

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

FORM 10-Q

**[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE
ACT OF 1934**

For the quarterly period ended March 31, 2019

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)

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 [X] 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 [X] 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. [X]

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

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

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

As of May 9, 2019, there were 14,149,507 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

	March 31, 2019	December 31, 2018
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 2,752,511	\$ 2,740,645
Accounts receivable	26,515	32,022
Prepaid expenses and other current assets	166,614	64,306
Total Current Assets	2,945,640	2,836,973
Property and equipment, net	24,887	26,153
Restricted cash	810,055	-
Operating lease right-of-use assets, net	1,030,527	-
Intangible assets, net	647,058	666,467
Security deposits and other assets	29,843	29,843
Total Assets	<u>\$ 5,488,010</u>	<u>\$ 3,559,436</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,095,866	\$ 1,077,122
Accrued expenses and other current liabilities	438,534	412,871
Deferred revenue - related party	33,000	33,000
Current portion of operating lease liabilities	271,101	-
Total Current Liabilities	1,838,501	1,522,993
Long-term operating lease liabilities	784,462	-
Total Liabilities	<u>2,622,963</u>	<u>1,522,993</u>
Commitments and Contingencies		
Stockholders' Equity:		
Preferred stock, par value \$0.00001, 10,000,000 shares authorized: no shares issued or outstanding	-	-
Common stock, par value \$0.00001, 50,000,000 shares authorized, 14,155,644 and 11,722,647 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	141	117
Additional paid-in capital	53,001,160	50,598,854
Accumulated deficit	(50,136,254)	(48,562,528)
Total Stockholders' Equity	<u>2,865,047</u>	<u>2,036,443</u>
Total Liabilities and Stockholders' Equity	<u>\$ 5,488,010</u>	<u>\$ 3,559,436</u>

See Notes to these Unaudited Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2019	2018
Revenues:		
Royalty income	\$ 31,243	\$ 31,065
Selling, general and administrative expenses	1,300,571	1,247,008
Research and development expenses	313,013	240,493
Loss from Operations	(1,582,341)	(1,456,436)
Other (Income) Expense:		
Amortization of debt discount	-	4,569,757
Gain on extinguishment of convertible notes payable	-	(1,524,791)
Interest (income) expense, net	(8,615)	210,462
Change in fair value of derivative liabilities	-	35,623
Total Other (Income) Expense	(8,615)	3,291,051
Net Loss	(1,573,726)	(4,747,487)
Deemed dividend to preferred stockholders	-	(129,141)
Net Loss Attributable to Common Stockholders	\$ (1,573,726)	\$ (4,876,628)
Net Loss Per Basic and Diluted Common Share:	\$ (0.13)	\$ (0.80)
Weighted Average Number of Common Shares Outstanding:		
Basic and Diluted	12,267,446	6,133,678

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' (Deficiency)
	Shares	Amount			
Balance at January 1, 2018	6,133,678	\$ 61	\$ 24,389,307	\$ (35,519,819)	\$ (11,130,451)
Stock-based compensation:					
Amortization of stock options	-	-	137,376	-	137,376
Net loss	-	-	-	(4,747,487)	(4,747,487)
Balance at March 31, 2018	<u>6,133,678</u>	<u>\$ 61</u>	<u>\$ 24,526,683</u>	<u>\$ (40,267,306)</u>	<u>\$ (15,740,562)</u>

	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 private placement offering ^[1]	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	<u>14,155,644</u>	<u>\$ 141</u>	<u>\$ 53,001,160</u>	<u>\$ (50,136,254)</u>	<u>\$ 2,865,047</u>

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

See Notes to these Unaudited Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2019	2018
Cash Flows from Operating Activities		
Net loss	\$ (1,573,726)	\$ (4,747,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	-	4,569,757
Gain on extinguishment of convertible notes payable	-	(1,524,791)
Stock-based compensation	104,310	137,376
Depreciation and amortization	22,473	33,206
Amortization of right-of-use assets	68,873	-
Change in fair value of derivatives	-	35,623
Changes in operating assets and liabilities:		
Accounts receivable	5,507	4,116
Inventory	-	(106,743)
Prepaid expenses and other current assets	(102,308)	57,544
Accounts payable	18,744	50,702
Accrued expenses	28,882	(134,722)
Payments on lease liabilities	(66,310)	-
Total adjustments	80,171	3,122,068
Net Cash Used in Operating Activities	(1,493,555)	(1,625,419)
Cash Flows from Investing Activities		
Purchase of property and equipment	(1,800)	-
Net Cash Used in Investing Activities	(1,800)	-
Cash Flows from Financing Activities		
Proceeds from private placement, net ^[1]	2,317,276	-
Initial public offering costs paid in cash	-	(341,890)
Repayments of notes payable	-	(275,000)
Repayments of notes payable - related party	-	(130,000)
Proceeds from issuance of convertible notes, net ^[2]	-	2,603,750
Net Cash Provided by Financing Activities	2,317,276	1,856,860
Net Increase in Cash, Cash Equivalent, and Restricted Cash	821,921	231,441
Cash, cash equivalents and restricted cash - Beginning of period	2,740,645	77,688
Cash, cash equivalents and restricted cash - End of period	\$ 3,562,566	\$ 309,129

[1] Net of cash offering costs of \$386,724

[2] Net of cash offering costs of \$293,750

See Notes to these Unaudited Condensed Financial Statements

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

	For the Three Months Ended March 31,	
	2019	2018
Supplemental Disclosures of Cash Flow Information:		
Cash Paid (Received) During the Period For:		
Interest, net	\$ (12,441)	\$ 303,888
Non-Cash Financing Activities		
Fair value of warrants issued in connection with convertible debt included in derivative liabilities	\$ -	\$ 1,942,362
Embedded conversion option in convertible debt included in derivative liabilities	\$ -	\$ 1,232,199

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. (“HJLI” or the “Company”) is a development stage 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. HJLI’s products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the existing 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. 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 two 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. For example, we developed, manufactured, and obtained FDA pre-market approval for the ProCol Vascular Bioprosthesis, a product for hemodialysis vascular access, which we sold to LeMaitre Vascular in March of 2016. Our current senior management team has been affiliated with more than 80 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 was FDA certified for commercial manufacturing of product.

Note 2 – Going Concern and Management’s Liquidity Plan

The accompanying 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 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 \$1,573,726 for the three months ended March 31, 2019 and had an accumulated deficit of \$50,136,254 at March 31, 2019. Cash used in operating activities was \$1,493,555 and \$1,625,419 for the three months ended March 31, 2019 and 2018, 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.

As of March 31, 2019, the Company had cash balance of \$2,752,511, restricted cash of \$810,055 and working capital of \$1,107,139.

The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital to sustain its operations, pursue its product development initiatives and penetrate markets for the sale of its products.

Management believes that the Company could have access to 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. 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 March 31, 2019, and for the three months ended March 31, 2019 and 2018. The results of operations for the three months ended March 31, 2019 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, 2018 included in the Company’s Form 10-K filed with the SEC on March 14, 2019. The condensed balance sheet as of December 31, 2018 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.

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 Series A and Series B Preferred Stock (“Preferred Stock”) that were issued in 2016 and 2017 and the beneficial conversion feature recorded in connection with the conversion of the Preferred Stock. Since the Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company’s IPO, there was no deemed dividend in the three months ended March 31, 2019.

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, plus the conversion of preferred stock or convertible notes, in the calculation of diluted net loss per common shares would have been anti-dilutive.

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

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 March 31, 2019 and 2018:

	March 31,	
	2019	2018
Shares of common stock issuable upon conversion of preferred stock	-	629,746
Shares of common stock issuable upon exercise of preferred stock warrants and the subsequent conversion of the preferred stock issued therewith	-	50,285
Shares of common stock issuable upon the conversion of convertible debt	-	470,666
Shares of common stock issuable upon exercise of warrants	4,003,679	633,761
Shares of common stock issuable upon exercise of options	1,182,624	1,422,000
Potentially dilutive common stock equivalents excluded from diluted net loss per share	<u>5,186,303</u>	<u>3,206,458</u>

Revenue Recognition

The Company recognizes revenue when goods or services are transferred to customers in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. Revenue is recognized from contracts with customers either at a “point in time” or “over time”, depending on the facts and circumstances of the arrangement that the Company evaluates using the following five-step analysis: (i) identification of contract with customer; (ii) determination of performance obligations; (iii) measurement of the transaction price; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The following table lists the Company’s revenue recognized in the accompanying condensed statements of operations:

	For the Three Months Ended	
	March 31,	
	2019	2018
Royalty income	<u>\$ 31,243</u>	<u>\$ 31,065</u>

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

Royalty revenue, which is based on resales of ProCol Vascular Bioprosthesis to third-parties, will be recorded when the third-party sale occurs and the performance obligation has been satisfied.

Information on Remaining Performance Obligations and Revenue Recognized from Past Performance

Information about remaining performance obligations pertaining to contracts that have an original expected duration of one year or less is not disclosed. The transaction price allocated to remaining unsatisfied or partially unsatisfied performance obligations with an original expected duration exceeding one year was not material at March 31, 2019.

Contract Balances

The timing of our revenue recognition may differ from the timing of payment by our customers. A receivable is recorded when revenue is recognized prior to payment and the Company has an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, deferred revenue is recorded until the performance obligations are satisfied. The Company had deferred revenue of \$33,000 as of March 31, 2019 and December 31, 2018 related to cash received in advance for contract research and development services. The Company expects to satisfy its remaining performance obligations for contract research and development services and recognize the deferred revenue over the next twelve months.

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.

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 \$3,312,566 as of March 31, 2019.

For the three months ended March 31, 2019 and 2018, 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.

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.

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

Note 4 – Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist principally of deposit accounts and money market accounts as of March 31, 2019 and December 31, 2018.

As of March 31, 2019, the Company had \$810,055 in restricted cash. On January 18, 2019, the Superior Court granted ATSCO, Inc. (see Note 8 - Commitments and Contingencies - *Litigations Claims and Assessments*) a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of \$810,055, which the Company plans on appealing.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the balance sheets that sum to the total of the same amounts shown in the statement of cash flows.

	March 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 2,752,511	\$ 2,740,645
Restricted cash	810,055	-
Total cash, cash equivalents, and restricted cash in the balance sheet	<u>\$ 3,562,566</u>	<u>\$ 2,740,645</u>

Note 5 – Property and Equipment

As of March 31, 2019 and December 31, 2018, property and equipment consist of the following:

	March 31, 2019	December 31, 2018
Lab equipment	\$ 94,905	\$ 94,905
Furniture and fixtures	93,417	93,417
Computer software and equipment	28,629	26,830
Leasehold improvements	158,092	158,092
Total property and equipment	<u>375,043</u>	<u>373,244</u>
Less: accumulated depreciation	(350,156)	(347,091)
Property and equipment, net	<u>\$ 24,887</u>	<u>\$ 26,153</u>

Depreciation expense amounted to \$3,065 and \$2,380 for the three months ended March 31, 2019 and 2018, respectively. Depreciation expense is reflected in general and administrative expenses in the accompanying statements of operations.

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

Note 6 – Right-of-Use Assets and Lease Liabilities

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 ASC Topic 842, Leases (Topic 842) effective January 1, 2019 using the prospective approach. In addition, the Company elected not to apply ASC Topic 842 to arrangements with lease terms of 12 months or less. On January 1, 2019, upon adoption of ASC 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.

Our operating lease cost is as follows:

	For the Three Months Ended March 31, 2019	
Operating lease cost	\$	84,492

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

	For the Three Months Ended March 31, 2019	
Operating cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities	\$	82,929

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

	March 31, 2019	
Remaining lease term		4 years
Discount rate		8.5%

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

Nine months ended December 31, 2019	\$	251,274
Year ended December 31, 2020		344,229
Year ended December 31, 2021		354,561
Year ended December 31, 2022		271,854
Total	\$	1,221,918
Less: Imputed interest		(166,355)
Present value of our lease liability	\$	1,055,563

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

Note 7 – Accrued Expenses and Accrued Interest – Related Party

As of March 31, 2019 and December 31, 2018, accrued expenses consist of the following:

	March 31, 2019	December 31, 2018
Accrued compensation costs	\$ 274,035	\$ 288,549
Accrued professional fees	118,138	55,300
Deferred rent	-	22,473
Accrued franchise taxes	27,107	26,985
Accrued stock compensation expense	19,254	-
Accrued research and development	-	17,064
Other accrued expenses	-	2,500
Accrued expenses	<u>\$ 438,534</u>	<u>\$ 412,871</u>

Included in accrued compensation costs in the table above is accrued severance expense of \$92,308 and \$166,154 for the three months ended March 31, 2019 and year ended December 31, 2018, respectively, pursuant to the terms of the employment agreement for the Company's prior Chief Financial Officer, who was terminated effective July 20, 2018.

Note 8 – Commitments and Contingencies

Litigations Claims and Assessments

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

On September 25, 2018, ATSCO, Inc., filed a complaint 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. The Company is disputing the amount owed and that the Agreement called for a fixed monthly fee regardless of tissue delivered. The Company believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate the fees when they were not delivering tissues and not incurring any costs; \$173,400 of the amount that ATSCO is seeking are for invoices to Hancock Jaffe Laboratory Aesthetics, Inc. (in which the Company owns a minority interest of 28.0% as described in Note 4 to the Financial Statements – Significant Accounting Policies - *Investments*) and is not the obligation of HJLI; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of HJLI stock transferred to ATSCO's principal and owner; the yields of the materials delivered by ATSCO to HJLI was inferior; and the Agreement was constructively terminated. On January 18, 2019, the Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of \$810,055, which the Company plans on appealing. The attachment order is not a binding ruling on the merits of the case and the Company plans on filing a Cross-Complaint for abuse of process and excessive and wrongful attachment as \$173,400 of the claim is to a wholly separate company, and over \$500,000 of the claim is attributable to invoices sent without delivery of any tissue. On March 26, 2019, ATSCO filed a First Amended Complaint with the Superior Court increasing its claim to \$1,606,820 plus incidental damages and interest, on the basis of an alleged additional oral promise not alleged in its original Complaint. The Company continues to firmly believe it has numerous meritorious defenses to the new claim, including those described above, and expects to continue a vigorous defense and to continue pursuing its Cross-Complaint. The Company recorded the disputed invoices in accounts payable and as of March 31, 2019, the Company believes that it has fully accrued for the outstanding claim against the Company. A Mandatory Settlement Conference is scheduled for July 26, 2019 and the Jury Trial is scheduled for September 9, 2019. The Company has entered into new supply relationships with two domestic and one international company to supply porcine and bovine tissues.

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

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 March 31, 2019, the Company has fully accrued for the outstanding claim against the Company.

The Company has been contacted by an individual that claims to be owed a fee for introducing the Company to Alexander Capital, who was the placement agent for the capital raise of the convertible notes issued in 2017 and 2018. The Company has conducted its own factual investigation and legal analysis and believes that the claim is without merit. The individual has threatened to file a lawsuit, and in the event that a lawsuit is filed, the Company would have numerous defenses including without limitation that the individual was unlicensed to provide the services he alleges he provided.

Note 9 –Stockholders’ Equity (Deficiency)

Common Stock

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 is for a term of twelve (12) months and can be cancelled by either party at the end of six (6) months with thirty (30) days’ notice. MZ will receive compensation of \$8,000 per month and eighty-five thousand (85,000) restricted shares that vest quarterly over a year, with a 6 month cliff. If the MZ Agreement is terminated by MZ at the end of six months, MZ forfeits the restricted shares.

On March 12, 2019, the Company raised \$2,704,000 in gross proceeds in a private placement offering of its common stock to certain accredited investors (the “Offering”). The Company sold an aggregate of 2,329,615 shares of common stock in the Offering for a purchase price of \$1.15 per share pursuant to a share purchase agreement between the Company and each of the investors in the Offering. Our CEO also participated in the Offering purchasing 18,382 shares at a price of \$1.36 per share, the final bid price of our common stock as reported on The Nasdaq Capital Market on the date of the Offering.

Warrants

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. The warrants shall vest equally monthly over a 12 month period provided that the Alere Agreement remains in effect.

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

The placement agent for the March 12, 2019 Offering is entitled to a warrant to purchase such number of shares of the Company's common stock equal to 8% of the total shares of common stock sold in the Offering or 188,108 shares. Such warrant will be exercisable for a period of five years from the date of issuance and will have an exercise price of \$1.50 per share.

Stock Options

On February 7, 2019, in connection with her Employment Agreement, the Company granted non-qualified stock options for the purchase of 150,000 shares of common stock at an exercise price of \$1.59 to H. Chris Sarner, our Vice President Regulatory Affairs and Quality Assurances. The exercise price was equal to the closing price of our common stock on February 7, 2019, the date that the Board approved the option grant. The options have a ten-year term and 50,000 of the options will vest on the first anniversary of Ms. Sarner's employment with the Company, and the remaining 100,000 options will vest on a quarterly basis over the following two-year period. The options had grant date fair value of \$0.58 per share for an aggregate grant date fair value of \$87,000, using the Black Scholes method with the following assumptions used: stock price of \$1.59, risk-free interest rate of 2.47%, volatility of 36.3%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On February 7, 2019, the Company's board of directors approved the grant of 30,000 non-qualified options to purchase shares of the Company's common stock to H. Jorge Ulloa as compensation for services provided as the Company's Primary Investigator for the first-in-human trials of our VenovaValve in Colombia in February and April 2019. The stock options were granted at an exercise price of \$1.59, equal to the closing price of our common stock on the date that the Board approved the option grant. The options vest monthly, over a one (1) year period. The options had grant date fair value of \$0.58 per share for an aggregate grant date fair value of \$17,400, using the Black Scholes method with the following assumptions used: stock price of \$1.59, risk-free interest rate of 2.47%, volatility of 36.1%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

On January 7, 2019, Dr. Peter Pappas agreed to join the Company's Medical Advisory Board for a term of two years. The Company's board of directors approved the grant on March 6, 2019 of 20,000 non-qualified options to purchase shares of the Company's common stock to Dr. Pappas as compensation. The stock options were granted at an exercise price of \$1.38, equal to the closing price of our common stock on the date that the Board approved the option grant. The options will vest monthly in twenty-four (24) equal installments for each month that he remains a member of the Company's Medical Advisory Board. The options had grant date fair value of \$0.50 per share for an aggregate grant date fair value of \$10,000, using the Black Scholes method with the following assumptions used: stock price of \$1.38, risk-free interest rate of 2.50%, volatility of 35.9%, annual rate of quarterly dividends of 0%, and a contractual term of 5.3 years.

The Company recognized \$82,720 and \$137,376 of stock-based compensation related to stock options during the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, there was \$680,246 of unrecognized stock-based compensation expense related to outstanding stock options that will be recognized over the weighted average remaining vesting period of 1.4 years.

Restricted Stock Units

In April 2019, Mr. Marcus Robins, a Director on the Company's Board of Directors passed away. Per his restricted stock unit Award Agreement, upon his death, 29,183 units representing the non-vested portion of his restricted stock units were forfeited.

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, 2018, 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 development stage company developing biologic-based solutions that are designed to be life sustaining or life enhancing for patients with cardiovascular disease, and peripheral arterial and venous disease. HJLI's products are being developed to address large unmet medical needs by either offering treatments where none currently exist or by substantially increasing the type of treatment. 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. Our current products are being developed for approval by the U.S. Food and Drug Administration ("FDA"). 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. For example, we developed, manufactured, and obtained FDA pre-market approval for the ProCol Vascular Bioprosthesis, a product for hemodialysis vascular access, which we sold to LeMaitre Vascular in March of 2016. Our current senior management team has been affiliated with more than 80 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 was FDA certified for commercial manufacturing of product.

Each of our product candidates will be required to successfully complete significant clinical trials to demonstrate the safety and efficacy of the product candidate before it will be able to be approved by the FDA. The completion of these clinical trials will require a significant amount of capital and the hiring of additional personnel.

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

VenoValve

The VenoValve is a porcine based valve developed at HJLI to be implanted in the deep vein system of the leg. 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. Initially, the VenoValve will be surgically implanted into the patient on an outpatient basis via a 5 to 6 inch incision in the upper thigh.

There are presently no medical or nonsurgical treatments for reflux occurring in the deep vein system. Compression garments or constant leg elevation address the symptoms, but ignore the underlying cause. Compliance with compression garments and leg elevation is extremely low, especially among the elderly. When CVI is isolated to the superficial veins, ablation or surgical excision of the affected saphenous vein is an option. For the deep vein system, valve transplants have been attempted but with very-poor results. Another potential option, the creation of valves using fibrous tissue, has only been performed in few centers worldwide. We believe that the reestablishment of proper direction of venous flow to the heart is the only reasonable remedy to the problem of reflux based CVI. Currently, however, there is no known devices or medicines available that would restore venous flow in the deep venous system.

The initial potential U.S. market for the first iteration of the VenoValve are the 2.6 million severe CVI sufferers with deep venous reflux. Future iterations of the VenoValve may also be appropriate for the superficial vein system, which would increase the potential market to all of the 4.8 million severe CVI sufferers with deep vein or superficial vein reflux.

We are conducting a small first-in-human study of between 5 to 10 patients for the VenoValve overseas prior to initiating our pivotal U.S. trial. The first-in-human study will provide us with valuable feedback to make any necessary product modifications or adjustments to our surgical implantation procedures prior to conducting our 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 U.S. Food and Drug Administration, for our first-in-human trial for the VenoValve. On February 19, 2019, we announced that the first VenoValve was successfully implanted in a patient in Bogota, Colombia, that the VenoValve appears to be functioning as it should, and that there were no signs of any early adverse events. On April 11, 2019, we announced that the VenoValve was implanted in four additional patients and that the surgeries went well and there were no early signs of adverse events. We expect preliminary results from the first-in-human study to be made public in June of 2019, with additional study results to be made available in the fourth quarter of 2019.

CoreoGraft

The CoreoGraft is a bovine based off the shelf conduit that could potentially be used to revascularize the heart, instead of harvesting the saphenous vein from the patient’s leg. In addition to avoiding the invasive and painful saphenous vein graft (“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 SVG.

In addition to providing an 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 left internal mammary artery (“LIMA”), an artery running inside the ribcage and close to the sternum, to re-vascularize the left side of the heart, 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.

Comparison of the three months ended March 31, 2019 and 2018

Overview

We reported net losses of \$1,573,726 and \$4,747,487 for the three months ended March 31, 2019 and 2018, respectively, representing a decrease in net loss of \$3,173,761, or 67%, resulting primarily from a decrease in amortization of debt discount of \$4,569,757 (see below) and a decrease of \$219,077 in interest expense, net, partially offset by decrease in the gain on extinguishment of convertible note payable of \$1,524,791 (see below) and an increase in operating expenses of \$126,083.

Revenues

Revenues earned during the three months ended March 31, 2019 and 2018 were flat and consist entirely of royalty income of \$31,243 and \$31,065, respectively. Royalty income is 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. After March 18, 2019, we will no longer generate royalty revenue until one of our product candidates that secure regulatory approval is licensed, if ever.

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 March 31, 2019, selling, general and administrative expenses increased by \$53,563 or 4%, to \$1,300,571 from \$1,247,008 for the three months ended March 31, 2018. The increase is primarily due to increases of approximately \$66,000 in insurance expenses primarily in D&O insurance from being a public company and \$86,000 in legal and professional fees primarily in connection to our litigations (see Note 8 - Commitments and Contingencies - *Litigations Claims and Assessments*), partially offset by a decrease of approximately \$98,000 in labor and benefit expenses during the period as certain personnel focused on research and development activities.

Research and Development Expenses

For the three months ended March 31, 2019, research and development expenses increased by \$72,520 or 30%, to \$313,013 from \$240,493 for the three months ended March 31, 2018. The increase is primarily due to increased labor costs, benefits and supplies and materials associated with research and development activities supporting the first-in-human trials for the VenoValve occurring in February and April 2019 in Columbia.

Interest Expense

For the three months ended March 31, 2019, interest expense, net decreased by \$219,077, or 104%, as compared to the three months ended March 31, 2018, due to the conversion of the convertible notes into shares of our common stock upon the consummation of our IPO on June 4, 2018. On this date, principal and interest totaling \$5,743,391 owed in connection with the convertible notes were converted into 1,650,537 shares of our common stock at a conversion price of \$3.50 per share. Interest income of \$9,081 was earned during the three months ended March 31, 2019.

Amortization of Debt Discount

During the three months ended March 31, 2018, we recognized non-cash amortization of debt discount expense of \$4,569,757 related to the embedded conversion option in the convertible notes issued during the period from June 2017 through January 2018 (“Notes”), as well as the warrants issued with the Notes. Since the Notes were converted on June 4, 2018 into common stock in connection with the Company’s IPO, there was no amortization of debt discount in the three months ended March 31, 2019.

Gain on extinguishment of convertible notes payable

During the three months ended March 31, 2018, we recognized non-cash gain on the extinguishment of convertible notes payable of \$1,524,791. On February 28, 2018, the Notes were amended such that the maturity date was extended to May 15, 2018, the warrants issued in connection with the convertible notes issued in 2017 became exercisable for the number of shares of common stock equal to 100% of the total shares issuable upon conversion and the warrants issued in connection with the convertible notes issued in 2018 became exercisable for the number of shares of common stock equal to 75% of the total shares issuable upon the conversion. The amendment of the Notes was deemed to be a debt extinguishment. Since the Notes were converted on June 4, 2018 into common stock in connection with the Company’s IPO, there was no extinguishment of convertible notes payable in the three months ended March 31, 2019.

Change in Fair Value of Derivative Liability

For the three months ended March 31, 2018, we recorded a gain on the change in fair value of derivative liabilities of \$35,623. The derivative liabilities are related to warrants issued in connection with our Series A preferred stock and Series B preferred stock financings during the period of 2016 to 2017 (“Preferred Stock”), plus warrants issued in connection with the Notes, as well as the embedded conversion options in the Notes. Since the Notes and Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company’s IPO, there was no change in fair value of derivative liabilities in the three months ended March 31, 2019.

Deemed Dividend

We recorded a deemed dividend of \$129,141 for the three months ended March 31, 2018. The deemed dividend for the three months ended March 31, 2018 resulted primarily from the 8% cumulative dividend on the Preferred Stock. Since the Preferred Stock were converted on June 4, 2018 into common stock in connection with the Company’s IPO, there was no deemed dividend in the three months ended March 31, 2019.

Liquidity and Capital Resources

We have incurred losses since inception and negative cash flows from operating activities for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of \$50,136,254. Since inception, we have funded our operations primarily through our IPO, private placements of equity and convertible debt securities as well as modest revenues from royalties, contract research and sales of the ProCol Vascular Bioprosthesis.

On March 12, 2019, the Company raised \$2,704,000 in gross proceeds in a private placement offering of its common stock to certain accredited investors (the “Offering”). The Company sold an aggregate of 2,329,615 shares of common stock in the Offering for a purchase price of \$1.15 per share. Our CEO also participated in the Offering purchasing 18,382 shares at a price of \$1.36 per share, the final bid price of our common stock as reported on The Nasdaq Capital Market on the date of the Offering. On March 29, 2019, the Company filed a registration statement with the Securities and Exchange Commission for the resale of the shares sold in the Offering. The registration statement was declared effective on April 29, 2019.

As of May 8, 2019, we had a cash balance of \$2,105,061 and restricted cash balance of \$810,055.

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

	March 31, 2019	December 31, 2018
	(unaudited)	
Cash and cash equivalents	\$ 2,752,511	\$ 2,740,645
Restricted Cash	810,055	
Working capital	<u>\$ 1,107,139</u>	<u>\$ 1,313,980</u>

Based upon our cash and working capital as of March 31, 2019, we will require additional capital resources in order to meet our obligations as they become due within one year after the date of this Report and sustain operations. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

We will require significant amounts of additional capital to continue to fund our operations and complete our research and development activities. If we are not able to obtain additional cash resources, we will not be able to continue operations. We will continue seeking additional financing sources to meet our working capital requirements, to make continued investment in research and development and to make capital expenditures needed for us to maintain and expand our business. We may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth, continue research and to respond to business challenges could be significantly limited, or we may have to cease our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock.

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 March 31, 2019, pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2019.

Changes in Internal Control over Financial Reporting

During the three months ended March 31, 2019, there were no changes in our internal controls over financial reporting, or in other factors that could significantly affect these controls, that materially affected, or are 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 its insurance coverage, and even if they are, if claims against us are successful, they may exceed the limits of applicable insurance coverage.

On September 25, 2018, ATSCO, Inc., filed a complaint 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. The Company is disputing the amount owed and that the Agreement called for a fixed monthly fee regardless of tissue delivered. The Company believes it has numerous defenses and rights of setoff including without limitation: that ATSCO had an obligation to mitigate the fees when they were not delivering tissues and not incurring any costs; \$173,400 of the amount that ATSCO is seeking are for invoices to Hancock Jaffe Laboratory Aesthetics, Inc. (in which the Company owns a minority interest of 28.0% as described in Note 4 to the Financial Statements – Significant Accounting Policies - *Investments*) and is not the obligation of HJLI; the Company has a right of setoff against any amounts owed to ATSCO for 120,000 shares of HJLI stock transferred to ATSCO’s principal and owner; the yields of the materials delivered by ATSCO to HJLI was inferior; and the Agreement was constructively terminated. On January 18, 2019, the Superior Court granted a Right to Attach Order and Order for Issuance of Writ of Attachment in the amount of \$810,055, which the Company plans on appealing. The attachment order is not a binding ruling on the merits of the case and the Company plans on filing a Cross-Complaint for abuse of process and excessive and wrongful attachment as \$173,400 of the claim is to a wholly separate company, and over \$500,000 of the claim is attributable to invoices sent without delivery of any tissue. On March 26, 2019, ATSCO filed a First Amended Complaint with the Superior Court increasing its claim to \$1,606,820 plus incidental damages and interest, on the basis of an alleged additional oral promise not alleged in its original Complaint. The Company continues to firmly believe it has numerous meritorious defenses to the new claim, including those described above, and expects to continue a vigorous defense and to continue pursuing its Cross-Complaint. The Company recorded the disputed invoices in accounts payable and as of March 31, 2019, the Company believes that it has fully accrued for the outstanding claim against the Company. A Mandatory Settlement Conference is scheduled for July 26, 2019 and the Jury Trial is scheduled for September 9, 2019. The Company 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 March 31, 2019, the Company has fully accrued for the outstanding claim against the Company.

The Company has been contacted by an individual that claims to be owed a fee for introducing the Company to Alexander Capital, who was the placement agent for the capital raise of the convertible notes issued in 2017 and 2018. The Company has conducted its own factual investigation and legal analysis and believes that the claim is without merit. The individual has threatened to file a lawsuit, and in the event that a lawsuit is filed, the Company would have numerous defenses including without limitation that the individual was unlicensed to provide the services he alleges he provided.

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, our current risk factors are set forth in our Form 10-K, filed with the SEC on March 14, 2019.

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

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 Company issued to Alere five-year warrants to purchase 35,000 shares of the Company’s common stock at an exercise price of \$1.59. The warrants shall vest equally monthly over a 12 month period provided that the Alere Agreement remains in effect. For these sales of securities, no general solicitation was used, and the Company relied on the exemption from registration available under Section 4(a)(2) of the Securities Act.

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 Company issued eighty-five thousand (85,000) restricted shares that vest quarterly over a year, with a 6 month cliff. The MZ Agreement is for a term of twelve (12) months, provided that either party can terminate the MZ agreement after 6 months but if the MZ agreement is terminated by MZ at the end of six months, MZ forfeits the restricted shares. For these sales of securities, no general solicitation was used, and the Company relied on the exemption from registration available under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, with respect to transactions by an issuer not involving any public offering.

On March 12, 2019, the Company raised \$2,704,000 in gross proceeds in the Offering. The Company sold an aggregate of 2,329,615 shares of common stock in the Offering for a purchase price of \$1.15 per share pursuant to a share purchase agreement between the Company and each of the investors in the Offering (the “Purchase Agreement”). Our CEO also participated in the Offering purchasing 18,382 shares at a price of \$1.36 per share, the final bid price of our common stock as reported on The Nasdaq Capital Market on the date of the Offering. Pursuant to the terms of the Purchase Agreement, the Company filed a registration statement with the Securities and Exchange Commission for the resale of the purchasers’ shares on March 29, 2019. The registration statement was declared effective on April 30, 2019. The Purchase Agreement also contains customary representations, warranties and agreements. The Company engaged Network 1 Financial Securities, Inc., a FINRA-member (the “Placement Agent”), to act as exclusive placement agent for the Offering. In consideration for the Placement Agent’s services in the Offering, the Company agreed to pay a fee in cash equal to 10% of the aggregate gross proceeds raised by the Placement Agent in the Offering and to reimburse up to \$25,000 in accountable expenses. Additionally, the Company paid to the Placement Agent as a non-accountable expense 1% of the proceeds of the Offering. The Placement Agent is also entitled to a warrant to purchase such number of shares of the Company’s common stock equal to 8% of the total shares of common stock sold in the Offering. Such warrant will be exercisable for a period of five years from the date of issuance and will have an exercise price of \$1.50. The Company intends to use the proceeds of the Offering to fund the continued development of its two lead products, VenoValve and the CoreoGraft, and for working capital and general corporate purposes. The securities issued in the Offering are exempt from the registration requirements of the Securities Act pursuant to Section 4(a)(2) of the Securities Act and/or Rule 506(b) of Regulation D promulgated thereunder because, among other things, the transaction did not involve a public offering, the investors are accredited investors, the investors took the securities for investment and not resale and the Company took appropriate measures to restrict the transfer of the securities.

