

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q**

(Mark One)

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

For the Quarterly Period Ended: **September 30, 2019**

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

For the transition period from _____ to _____

Commission File Number: **001-36856**

HEPION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

46-2783806
(I.R.S. Employer Identification No.)

399 Thornall Street, First Floor, Edison, New Jersey
(Address of principal executive offices)

08837
(Zip Code)

(732) 902-4000
(Registrant's telephone number)

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

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
Common Stock, par value \$.0001 per share	HEPA	Nasdaq Capital Market

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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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.

The number of the registrant's shares of common stock outstanding was 3,453,755 as of November 11, 2019.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for Hepion Pharmaceuticals, Inc. may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such forward-looking statements are characterized by future or conditional verbs such as “may,” “will,” “expect,” “intend,” “anticipate,” “believe,” “estimate” and “continue” or similar words. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Factors that may cause such differences include, but are not limited to, those discussed under Item 1A. Risk Factors and elsewhere in the audited condensed consolidated financial statements as of and for the year ended December 31, 2018 contained in the Company’s Annual Report on Form 10-K (“Form 10-K”) filed with the Securities and Exchange Commission (“SEC”) on March 14, 2019. These factors include the uncertainties associated with product development, the risk that products that appeared promising in early clinical trials do not demonstrate safety and efficacy in larger-scale clinical trials, the risk that we will not obtain approval to market our products, the risks associated with dependence upon key personnel and the need for additional financing. We do not assume any obligation to update forward-looking statements as circumstances change and thus you should not unduly rely on these statements.

HEPION PHARMACEUTICALS, INC.

FORM 10-Q

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PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

HEPION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash	\$ 14,863,946	\$ 2,832,429
Prepaid expenses	320,706	135,591
Total current assets	<u>15,184,652</u>	<u>2,968,020</u>
Property and equipment, net	57,574	32,434
Right of use assets	642,405	—
In-process research and development	3,190,000	3,190,000
Goodwill	1,870,924	1,870,924
Other assets	127,940	127,794
Total assets	<u>\$ 21,073,495</u>	<u>\$ 8,189,172</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 675,470	\$ 748,428
Accrued expenses	308,387	661,421
Operating lease liabilities, current	191,254	—
Convertible debt	330,000	1,440,000
Total current liabilities	<u>1,505,111</u>	<u>2,849,849</u>
Contingent consideration	2,520,000	2,590,000
Deferred tax liability	360,700	360,700
Operating lease liabilities, non-current	460,685	—
Deferred rent liability	—	9,235
Derivative financial instruments, at estimated fair value-warrants	409	404,337
Total liabilities	<u>4,846,905</u>	<u>6,214,121</u>
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Convertible Preferred stock, par value \$0.0001 per share. Authorized 20,000,000 shares		
Series A convertible stock, stated value \$10.00 per share, 85,581 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	855,808	855,808
Series C convertible stock, stated value \$1,000 per share, 1,827 and 1,974 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	861,033	930,311
Common stock, par value of \$.0001 per share. Authorized 120,000,000 shares, and 3,453,755 and 247,0130 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	345	25
Additional paid-in capital	95,797,628	76,652,839
Accumulated deficit	(81,288,224)	(76,463,932)
Total stockholders' equity	<u>16,226,590</u>	<u>1,975,051</u>
Total liabilities and stockholders' equity	<u>\$ 21,073,495</u>	<u>\$ 8,189,172</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

HEPION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2019	2018	2019	2018
Revenues	\$ —	\$ —	\$ —	\$ —
Cost and expenses:				
Research and development	846,453	2,167,951	2,120,152	6,551,553
General and administrative	1,064,081	1,684,594	3,407,650	5,047,000
Loss from operations	<u>(1,910,534)</u>	<u>(3,852,545)</u>	<u>(5,527,802)</u>	<u>(11,598,553)</u>
Other income (expense):				
Change in fair value of debt	(22,197)	(14,542)	(175,992)	17,406
Interest expense	(15,354)	(55,458)	(555,441)	(287,406)
Change in fair value of derivative instruments-warrants and contingent consideration, net	128,402	3,765,487	473,929	4,455,932
Loss before income taxes	<u>(1,819,683)</u>	<u>(157,058)</u>	<u>(5,785,306)</u>	<u>(7,412,621)</u>
Income tax benefit	—	—	961,014	536,000
Net loss	<u>(1,819,683)</u>	<u>(157,058)</u>	<u>(4,824,292)</u>	<u>(6,876,621)</u>
Deemed dividend (see note 6)	(8,460)	(8,805,809)	(5,444,826)	(8,805,809)
Net loss attributable to common shareholders	<u>\$ (1,828,143)</u>	<u>\$ (8,962,867)</u>	<u>\$ (10,269,118)</u>	<u>\$ (15,682,430)</u>
<i>Weighted Average Common Shares Outstanding</i>				
Basic and Diluted	<u>3,453,628</u>	<u>202,451</u>	<u>1,532,927</u>	<u>166,687</u>
<i>Net Loss per Common Share</i>				
Basic and Diluted	<u>\$ (0.53)</u>	<u>\$ (44.27)</u>	<u>\$ (6.70)</u>	<u>\$ (94.08)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

HEPION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock Series A		Preferred Stock Series C		Preferred Stock Series D		Preferred Stock Series E		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2019	85,581	\$ 855,808	1,974	\$ 930,311	—	\$ —	—	\$ —	—	247,013	\$ 25	\$76,652,839	\$ (76,463,932)	\$ 1,975,051
Issuance of common stock, Private Placement	—	—	—	—	—	—	—	—	47,429	5	486,278	—	—	486,283
Issuance of common stock, Debt Redemption	—	—	—	—	—	—	—	—	11,883	1	149,917	—	—	149,918
Accretion of Series C Preferred stock discount upon conversion	—	—	—	24,321	—	—	—	—	—	—	(24,321)	—	—	—
Conversion of Series C Preferred	—	—	(46)	(46,000)	—	—	—	—	424	0	46,000	—	—	0
Stock based compensation expense	—	—	—	—	—	—	—	—	—	—	17,506	—	—	17,506
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,983,711)	(1,983,711)	(1,983,711)
Balance at March 31, 2019	85,581	\$ 855,808	1,928	\$ 908,632	—	\$ —	—	\$ —	—	306,748	\$ 31	\$77,328,219	\$ (78,447,643)	\$ 645,047
Issuance of common stock, Debt Redemption	—	—	—	—	—	—	—	—	42,439	4	400,059	—	—	400,063
Issuance of common stock, Private Placement	—	—	—	—	—	—	—	—	—	—	330	—	—	330
Issuance of common stock, net	—	—	—	—	—	—	—	—	1,031,071	103	5,844,421	—	—	5,844,524
Issuance of Preferred Stock	—	—	—	—	521	312,600	10,570	6,976,201	—	—	3,802,201	—	—	11,091,002
Offering cost related to issuance of preferred stock	—	—	—	—	—	(29,526)	—	(472,311)	—	—	(536,787)	—	—	(1,038,624)
Placement agents warrants	—	—	—	—	—	(48,250)	—	(244,895)	—	—	293,145	—	—	—
Beneficial conversion feature of preferred stock	—	—	—	—	—	(186,692)	—	(581,350)	—	—	768,042	—	—	—
Accretion of beneficial conversion feature of preferred stock	—	—	—	—	—	186,692	—	581,350	—	—	(768,042)	—	—	—
Accretion of preferred stock discount upon conversion	—	—	—	44,941	—	286,176	—	4,311,007	—	—	(4,642,124)	—	—	—
Conversion of preferred stock	—	—	(85)	(85,000)	(521)	(521,000)	(10,570)	(10,570,002)	1,824,473	182	11,175,820	—	—	—
Exercise of warrants	—	—	—	—	—	—	—	—	248,877	25	2,090,542	—	—	2,090,567
Stock based compensation expense	—	—	—	—	—	—	—	—	—	—	17,133	—	—	17,133
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,020,898)	(1,020,898)	(1,020,898)
Balance at June 30, 2019	85,581	\$ 855,808	1,843	\$ 868,573	—	\$ —	—	\$ —	—	3,453,608	\$ 345	\$95,772,959	\$ (79,468,541)	\$ 18,029,144
Accretion of preferred stock discount upon conversion	—	—	—	8,460	—	—	—	—	—	—	(8,460)	—	—	—
Conversion of preferred stock	—	—	(16)	(16,000)	—	—	—	—	147	—	16,000	—	—	—
Stock based compensation expense	—	—	—	—	—	—	—	—	—	—	17,129	—	—	17,129
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,819,683)	(1,819,683)	(1,819,683)
Balance at September 30, 2019	85,581	\$ 855,808	1,827	\$ 861,033	—	\$ —	—	\$ —	—	3,453,755	\$ 345	\$95,797,628	\$ (81,288,224)	\$ 16,226,590

The accompanying notes are an integral part of these condensed consolidated financial statements.

HEPION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock Series A		Preferred Stock Series C		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2018	104,013	\$ 1,040,128	—	\$ —	139,893	\$ 14	\$69,677,652	\$(67,014,637)	\$ 3,703,157
Issuance of common stock, net	—	—	—	—	11,806	1	1,821,074	—	1,821,075
Stock based compensation expense	—	—	—	—	—	—	217,387	—	217,387
Net loss	—	—	—	—	—	—	—	(2,690,488)	(2,690,488)
Balance at March 31, 2018	104,013	\$ 1,040,128	—	\$ —	151,699	\$ 15	\$71,716,113	\$(69,705,125)	\$ 3,051,131
Issuance of common stock, net	—	—	—	—	361	0	73,663	—	73,663
Conversion of Series A Preferred	(18,432)	(184,320)	—	—	686	0	184,320	—	0
Stock based compensation expense	—	—	—	—	—	—	152,764	—	152,764
Net loss	—	—	—	—	—	—	—	(4,029,075)	(4,029,075)
Balance at June 30, 2018	85,581	\$ 855,808	—	\$ —	152,746	\$ 15	\$72,126,860	\$(73,734,200)	\$ (751,517)
Issuance of Series C Preferred	—	—	10,826	9,853,148	—	—	—	—	9,853,148
Conversion of Series C Preferred	—	—	(8,573)	(4,535,392)	79,014	8	4,535,384	—	—
Fair value of warrant issued in connection with issuance of Series C	—	—	—	(5,091,373)	—	—	—	—	(5,091,373)
Costs related to warrants issued in rights offering	—	—	—	—	—	—	561,593	—	561,593
Warrants	—	—	—	—	1,314	0	176,736	—	176,736
Stock based compensation expense	—	—	—	—	—	—	62,881	—	62,881
Net loss	—	—	—	—	—	—	—	(157,058)	(157,058)
Balance at September 30, 2018	85,581	\$ 855,808	2,253	\$ 226,383	233,074	\$ 23	\$77,463,454	\$(73,891,258)	\$ 4,654,410

The accompanying notes are an integral part of these condensed consolidated financial statements.

HEPION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30, (unaudited)	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,824,292)	\$ (6,876,621)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	51,768	433,032
Change in fair value of derivative instrument-warrants	(403,928)	(4,380,932)
Change in fair value of contingent consideration	(70,000)	(75,000)
Change in fair value of debt	175,992	(17,406)
Non-cash interest expense	—	87,406
Amortization of debt discount recorded as interest expense	486,608	—
Non-cash offering costs related to warrants in rights offering	—	561,593
Non-cash interest for shares issued for debt redemption payments	49,732	—
Change in deferred tax liability	—	(536,000)
Loss on the sale of assets	—	4,474
Depreciation and amortization expense	20,196	14,146
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	(425,992)	293,072
Deferred rent liability	—	8,321
Prepaid expenses and other assets	(184,962)	(69,622)
Net cash used in operating activities	<u>(5,124,878)</u>	<u>(10,553,537)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(45,336)	—
Proceeds from the sale of fixed assets	—	900
Net cash (used in) provided by investing activities	<u>(45,336)</u>	<u>900</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds of issuance of common stock, net of issuance costs	5,844,530	1,635,140
Proceeds from issuance of Series C and warrants, net of issuance costs	—	9,853,148
Proceeds from issuance of Series D and warrants, net of issuance costs	403,120	—
Proceeds from issuance of Series E and warrants, net of issuance costs	9,649,258	—
Proceeds from the exercise of warrants	2,090,567	142,600
Proceeds from debt financing	—	2,000,000
Proceeds from issuance of debt and common stock in private placement	1,250,000	—
Repayment of convertible debt	(785,744)	—
Repayment of debt financing	(1,250,000)	—
Net cash provided by financing activities	<u>\$ 17,201,731</u>	<u>\$ 13,630,888</u>
Net change in cash	<u>12,031,517</u>	<u>3,078,251</u>
Cash, beginning of period	2,832,429	5,954,017
Cash, end of period	<u>\$ 14,863,946</u>	<u>\$ 9,032,268</u>
Supplementary Disclosure of Cash Financing Activities :		
Cash paid for interest	\$ 26,756	\$ —
Supplementary Disclosure of Non-Cash Financing Activities:		
Stock issued to employees in lieu of cash payment for accrued bonuses	\$ —	\$ 259,598
Reclass of derivative liability for warrant exercise	\$ —	\$ 34,136
Conversion of Series A convertible preferred stock	\$ —	\$ 184,320
Conversion of Series C convertible preferred stock	\$ 147,000	\$ 4,535,392
Conversion of Series D convertible preferred stock	\$ 521,000	\$ —
Conversion of Series E convertible preferred stock	\$ 10,570,002	\$ —
Accretion of Series C, D, and E preferred stock discount upon conversion	\$ 4,674,905	\$ —
Fair value of warrants issued in conjunction with Series C preferred stock offering	\$ —	\$ 5,091,373
Beneficial Conversion Factor of preferred stock accreted as deemed dividend	\$ 768,042	\$ 3,771,639
Issuance of common stock for debt redemption	\$ 500,248	\$ —
Adoption of Lease Accounting	\$ 642,405	\$ —
Warrants issued to Placement Agent	\$ 293,145	\$ 221,269

The accompanying notes are an integral part of these condensed consolidated financial statements.

HEPION PHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

1. Business Overview

Hepion Pharmaceuticals, Inc. (“Hepion” or the “Company”) is a biopharmaceutical company headquartered in Edison, New Jersey, focused on the development of pleiotropic drug therapy for treatment of chronic liver disease. This therapeutic approach targets fibrosis and hepatocellular carcinoma (“HCC”) associated with non-alcoholic steatohepatitis (“NASH”), viral hepatitis, and other liver diseases. The Company’s cyclophilin inhibitor, CRV431, is being developed to offer benefits to address these multiple complex pathologies. CRV431 is a cyclophilin inhibitor that targets multiple biochemical pathways involved in the progression of liver disease. Preclinical studies with CRV431 in NASH models demonstrated consistent reductions in liver inflammation, fibrosis, and cancerous tumors. CRV431 additionally shows antiviral activity towards hepatitis B, C, and D viruses which also trigger liver disease.

On July 18, 2019, the Company filed a certificate of amendment (the “Certificate of Amendment”) to the Company’s certificate of incorporation (the “Certificate”) to change the Company’s name from “ContraVir Pharmaceuticals, Inc.” to “Hepion Pharmaceuticals, Inc.” The name change became effective as of July 18, 2019.

The Company is developing CRV431 as its lead molecule. CRV431 is a cyclophilin inhibitor that targets specific isomerases that play an important role in protein folding in health and in disease. To date, *in vitro* and/or *in vivo* studies have demonstrated reductions in HBV DNA, HBsAg, HBeAg, inhibition of virus uptake (NTCP transport inhibition), and stimulation of innate immunity. Importantly, *in vivo* studies in a NASH model of fibrosis and HCC have repeatedly demonstrated CRV431 reduces fibrosis scores and overall liver tumor burden. Hence, CRV431 is a pleiotropic molecule that may not only treat liver disease but may also serve to reduce important risk factors (e.g., HBV) for developing the disease. The Company has completed a phase 1 study with CRV431 demonstrating safety, tolerability, and pharmacokinetics (PK).

CRV431

On May 10, 2018, the Company submitted an Investigational New Drug Application (“IND”) to the U.S. Food and Drug Administration (“FDA”) to support initiation of the Company’s CRV431 HBV clinical development program in the United States and received approval in June 2018. The Company completed the first segment of Phase 1 clinical activities for CRV431 in October 2018 wherein the Company reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (“Ciclofilin”) and the Company paid a related milestone payment of \$1,000,000 and issued 1,439 shares of the Company’s common stock with a fair value of \$55,398, representing 2.5% of the Company’s issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders.

On June 17, 2019, the Company submitted an IND to the FDA to support initiation of the Company’s CRV431 NASH clinical development program in the United States and received approval in July 2019.

TXL

On December 18, 2014, the Company and Chimerix, Inc. (“Chimerix”), entered into a Licensing Agreement pursuant to which it licensed CMX157 (now known as tenofovir exalidex, “TXL”) from Chimerix for further clinical development and commercialization for an upfront payment of 120,000 shares of our preferred stock, valued at \$1.2 million.

The termination of the License Agreement became effective on June 1, 2019. Upon the effectiveness of the termination of the License Agreement, Chimerix reacquired all worldwide rights to TXL. The Company made the decision to terminate the License Agreement following the decision to no longer pursue development of TXL, and to focus the Company’s resources and development programs on further advancing CRV431. The Company does not owe any fees or payments to Chimerix.

2. Basis of Presentation and Going Concern

These unaudited condensed consolidated financial statements have been prepared following the requirements of the Securities and Exchange Commission (“SEC”) and accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim reporting. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company’s interim financial information. The condensed consolidated balance sheet as of December 31, 2018 was derived from the audited annual consolidated financial statements but does not include all disclosures required by GAAP. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2018 contained in the Company’s Annual Report on Form 10-K (“Form 10-K”) filed with the SEC on March 14, 2019.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Hepion and the Company’s subsidiaries, Hepion Research Inc. and Hepion Research Corp, which conducts its operations in Canada. All intercompany balances and transactions have been eliminated in consolidation.

Reverse Stock Split

On May 28, 2019, the Company effected a 1 for 70 reverse stock split of the Company’s common stock. The par value and the number of authorized shares of the common and convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these financial statements have been adjusted retroactively to reflect the reverse stock split.

Going Concern

As of September 30, 2019, the Company had \$14.9 million in cash. Net cash used in operating activities was \$5.1 million for the nine months ended September 30, 2019. Net loss for the nine months ended September 30, 2019 was \$4.8 million. As of September 30, 2019, the Company had working capital of \$13.7 million. The Company has not generated revenue to date and has incurred substantial losses and negative cash flows from operations since inception. The Company has historically funded operations through issuances of convertible debt, common stock and preferred stock. The Company expects to continue to incur losses for the next several years as it expands research, development and clinical trials of CRV431. The Company is unable to predict the extent of any future losses or when the Company will become profitable, if at all.

These condensed consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Due to the Company’s recurring and expected continuing losses from operations, the Company has concluded there is substantial doubt in the Company’s ability to continue as a going concern within one year of the issuance of these condensed consolidated financial statements without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. The condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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The Company will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that the Company raises additional funds by issuing equity securities, the Company's stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact the Company's ability to conduct business. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that the Company would otherwise seek to develop or commercialize on unfavorable terms.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2018 included in the Company's Form 10-K filed with the SEC on March 14, 2019. Since the date of such consolidated financial statements, there have been no changes to the Company's significant accounting policies.

Cash

As of September 30, 2019, and December 31, 2018, the amount of cash was approximately \$14.9 million and \$2.8 million, respectively, consisting primarily of checking accounts held at U.S. and Canadian commercial banks. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced losses related to these balances.

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurement ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC Topic 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2—Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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Financial instruments consist of cash and accounts payable, derivative instruments — warrants, convertible debt and contingent consideration. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short term nature, except for derivative instruments— warrants, convertible debt and contingent consideration, which were marked to market at the end of each reporting period. See Note 7 for additional information of the fair value of the derivative liabilities. The Company recorded contingent consideration from the 2016 acquisition of Ciclofilin, which is required to be carried at fair value. See Note 7 for additional information on the fair value of the contingent consideration.

Derivative financial instruments

The Company has issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments based on certain contingent put features, was recorded as a derivative liability under the provisions of ASC Topic 815 Derivatives and Hedging (“ASC 815”) upon issuance. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in fair value of derivative liabilities are recorded in the statements of operations under the caption “Change in fair value of derivative financial instruments— warrants.” See Note 6 for additional information.

The fair value of the warrants, issued in connection with the October 2015, April 2016 and April 2017 common stock offerings and deemed to be derivative instruments due to a certain contingent put feature, was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the warrants issued, including a fixed term and exercise price.

The warrants, issued in connection with the July 2018 Rights Offering (See Note 6) are deemed to be derivative instruments since if the Company does not maintain an effective registration statement, the Company is obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside of the control of the Company. Therefore, the fair value of the warrants was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the warrants issued, including a fixed term and exercise price.

The fair value of warrants was affected by changes in inputs to the Black-Scholes option pricing model including the Company’s stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At September 30, 2019 and December 31, 2018, the fair value of such warrants was approximately \$409 and \$0.4 million, respectively, which are classified as a long-term derivative liability on the Company’s balance sheets.

Property, equipment and depreciation

As of September 30, 2019, and December 31, 2018 the Company had \$57,574 and \$32,434, respectively, of property and equipment, consisting primarily of computer equipment, furniture and fixtures. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the depreciable assets are 3 to 5 years. Leasehold improvements are amortized using the straight-line method over their estimated useful lives, or the remaining term of the lease, whichever is shorter. Depreciation and amortization expense for the nine months ended September 30, 2019, and the nine months ended September 30, 2018, was \$20,196 and \$14,146, respectively. Expenditures for repairs and maintenance are charged to operations as incurred. The Company will periodically evaluate whether current events or circumstances indicate that the carrying value of depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at September 30, 2019 and December 31, 2018.

Goodwill and In-Process Research & Development

In accordance with ASC Topic 350, *Intangibles — Goodwill and Other* (“ASC Topic 350”), goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually, in the Company’s fourth quarter, and between annual tests if the Company becomes aware of an event or a change in circumstances that would indicate the carrying value may be impaired. Pursuant to ASU No. 2011-08, *Intangibles — Goodwill and Other (Topic 350): Testing Goodwill for Impairment* and ASU No. 2012-02, *Intangibles — Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the Company to determine that it is more likely than not (that is, a likelihood of more than 50%) that the goodwill or the acquired IPR&D is impaired. If the Company chooses to first assess qualitative factors and determines that it is not more likely than not goodwill or acquired IPR&D is impaired, the Company is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which the Company may choose to do in some periods but not in others. The Company’s CRV431 intangible asset and goodwill are assessed for impairment annually as of December 31st of the Company’s fiscal year or more frequently if impairment indicators exist.

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If the Company performs a quantitative assessment of goodwill, it utilizes the two-step approach prescribed under ASC Topic 350. Step 1 requires a comparison of the carrying value of a reporting unit, including goodwill, to its estimated fair value. The Company tests for impairment at the entity level because it operates on the basis of a single reporting unit. If the carrying value exceeds fair value, the Company then performs Step 2 to measure the amount of impairment loss, if any. In Step 2, the Company estimates the fair value of individual assets, including identifiable intangible assets, and liabilities to determine the implied fair value of goodwill. The Company then compares the carrying value of goodwill to the implied fair value. The excess of the carrying value of goodwill over implied fair value, if any, is recorded as an impairment charge.

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. There was no impairment of goodwill for the nine months ended September 30, 2019, or the nine months ended September 30, 2018.

IPR&D acquired in a business combination is capitalized as indefinite-lived assets on the Company's condensed consolidated balance sheets at the acquisition-date fair value. Once the project is completed, the carrying value of the IPR&D is reclassified to other intangible assets, net and is amortized over the estimated useful life of the asset. Post-acquisition research and development expenses related to the IPR&D projects are expensed as incurred. The projected discounted cash flow models used to estimate the fair values of the Company's IPR&D assets, acquired in connection with the Ciclofilin acquisition, reflect significant assumptions regarding the estimates a market participant would make in order to evaluate a drug development asset, including: (i) probability of successfully completing clinical trials and obtaining regulatory approval; (ii) market size, market growth projections, and market share; (iii) estimates regarding the timing of and the expected costs to advance clinical programs to commercialization; (iv) estimates of future cash flows from potential product sales; and (v) a discount rate. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of related impairments, if any.

If IPR&D becomes impaired or is abandoned, the carrying value of the IPR&D is written down to the revised fair value with the related impairment charge recognized in the period in which the impairment occurs. If the carrying value of the asset becomes impaired as the result of unfavorable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercializing the Company's programs, the Company could incur significant charges in the period in which the impairment occurs.

There was no impairment of IPR&D for the nine months ended September 30, 2019 or the nine months ended September 30, 2018.

Income Taxes

The Company accounts for income taxes under the asset and liability method. The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as for operating loss and tax credit carry-forwards. The Company measures deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which the Company expects to recover or settle those temporary differences. The Company recognizes the effect of a change in tax rates on deferred tax assets and liabilities in the results of operations in the period that includes the enactment date. The Company reduces the measurement of a deferred tax asset, if necessary, by a valuation allowance if it is more likely than not that the Company will not realize some or all of the deferred tax asset. The Company accounts for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is "more-likely-than-not" that the position will be sustained upon examination. Potential interest and penalties associated with unrecognized tax positions are recognized in income tax expense.

In conjunction with the acquisition of Ciclofilin in June 2016, a deferred tax liability of \$1.3 million was recorded reflecting the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset the deferred tax assets when analyzing the Company's valuation allowance as the acquired IPR&D is considered to have an indefinite life until the Company completes or abandons development of the related IPR&D. The re-measurement of the deferred tax balances to the new corporate rate was completed as of December 31, 2017 and resulted in an adjustment of approximately \$900,000 recorded as a reduction in the deferred tax liability offset by a credit to Income Tax benefit at that time. The 2017 Tax Act also changed the Net Operating Loss carry forwards' period to now have an indefinite life. The Company performed an evaluation with regard to the impact of Deferred Tax Assets ("DTA") that were generated by Temporary Differences (such as Stock Compensation, Accrued Vacation, depreciation, etc.) which would reverse and turn into indefinite lived NOL carry forwards and whether the Deferred Tax Liability associated with In-Process R&D could be used to offset indefinite lived DTAs. In March 2018, the Company recorded an adjustment to the valuation allowance in the approximate amount of \$536,000. This adjustment reflects the adjustment allowed by the Tax Cuts and Jobs Act of 2017 to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets in conjunction with the evaluation of the amount of valuation allowance needed.

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In April 2019, the Company transferred state net operating loss tax credits and received approximately \$1.0 million in connection with the sale of the state net operating losses to a third party recorded as an income tax benefit in the condensed consolidated statement of operations. The Company received approval for the sale of net operating losses through participation in the New Jersey Technology Business Tax Certificate Transfer (NOL) Program.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of the Company's business that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with ASC Topic 450, Accounting for Contingencies, ("ASC 450"), the Company records accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. The Company, in accordance with this guidance, does not recognize gain contingencies until realized.

Research and Development

Research and development costs, which include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, license costs, regulatory and scientific consulting fees, as well as contract research, insurance and FDA consultants, are accounted for in accordance with ASC Topic 730, Research and Development, ("ASC 730"). Also, as prescribed by this guidance, patent filing and maintenance expenses are considered legal in nature and therefore classified as general and administrative expense, if any.

The Company does not currently have any commercial biopharmaceutical products, and does not expect to have such for several years, if at all. Accordingly, our research and development costs are expensed as incurred. While certain of the Company's research and development costs may have future benefits, the Company's policy of expensing all research and development expenditures is predicated on the fact that the Company has no history of successful commercialization of product candidates to base any estimate of the number of future periods that would be benefited.

Also as prescribed by ASC 730, non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. At September 30, 2019 and December 31, 2018, the Company had prepaid research and development costs of \$214,963 and \$41,514, respectively.

Share-based payments

ASC Topic 718 "Compensation—Stock Compensation" ("ASC 718") requires companies to measure the cost of employee and non-employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company has a limited trading history in the Company's common stock and lacks company-specific historical and implied volatility information. Therefore, the Company estimates expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of the Company's own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Foreign Exchange

The functional currency of Hepion and ContraVir Research Inc. is the U.S. dollar. The functional currency of ContraVir Research Corp. is the Canadian dollar. The Company's reporting currency is the U.S. dollar. The assets and liabilities of Ciclofilin are translated into U.S. dollars using period-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a

separate component of shareholders' equity. The amount of currency translation adjustment was immaterial at September 30, 2019 and December 31, 2018.

Transactions in foreign currencies are remeasured into the functional currency of the relevant subsidiaries at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Resulting gains and losses are recorded in other foreign exchange (gain) loss within the condensed consolidated statements of operations. The impact of foreign exchange gains (losses) was immaterial for the nine months ended September 30, 2019 and 2018.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company, through the chief operating decision maker, views the Company's operations and manages the business in one segment.

Net loss per share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, ("ASC 260") for all periods presented. In accordance with this guidance, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholder by the weighted-average common shares outstanding during the period.

4. Recent Accounting Pronouncements

In August of 2018, the FASB issued ASU 2018-13 —*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13")*, which amends disclosure requirements on fair value measurements in Topic 820. This amendment modifies the valuation process of fair value measurements by removing the disclosure requirements for the valuation processes for Level 3 fair value measurements, clarifying the timing of the measurement uncertainty disclosure, and including the changes in unrealized gains and losses for recurring Level 3 fair value measurements in other comprehensive income if held at the end of the reporting period. It also allows the disclosure of other quantitative information in lieu of the weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019 and should be applied prospectively for the most recent period presented in the initial fiscal year of adoption. The Company is currently evaluating the impact that this guidance will have on the Company's results of operations, financial position and cash flows.

In July of 2018, the FASB issued ASU 2018-11 —*Leases (Topic 842) Targeted Improvements ("ASU 2018-11")*, which addresses stakeholder's inquiries that are applicable to the Company regarding reporting requirements for initial adoption of ASU 2016-02. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard in ASU 2016-02, allowing an entity to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840.

Additionally, in July of 2018, the FASB issued ASU 2018-10 —*Codification Improvements to Topic 842, Leases ("ASU 2018-10")*, which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02 based on comments and questions raised by stakeholders during the assessment and implementation of ASU 2016-02. The Company has adopted this guidance in conjunction with the adoption of FASB issued ASU 2016-02, *Leases (Topic 842) ("ASU 2016-02")*. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at or entered after the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company's primary lease arrangements are associated with a lease for the Company's corporate office. ASU 2016-02 became effective for the Company on January 1, 2019. The Company adopted ASU 2016-02 using a modified retrospective transition approach as of the effective date as permitted by the amendments in ASU 2018-11, which provides an alternative modified retrospective transition method (See Note 12). As a result, the Company was not required to adjust comparative period financial information for effects of the standard or make the new required lease disclosures for periods before the date of adoption (i.e. January 1, 2019). The Company has elected to adopt the package of transition practical expedients and, therefore, have not reassessed (1) whether existing or expired contracts contain a lease, (2) lease classification for existing or expired leases or (3) the accounting for initial direct costs that were previously capitalized. As of January 1, 2019, the Company recorded an operating lease liability of approximately \$773 thousand and operating right of use assets of approximately \$764 thousand.

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In June of 2018, the FASB issued ASU 2018-07 — *Compensation — Stock Compensation (Topic 718)* (“ASU 2018-07”), which expands the scope of Topic 718 to include share-based payment transaction for acquiring goods and services from nonemployees. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company adopted this ASU with no significant impact on the Company’s condensed consolidated financial statements.

In July of 2017 the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity Topic (480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instrument with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non controlling Interests with a Scope Exception* (“ASU 2017-11”), which modifies the classification of some financial instruments. A down round feature no longer precludes equity classification, therefore a freestanding equity feature would no longer be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities present earnings per share in accordance with Topic 260, and to recognize the effect of the down round feature when triggered. Convertible instruments are now subject to specialized contingent beneficial conversion features. The Company adopted this ASU with no significant impact on the Company’s condensed consolidated financial statements.

In January of 2017, the FASB issued ASU No. 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (“ASU 2017-04”), which amended the 2014 amendments to the FASB Accounting Standards Codification that allowed companies an alternative accounting treatment for subsequently measuring goodwill. This amendment is Phase 1 of a project by the FASB Board to simplify how an entity is required to test goodwill for impairment by eliminating step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. These amendments are to be applied on a prospective basis and are required to be adopted for annual and any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that this guidance will have on the Company’s results of operations, financial position and cash flows.

5. Debt

On May 8, 2018, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with Iliad Research and Trading, L.P. (“IRT”), pursuant to which the Company issued to IRT a secured convertible promissory note (the “Note”) in the aggregate principal amount of \$3,325,000 for an aggregate purchase price of \$2,000,000 cash and \$1,000,000 aggregate principal amount of investor notes (the “Investor Notes”) payable to the Company in four tranches of \$250,000 upon request by the Company. Closing occurred on May 9, 2018. The Note carries an original issue discount of \$300,000, and the initial principal balance of \$2,225,000 also includes original issue discount of \$200,000 and \$25,000 to cover IRT’s transaction expenses. The Investor Notes have not been drawn as of September 30, 2019. The Note bears interest at the rate of 10% per annum and matures on November 8, 2019. Beginning on November 8, 2018, IRT has the right to redeem all or any portion of the Note up to the Maximum Monthly Redemption Amount which is \$500,000. Payments of each redemption amount may be made in cash or shares of Company common stock at Company’s election (so long as the various conditions to paying stock set forth in the Note are satisfied) provided, however, that if the Company’s common stock is trading below \$112.00 per share (as adjusted for the reverse stock split), the redemption(s) must be in cash. Common stock issued upon redemption will be issued at a price equal to 80% of the lowest trade price of the common stock for the 20 consecutive trading days prior to the date of redemption, subject to adjustments; provided, however, that in no event will the redemption price be less than \$112.00. The Company has obtained a waiver to the redemption price to enable the Company to be able to redeem balances of the debt with the Company’s common stock. Because of this feature which allows the lender to redeem the entire outstanding balance at the Company’s option within twelve (12) months of initial issuance, the debt is classified as current. The Company also entered into a security agreement with IRT, pursuant to which IRT will receive a security interest in substantially all of the Company’s assets, except for intellectual property. The Company identified numerous embedded features to which bifurcation would be required. The Securities Purchase Agreement requires that the Company comply with certain non-financial covenants customary for financing of this nature which the Company complied with as of September 30, 2019.

The Company is eligible to elect the fair value option under ASC 815 and bypass analysis of potential embedded derivatives and further analysis of bifurcation of any such derivatives and has elected such option. Therefore, the debt will be recorded at fair value upon issuance and subsequently re-measured at each reporting period until maturity. Additionally, all issuance costs incurred in connection with a debt instrument that is measured at fair value pursuant to the election of the fair value option are expensed during the period the debt is acquired.

The Note carries total debt discount of \$225,000 (comprising of original issue discount of \$200,000 and \$25,000 payment to IRT for transaction expenses) which was not recorded due to the election of the fair value option.

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During the nine-month period ended September 30, 2019, the Company made a cash redemption payment on the debt to IRT totaling \$0.8 million. The Company also made redemption payments on the debt to IRT utilizing the Company's common stock totaling 54,322 shares with a redemption fair value of \$0.5 million, \$0.5 million of which was applied to principal, resulting in a \$0.3 million balance of remaining principal as of September 30, 2019.

On March 13, 2019, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an accredited investor (the "Investor"). Pursuant to the Securities Purchase Agreement, the Company issued to the Investor in a private placement (i) 47,429 shares of the Company's common stock and (ii) an unsecured \$1.25 million aggregate principal amount debenture (the "Debenture"). The maturity date of the Debenture was June 30, 2019. Prior to the maturity date, no interest accrued on the Debenture. Upon an event of default, including upon the non-repayment of the principal amount at the maturity date, interest shall accrue on the Debenture at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law until such principal amount is paid in full. The Debenture ranks junior to the Company's existing secured indebtedness. The relative fair value of Company shares of common stock issued was approximately \$487 thousand and was recorded as a debt discount, of which \$69,516 was amortized as interest expense during the three months ended March 31, 2019. The Company repaid the outstanding debt balance in June 2019 and recorded the remaining unamortized debt discount of \$417 thousand as non cash interest expense during the three months ended June 30, 2019.

6. Stockholder's Equity and Derivative Liability - Warrants

Preferred Stock, Common Stock and Warrant Offering

During the period from August 5, 2016 to September 30, 2018, certain holders of the Company's Series A Convertible Preferred Stock elected to convert approximately 1.2 million shares of Series A Convertible Preferred stock into 43,319 shares of the Company's common stock.

Series E Convertible Preferred Stock Issuance

On June 18, 2019, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State creating a new series of authorized preferred stock, par value \$0.0001 per share, designated as the "Series E Convertible Preferred Stock" (the "Series E Preferred Stock"). The number of shares initially constituting the Series E Preferred Stock was set at 10,570 shares.

On June 18, 2019 the Company announced the pricing of a public offering with total gross proceeds of \$15.6 million before deducting placement agent fees and other offering expenses payable by the Company (the "Offering") of approximately \$1.6 million inclusive of \$0.3 million placement agent warrants. The gross proceeds of \$15.6 million comprised of proceeds from issuance of common stock of \$5 million and Series E preferred stock of \$10.6 million. The Company incurred total offering cost of \$1.4 million, excluding \$0.3 million of the placement agent warrants, of which \$0.4 million was allocated to the common stock issuance, \$0.5 million allocated to the issuance of Series E preferred stock and \$0.5 million allocated to the common stock warrants. The Offering closed on June 20, 2019. The securities offered by the Company consisted of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$6.00 per Class A Unit, and (ii) Class B Units each consisting of one share of Series E Preferred Stock, with a stated value of \$1,000 per share, and convertible into approximately 167 shares of Common Stock per share of Series E Preferred Stock, and Warrants to purchase 167 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock to be issued pursuant to the Class A Units and issuable upon conversion of all the Series E Preferred Stock is 2,600,000. The aggregate number of Warrants issued in the offering was 2,600,000. The Warrants have an exercise price of \$6.00, are exercisable upon issuance and expire five years from the date of issuance.

The Company determined that the Series E Convertible Preferred stock should not be classified as temporary equity due to the lack of senior liquidation preferences and is not redeemable on a fixed or determinable date.

Conversion. Each share of Series E Preferred is convertible by the holder at any time, into the number of shares of our common stock determined by dividing the \$1,000 stated value per share of the Series E Preferred by \$6.00 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series E Preferred will not have the right to convert any portion of the Series E Preferred to the extent that, after giving effect to the conversion, the holder, together with the Company's affiliates, would beneficially own in excess of 4.99% (or, at the election of the purchaser prior to the date of issuance, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to conversion.

Fundamental Transactions. In the event the Company effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, the Company consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate

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ordinary voting power represented by the Company's issued and outstanding common stock, then, upon any subsequent conversion of the Series E Preferred, the holders of the Series E Preferred will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series E Preferred.

Dividends. Holders of Series E Preferred shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

Voting. Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series E Preferred has no voting rights.

Liquidation Preference. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series E Preferred will be entitled to receive out of our assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series E Preferred were fully converted.

Redemption Rights. The Company are not obligated to redeem or repurchase any shares of Series E Preferred. Shares of Series E Preferred are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

The gross proceeds of the offering were allocated to the Class A units based upon the \$6.00 per Class A Unit value and the residual proceeds were allocated between the Series E and warrants based upon their respective relative fair values at that time. All offering costs were allocated between the Series E and the warrants. In addition, the placement agent received, as compensation for the transaction, registered equity warrants to purchase 117,000 shares of the Company's common stock priced at \$7.50 per share. The fair value of the placement agent equity classified warrants was \$0.2 million at the time of issuance.

In connection with the issuance of the Series E and common stock warrants, the Company recognized the intrinsic value of a beneficial conversion feature of \$0.6 million. The beneficial conversion amount was computed as the difference between the Series E effective conversion price and the fair value of the Company's common stock multiplied by that number of shares issuable upon conversion.

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series E, recognize any unamortized discount resulting from the initial allocation of proceeds issued to the common stock warrants. During the three months ended September 30, 2019, there were no Series E shares issued and outstanding. During the nine months ended September 30, 2019, the holders of Series E shares converted 10,570 shares of Series E into 1,761,667 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of \$4.3 million associated with the difference between the stated and carrying per share values of the Series E, including a \$0.7 million accretion related to issuance costs that had been allocated to the Series E which have been presented as a component of the net loss attributable to common stockholders in the Company's condensed consolidated statement of operations.

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Beneficial Conversion Feature-Series E Convertible Preferred Stock

Each share of Series E is convertible into shares of common stock, at any time at the option of the holder at a conversion price of \$6.00 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series E preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series E was \$0.6 million and the preferred stock was discounted by this amount. The beneficial conversion amount of \$0.6 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The \$0.6 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's condensed consolidated statement of operations for the nine months ended September 30, 2019.

Series D Convertible Preferred Stock Issuance

On April 26, 2019, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State creating a new series of the Company's authorized preferred stock, par value \$0.0001 per share, designated as the "Series D Convertible Preferred Stock" (the "Series D Preferred Stock"). The number of shares initially constituting the Series D Preferred Stock was set at 521 shares.

On April 25, 2019, the Company announced the pricing of a public offering with total gross proceeds of \$2,140,000 before deducting placement agent fees and other offering expenses payable by the Company (the "Offering") which approximated \$0.5 million inclusive of \$0.1 million placement agent warrants. The gross proceeds of \$2.1 million comprised of proceeds from issuance of common stock of \$1.6 million and Series D preferred stock of \$0.5 million. The Company incurred total offering cost of \$0.4 million, excluding \$0.1 million of placement agent warrants, of which \$0.3 million was allocated to the common stock issuance and \$0.1 million was allocated to the issuance of Series D preferred stock. The Offering closed on April 29, 2019. The securities offered by the Company consisted of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$8.40 per Class A Unit, and (ii) Class B Units each consisting of one share of Series D Preferred Stock, with a stated value of \$1,000 per share, and convertible into approximately 119 shares of Common Stock per share of Series D Preferred Stock, and Warrants to purchase 119 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock to be issued pursuant to the Class A Units and issuable upon conversion of all the Series D Preferred Stock is 254,762. The aggregate number of Warrants issued in the offering was 254,762. The Warrants have an exercise price of \$8.40, are exercisable upon issuance and expire five years from the date of issuance.

Each share of Series D Preferred Stock is convertible at the option of the holder at any time, into the number of shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock") determined by dividing the \$1,000 stated value per share of the Series D Preferred Stock by a conversion price of \$8.40 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series D Preferred Stock will not have the right to convert any portion of the Series D Preferred Stock to the extent that, after giving effect to the conversion, the holder, together with the Company's affiliates, would beneficially own in excess of 4.99% of the number of shares of the Company's Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of the holder's shares of Series D Preferred Stock. The holder upon notice to the Company, may increase or decrease the beneficial ownership limitation applicable to shares of Series D Preferred Stock, provided that in no event shall the limitation exceed 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of the holder's shares of Series D Preferred Stock.

The Company determined that the Series D Convertible Preferred stock should not be classified as temporary equity due to the lack of senior liquidation preferences and is not redeemable on a fixed or determinable date.

Conversion. Each share of Series D Preferred is convertible by the holder at any time, into the number of shares of our common stock determined by dividing the \$1,000 stated value per share of the Series D Preferred by a conversion price of \$8.40 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series D Preferred will not have the right to convert any portion of the Series D Preferred to the extent that, after giving effect to the conversion, the holder, together with the Company's affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to conversion.

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Fundamental Transactions. In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series D Preferred, the holders of the Series D Preferred will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series D Preferred.

Dividends. Holders of Series D Preferred shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

Voting Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series D Preferred has no voting rights.

Liquidation Preference. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series D Preferred will be entitled to receive out of our assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series D Preferred were fully converted.

Redemption Rights. The Company are not obligated to redeem or repurchase any shares of Series D Preferred. Shares of Series D Preferred are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

Common Stock Warrant Pricing Adjustments. The Common Stock Warrants issued to the investors of the common stock included certain provisions that allow for subsequent adjustments to the exercise price upon the issuance of subsequent financial instrument issuances. The Company evaluated these provisions in consideration of the guidance in ASU 2017-11, *Accounting for Financial Instruments with Down Round Features*, and concluded that equity classification of the common stock warrants was not precluded as the common stock warrant exercise price could only adjust based upon issuances of future financial instruments.

The gross proceeds of the offering were allocated to the Class A units based upon the \$8.40 per Class A Unit value and the residual proceeds were allocated between the Series D and warrants based upon their respective relative fair values at that time. All offering costs were allocated between the Series D and the warrants. In addition, the placement agent received, as compensation for the transaction, unregistered equity warrants to purchase 10,196 shares of the Company's common stock priced at \$8.40 per share prior to any pricing adjustment or \$6.00 per share subsequent to the common stock warrant pricing adjustment triggered by the Series E Convertible Preferred stock and accompanying warrants issuance. The impact of the down round adjustment was not material. The fair value of the placement agent equity classified warrants was \$0.1 million at the time of issuance.

In connection with the issuance of the Series D and common stock warrants, the Company recognized the intrinsic value of a beneficial conversion feature of \$0.1 million. The beneficial conversion amount was computed as the difference between the Series D effective conversion price and the fair value of the Company's common stock multiplied by that number of shares issuable upon conversion.

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series D, recognize any unamortized discount resulting from the initial allocation of proceeds issued to the common stock warrants. During the three months ended September 30, 2019, there were no Series D shares issued and outstanding. During the nine months ended September 30, 2019, the holders of Series D shares converted 521 shares of Series D into 62,064 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of \$0.3 million associated with the difference between the stated and carrying per share values of the Series D, including a \$0.1 million accretion related to issuance costs that had been allocated to the Series D which have been presented as a component of net loss attributable to common stockholders in the Company's condensed consolidated statement of operations.

Beneficial Conversion Feature-Series D Convertible Preferred Stock

Each share of Series D is convertible into shares of common stock, at any time at the option of the holder at a conversion price of \$8.40 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series D preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series D was \$0.1 million and the preferred stock was discounted by this amount. The beneficial conversion amount of \$0.1 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The \$0.1 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's condensed consolidated statement of operations for the nine months ended September 30, 2019.

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Series C Convertible Preferred Stock Issuance

On July 3, 2018, the Company completed a rights offering pursuant to the Company's effective registration statement on Form S-1. The Company offered for sale units in the rights offering and each unit sold in connection with the rights offering consists of 1 share of the Company's Series C Convertible Preferred Stock, or Series C, and 8 common stock warrants (the "Rights Offering"). Upon completion of the offering, pursuant to the rights offering, the Company sold an aggregate of 10,826 units at an offering price of \$1,000 per unit comprised of 10,826 shares of Series C and 88,928 common stock warrants. The Company received net proceeds of \$9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and offering expenses, totaling approximately \$0.9 million, and excluding any proceeds received upon exercise of any warrants.

The common stock warrants are exercisable at \$108.50 per share and subject to adjustments upon the occurrence of certain dilutive events. The warrants expire on the fifth anniversary from their original issuance date. The Company may redeem the warrants for \$0.70 per warrant if the Company's common stock closes above \$434.00 per share for ten consecutive trading days provided that the Company may not do so prior to the first anniversary of the closing of the unit offering. The warrants were sold under a written public offering. If a warrant is exercised during a period where a registration statement is not declared effective, the Company cannot assert that settlement in unregistered shares is permitted. As a result, the warrants are liability classified and carried at their estimated fair value at each reporting until they are exercised, terminated or otherwise settled.

The Company determined that the Series C should not be classified as temporary equity due to the lack of senior liquidation preferences and is not redeemable on a fixed or determinable date.

The rights and preferences of the Series C are as follows:

Dividends

Holders of Series C shares are entitled to dividends, if and when declared on shares of common stock, on an "as-converted" basis.

Voting

Subject to certain preferred stock class votes specified in the certificate of designation, the holders of Series C shares shall have no voting rights.

Liquidation

Upon any voluntary or involuntary liquidation, dissolution or winding-up of the Company, holder of Series C shares shall be entitled to receive the same consideration as the holders of the Company's common stock on an "as converted" basis.

Conversion

Each share of Series C is convertible into common stock at any time at the option of the holder thereof at the conversion price then in effect. The conversion price for the Series C is determined by dividing the stated value of \$1,000 per share by \$108.50 per share (subject to adjustments upon the occurrence of certain dilutive events).

At any time after the first anniversary of the original issuance date, the Company may, subject to certain conditions, require the conversion of Series C shares.

The gross proceeds of the offering were first allocated to the warrants based on the fair value of the warrants at that time, with the residual proceeds allocated to the Series C. All offering costs were allocated between the Series C and the warrants. In addition, the placement agent received, as compensation for the transaction, unregistered equity warrants to purchase 3,991 shares of the Company's common stock priced at \$119.70 per share. The fair value of the placement agent equity classified warrants was \$0.2 million at the time of issuance and \$0.1 million was allocated to the Series C and \$0.1 million was allocated to the liability classified common stock warrants. All costs allocated to the liability classified warrants were expensed immediately and as a component of general and administrative expenses within the Company's condensed consolidated statement of operations.

In connection with the issuance of the Series C and liability classified warrants, the Company recognized the intrinsic value of a beneficial conversion feature of \$3.8 million. The beneficial conversion amount was computed as the difference between the Series C effective conversion price and the fair value of the Company's common stock multiplied by that number of shares issuable upon conversion.

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series C, recognize any unamortized discount resulting from the initial allocation of proceeds

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issued to the liability classified warrants. During the nine months ended September 30, 2019, the holders of Series C shares converted 147 shares of Series C into 1,353 shares of common stock. As a result of the conversion, the Company recognized a preferred stock discount amortization to additional paid in capital of \$77,721 as deemed dividends. During the year ended December 31, 2018, the holders of Series C shares converted 8,852 shares of Series C into 81,585 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of \$4.7 million associated with the difference between the stated and carrying per share values of the Series C, including a \$0.5 million accretion related to issuance costs that had been allocated to the Series C which have been presented as a component of net loss attributable to common stockholders in the Company's condensed consolidated statement of operations.

Beneficial Conversion Feature-Series C Convertible Preferred Stock

Each share of Series C is convertible into shares of common stock, at any time at the option of the holder at a conversion price of \$108.50 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series C preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series C was \$3.8 million and the preferred stock was discounted by this amount. The beneficial conversion amount of \$3.8 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The \$3.8 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations for the year ended December 31, 2018.

Common Stock and Warrant Offering

On October 7, 2015, the Company entered into an underwriting agreement related to the public offering and sale of 8,929 shares of common stock and warrants to purchase up to 5,357 shares of common stock, at a fixed combined price to the public of \$1,680 under the Company's prior shelf registration statement on Form S-3. The shares of common stock and warrants were issued separately on October 13, 2015. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of \$2,380.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering contemplated by the Underwriting Agreement.

The gross proceeds to the Company were \$15.0 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately \$1.5 million. If the warrants were exercised in full, Hepion would receive additional proceeds of approximately \$12.8 million.

If the Company consummates any merger, consolidation, sale or other reorganization event in which the Company's common stock is converted into or exchanged for securities, cash or other property ("Fundamental transaction"), then the Company shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the fundamental transaction and continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such fundamental transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in the Company's statements of operations. Upon the issuance of these warrants, the fair value of approximately \$4.4 million was recorded as derivative financial instruments liability-warrants.

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The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. The Company develops its own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility of comparable companies, the contractual term of the warrants, risk free interest rates and dividend yields. The Company has a limited trading history in its common stock, therefore, expected volatility is based on that of comparable public development stage biotechnology companies. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Price of Hepion common stock	\$ 2.42	\$ 19.74
Expected warrant term (years)	1.03 years	1.78 years
Risk-free interest rate	1.75%	2.48%
Expected volatility	72%	74%
Dividend yield	—	—

On April 4, 2016, the Company closed a public offering of 8,803 shares of its common stock and warrants to purchase up to 4,401 shares of common stock, at a fixed combined price to the public of \$795.20 under the Company's prior shelf registration statement on Form S-3. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of \$952.00 per share. The gross proceeds to the Company were \$7.0 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately \$0.7 million. If the warrants were exercised in full, Hepion would receive additional proceeds of approximately \$4.2 million.

If the Company consummates any merger, consolidation, sale or other reorganization event in which its common stock is converted into or exchanged for securities, cash or other property ("Fundamental transaction"), then the Company shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the Fundamental transaction and continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such Fundamental transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in the Company's statement of operations. Upon the issuance of these warrants, the fair value of approximately \$1.5 million was recorded as derivative financial instruments liability-warrants.

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. The Company develops its own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility of comparable companies, the contractual term of the warrants, risk free interest rates and dividend yields. The Company has a limited trading history in its common stock, therefore, expected volatility is based on that of comparable public development stage biotechnology companies. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Price of Hepion common stock	\$ 2.42	\$ 19.74
Expected warrant term (years)	1.51 years	2.26 years
Risk-free interest rate	1.69%	2.48%
Expected volatility	68%	74%
Dividend yield	—	—

On April 25, 2017, the Company closed a public offering of 21,429 shares of its common stock and warrants to purchase up to 10,714 shares of common stock, at a fixed combined price to the public of \$560.00 under the Company's prior shelf registration statement on Form S-3. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of \$700.00 per share. The gross proceeds to the Company were \$12.0 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately \$0.5 million. If the warrants were exercised in full, Hepion would receive additional proceeds of approximately \$7.5 million.

If the Company consummates any merger, consolidation, sale or other reorganization event in which its common stock is converted into or exchanged for securities, cash or other property ("Fundamental transaction"), then the Company shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the Fundamental transaction and

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continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such fundamental transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in the Company's statement of operations. Upon the issuance of these warrants, the fair value of approximately \$4.0 million was recorded as derivative financial instruments liability - warrants.

The fair value of these liability classified warrants were estimated using the Black-Scholes option pricing model. The Company develops its own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility of comparable companies, the contractual term of the warrants, risk free interest rates and dividend yields. The Company has a limited trading history in its common stock, therefore, expected volatility is based on that of comparable public development stage biotechnology companies. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Price of Hepion common stock	\$ 2.42	\$ 19.74
Expected warrant term (years)	2.56 years	3.31 years
Risk-free interest rate	1.60%	2.46%
Expected volatility	63%	74%
Dividend yield	—	—

The warrants, issued in connection with the July 2018 Rights Offering are deemed to be derivative instruments since if the Company does not maintain an effective registration statement, the Company is obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside of the control of the Company. Therefore, the fair value of the warrants was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the warrants issued, including a fixed term and exercise price.

The fair value of these liability classified warrants were estimated using the Black-Scholes option pricing model. The Company develops its own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility of comparable companies, the contractual term of the warrants, risk free interest rates and dividend yields. The Company has a limited trading history in its common stock, therefore, expected volatility is based on that of comparable public development stage biotechnology companies. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Price of Hepion common stock	\$ 2.42	\$ 19.74
Expected warrant term (years)	3.76 years	4.50 years
Risk-free interest rate	1.56%	2.51%
Expected volatility	63%	74%
Dividend yield	—	—

The following table sets forth the components of changes in the Company's derivative financial instruments liability balance for the nine months ended September 30, 2019:

Date	Description	Number of Warrants Outstanding	Derivative Instrument Liability
December 31, 2018	Balance of derivative financial instruments liability	107,997	\$ 404,337
	Change in fair value of warrants for the nine months ended September 30, 2019	—	(403,928)
September 30, 2019	Balance of derivative financial instruments liability	107,997	\$ 409

7. Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of September 30, 2019 and December 31, 2018.

	Fair value	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of September 30, 2019				
Convertible Debt	\$ 330,000	\$ —	\$ —	\$ 330,000
Derivative liabilities related to warrants	\$ 409	\$ —	\$ —	\$ 409
Contingent consideration	\$ 2,520,000	\$ —	\$ —	\$ 2,520,000
As of December 31, 2018				
Convertible Debt	\$ 1,440,000	\$ —	\$ —	\$ 1,440,000
Derivative liabilities related to warrants	\$ 404,337	\$ —	\$ —	\$ 404,337
Contingent consideration	\$ 2,590,000	\$ —	\$ —	\$ 2,590,000

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities-warrants in the Company's statements of operations. See Note 6 for a roll forward of the derivative liability for the nine months ended September 30, 2019. The financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

A lattice-based model is used to estimate the fair value of the Secured Convertible Note. The lattice model utilizes a "decision tree" whereby future movement in the company's common stock price is estimated based on a volatility factor. The Company classified the fair value of the Secured Convertible Note as a Level 3 measurement due to the lack of observable market data. The lattice model requires the development and use of assumptions including the Company's stock price volatility returns, an appropriate risk-free interest rate, default intensity rate and expected recovery rate given default. The estimated fair value of the Secured Convertible Note as of September 30, 2019 was \$0.3 million and was based on the following inputs: stock volatility of 150.0 percent, risk-free rate of 1.91 percent related to assumed term of 0.11 years, default intensity of 23.7 percent and a recovery rate of 30.0 percent.

The following table summarizes the changes in fair value of the convertible debt for which the Company has used Level 3 inputs to determine fair value.

	Fair Value of Convertible Debt
Balance at December 31, 2018	\$ 1,440,000
Change in fair value	175,992
Repayment of principal of debt financing	(1,285,992)
Balance at September 30, 2019	\$ 330,000

Contingent consideration was recorded for the acquisition of Ciclofilin on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of \$19.60. The Company completed the first segment of its Phase 1 clinical activities for CRV431 in October 2018 wherein the Company reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) and in the fourth quarter of 2018, the Company paid a related milestone payment of \$1,000,000 and issued 1,439 shares of the Company's common stock with a fair value of \$55,398, representing 2.5% of the Company's issued and outstanding common stock as of June, 2016, to the Ciclofilin shareholders. As of September 30, 2019, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability. The following table presents the change in fair value of the contingent consideration for the nine months ended September 30, 2019.

	Acquisition- related Contingent Consideration
Liabilities	
Balance at December 31, 2018	\$ 2,590,000
Change in fair value recorded in earnings	(70,000)
Balance at September 30, 2019	<u>\$ 2,520,000</u>

8. Indefinite-lived Intangible Assets and Goodwill

IPR&D

The Company's IPR&D asset consisted of the following at:

	Indefinite-lived Intangible Asset
IPR&D asset:	
CRV431 balance at December 31, 2018	\$ 3,190,000
Changes during the nine months ended September 30, 2019	—
CRV431 balance at September 30, 2019	<u>\$ 3,190,000</u>

No impairment losses were recorded on IPR&D during the nine months ended September 30, 2019.

Goodwill

The table below provides a roll-forward of the Company's goodwill balance:

	Amount
Goodwill balance at December 31, 2018	\$ 1,870,924
Changes during the nine months ended September 30, 2019	—
Goodwill balance at September 30, 2019	<u>\$ 1,870,924</u>

No impairment losses were recorded on goodwill during the nine months ended September 30, 2019.

9. Accrued Liabilities

The Company's accrued expenses consist of the following:

	September 30, 2019	December 31, 2018
Payroll and related costs	\$ 306,602	\$ 280,235
Research and development	—	184,120
Legal fees	—	34,072
Professional fees	—	151,812
Other	1,785	11,182
Total accrued expenses	<u>\$ 308,387</u>	<u>\$ 661,421</u>

10. Accounting for Share-Based Payments

On June 3, 2013, Hepion adopted the 2013 Equity Incentive Plan (the "Plan"). Stock options granted under the Plan typically will vest after three years of continuous service from the grant date and will have a contractual term of ten years. Stockholder and Board approval was obtained on December 2, 2014 to increase the number of authorized shares to 11,607 and on December 14, 2016 Stockholder and Board approval was obtained to increase the number of authorized shares to 13,750. Stockholder and Board approval was obtained on February 21, 2018 to increase the number of authorized shares to 40,535. As of September 30, 2019, the Company had 11,155 shares of common stock available for grant under the Plan.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified. The following table presents the stock based compensation expense for the periods indicated:

	Three months ended September 30, 2019	Three months ended September 30, 2018	Nine months ended September 30, 2019	Nine months ended September 30, 2018
General and administrative	\$ 10,371	\$ 73,545	\$ 31,107	\$ 381,869
Research and development	6,760	(10,573)	20,661	51,163
Total stock-based compensation expense	<u>\$ 17,131</u>	<u>\$ 62,881</u>	<u>\$ 51,768</u>	<u>\$ 433,032</u>

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A summary of stock option activity and of changes in stock options outstanding under the Plan for the nine months ended September 30, 2019 is presented below:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, January 1, 2019	9,923	\$61.60—\$2,144.80	\$ 862.70	\$ —	6.02
Granted	20,239	\$3.24	\$ 3.24	—	9.85
Cancelled	(151)	\$324.80—\$2,016.00	\$ 485.12	—	—
Forfeited	(12)	\$162.40—\$305.20	\$ 467.60	—	—
Balance outstanding, September 30, 2019	30,129	\$3.24—\$2,144.80	\$ 265.99	—	8.24
Vested awards and those expected to vest at September 30, 2019	29,068	\$3.24—\$2,144.80	\$ 276.19	—	8.24
Vested and exercisable at September 30, 2019	14,295	\$3.24—\$2,144.80	\$ 545.96	—	6.55

There were 20,369 and 0 options granted to employees during the nine months ended September 30, 2019 and 2018, respectively. The total value of the shares vested during the nine months ended September 30, 2019 was de minimis.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

As of September 30, 2019, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was approximately \$50,767 to be recognized over a weighted-average remaining vesting period of approximately 3.67 years.

The following weighted-average assumptions were used in the Black-Scholes valuation model to estimate fair value of stock option awards to employees during the nine months ended September 30, 2019 and 2018.

	Nine months ended September 30, 2019	Nine months ended September 30, 2018
Stock price	\$ 3.24	\$ —
Risk-free interest rate	1.85%	—
Dividend yield	—	—
Expected volatility	76.5%	—
Expected term (in years)	6.0 years	—

Risk-free interest rate—Based on the daily yield curve rates for U.S. Treasury obligations with maturities which correspond to the expected term of the Company's stock options.

Dividend yield—Hepion has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

Expected volatility—Because Hepion has a limited trading history in its common stock, the Company based expected volatility on that of comparable public development stage biotechnology companies.

Expected term—The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in SAB No. 107. Options are considered to be “plain vanilla” if they have the following basic characteristics: (i) granted “at-the-money”; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable.

In December 2007, the SEC issued SAB No. 110, *Share-Based Payment*, (“SAB No. 110”). SAB No. 110 was effective January 1, 2008 and expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of “plain vanilla” share options in accordance with ASC 718. The Company will use the simplified method until it has the historical data necessary to provide a reasonable estimate of expected life in accordance with SAB No. 107, as amended by SAB No. 110. For the expected term, the Company has “plain-vanilla” stock options, and therefore used a simple average of the vesting period and the contractual term for options granted as permitted by SAB No. 107.

Forfeitures—ASC 718 allows for the election of forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. At April 1, 2016, the Company determined that it had sufficient history of issuing stock options and decreased its estimated forfeiture rate from 10%, which was based on the historical experience of its former parent, to 3%, which is the Company's actual historical forfeiture rate. The forfeiture rate was 10% through the end of the 3rd fiscal quarter ended March 31, 2016 and was adjusted to 3% through the end of the fiscal year June 30, 2016 based on the aforementioned historical analysis. The forfeiture rate was 3% for the nine months ended September 30, 2019 and the nine months ended September 30, 2018. The Company will continue to analyze the forfeiture rate on at least an annual basis or when there are any identified triggers that would justify immediate review.

11. Loss per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, (“ASC Topic 260”) for all periods presented. In accordance with ASC Topic 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. In addition, the net loss attributable to common stockholders' is adjusted for the preferred stock deemed dividends related to the beneficial conversion feature and accretion on this instrument for the periods presented. The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

Basic net (loss) income per common share	Three months ended		Nine months ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Numerator:				
Net loss	\$ (1,819,683)	\$ (157,058)	\$ (4,824,292)	\$ (6,876,621)
Preferred stock deemed dividend	(8,460)	(8,805,809)	(5,444,826)	(8,805,809)
Net loss attributable to common shareholders	<u>(1,828,143)</u>	<u>\$ (8,962,867)</u>	<u>\$ (10,269,118)</u>	<u>\$ (15,682,430)</u>
Denominator:				
Weighted average common shares outstanding	<u>3,453,628</u>	<u>202,451</u>	<u>1,532,927</u>	<u>166,687</u>
Net loss per share of common stock—basic and diluted	<u>\$ (0.53)</u>	<u>\$ (44.27)</u>	<u>\$ (6.70)</u>	<u>\$ (94.08)</u>

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The following outstanding securities at September 30, 2019 and 2018 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Nine months ended September 30, 2019	Nine months ended September 30, 2018
Common shares issuable upon conversion of Series A preferred stock	3,184	3,184
Common shares issuable upon conversion of Series C preferred stock	16,840	20,765
Stock options	30,129	11,857
Warrants — equity classified	2,733,076	—
Warrants — liability classified	107,997	107,997
Total	2,891,226	143,803

The liability classified warrants disclosed above have been excluded from the computation of diluted earnings per share because their exercise price exceeds the average market price of the Company's common stock for the period they were outstanding.

12. Commitments and Contingencies

License Agreement with Chimerix, Inc.

On December 17, 2014, the Company entered into an exclusive license agreement with Chimerix pursuant to which the Company has licensed TXL from Chimerix for further clinical development and commercialization. TXL is a highly potent analog of the antiviral drug tenofovir DF (Viread®). Under the terms of the agreement, Hepion licensed TXL from Chimerix in exchange for an upfront payment consisting of 120,000 shares of Hepion Series B Convertible Preferred Stock. In addition, Chimerix is eligible to receive up to approximately \$20.0 million in clinical, regulatory and initial commercial milestone payments in the United States and Europe, as well as royalties and additional milestone payments based on commercial sales in those territories. Either party may terminate the License Agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy or insolvency of the other party. The Company may also terminate the License Agreement without cause on a country by country basis upon sixty days' prior written notice to Chimerix.

On April 2, 2019, the Company delivered a notification to Chimerix of its intention to terminate the License Agreement by and between the Company and Chimerix, dated December 17, 2014. The termination of the License Agreement became effective on June 1, 2019. Pursuant to the License Agreement, Chimerix granted Hepion rights for the development and commercialization of TXL. Upon the effectiveness of the termination of the License Agreement on June 1, 2019, Chimerix reacquired all worldwide rights to TXL. Hepion made the decision to terminate the License Agreement following its decision to no longer pursue development of CMX157, and to focus its resources and development programs on further advancing CRV431.

Contractual Obligations

In August 2014, the Company entered into a lease for corporate office space in Edison, New Jersey. In December 2017, the Company entered an amendment to the lease for corporate office space in Edison, New Jersey expanding the office footprint and extending the lease for an approximate 5-year period. Rent expense for the three months ended September 30, 2019 was \$50,789.

In May 2018, the Company entered a lease for office equipment to be used at the Company's corporate office space in Edison, New Jersey. This term of this lease is 3 years and the Company has incurred expenses of approximately \$848 relating to this lease for the period ended September 30, 2019.

The Company also leases office and research laboratory space in Edmonton, Canada that is currently on a month to month basis.

Leases

The Company accounts for leases in accordance with ASC Topic 842, *Leases*, ("ASC 842"). The Company determines if an arrangement is a lease at contract inception. A lease exists when a contract conveys to the customer the right to control the use of

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identified property, plant, or equipment for a period in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the customer has the right to control the use of the identified asset.

Prior to January 1, 2019, the Company recorded monthly rent expense on a straight-line basis, from the commencement of the lease to December 31, 2018. As of December 31, 2018, the balance of the Deferred rent liability was \$9,235, representing the difference between cash rent paid and the straight-line rent expense.

The following table summarizes annual rental payments for each of the following fiscal years as of December 31, 2018:

2019	\$	202,734
2020		194,529
2021		209,170
2022 and thereafter		266,290
Total	\$	<u>872,723</u>

Beginning January 1, 2019, the Company accounts for leases according to the FASB issued ASU 2016-02.

Operating leases where the Company is the lessee are included under the caption “Right of Use Assets” on the Company’s condensed consolidated balance sheets. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. Key estimates and judgments include how the Company determines (1) the discount rate used to discount the unpaid lease payments to present value, (2) lease term and (3) lease payments.

The Right-Of-Use (“ROU”) asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company adopted ASC 842 in the first quarter of 2019 using an alternative modified retrospective approach, in which prior periods will not be restated. As a result of the adoption, as of January 1, 2019, the Company recognized an operating lease liability of \$773 thousand based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of \$764 thousand. As of September 30, 2019, the lease liabilities are \$652 thousand, of which \$191 thousand is current and \$461 thousand are non-current. The ROU assets are \$642 thousand. The discount rate used to account for the Company’s operating leases under ASC 842 is the Company’s estimated incremental borrowing rate of 6.5%.

Rent expense related to the Company’s operating leases was approximately \$188 thousand and \$222 thousand for the nine months ended September 30, 2019 and 2018, respectively. Cash paid for amounts included in the measurement of the lease liabilities was approximately \$153 thousand for the nine months ended September 30, 2019. The weighted average remaining term of the Company’s noncancelable operating leases is 3.49 years. Future minimum rental payments under the Company’s noncancelable operating leases at September 30, 2019 is as follows:

2019	\$	51,531
2020		197,828
2021		210,583
2022		212,388
2023		53,901
Total		<u>726,231</u>
Present Value Adjustment		<u>(74,292)</u>
Lease liability at September 30, 2019	\$	<u>651,939</u>

Employment Agreements

The Company also has employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur.

13. Related Party Transactions

One of the Company’s Directors, Timothy Block, is President of the Baruch S. Blumberg Institute (“Blumberg Institute”). On May 29, 2015, the Company entered into a Sponsored Research Agreement (“Agreement”) with Blumberg Institute, pursuant to which the Company is sponsoring research by investigators affiliated with the Blumberg Institute with respect to TXL. The Company

incurred expenses related to the agreement of approximately \$0 and \$50,000 for the nine months ended September 30, 2019 and 2018, respectively.

14. Income Taxes

On December 22, 2017, new federal tax reform legislation was enacted in the United States, resulting in significant changes from previous tax law. The 2017 Tax Act reduces the federal corporate income tax rate to 21% from 35% effective January 1, 2018. The key impacts of the Tax Act on the Company's condensed consolidated financial statements were the re-measurement of deferred tax balances to the new corporate tax rate. The re-measurement of the deferred tax balances to the new corporate rate was completed as of December 31, 2017 and resulted in an adjustment of approximately \$373,000 recorded as a reduction in the deferred tax liability offset by a credit to Income Tax benefit at that time. The 2017 Tax Act also changed the Net Operating Loss carry forwards' period to now have an indefinite life. In connection with the preparation of the unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2018, the Company identified an error related to an additional reduction that should have been recorded to the valuation allowance in the approximate amount of \$536,000 to reflect the adjustment allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets in conjunction with the evaluation of the amount of valuation allowance needed. This error was determined to be immaterial and was corrected as an out of period adjustment previously recorded in the quarter ended March 31, 2018.

15. Subsequent Event

On October 3, 2019, the Company paid the last installment of \$330,000 to Illiad Research pertaining to the secured convertible promissory note dated May 8, 2018.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our condensed consolidated financial statements and other financial information appearing elsewhere in this quarterly report. In addition to historical information, the following discussion and other parts of this quarterly report contain forward-looking statements. You can identify these statements by forward-looking words such as "plan," "may," "will," "expect," "intend," "anticipate," "believe," "estimate" and "continue" or similar words. Forward-looking statements include information concerning possible or assumed future business success or financial results. You should read statements that contain these words carefully because they discuss future expectations and plans, which contain projections of future results of operations or financial condition or state other forward-looking information. We believe that it is important to communicate future expectations to investors. However, there may be events in the future that we are not able to accurately predict or control. Accordingly, we do not undertake any obligation to update any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties set forth under "Risk Factors" in our Annual Report on Form 10-K ("Form 10-K") as of and for the year ended December 31, 2018 filed with the United States Securities and Exchange Commission ("SEC") on March 14, 2019. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of us, please be advised that our actual financial condition, operating results and business performance may differ materially from that projected or estimated by us in forward-looking statements, and you should not unduly rely on such statements.

Business Overview

We are a biopharmaceutical company headquartered in Edison, New Jersey, focused on the development of pleiotropic drug therapy for treatment of chronic liver disease. This therapeutic approach targets fibrosis and hepatocellular carcinoma ("HCC") associated with non-alcoholic steatohepatitis ("NASH"), viral hepatitis, and other liver diseases. Our cyclophilin inhibitor, CRV431, is being developed to offer benefits to address these multiple complex pathologies. CRV431 is a cyclophilin inhibitor that targets multiple biochemical pathways involved in the progression of liver disease. Preclinical studies with CRV431 in NASH models demonstrated consistent reductions in liver inflammation, fibrosis, and cancerous tumors. CRV431 additionally shows antiviral activity towards hepatitis B, C, and D viruses which also trigger liver disease.

NASH is the form of liver disease that is triggered by what has come to be known as the "Western diet", characterized especially by high-fat, high-sugar, and processed foods. Among the effects of a prolonged Western diet is fat accumulation in liver cells (steatosis) which is described as non-alcoholic fatty liver disease ("NAFLD") and can predispose cells to injury. NAFLD may evolve into NASH when the fatty liver begins to progress through stages of cell injury, inflammation, fibrosis, and carcinogenesis. People who develop NASH often have additional predisposing conditions such as diabetes and hypertension, but the exact biochemical events that trigger and maintain the progression are not well known. Many people in the early stages of disease do not have significant symptoms and therefore do not know that they have it. NASH becomes evident and a major concern when the liver becomes fibrotic and puts the individual at increased risk of developing cirrhosis and other complications. Individuals with advanced

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liver fibrosis has significantly higher risk of developing liver cancer, although cancer may also arise in some patients before significant hepatitis or fibrosis. NASH is increasing worldwide at an alarming rate due to the spread of the Western diet, obesity, and other related conditions. Approximately 4-5% of the global population is estimated to have NASH, and that proportion is higher in the USA. It is predicted that NASH will become the leading reason for individuals requiring a liver transplant in the USA as early as 2020. Considering the serious outcomes linked to advancing NASH, the economic and social burden of the disease is enormous. There are no simple blood tests to diagnose or track the progression of NASH, and no drugs are approved to specifically treat the disease.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2019, we have an accumulated deficit of approximately \$81.3 million. From inception through September 30, 2019, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

On July 3, 2018, we completed a rights offering pursuant to an effective registration statement on Form S-1. We offered units in the rights offering and each unit sold in connection with the rights offering consists of 1 share of our Series C Convertible Preferred Stock, or Series C, and 8 common stock warrants. Upon completion of the offering, pursuant to the rights offering, we sold an aggregate of 10,826 units at an offering price of \$1,000 per unit comprised of 10,826 shares of Series C and 88,928 common stock warrants. We received net proceeds of \$9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and offering expenses, totaling approximately \$0.9 million, and excluding any proceeds received upon exercise of any warrants. The common stock warrants are exercisable at \$108.50 per share and subject to adjustments upon the occurrence of certain dilutive events. The warrants expire on the fifth anniversary from their original issuance date. We may redeem the warrants for \$0.01 per warrant if our common stock closes above \$434 per share for ten consecutive trading days, provided that we may not do so prior to the first anniversary of the closing of the unit offering. If a warrant is exercised during a period where a registration statement is not declared effective, we cannot assert that settlement in unregistered shares is permitted. As a result, the warrants are liability classified and carried at their estimated fair value at each reporting until they exercised, terminated or otherwise settled.

On March 13, 2019, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with an accredited investor (the "Investor"). Pursuant to the Securities Purchase Agreement, we issued to the Investor in a private placement (the "Private Placement") (i) 47,429 shares of our common stock and (ii) an unsecured \$1.25 million aggregate principal amount debenture (the "Debenture"). The maturity date of the Debenture was June 30, 2019. Prior to the maturity date, no interest accrued on the Debenture. Upon an event of default, including upon the non-repayment of the principal amount at the maturity date, interest shall accrue on the Debenture at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law until such principal amount is paid in full. The Debenture ranks junior to our existing secured indebtedness. We repaid the outstanding debt balance in June, 2019 and recorded the remaining debt discount of \$417 thousand as non cash interest expense during the three months ended June 30, 2019.

On April 25, 2019, we announced the pricing of a public offering with total gross proceeds of approximately \$2,140,000 before deducting placement agent fees and other offering expenses payable by us that closed on April 29, 2019. The securities offered by us consist of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$8.40 per Class A Unit, and (ii) Class B Units each consisting of one share of Series D Convertible Preferred Stock, with a stated value of \$1,000 per share, and convertible into 119 shares of Common Stock per share of Series D Convertible Preferred Stock, and Warrants to purchase 119 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock to be issued pursuant to the Class A Units and issuable upon conversion of all of the Series D Convertible Preferred Stock is 254,762. The aggregate number of Warrants issued in the offering was 254,762. The Warrants have an exercise price of \$8.40, are exercisable upon issuance and expire five years from the date of issuance.

On June 18, 2019, we announced the pricing of a public offering with total gross proceeds of \$15,600,000 before deducting placement agent fees and other offering expenses payable by us (the "Offering"). The Offering closed on June 20, 2019. The securities offered by us consisted of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$6.00 per Class A Unit, and (ii) Class B Units each consisting of one share of Series E Preferred Stock, with a stated value of \$1,000 per share, and convertible into approximately 167 shares of Common Stock per share of Series E Preferred Stock, and Warrants to purchase 167 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock to be issued pursuant to the Class A Units and issuable upon conversion of all the Series E Preferred Stock is 2,600,000. The aggregate number of Warrants issued in the offering was 2,600,000. The Warrants have an exercise price of \$6.00, are exercisable upon issuance and expire five years from the date of issuance.

Our product development efforts are in their early stages and we cannot make estimates of the costs or the time they will take to complete. The risk of completion of any program is high because of the many uncertainties involved in bringing new drugs to market including the long duration of clinical testing, the specific performance of proposed products under stringent clinical trial protocols, the extended regulatory approval and review cycles, our ability to raise additional capital, the nature and timing of research and development expenses and competing technologies being developed by organizations with significantly greater resources.

CRITICAL ACCOUNTING POLICIES

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of condensed consolidated financial statements. Our accounting policies are described in ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA of our Annual Report on Form 10-K (“Form 10-K”) as of and for year ended December 31, 2018, filed with the SEC on March 14, 2019. There have been no changes to our critical accounting policies since December 31, 2018.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2019.

RECENT ACCOUNTING PRONOUNCEMENTS

Please refer to Note 4 of Notes to Condensed Financial Statements, *Recent Accounting Pronouncements*, in this Quarterly Report on Form 10-Q.

JOBS Act

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- requirement to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We have irrevocably elected not to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We may take advantage of these provisions up to the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the distribution; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

To the extent that we continue to qualify as a “smaller reporting company,” as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (2) scaled executive compensation disclosures; and (3) the requirement to provide only two years of audited financial statements, instead of three years.

RESULTS OF OPERATIONS**Comparison of Three Months Ended September 30, 2019 and 2018**

	For the Three Months Ended		Change Dollars
	September 30,		
	2019	2018	
Revenues	\$ —	\$ —	\$ —
Cost and expenses:			
Research and development	846,453	2,167,951	(1,321,498)
General and administrative	1,064,081	1,684,594	(620,513)
Loss from operations	(1,910,534)	(3,852,545)	1,942,011
Other income (expense):			
Change in fair value of debt	(22,197)	(14,542)	(7,655)
Interest expense	(15,354)	(55,458)	40,104
Change in fair value of derivative instruments-warrants and contingent consideration, net	128,402	3,765,487	(3,637,085)
Other income (expense), net	90,851	3,695,487	(3,604,636)
Loss before income taxes	(1,819,683)	(157,058)	(1,662,625)
Income tax benefit	—	—	—
Net loss	<u>\$ (1,819,683)</u>	<u>\$ (157,058)</u>	<u>\$ (1,662,625)</u>

We had no revenues during the three months ended September 30, 2019 or 2018 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the three months ended September 30, 2019 and 2018 amounted to \$0.8 million and \$2.1 million, respectively. The approximate \$1.3 million decrease was primarily comprised of a decrease of \$1.0 million of costs attributable to the execution and the completion of the phase 1 study related to CRV-431 and a \$0.3 million decrease in salary and related costs associated with a reduction in research and development headcount.

General and administrative expenses for the three months ended September 30, 2019 and 2018 amounted to \$1.1 million and \$1.7 million, respectively. The decrease of \$0.6 million is primarily due to a \$0.5 million reduction in costs related to the issuance of warrants in connection with the July 2018 rights offering and a decrease in salary and related costs associated with a reduction in headcount of \$0.1 million.

Other income (expense) for the three months ended September 30, 2019 and 2018 amounted to \$0.1 million and \$3.7 million, respectively. The \$3.6 million decrease in other income (expense) was primarily attributable due to the \$3.6 million decrease in the fair value of the outstanding warrants due to the utilization of a lower stock price and a decrease in the fair value of the contingent consideration.

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Comparison of Nine Months Ended September 30, 2019 and 2018

	For the Nine Months Ended September 30,		Change Dollars
	2019	2018	
Revenues	\$ —	\$ —	\$ —
Cost and expenses:			
Research and development	2,120,152	6,551,553	(4,431,401)
General and administrative	3,407,650	5,047,000	(1,639,350)
Loss from operations	(5,527,802)	(11,598,553)	6,070,751
Other income (expense):			
Change in fair value of debt	(175,992)	17,406	(193,398)
Interest expense	(555,441)	(287,406)	(268,035)
Change in fair value of derivative instruments-warrants and contingent consideration, net	473,929	4,455,932	(3,982,003)
Other income (expense), net	(257,504)	4,185,932	(4,443,436)
Loss before income taxes	(5,785,306)	(7,412,621)	1,627,315
Income tax benefit	961,014	536,000	425,014
Net loss	\$ (4,824,292)	\$ (6,876,621)	\$ 2,052,329

We had no revenues during the nine months ended September 30, 2019 or 2018 because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the nine months ended September 30, 2019 and 2018 amounted to \$2.1 million and \$6.5 million, respectively. The approximate \$4.4 million decrease was primarily comprised of a decrease of \$2.1 million of costs attributable to the decision to discontinue clinical development of TXL and Valnivudine, a \$1.0 million decrease in salary and related costs associated with a reduction in research and development headcount, and a \$1.3 million decrease in expenses related to continued development of CRV431.

General and administrative expenses for the nine months ended September 30, 2019 and 2018 amounted to \$3.4 million and \$5.0 million, respectively. The decrease of \$1.6 million is primarily due to \$0.7 million decrease in professional fees and consultants, and a \$0.2 million decrease in salary and related costs associated with a reduction in headcount, and a \$0.4 million reduction of costs relate to the July 2018 rights offering.

Other income (expense) for the nine months ended September 30, 2019 and 2018 amounted to \$(0.3) million and \$4.2 million, respectively. The \$4.5 million decrease in other income (expense) was primarily due to a \$3.9 million decrease related to the change in fair value of our outstanding warrants and contingent consideration related to a lower stock price used to mark to market our derivative instruments, and a \$0.2 million reduction in the fair value of debt.

The \$0.4 million change in the Income Tax Benefit was due to the receipt of \$1.0 million of proceeds from the sale of state net operating losses.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2019, we had working capital of \$13.7 million compared to working capital of \$3.5 million as of September 30, 2018. The increase of \$10.2 million in working capital is mainly related to an increase in cash and cash equivalents of \$5.8 million, a decrease in accounts payable of \$1.5 million, a decrease in convertible debt of \$1.7 million, and a decrease in the current portion of contingent consideration (see note 7) of \$1.0 million.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine months ended	
	September 30, 2019	September 30, 2018
Net cash (used in) provided by:		
Operating activities	\$ (5,124,878)	\$ (10,553,537)
Investing activities	(45,336)	900
Financing activities	17,201,731	13,630,888
Net increase in cash	\$ 12,031,517	\$ 3,078,251

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As of September 30, 2019, we had approximately \$14.9 million in cash. Net cash used in operating activities was approximately \$5.1 million for the nine months ended September 30, 2019. The net cash used in operating activities during the nine months ended September 30, 2019 primarily consisted of clinical development activities related to CRV431 as well as SG&A expenses and a reduction in working capital accounts due mainly to lower accounts payable.

As of September 30, 2018, we had approximately \$9.0 million in cash. Net cash used in operating activities was approximately \$10.6 million for the nine months ended September 30, 2018. Cash was consumed from continuing operations by the loss of \$6.9 million, and non-cash items consisting mainly of the changes in fair value of derivative instruments and contingent consideration totaling \$4.5 million. Changes in working capital accounts had a positive impact of \$0.2 million on cash.

Net cash used in investing activities during the nine months ended September 30, 2019 and September 30, 2018 was immaterial in both periods.

Net cash provided by financing activities was approximately \$17.2 million for the nine months ended September 30, 2019 due primarily to issuance of common stock in our April and June 2019 offerings of \$5.8 million, proceeds from issuance of preferred stock and warrants of \$10.1 million, and proceeds from the exercise of warrants of \$2.1 million, partially offset by the repayment of convertible debt of \$0.8 million.

Net cash provided by financing activities was approximately \$13.6 million for the nine months ended September 30, 2018 due primarily to issuance of common stock in our May and July 2018 offerings of \$1.6 million, proceeds from issuance of preferred stock and warrants of \$9.8 million, and proceeds from debt financing of \$2 million.

On June 18, 2019 we announced the pricing of a public offering with total gross proceeds of \$15,600,000 before deducting placement agent fees and other offering expenses payable by us (the "Offering"). The Offering closed on June 20, 2019. The securities offered by us consisted of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$6.00 per Class A Unit, and (ii) Class B Units each consisting of one share of Series E Preferred Stock, with a stated value of \$1,000 per share, and convertible into approximately 167 shares of Common Stock per share of Series E Preferred Stock, and Warrants to purchase 167 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock to be issued pursuant to the Class A Units and issuable upon conversion of all the Series E Preferred Stock is 2,600,000. The aggregate number of Warrants issued in the offering was 2,600,000. The Warrants have an exercise price of \$6.00, are exercisable upon issuance and expire five years from the date of issuance.

On April 25, 2019 we announced the pricing of a public offering with total gross proceeds of approximately \$2,140,000 before deducting placement agent fees and other offering expenses payable by us that closed on April 29, 2019. The securities offered by us consist of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$8.40 per Class A Unit, and (ii) Class B Units each consisting of one share of Series D Convertible Preferred Stock, with a stated value of \$1,000 per share, and convertible into 119 shares of Common Stock per share of Series D Convertible Preferred Stock, and Warrants to purchase 119 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock issued to the Class A Units and issued upon conversion of the Series D Convertible Preferred Stock was 254,762. The aggregate number of Warrants issued in the offering was 254,762. The Warrants have an exercise price of \$8.40, are exercisable upon issuance and expire five years from the date of issuance. A total of 254,762 warrants were exercised during the nine months ended September 30, 2019 resulting in proceeds of approximately \$2.0 million.

On March 13, 2019, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with an accredited investor (the "Investor"). Pursuant to the Securities Purchase Agreement, we issued to the Investor in a private placement (the "Private Placement") (i) 47,429 shares of our common stock and (ii) an unsecured \$1.25 million aggregate principal amount debenture (the "Debenture"). The maturity date of the Debenture is June 30, 2019. Prior to the maturity date, no interest will accrue on the Debenture. Upon an event of default, including upon the non-repayment of the principal amount at the maturity date, interest shall accrue on the Debenture at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law until such principal amount is paid in full. The Debenture ranks junior to our existing secured indebtedness. We repaid the outstanding debt balance in June, 2019 and recorded the remaining debt discount of \$417 thousand as non cash interest expense during the three months ended June 30, 2019.

On July 3, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in May 2018 (the "Rights Offering"). Pursuant to the Rights Offering, we sold an aggregate of 10,826 units consisting of an aggregate 10,826 shares of Series C Preferred Stock and 88,928 warrants, with each warrant exercisable for one share of common stock at an exercise price of \$108.50 per share, resulting in net proceeds to us of approximately \$9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

The gross proceeds of the offering were first allocated to the warrants based on the fair value of the warrants at that time, with the residual proceeds allocated to the Series C. All offering costs were allocated between the Series C and the warrants. In

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addition, pursuant to a private offering, the placement agent received, as compensation for the transaction, equity warrants to purchase 3,991 shares of our common stock priced at \$119.70 per share. The fair value of the placement agent equity classified warrants was \$0.2 million at the time of issuance and \$0.1 million was allocated to the Series C and \$0.1 million was allocated to the liability classified common stock warrants. All costs allocated to the liability classified warrants were expensed immediately and as a component of general and administrative expenses within our condensed consolidated statement of operations.

Each share of Series C Preferred Stock (“Series C”) will be convertible, at our option at any time on or after the first anniversary of the closing of the Rights Offering (as defined below) or at the option of the holder at any time, into the number of shares of our common stock, par value \$0.0001 per share (the “Common Stock”) determined by dividing the \$1,000 stated value per share of the Series C by a conversion price of \$108.50 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications.

On May 8, 2018, we entered into a securities purchase agreement (the “Securities Purchase Agreement”) with Iliad Research and Trading, L.P. (“IRT”), pursuant to which we issued to IRT a secured convertible promissory note (the “Note”) in the aggregate principal amount of \$3,325,000 for an aggregate purchase price of \$2,000,000 cash and \$1,000,000 aggregate principal amount of investor notes (the “Investor Notes”) payable to us in four tranches of \$250,000 upon request by us. Closing occurred on May 9, 2018. The Note carries an original issue discount of \$300,000, and the initial principal balance of \$2,225,000 also includes original issue discount of \$200,000 and \$25,000 to cover IRT’s transaction expenses. The Investor Notes have not been drawn as of September 30, 2019. We are using the proceeds for the continued development of our CRV431 compound for the treatment of Hepatitis B Virus and general corporate purposes. The Note bears interest at the rate of 10% per annum and matures on November 8, 2019. Beginning on November 8, 2018, IRT has the right to redeem all or any portion of the Note up to the Maximum Monthly Redemption Amount which is \$500,000. Payments of each redemption amount may be made in cash or shares of our common stock at our election (so long as the various conditions to paying stock set forth in the Note are satisfied) provided, however, that if our common stock is trading below \$112.00 per share (as adjusted for the reverse stock split), the redemption(s) must be in cash. Common stock issued upon redemption will be issued at a price equal to 80% of the lowest trade price of the common stock for the 20 consecutive trading days prior to the date of redemption, subject to adjustments; provided, however, that in no event will the redemption price be less than \$112.00. We have obtained a waiver to the redemption price to enable us to be able to redeem balances of the debt with our common stock. Because of this feature which allows the lender to redeem the entire outstanding balance at its option within twelve (12) months of initial issuance, the debt is classified as current. We also entered into a security agreement with IRT, pursuant to which IRT will receive a security interest in substantially all our assets, except for intellectual property. We identified numerous embedded features to which bifurcation would be required. The Securities Purchase Agreement requires that we comply with certain non-financial covenants customary for financing of this nature which we were in compliance with as of September 30, 2019. During November and December of 2018, we received redemption requests totaling \$0.8 million from IRT, approximately \$0.1 million of which was attributed to interest. During the nine months ended September 30, 2019, we made a cash redemption payment on the debt to IRT totaling \$812,500 and we also made redemption payments on the debt to IRT utilizing company common stock totaling 54,322 shares with a redemption fair value of \$549,977.

On April 25, 2017 we closed a public offering of 21,429 shares of our common stock and warrants to purchase up to 10,714 shares of common stock, at a fixed combined price to the public of \$560.00 under a shelf registration statement on Form S-3, which expired on March 16, 2018. The warrants are exercisable for a period of 5 years from the date of issuance at an exercise price of \$700.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering. The gross proceeds to us were \$12.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately \$0.9 million.

On March 9, 2015, we entered into a Controlled Equity Offering Sales Agreement (the “Agreement”), with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock, par value \$0.0001 per share (the “Shares”), up to an aggregate offering price of \$50.0 million.

For the nine months ended September 30, 2019 and 2018, we sold 0 and 6.1 million shares of our common stock resulting in net proceeds of approximately \$0 and \$1.6 million, respectively, under the Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent.

Operating and Capital Expenditure Requirements

As of September 30, 2019, we had an accumulated deficit of \$81.3 million, and expect to incur significant and increasing operating losses for the next several years as we expand our research, development and clinical trials of CRV431. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our unaudited condensed consolidated financial statements as of September 30, 2019 have been prepared under the assumption that we will continue as a going concern within one year of the issuance of these condensed consolidated financial statements, contemplates the realization of assets and satisfaction of liabilities in the normal course of business and do not include any

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adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Due to our recurring and expected continuing losses from operations, we have concluded there is substantial doubt in our ability to continue as a going concern without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will be required to raise additional capital within the next year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. Recently worldwide economic conditions and the international equity and credit markets have significantly deteriorated and may remain difficult for the foreseeable future. These developments will make it more difficult to obtain additional equity or credit financing, when needed. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct, delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize on unfavorable terms.

Contractual Obligations and Commitments

We had a contractual cash obligation as of September 30, 2019, comprised of our debt with IRT that we repaid in full on October 3, 2019.

Leases

We account for leases in accordance with ASC Topic 842, *Leases*, (“ASC 842”). We determine if an arrangement is a lease at contract inception. A lease exists when a contract conveys to the customer the right to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. The definition of a lease embodies two conditions: (1) there is an identified asset in the contract that is land or a depreciable asset (i.e., property, plant, and equipment), and (2) the customer has the right to control the use of the identified asset.

Prior to January 1, 2019, we recorded monthly rent expense on a straight-line basis, from the commencement of the lease to December 31, 2018. As of December 31, 2018, the balance of the Deferred rent liability was \$9,235, representing the difference between cash rent paid and the straight-line rent expense.

The following table summarizes annual rental payments for each of the following fiscal years as of December 31, 2018:

2019	\$	202,734
2020		194,529
2021		209,170
2022 and thereafter		266,290
Total	\$	<u>872,723</u>

Beginning January 1, 2019, we accounted for leases according to the FASB issued ASU 2016-02. Operating leases where we are the lessee are included in other assets on our condensed consolidated balance sheets. The lease liabilities are initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date. Key estimates and judgments include how we determine (1) the discount rate used to discount the unpaid lease payments to present value, (2) lease term and (3) lease payments.

The Right-Of-Use (“ROU”) asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

We adopted ASC 842 as of January 1, 2019 using a modified retrospective approach and because of the adoption, we recognized an operating lease liability of \$773 thousand based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of \$764 thousand, which is included in other assets in the condensed consolidated balance sheets. As of September 30, 2019, the lease liabilities and the ROU asset are \$652 thousand and \$642 thousand, respectively, which are included in current liabilities and other non-current liabilities and non-current assets in the condensed consolidated balance sheets, respectively.

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The discount rate used to account for our operating leases under ASC 842 is the Company's estimated incremental borrowing rate of 6.5%.

Rent expense related to our operating leases was approximately \$188 thousand and \$222 thousand for the nine months ended September 30, 2019 and 2018, respectively. The weighted average remaining term of our noncancelable operating leases is 3.49 years. Future minimum rental payments under the our noncancelable operating leases at September 30, 2019 is as follows:

2019	\$	51,531
2020		197,828
2021		210,583
2022		212,388
2023		53,901
Total		<u>726,231</u>
Present Value Adjustment		<u>(74,292)</u>
Lease liability at September 30, 2019	\$	<u>651,939</u>

Contingent consideration

We have recorded contingent consideration related to the acquisition of Ciclofilin on June 10, 2016 as well as executed several license agreements, as discussed in Note 7 and Note 12 to the condensed consolidated financial statements, respectively. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) and we paid a related milestone payment of \$1,000,000 and issued 1,439 shares of our common stock with a fair value of \$55,398, representing 2.5% of our issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders. As of September 30, 2019, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability.

Employment agreements

We also have employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control or termination without cause, occur.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures. Based on an evaluation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) required by paragraph (b) of Rule 13a-15 or Rule 15d-15, as of June 30, 2019, our Principal Executive Officer and Principal Financial Officer have concluded that, due to the material weaknesses in our internal control over financial reporting, our disclosure controls and procedures were not effective. We are committed to the remediation of the material weaknesses described in our Annual Report on Form 10-K, as well as the continued improvement of our internal control over financial reporting. We are in the process of taking steps to remediate the identified material weaknesses and continue to evaluate our internal controls over financial reporting, including utilizing the services of external consultants for non-routine and/or technical accounting issues as they arise. As we continue our evaluation and improve our internal control over financial reporting, management may identify and take additional measures to address control deficiencies. We cannot assure you that we will be successful in remediating the material weaknesses in a timely manner.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. There have been no changes in our internal controls over financial reporting during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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ITEM 6. EXHIBITS

- 3.1 [Certificate of Amendment to the Certificate of Incorporation, dated July 18, 2019 \(incorporated by reference to Exhibit 3.1 to Form 8-K filed on July 23, 2019\)](#)
- 31.1 [Certification of Chief Executive Officer required under Rule 13a-14\(a\)/15d-14\(a\) under the Exchange Act.](#)
- 31.2 [Certification of Principal Financial Officer required under Rule 13a-14\(a\)/15d-14\(a\) under the Exchange Act.](#)
- 32.1 [Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2 [Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase
- 101.DEF XBRL Taxonomy Extension Definition Linkbase
- 101.LAB XBRL Taxonomy Label Linkbase
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase

CERTIFICATIONS

I, Robert Foster, certify that:

- 1) I have reviewed this report on Form 10-Q of Hepion Pharmaceuticals, 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 we 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - 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.

Date: November 14, 2019

/s/ Robert Foster

Robert Foster

Chief Executive Officer and Director (Principal Executive Officer)

CERTIFICATIONS

I, John Cavan, certify that:

- 1) I have reviewed this report on Form 10-Q of Hepion Pharmaceuticals, 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 we 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - 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.

Date: November 14, 2019

/s/ John Cavan
John Cavan
Chief Financial Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HEPION PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2019
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Executive Officer of Hepion Pharmaceuticals, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2019 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2019

/s/ Robert Foster

Robert Foster

Chief Executive Officer and Director (Principal Executive Officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
HEPION PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2019
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

I am the Chief Financial Officer of Hepion Pharmaceuticals, Inc., a Delaware corporation (the "Company"). I am delivering this certificate in connection with the Form 10-Q of the Company for the quarter ended September 30, 2019 and filed with the Securities and Exchange Commission ("Form 10-Q").

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I hereby certify that, to the best of my knowledge, the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 14, 2019

/s/ John Cavan

John Cavan

Chief Financial Officer
