recorded as a liability at fair value and are marked-to-market as of each balance sheet date. The change in fair value at each balance sheet date is recorded as a change in the fair value of derivative liabilities on the statement of operations for each reporting period. The fair value of the derivative liabilities was determined using a Monte Carlo simulation, incorporating observable market data and requiring judgment and estimates. The Company reassesses the classification of the financial instruments at each balance sheet date. If the classification changes as a result of events during the period, the financial instrument is marked to market and reclassified as of the date of the event that caused the reclassification. On September 15, 2020, the fair value of derivative liabilities was reclassified to equity when the Company's stockholders approved the increase of its authorized shares of capital stock. (See Note 10 –Stockholders' Equity (Deficiency) *Common Stock*).

The Company recorded a gain on the change in fair value of derivative liabilities of \$211,807 during the nine months ended September 30, 2020 and a loss on the change in fair value of derivative liabilities of \$53,046 during the quarter ended September 30, 2020.

*Sequencing Policy*

On July 15, 2020, the Company adopted a sequencing policy, whereby, in the event that reclassification of contracts from equity to assets or liabilities is necessary pursuant to ASC 815 due to the Company's inability to demonstrate it has sufficient authorized shares, shares will be allocated on the basis of the earliest issuance date of potentially dilutive instruments, with the earliest grants receiving the first allocation of shares. Pursuant to ASC 815, issuances of securities to the Company's employees and directors, or to compensate grantees in a share-based payment arrangement, are not subject to the sequencing policy.

*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. Net loss attributable to common stockholders consists of net loss, adjusted for the convertible preferred stock deemed dividend resulting from the 8% cumulative dividend on the Preferred Stock (see Note 10 - Stockholders Equity (Deficiency) *Series C Convertible Preferred Stock*). 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.

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 September 30, 2020 and 2019:

	September 30,	
	2020	2019
Shares of common stock issuable upon exercise of warrants	34,022,068	4,366,960
Shares of common stock issuable upon exercise of options	5,315,540	1,517,000
Potentially dilutive common stock equivalents excluded from diluted net loss per share	39,337,608	5,883,960

*Stock-Based Compensation*

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and recognized over the period services are required to be provided in exchange for the award, usually the vesting period. Forfeitures of unvested stock options are recorded when they occur.

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

*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 were aggregate uninsured cash balances of \$5,379,003 and \$1,867,286 as of September 30, 2020 and December 31, 2019, respectively. The Company periodically evaluates the financial stability of the financial institutions with whom it maintains its cash balances. As of September 30, 2020, and as of the date of filing this report, the Company is not aware of any circumstances which would indicate they are not financially sound.

For the nine months ended September 30, 2019, all of the Company’s revenues were from royalties as a result of the three-year Post-Acquisition Supply Agreement with LeMaitre Vascular, Inc. that was effective from March 18, 2016 to March 18, 2019. The Company did not have any similar revenue in the nine months ended September 30, 2020.

*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, except as disclosed in Note 11 - Subsequent Events.

*Recent Accounting Pronouncements*

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, and early adoption is permitted. We are currently evaluating the impact that this guidance will have on our condensed financial statements.

**Note 4 – Restricted Cash**

As of September 30, 2020, the Company did not have any restricted cash. Previously, the Company had maintained a restricted cash balance in connection with a vendor litigation matter with ATSCO, Inc. (see Note 9 - Commitments and Contingencies - *Litigations Claims and Assessments*). The matter was resolved on July 20, 2020, and on August 28, 2020 ATSCO took possession of the restricted cash as full settlement of the dispute.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the balance sheet as of September 30, 2019 and that sum to the total of the same amounts shown in the statement of cash flows for the nine months ending September 30, 2019 with the comparative cash balance without restricted cash as of September 30, 2020.

	<b>As of September 30,</b>	
	<b>2020</b>	<b>2019</b>
Cash and cash equivalents	\$ 5,629,003	\$ 2,943,409
Restricted cash	-	810,055
Total cash, cash equivalents, and restricted cash in the balance sheets	\$ 5,629,003	\$ 3,753,464

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**Note 5 – Property and Equipment**

As of September 30, 2020 and December 31, 2019, property and equipment consist of the following:

	<b>September 30,</b>	<b>December 31,</b>
	<b>2020</b>	<b>2019</b>
Laboratory equipment	\$ 332,126	\$ 214,838
Furniture and fixtures	93,417	93,417
Computer software and equipment	61,771	50,403
Leasehold improvements	158,092	158,092
Construction Work in Progress – Software	244,479	220,384
	889,885	737,134
Less: accumulated depreciation	(464,359)	(393,107)
Property and equipment, net	\$ 425,526	\$ 344,027

Depreciation expense amounted to \$66,857 and \$26,828 for the nine months ended September 30, 2020 and 2019, respectively. Depreciation expense is reflected in general and administrative expenses in the accompanying statements of operations.

**Note 6 – 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 60-month term at the end of 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 adopted Accounting Standards Codification (“ASC”) Topic 842, Leases (Topic 842) effective January 1, 2019 using the modified-retrospective method and elected the package of transition practical expedients for expired or existing contracts, which does not require reassessment of previous conclusions related to contracts containing leases, lease classification and initial direct costs, and therefore the comparative periods presented are not adjusted. In addition, the Company elected to adopt the short-term lease exception and not apply Topic 842 to arrangements with lease terms of 12 months or less. On January 1, 2019, upon adoption of Topic 842, the Company recorded right-of-use assets of \$1,099,400, lease liabilities of \$1,121,873 and eliminated deferred rent of \$22,473. The Company determined the lease liabilities using the Company’s estimated incremental borrowing rate of 8.5% to estimate the present value of the remaining monthly lease payments.

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Our operating lease cost is as follows:

	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2020
Operating lease cost	\$ 85,492	\$ 256,475

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

	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2020
<b>Operating Cash Flow Information:</b>		
Cash paid for amounts in the measurement of lease liabilities	\$ 85,416	\$ 256,248

Remaining lease term and discount rate for our operating lease is as follows:

	September 30, 2020
Remaining lease term	2 years
Discount rate	8.5%

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

Three months ended December 31, 2020	\$ 87,981
Year ended December 31, 2021	354,561
Year Ended December 31, 2022	271,854
Total	\$ 714,396
Less: Imputed Interest	(74,277)
Present value of our lease liability	\$ 640,119

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**Note 7 – Accrued Expenses and Accrued Interest**

As of September 30, 2020, and December 31, 2019, accrued expenses consist of the following:

	September 30, 2020	December 31, 2019
Accrued compensation costs	\$ 233,428	\$ 151,858
Accrued professional fees	23,000	141,310
Accrued franchise taxes	25,607	30,270
Accrued research and development	5,637	-
Other accrued expenses	-	10,000
Accrued expenses	<u>\$ 287,672</u>	<u>\$ 333,438</u>

**Note 8 – Note Payable**

On April 12, 2020, the Company obtained loan (the “Loan”) in the amount of \$312,700, pursuant to the Paycheck Protection Program (the “PPP”) under Division A, Title I of the CARES Act, which was enacted March 27, 2020.

The Loan, which was in the form of a Note dated April 12, 2020, matures on April 12, 2022 and bears interest at a rate of 1% per annum, payable monthly commencing on November 12, 2020. The Note may be prepaid at any time before maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, costs used to continue group health care benefits, mortgage payments, rent, utilities, and interest on other debt obligations incurred before February 15, 2020. The Company believes it has used the entire Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act.

As of September 30, 2020, the note payable balance was \$312,700.

**Note 9 – 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.

On September 21, 2018, ATSCO, Inc., a vendor, filed a lawsuit with the Superior Court seeking payment of \$809,520 plus legal costs for disputed invoices to the Company dated from 2015 to June 30, 2018. The Company had entered into a Services and Material Supply Agreement (“Agreement”), dated March 4, 2016 for ATSCO to supply porcine and bovine tissue to the Company. On January 18, 2019, the Orange County Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of \$810,055 (the “Disputed Amount”) and on March 21, 2019, the Santa Clara, CA sheriff department served the Writ of Attachment and took custody of and was holding the Disputed Amount (see Note 4 – Restricted Cash). On July 20, 2020, the Company and ATSCO agreed to settle the dispute. Pursuant to the terms of the settlement, the Company agreed to release the Disputed Amount of restricted cash in exchange for a full release from all claims made by ATSCO related to this matter. On August 28, 2020, ATSCO took possession of the Restricted Cash. Accordingly, as of September 30, 2020, the Company has removed the restricted cash and related accounts payable from its financial statements.



The Company has replaced ATSCO and has entered into new supply relationships with two domestic and one international company to supply porcine and bovine tissues.

On October 8, 2018, Gusrae Kaplan Nusbaum PLLC (“Gusrae”) filed a complaint with the Supreme Court of the State of New York seeking payment of \$178,926 plus interest and legal costs for invoices to the Company dated from November 2016 to December 2017. In July 2016, the Company retained Gusrae to represent the Company in connection with certain specific matters. The Company believes that Gusrae has not applied all of the payments made by the Company along with billing irregularities and errors and is disputing the amount owed. The Company recorded the disputed invoices in accounts payable and as of June 30, 2020, the Company has fully accrued for the outstanding claim against the Company.

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 as the Company’s Chief Financial Officer, Secretary and Treasurer on March 30, 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. The complaint seeks, among other things, back pay, unpaid wages, compensatory damages, punitive damages, attorneys’ fees, and costs. The Company intends to vigorously defend the claims, investigate the allegations, and assert counterclaims.

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**Note 10 –Stockholders’ Equity (Deficiency)**

On September 15, 2020, the Company completed a special meeting of stockholders (the “Special Meeting”). At the Special Meeting, the Company’s stockholders, among other things, (i) approved an amendment to the Company’s Amended and Restated Certificate of Incorporation (the “A&R Certificate of Incorporation”) to increase the aggregate number of authorized shares of common stock by 200,000,000 shares from 50,000,000 to 250,000,000 shares; (ii) approved an amendment to the A&R Certificate of Incorporation to reduce the vote required to amend, repeal, or adopt any provisions of the A&R Certificate of Incorporation from the approval of 66 2/3% of the voting power of the shares of the then outstanding voting stock of the Company entitled to vote to a majority of such shares; and (iii) approved a reverse stock split of the Company’s common stock at a ratio of between one-for-five and one-for-twenty-five, with such ratio to be determined at the sole discretion of the Company’s Board of Directors (the “Board”) and with such reverse stock split to be effected at such time and date, if at all, as determined by the Board in its sole discretion.

*Common Stock*

On February 25, 2020, the Company raised \$650,000 in gross proceeds through a private placement bridge offering of its common stock and warrants to purchase its common stock to certain accredited investors (the “Bridge Offering”). The Company sold an aggregate of 1,300,000 shares of common stock and warrants to purchase 1,300,000 shares of common stock in the Bridge Offering pursuant to a securities purchase agreement between the Company and each of the investors in the Bridge Offering (the “Purchase Agreement”). The warrants are exercisable for a the period commencing the date the Company’s stockholders approve either an increase in the number of the Company’s authorized shares or a reverse stock split and ending on February 25, 2025 and have an exercise price of \$0.79 per share. Pursuant to the terms of the Purchase Agreement, the Company agreed to hold a meeting of its stockholders on or prior to May 25, 2020 for the purpose of seeking approval of either an increase in the number of shares of common stock the Company is authorized to issue or a reverse split of the Company’s common stock (a “Capital Event”). The Company did not hold a meeting until September 15, 2020, at which time the Company’s stockholders approved various measures including those comprising a Capital Event.

On April 24, 2020, the Company entered into a Securities Purchase Agreement (the “April 2020 Purchase Agreement”) with certain investors for the purpose of raising approximately \$1.0 million in gross proceeds for the Company. Pursuant to the terms of the April 2020 Purchase Agreement, the Company agreed to sell, in a registered direct offering, an aggregate of 1,886,793 shares of the Company’s common stock, at a purchase price of \$0.405 per share, and in a concurrent private placement, warrants to purchase up to 1,886,793 shares of common stock, at a purchase price of \$0.125 per warrant, for a combined purchase price per share and warrant of \$0.53. The warrants are exercisable immediately on the date of issuance at an exercise price of \$0.405 per share and will expire five years following the date of issuance.

The closing of the sales of these securities under the April 2020 Purchase Agreement occurred on April 28, 2020. Net proceeds to the Company from the transactions, after deducting the placement agent’s fees and expenses but before paying the Company’s estimated offering expenses, and excluding the proceeds, if any, from the exercise of the warrants, were \$811,641.

On June 1, 2020, the Company entered into a Securities Purchase Agreement (the “June 2020 Purchase Agreement”) with certain investors for the purpose of raising approximately \$1,333,000 in gross proceeds for the Company. Pursuant to the terms of the June 2020 Purchase Agreement, the Company agreed to sell, in a registered direct offering, an aggregate of 2,930,402 shares of the Company’s common stock at a purchase price of \$0.33 per share, and in a concurrent private placement, warrants to purchase up to 2,930,402 shares of common stock at a purchase price of \$0.125 per warrant, for a combined purchase price per share and warrant of \$0.455. The warrants are exercisable immediately on the date of issuance at an exercise price of \$0.33 per share and will expire five years following the date of issuance.

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The closing of the sales of these securities under the June 2020 Purchase Agreement occurred on June 3, 2020. Net proceeds to the Company from the transactions, after deducting the placement agent's fees and expenses but before paying the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the warrants, were \$1,161,667.

On July 17, 2020, the Company entered into an Underwriting Agreement relating to a firm commitment public offering (the "Public Offering") of 12,500,000 units (the "Units"), consisting of an aggregate of 12,500,000 shares of common stock and warrants to purchase up to 12,500,000 shares of common stock at a public offering price of \$0.32 per Unit. Pursuant to the terms of the Underwriting Agreement, the underwriters also exercised their overallocation option in full, purchasing an additional 1,875,000 shares of common stock and warrants to purchase up to 1,875,000 shares of common stock for an aggregate purchase of 14,375,000 shares and warrants to purchase up to 14,375,000 shares of common stock. The warrants have an initial exercise price of \$0.32 per share, subject to customary adjustments, and will expire seven years from the date of issuance. Exercisability of the warrants was subject to stockholder approval of an increase in the number of authorized shares of common stock or a reverse stock split, in either case, in an amount sufficient to permit exercise in full of the warrants, which was obtained on September 15, 2020.

Pursuant to the Underwriting Agreement, the Company also issued to the underwriters as compensation a warrant to purchase up to 750,000 shares of common stock with substantially the same terms as the warrants issued in the Public Offering.

The closing of this transaction occurred on July 21, 2020. Net proceeds to the Company, after deducting the underwriters and placement agent's fees and expenses, including the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the Public Offering, were \$3,882,000. As of the July 21, 2020 closing, did not have sufficient authorized common shares to share settle all outstanding stock options and warrants.

On February 7, 2019, the Company entered into an Agreement ("MZ Agreement") with MZHCI, LLC a MZ Group Company ("MZ") for MZ to provide investor relations advisory services. The MZ Agreement was for an initial term of twelve (12) months with six-month automatic extension periods. MZ received cash compensation of \$8,000 per month and eighty-five thousand (85,000) restricted shares which vested quarterly over the initial twelve-month term. Effective on July 24, 2020, the Company and MZ terminated the agreement.

*Series C Convertible Preferred Stock*

In a private placement occurring concurrently with the Public Offering, the Company entered into a Securities Purchase Agreement with certain investors pursuant to which the Company agreed to sell 4,205,406 shares of its Series C Convertible Preferred Stock (the "Preferred Stock") and warrants to purchase up to 6,078,125 shares of its common stock for a combined purchase price per share and warrant of \$0.37. Pursuant to its terms, the Preferred Stock may convert into 6,078,125 shares of common stock. The warrants issued have an initial per share exercise price of \$0.32, subject to customary adjustments, and will expire seven years from the date of issuance.

The gross proceeds were \$1,556,000 and the net proceeds to the Company from the transaction, after deducting the underwriters and placement agent's fees and expenses, including the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the warrants issued in the private placement, were \$1,358,000.

The holders of the Company's Preferred Stock vote with holders of the Common Stock, and with any other shares of preferred stock that vote with the Common Stock, with each holder of Preferred Stock being entitled to one vote per share of Preferred Stock, and are entitled to receive 8% non-compounding cumulative dividends, payable when, as and if declared by the Board of Directors. The Series C Preferred Stock ranks senior to the common stock as to dividends and the distribution of assets in the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary or any sale of the Company.

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In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, or any sale of the Company, the holders of Preferred Stock are entitled to receive, before and in preference to any distribution of any of the assets to the holders of the common stock, or any other series of the Company's preferred stock that is junior to the Preferred Stock, an amount per share equal to \$0.37 for each outstanding share of Preferred Stock (the "Original Series C Issue Price"), plus all accrued but unpaid dividends thereon through the date of such event.

As of September 30, 2020, the holders of Preferred Stock are entitled to receive a liquidation preference payment of \$0.37 per share, plus accrued and unpaid dividends totaling, in the aggregate, \$23,859. During the three and nine months ended September 30, 2020, the Company recognized the \$23,859 as a deemed dividend for the purpose of calculating loss attributable to common stockholders and loss per share. The liquidation preference of the Preferred Stock is subordinate and ranks junior to all indebtedness of the Company.

The Company may elect to convert the Preferred Stock to common stock in the event the Company either (i) consummates a merger, or (ii) raises an aggregate of at least \$8,000,000 in gross proceeds in a transaction or series of transactions within any twelve (12) month period. In the event the Company elects to effect such a conversion, each share of Series C Preferred Stock is convertible into 1.445 shares of common stock.

The Company determined that the Preferred Stock represented permanent equity due to the absence of a redemption feature and the embedded conversion option was clearly and closely related to the equity host and did not require bifurcation. The \$2,431,250 fair value of the warrants was calculated using the Black-Scholes option pricing model, using the \$0.44 stock price, an expected term of 7.0 years, volatility of 118.7%, a risk-free rate of 0.47% and expected dividends of 0.00%. The \$1,556,000 of gross proceeds were allocated on a relative fair value basis of \$607,220 to the Preferred Stock and \$948,781 to the warrants. The Preferred Stock includes a contingent beneficial conversion feature ("BCF") which was valued at its \$2,067,155 intrinsic value using the commitment date stock price of \$0.44 per share and the effective conversion price of \$0.10 per share, but was limited to the \$607,220 of proceeds that were allocated to the Preferred Stock. The contingent BCF will be recognized when the contingency is resolved. If the BCF is recognized, it will be recorded as a deemed dividend for the purposes of calculating earnings per share. In addition, since the Company does not have retained earnings, the dividend will be recorded against additional paid-in capital.

#### *Warrants*

Certain investors in the Public Offering agreed with the underwriter to enter into a lock-up and voting agreement (the "Lock-Up and Voting Agreements") whereby each such investor was subject to a lock-up period through July 21, 2020 and agreed to vote all shares of common stock each beneficially owned on the closing date of the Public Offering with respect to any proposals presented to the stockholders of the Company. Additionally, certain investors that agreed to enter into the Lock-Up and Voting Agreements, as consideration for their waiver of certain rights described in the April 2020 Purchase Agreement and June 2020 Purchase Agreement, were issued unregistered warrants (the "Waiver Warrants") to purchase an aggregate of 3,495,000 shares of common stock. These warrants were substantially similar to the warrants issued in the concurrent private placement, except that they warrants have a term of five (5) years, an exercise price equal to \$0.37 per share and carry piggy-back registration rights.

Exercisability of the warrants issued in the February 25 transaction was subject to stockholder approval of a Capital Event. The warrants issued in the April and June transactions were immediately exercisable. Exercisability of the warrants issued in the July Public Offering and Private Placement was subject to the later to occur of (i) date that the Company files an amendment to its amended and restated certificate of incorporation to reflecting stockholder approval of either an increase in the number of our authorized shares of Common Stock or a reverse stock split (in either case in an amount sufficient to permit the conversion in full of the Preferred Stock and exercise in full of the warrants), and (ii) the date of approval as may be required by the applicable rules and regulations of The Nasdaq Stock Market LLC (or any successor entity) from the stockholders of the Company with respect to the transactions contemplated by the Securities Purchase Agreement, including the issuance of all of the shares issuable upon conversion of the Preferred Stock and warrants in excess of 19.99% of the issued and outstanding common stock on the closing date of the private placement.

On June 15, 2020, the Company filed a registration statement covering the warrants issued in the April and June transactions. The registration statement was declared effective on June 23, 2020. At the Special Meeting held on September 15, 2020, the Company's stockholders approved measures comprising a Capital Event, as defined in the February transaction, increasing the authorized common shares by an amount sufficient to cover the exercise of warrants purchased in that transaction as well as the Public Offering and Private Placement, and including common shares issuable upon conversion of the Company's Series C Preferred Stock. The Company filed its amended and restated certificate of incorporation on September 17, 2020 and filed a registration statement covering the warrants issued in the February and July transactions. This registration statement became effective on October 22, 2020, such that all of the warrants issued in 2020 are now exercisable.

On January 3, 2019, the Company entered into an Agreement ("Alere Agreement") with Alere Financial Partners, a division of Cova Capital Partners LLC ("Alere") for Alere to provide capital markets advisory services. The Alere Agreement is on a month to month basis that can be cancelled by either party with thirty (30) days advance notice. The Company will pay a monthly fee of \$7,500 and issued to Alere five-year warrants to purchase 35,000 shares of the Company's common stock at an exercise price of \$1.59, equal to the closing price of the Company's common stock on February 7, 2019, the date of approval by the Company's board of directors. On June 11, 2019, both parties agreed to terminate the Alere Agreement as of June 30, 2019 and the unvested warrants as of June 30, 2019, totaling 17,500, were forfeited.

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In addition to the warrants issued to investors in the Bridge Offering described above, the placement agent received a warrant to purchase 130,000 shares of the Company's common stock containing substantially the same terms as the warrant issued to investors in that transaction. The Company determined that all of the warrants issued in connection with the Bridge Offering were derivative instruments because the Company did not have control of the obligation to obtain shareholder approval by May 25, 2020 to increase the number of authorized shares or to approve a reverse stock split. The accounting treatment of derivative financial instruments requires that the Company record the warrants as a liability at fair value and mark-to-market the instruments at fair values as of each subsequent balance sheet date. Any change in fair value is recorded as a change in the fair value of derivative liabilities for each reporting period at each balance sheet date.

The fair value of the warrants was determined using a Monte Carlo simulation, incorporating observable market data and requiring judgment and estimates. The Company reassesses the classification at each balance sheet date. If the classification changes as a result of events during the period, the contract will be reclassified as of the date of the event that causes the reclassification.

The warrant derivatives were valued as of the February 25, 2020 issuance date, as of the quarter ended March 31, 2020, as of June 30, 2020, and as of September 15, 2020 when the Company's stockholders approved an increase in authorized shares in an amount sufficient to allow full exercise of these warrants. The value at issuance was \$546,036 and was recorded as a derivative liability. The value of the derivative liability was \$199,907 at March 31, 2020, \$281,183 at June 30, 2020, and \$334,229 at September 15, 2020.

The derivative liability increased \$53,046 and decreased \$211,807 during the three and nine months ended September 30, 2020, respectively. The changes in derivative liability is reflected in Other Income on the Condensed Statement of Operations.

On September 15, 2020, the fair value of derivative liabilities was reclassified to equity when the Company's stockholders approved items comprising a Capital Event. Accordingly, there is no fair value of derivative liabilities as of September 30, 2020.

The following inputs and assumptions were used for the valuation of the derivative liability:

	<u>February 25, 2020</u>	<u>March 31, 2020</u>	<u>June 30, 2020</u>	<u>September 15, 2020</u>
Stock Price	\$ 0.70	\$ 0.295	\$ 0.3859	\$ 0.4346
Projected Volatility	97.1%	102.7%	102.7%	110.7%
Risk-Free Rate	1.36%	0.38%	0.29%	0.31%

- It was assumed the stock price would fluctuate with the Company's projected volatility.
- The projected volatility was based on the historical volatility of the Company.
- If the Company was required to pay the fair value of the warrant in cash as of May 25, 2020, the obligation was discounted at the Company's estimated cost of debt based on short-term C-CCC bond ratings of 19.5% and 28.5%.
- The likelihood of the Company calling a shareholder meeting and achieving shareholder approval was 90% as of February 25, 2020.
- As June 30, 2020, the Company projected shareholder approval would not be obtained until approximately 8/31/20. No mandatory exercise was allowed prior to that date.
- Until the Company obtained shareholder approval to increase the authorized shares on September 15, 2020, we assumed the warrant holders have an option to require the Company to pay the fair value of the warrants. The derivative value at that date was \$334,229.

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*Warrant Exercises*

During the three and nine months ending September 30, 2020, warrants to purchase 1,818,682 shares of common stock were exercised resulting in proceeds to the Company of \$631,626.

*Stock Options*

From time to time, the Company issues options for the purchase of its common stock to employees and others. On July 18, 2020, the Company granted 100,000 options to each of its four independent directors and a total of 2,650,000 options to various executive officers, other employees and a consultant. The exercise price for these stock options is \$0.40 per share, the closing price of the Company's stock on the business day preceding the grant date. The Company recognized \$194,421 and \$159,865 of stock-based compensation related to stock options during the three months ended September 30, 2020 and 2019, respectively, and recognized \$363,027 and \$329,454 of stock-based compensation related to stock options during the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, there was \$1,138,934 of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 2.5 years.

*Restricted Stock Units*

On September 13, 2019, under the Company's nonemployee director compensation program, the Company granted two of its independent directors 78,125 restricted stock units each in connection with their appointment to the Board in accordance with the Option Plan, which, based on the Company's closing stock price on the grant date were valued at \$0.96 per unit for an aggregate grant date value of \$150,000. These units vest in equal annual portions on the anniversary of their grant.

**Note 11 – Subsequent Events**

On October 7, 2020, the Company entered into a Securities Purchase Agreement (the "October 2020 Purchase Agreement") with certain investors for the purpose of raising approximately \$5,100,000 million in gross proceeds for the Company. Pursuant to the terms of the October 2020 Purchase Agreement, the Company agreed to sell, in a registered direct offering, an aggregate of 9,532,709 shares of the Company's common stock at a purchase price of \$0.41 per share, and in a concurrent private placement, warrants to purchase up to 9,532,709 shares of common stock at a purchase price of \$0.125 per warrant, for a combined purchase price per share and warrant of \$0.535. The warrants are exercisable immediately on the date of issuance at an exercise price of \$0.41 per share and will expire five years following the date of issuance.

The closing of the sales of these securities under the October 2020 Purchase Agreement occurred on October 9, 2020. Net proceeds to the Company from the transactions, after deducting the placement agent's fees and expenses but before paying the Company's estimated offering expenses, and excluding the proceeds, if any, from the exercise of the warrants, were approximately \$4,450,000.

On November 10, 2020 the Company agreed to pay Spartan Capital Securities LLC \$355,000 in cash, and warrants to purchase 440,449 shares of common stock at a purchase price of \$0.32 per share, and warrants to purchase 451,402 shares of common stock at a purchase price of \$0.41 per share. These amounts were in dispute and were paid pursuant to an investment banking agreement dated February 12, 2020 in connection with financings which occurred in July and October. The investment banking agreement has now been terminated with no further obligations.

## 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.*

*The independent registered public accounting firm's report on the Company's financial statements as of December 31, 2019, and for each of the years in the two-year period then ended, includes a "going concern" explanatory paragraph, that describes substantial doubt about the Company's ability to continue as a going concern.*

*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 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 two lead products are: the Ven Valve®, 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 our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). We currently receive tissue for our products from one domestic supplier and one international supplier. Our current business model is to license, sell, or enter into strategic alliances with large medical device companies with respect to our products, either prior to or after FDA approval. 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.

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.

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, as a precursor to the U.S. pivotal trial, we are conducting a small first-in-man study for the VenoValve in Colombia. The first phase of the first-in-man Colombian trial included 11 patients. In addition to providing safety and efficacy data, the purpose of the first-in-man study is 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 first phase of the Colombian first-in-man study. Overall, VenoValves have been implanted in 11 patients. Endpoints for the VenoValve first-in-man study include 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.

Nine of 11 patients have now completed the one-year first-in-man trial. For those nine patients, reflux has improved an average of 50%, Venous Clinical Severity Scores (“VCSSs”) have improved an average of 58%, and VAS scores, which are used by patients to measure pain, have improved an average of 70%, all when compared to pre-surgery levels. VCSS scores are commonly used 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 improvements in VCSS scores is significant and indicates that VenoValve patients who had severe CVI pre-surgery, now have mild CVI or the complete absence of disease at one-year post surgery.



VenoValve safety incidences have been minor and include 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 have submitted a Pre-IDE filing with the FDA requesting a Pre-IDE meeting. An investigational device exemption or IDE form the FDA is required for a medical device company to proceed with a pivotal trial for a class III medical device. Next steps for the VenoValve include the Pre-IDE meeting with the FDA, the continued monitoring of the two remaining VenoValve patients in our first-in-human trial, and the completion of a series of functional tests and an animal safety study mandated by the FDA, which are pre-requisites for the filing of an IDE application. We expect to be in a position to file our IDE application with the FDA, seeking approval to proceed with the VenoValve U.S. pivotal trial, in Q1 of 2021.

## **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 a Saphenous Vein Graft (SVG). 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 performed 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 Council for the Republic of Paraguay to conduct a first-in-human trial for the CoreoGraft. Up to 5 patients that need coronary artery bypass graft surgery will 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.

On October 28, 2020, we announced the first successful implantation of the CoreoGraft in a patient in Colombia.

### **Comparison of the three months ended September 30, 2020 and 2019**

#### *Overview*

We reported net losses of \$1,974,769 and \$1,814,895 for the three months ended September 30, 2020 and 2019, respectively, representing an increase in net loss of \$159,874 or 9%, due to an increase in operating expenses of \$88,253, and a net increase in other income and expense of \$71,621.

#### *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 September 30, 2020, selling, general and administrative expenses increased by \$7,025 or 1%, to \$1,164,089 from \$1,157,064 for the three months ended September 30, 2019. The small net increase reflects increases in legal, consulting and insurance expenses totaling approximately \$170,000, partially offset by decreases in travel, compensation and other administrative expenses totaling approximately \$152,000.

Legal expenses increased approximately \$57,000 mainly due to the Company's increased level of public filing activity not directly related to funding transactions in 2020 when compared to 2019, partially offset by lower ATSCO litigation related expenses. Consulting expenses increased \$58,000 primarily due to placement agent fees for the Company's research and development director. Compensation cost was approximately \$95,000 lower due mainly to the change in classification of \$65,000 employee benefits charged to research and development expenses in 2020 that were previously included in Selling, General and Administrative Expenses, lower travel expenses of approximately \$43,000 in 2020 due to COVID-19 travel restrictions, and approximately \$22,000 in lower facility and office related expenses.

#### *Research and Development Expenses*

For the three months ended September 30, 2020, research and development expenses increased by \$81,228 or 12%, to \$758,198 from \$676,970 for the three months ended September 30, 2019. The increase is primarily due to increases of \$95,000 in compensation and related costs due to a larger team, \$41,000 in lab cost related to our APS study, partially offset by \$19,000 in lower tissue purchases in 2020 due to stay-at home work orders related to COVID-19, and \$11,000 in lower consulting expense due to the external cost being replaced with an employee in 2020.

#### *Interest Income*

Interest income of \$564 and \$19,139 was earned during the three months ended September 30, 2020 and 2019, respectively.

#### *Change in Fair Value of Derivative Liability*

For the quarter ended September 30, 2020, we recorded a loss on the change in fair value of derivative liabilities of \$53,046. Our derivative liabilities are related to warrants issued in connection with our Bridge Offering in February 2020.

### **Comparison of the nine months ended September 30, 2020 and 2019**

#### *Overview*

We reported net losses of \$4,761,483 and \$5,334,644 for the nine months ended September 30, 2020 and 2019, respectively, representing a decrease in net loss of \$573,161, or 11%, due to a decrease in operating expenses of \$399,609, and an increase in other income and expense of \$173,552.

#### *Revenues*

Revenue earned during the nine months ended September 30, 2019 was \$31,243 and consisted entirely of royalty income earned pursuant to the terms of our March 2016 asset sale agreement with LeMaitre Vascular, Inc., which three-year term ended on March 18, 2019. With the agreement reaching the end of its term in 2019, there was not any similar revenue in 2020.

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 nine months ended September 30, 2020, selling, general and administrative expenses decreased by \$987,554 or 25%, to \$3,001,720 from \$3,989,274 for the nine months ended September 30, 2019. The decrease is primarily due to decreases of approximately \$382,000 in stock-based compensation expense primarily from the settlement of a legal dispute in 2019 and from lower expense related to awards of common stock options to employees and consultants in 2020, \$67,000 in legal fees due to lower costs related to the ATSCO litigation, \$140,000 in lower consulting and outside services cost related to recruiting fees in 2019 that were not incurred in 2020 and reductions in other consulting, \$142,000 in lower travel costs due to COVID-19 travel restrictions, and in facility and other office expenses which were \$104,000 lower due to the office closure related to stay-at home work orders, partially offset by \$134,000 in higher insurance costs in 2020.

### *Research and Development Expenses*

For the nine months ended September 30, 2020, research and development expenses increased by \$556,702 or 39%, to \$1,974,995 from \$1,418,293 for the nine months ended September 30, 2019. The increase is primarily due to increases of \$272,000 in compensation and related costs due to a larger team, \$271,000 in lab cost related to our APS study, and \$39,000 in consulting related to support for our GLP protocol. These increases were partially offset by approximately 26,000 in lower tissue purchases due to COVID-19.

### *Interest Income*

Interest income of \$3,425 and \$41,680 was earned during the nine months ended September 30, 2020 and 2019, respectively.

### *Change in Fair Value of Derivative Liability*

For the nine months ended September 30, 2020, we recorded a gain on the change in fair value of derivative liabilities of \$211,807. Our derivative liabilities were related to warrants issued in connection with our Bridge Offering.

### **Liquidity and Capital Resources**

We have incurred losses since inception and negative cash flows from operating activities for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$60,949,408. These factors, among others, raise substantial doubt about our ability to continue as a going concern. Since inception, we have funded our operations primarily through our IPO, public and private placements of equity, and private placements of convertible debt securities as well as modest revenues from royalties, contract research and sales of the ProCol Vascular Bioprosthesis. To-date in 2020, including the October 2020 offering, we have closed five financings providing aggregate net proceeds of approximately \$12,200,000.

As of November 10, 2020, we had a cash balance of \$8,841,899.

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

	<b>September 30 2020</b>	<b>December 31, 2019</b>
	<b>(unaudited)</b>	
Cash	\$ 5,629,003	\$ 1,307,231
Restricted Cash	-	810,055
Working capital (deficiency)	<u>4,062,232</u>	<u>(452,434)</u>

Based upon our cash and working capital as of September 30, 2020, and after giving effect to the transactions completed on October 9, 2020, we believe we have sufficient cash to sustain the Company's operations at least one year after the date of filing 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 4 – 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, 2020, 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, 2020 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, 2020 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 October 8, 2018, Gusrae Kaplan Nusbaum PLLC (“Gusrae”) filed a complaint with the Supreme Court of the State of New York seeking payment of \$178,926 plus interest and legal costs for invoices to the Company dated from November 2016 to December 2017. In July 2016, the Company retained Gusrae to represent the Company in connection with certain specific matters. The Company believes that Gusrae has not applied all of the payments made by the Company along with billing irregularities and errors and is disputing the amount owed. The Company recorded the disputed invoices in accounts payable and as of June 30, 2019, the Company has fully accrued for the outstanding claim against the Company.

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 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. The complaint seeks, among other things, back pay, unpaid wages, compensatory damages, punitive damages, attorneys’ 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. However, in addition to our current risk factors are set forth in our Form 10-K, filed with the SEC on March 18, 2020, we have also identified the following additional risks to our company.

### ***Risks Related to COVID-19***

#### ***The COVID-19 pandemic has significantly negatively impacted our business.***

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 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. At this time, we have identified the following COVID-19 related risks that we believe have a greater likelihood of negatively impacting our company specific, including, but not limited to:

- Federal, State and local shelter-in-place directives which limit our employees from accessing our facility to manufacture, develop and test our product candidates.
- Travel restrictions and quarantine requirements which prevent us from initiating and continuing animal studies and patient trial both inside and outside of the United States.
- The burden on hospitals and medical personnel resulting in the cancellation of non-essential medical procedures such as surgical procedures needed to implant our product candidates for pre-clinical and clinical trials.
- Delays in the procurement of certain supplies and equipment that are needed to develop and test our product candidates.
- Erosion of the capital markets which make it more difficult to obtain the financing that we need to fund and continue our operations.
- Potential back-log at regulatory agencies such as the FDA which may result in delays in obtaining regulatory approvals.
- Travel restrictions which prevent patients from participating and continuing the participation in clinical trials.

### ***Risks Related to our Material Weakness***

***If we fail to maintain an effective system of internal controls, we may not be able to accurately report financial results or prevent fraud. If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our stock could be negatively affected.***

As described in Part I, Item 4 - Controls and Procedures, in connection with our issuance of warrants in the Bridge Offering, we identified a material weakness in our internal control over financial reporting with regard to our failure to record an associated derivative liability on a timely basis. This deficiency did not result in the revision of any of our issued financial statements. If we are unable to remediate this material weakness, or if we do not have these controls operating effectively for a sufficient amount of time, management may conclude that we did not maintain effective internal control over financial reporting as of December 31, 2020.

Effective internal controls are necessary to provide reliable financial reports and to assist in the effective prevention of fraud. Any inability to provide reliable financial reports or prevent fraud could harm our business. We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. 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. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

While 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 can offer no assurance that our remediation plan will ultimately have the intended effects. Any failure to maintain such internal controls could adversely impact our ability to report our financial results on a timely and accurate basis. If our financial statements are not accurate, investors may not have a complete understanding of our operations or may lose confidence in our reported financial information. Likewise, if our financial statements are not filed on a timely basis as required by the SEC and The Nasdaq Stock Market, we could face severe consequences from those authorities. In either case, it could result in a material adverse effect on our business or have a negative effect on the trading price of our common stock. Further, if we fail to remedy this deficiency (or any other future deficiencies) or maintain the adequacy of our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties or shareholder litigation. We can give no assurance that the measures we have taken and plan to take in the future will remediate the material weakness identified or that any additional material weaknesses will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of those controls.

Further, in the future, if we cannot conclude that we have effective internal control over our financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in our stock price. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, The Nasdaq Stock Market or other regulatory authorities.

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

On November 10, 2020 the Company agreed to pay Spartan Capital Securities LLC warrants to purchase 440,449 shares of common stock at a purchase price of \$0.32 per share, and warrants to purchase 451,402 shares of common stock at a purchase price of \$0.41 per share. These warrants were issued as consideration pursuant to an investment banking agreement dated February 12, 2020 in connection with financings which occurred in July and October. The investment banking agreement has now been terminated with no further obligations. The warrant shares were issued pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.



**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.

<b>Exhibit</b>	<b>Description</b>
31.1	<a href="#"><u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.</u></a> *
31.2	<a href="#"><u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Sarbanes-Oxley Act.</u></a> *
32	<a href="#"><u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act</u></a> **
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: November 17, 2020

**HANCOCK JAFFE LABORATORIES, INC.**

By: /s/ Robert Berman

Robert Berman  
Chief Executive Officer  
(Principal Executive Officer)

By: /s/ Craig Glynn

Craig Glynn  
Interim Chief Financial Officer  
(Principal Financing and Accounting Officer)

**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.

November 17, 2020

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

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**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.

November 17, 2020

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

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**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 September 30, 2020, 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*

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Robert Berman  
Chief Executive Officer and Principal Executive Officer

Dated: November 17, 2020

*/s/ Craig Glynn*

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Craig Glynn  
Chief Financial Officer and Principal Financial Officer

Dated: November 17, 2020

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.

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