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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, 2020

Or

☐ **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	**46-2783806**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

399 Thornall Street, First Floor
Edison, New Jersey 08837
(Address of Principal Executive Offices)

(732) 902-4000
Registrant's telephone number, including area code

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	HEPA	The 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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

The number of shares of the registrant's Common Stock outstanding as of November 10, 2020 was 9,025,153.

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, 2019 contained in the Company's Annual Report on Form 10-K and 10-K/A filed with the Securities and Exchange Commission. 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. Cautionary Note Regarding Forward-Looking Statements.

HEPION PHARMACEUTICALS, INC.
FORM 10-Q

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PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2020	December 31, 2019 (1)
Assets		
Current assets:		
Cash	$ 13,711,334	$ 13,922,972
Prepaid expenses	641,157	465,693
Total current assets	14,352,491	14,388,665
Property and equipment, net	45,476	57,166
Right-of-use assets	614,193	797,913
In-process research and development	3,190,000	3,190,000
Goodwill	1,870,924	1,870,924
Other assets	290,604	306,880
Total assets	$ 20,363,688	$ 20,611,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,296,545	$ 491,557
Accrued expenses	2,384,133	851,202
Operating lease liabilities, current	275,296	266,696
Total current liabilities	3,955,974	1,609,455
Contingent consideration	2,560,000	2,430,000
Long-term debt	176,585	—
Deferred tax liability	409,022	409,022
Operating lease liabilities, non-current	358,470	540,751
Derivative financial instruments, at estimated fair value—warrants	30,831	5,623
Total liabilities	7,490,882	4,994,851
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Series A convertible preferred stock, stated value $10 per share, 85,581 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	855,808	855,808
Series C convertible preferred stock, stated value $1,000 per share, 1,817 and 1,827 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	856,320	861,033
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 9,025,153 and 3,760,255 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	901	375
Additional paid in capital	110,309,541	97,651,006
Accumulated deficit	(99,149,764)	(83,751,525)
Total stockholders' equity	12,872,806	15,616,697
Total liabilities and stockholders' equity	$ 20,363,688	$ 20,611,548

(1) See Note 2

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues	$ —	$ —	$ —	$ —
Costs and expenses:				
Research and development	3,782,505	846,453	9,370,176	2,120,152
General and administrative	2,448,489	1,064,081	5,823,169	3,407,650
Total operating expenses	6,230,994	1,910,534	15,193,345	5,527,802
Loss from operations	(6,230,994)	(1,910,534)	(15,193,345)	(5,527,802)
Other income (expense):				
Change in fair value of debt	—	(22,197)	—	(175,992)
Interest expense	(16,159)	(15,354)	(16,159)	(555,441)
Change in fair value of derivative instruments—warrants and contingent consideration	(46,433)	128,402	(155,208)	473,929
Loss before income taxes	(6,293,586)	(1,819,683)	(15,364,712)	(5,785,306)
Income tax benefit (expense)	62,044	—	(33,527)	961,014
Net loss	(6,231,542)	(1,819,683)	(15,398,239)	(4,824,292)
Deemed dividend (see Note 5)	(5,287)	(8,460)	(5,287)	(5,444,826)
Net loss attributable to common shareholders	$ (6,236,829)	$ (1,828,143)	$ (15,403,526)	$ (10,269,118)
Weighted average common shares outstanding:				
Basic and diluted	9,025,139	3,453,628	7,294,790	1,532,927
Net loss per common share: (see Note 10)				
Basic and diluted	$ (0.69)	$ (0.53)	$ (2.11)	$ (6.70)

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
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 December 31, 2019	85,581	$ 855,808	1,827	$ 861,033	3,760,255	$ 375	$ 97,651,006	$ (83,751,525)	$ 15,616,697
Net loss	—	—	—	—	—	—	—	(4,226,617)	(4,226,617)
Stock-based compensation expense	—	—	—	—	—	—	8,246	—	8,246
Issuance of common stock, net	—	—	—	—	2,311,867	231	6,788,234	—	6,788,465
Warrant exercises	—	—	—	—	2,000	—	12,000	—	12,000
Balance at March 31, 2020	85,581	855,808	1,827	861,033	6,074,122	606	104,459,486	(87,978,142)	18,198,791
Net loss	—	—	—	—	—	—	—	(4,940,080)	(4,940,080)
Stock-based compensation expense	—	—	—	—	—	—	4,123	—	4,123
Issuance of common stock, net	—	—	—	—	2,950,939	295	4,460,054	—	4,460,349
Balance at June 30, 2020	85,581	855,808	1,827	861,033	9,025,061	901	108,923,663	(92,918,222)	17,723,183
Net loss	—	—	—	—	—	—	—	(6,231,542)	(6,231,542)
Stock-based compensation expense	—	—	—	—	—	—	1,381,165	—	1,381,165
Conversion of preferred stock to common	—	—	(10)	(10,000)	92	—	10,000	—	—
Accretion of discount	—	—	—	5,287	—	—	(5,287)	—	—
Balance at September 30, 2020	85,581	$ 855,808	1,817	$ 856,320	9,025,153	$ 901	$ 110,309,541	$ (99,149,764)	$ 12,872,806

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	85,581	$855,808	1,974	$930,311	—	$ —	—	$ —	247,013	$ 25	$76,652,839	$(76,714,187)	$ 1,724,796
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,983,711)	(1,983,711)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	17,506	—	17,506
Conversion of preferred stock to common	—	—	(46)	(46,000)	—	—	—	—	424	—	46,000	—	—
Accretion of discount	—	—	—	24,321	—	—	—	—	—	—	(24,321)	—	—
Issuance of common stock, private placement	—	—	—	—	—	—	—	—	47,429	5	486,278	—	486,283
Issuance of common stock, debt redemption	—	—	—	—	—	—	—	—	11,882	1	149,917	—	149,918
Balance at March 31, 2019	85,581	855,808	1,928	908,632	—	—	—	—	306,748	31	77,328,219	(78,697,898)	394,792
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,020,899)	(1,020,899)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	17,133	—	17,133
Issuance of preferred stock	—	—	—	—	521	312,600	10,570	6,976,201	—	—	3,802,201	—	11,091,002
Conversion of preferred stock to common	—	—	(85)	(85,000)	(521)	(521,000)	(10,570)	(10,570,002)	1,824,473	182	11,175,820	—	—
Offering costs	—	—	—	—	—	(29,526)	—	(472,311)	—	—	(536,787)	—	(1,038,624)
Placement agent warrants	—	—	—	—	—	(48,250)	—	(244,895)	—	—	293,145	—	—
Beneficial conversion feature	—	—	—	—	—	(186,692)	—	(581,350)	—	—	768,042	—	—
Accretion of beneficial conversion feature	—	—	—	—	—	186,692	—	581,350	—	—	(768,042)	—	—
Accretion of discount	—	—	—	44,941	—	286,176	—	4,311,007	—	—	(4,642,124)	—	—
Issuance of common stock, net	—	—	—	—	—	—	—	—	1,031,071	103	5,844,421	—	5,844,524
Issuance of common stock, private placement	—	—	—	—	—	—	—	—	—	—	330	—	330
Issuance of common stock, debt redemption	—	—	—	—	—	—	—	—	42,439	4	400,059	—	400,063
Warrant exercises	—	—	—	—	—	—	—	—	248,877	25	2,090,542	—	2,090,567
Balance at June 30, 2019	85,581	855,808	1,843	868,573	—	—	—	—	3,453,608	345	95,772,959	(79,718,797)	17,778,888
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,819,682)	(1,819,682)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	17,129	—	17,129
Conversion of preferred stock to common	—	—	(16)	(16,000)	—	—	—	—	147	—	16,000	—	—
Accretion of discount	—	—	—	8,460	—	—	—	—	—	—	(8,460)	—	—
Balance at September 30, 2019	85,581	$855,808	1,827	$861,033	—	$ —	—	$ —	3,453,755	$ 345	$95,797,628	$(81,538,479)	$ 15,976,335

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (15,398,239)	$ (4,824,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,393,534	51,768
Depreciation and amortization	20,933	20,196
Change in fair value of derivative instrument-warrants	25,208	(403,928)
Change in fair value of contingent consideration	130,000	(70,000)
Change in fair value of debt	—	175,992
Amortization of debt discount recorded as interest expense	—	486,608
Non-cash interest for shares issued for debt redemption payments	—	49,732
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	2,337,919	(425,992)
Prepaid expenses and other assets	(149,149)	(184,962)
Net cash used in operating activities	(11,639,794)	(5,124,878)
Cash flows from investing activities:		
Purchase of property and equipment	(11,437)	(45,336)
Proceeds from disposal of property and equipment	2,194	—
Net cash used in investing activities	(9,243)	(45,336)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	11,248,814	5,844,530
Proceeds from the issuance of Series D and warrants, net of issuance costs	—	403,120
Proceeds from the issuance of Series E and warrants, net of issuance costs	—	9,649,258
Proceeds from the exercise of warrants	12,000	2,090,567
Proceeds from debt financing	176,585	1,250,000
Repayment of debt financing	—	(1,250,000)
Repayment of convertible debt	—	(785,744)
Net cash provided by financing activities	11,437,399	17,201,731
Net (decrease) increase in cash	(211,638)	12,031,517
Cash at beginning of period	13,922,972	2,832,429
Cash at end of period	$ 13,711,334	$ 14,863,946
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ 26,756
Supplementary disclosure of non-cash financing activities:		
Conversion of Series C convertible preferred stock (part of Series C deemed dividend)	$ 10,000	$ 147,000
Conversion of Series D convertible preferred stock	—	521,000
Conversion of Series E convertible preferred stock	—	10,570,002
Accretion of Series C preferred stock discount upon conversion	5,287	4,674,905
Beneficial conversion factor of preferred stock accreted as deemed dividend	—	768,042
Issuance of common stock for debt redemption	—	500,248
Adoption of lease accounting	—	642,405
Warrants issued to placement agent	—	293,145

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Business Overview

Hepion Pharmaceuticals, Inc. (we, our, or us) 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. 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.

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

We are developing CRV431 as our 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. We have completed a Phase 1 study with CRV431 demonstrating safety, tolerability, and pharmacokinetics (PK). We are currently conducting a Phase 2a study in NASH patients with fibrosis scores of F2 and F3. The first dosing cohort of 75 mg CRV431 once daily orally is underway.

CRV431

On May 10, 2018, we submitted an Investigational New Drug Application (“IND”) to the U.S. Food and Drug Administration (“FDA”) to support initiation of our CRV431 HBV clinical development program in the United States and received approval in June 2018. 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 approximately $346,000 to Aurinia Pharmaceuticals, Inc. ("Aurinia") and $654,000 to the former Ciclofilin shareholders along with the issuance of 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 former Ciclofilin shareholders. Our CEO is a former Ciclofilin shareholder and received approximately $274,000 and 603 shares of common stock and Petrus Wijngaard, a director of our company, received $2,805 and 6 shares of common stock.

Additional milestone payments could potentially be payable to the former Ciclofilin shareholders pursuant to the Ciclofilin Merger Agreement as follows: (i) upon receipt of Phase II positive data from a proof of concept clinical trial of CRV431 in humans - 4,317 shares of common stock and $3,000,000, (ii) upon initiation of a Phase III trial of CRV431 - $5,000,000, and (iii) upon acceptance by the FDA of a new drug application for CRV431 - $8,000,000. In addition, on February 14, 2014, Ciclofilin had entered into a Purchase and Sale Agreement to acquire Aurinia’s entire interest in CRV431. This agreement contains future milestone payments payable by us based on clinical and marketing milestones of up to CAD $2.45 million. The milestone payments payable to the former Ciclofilin shareholders will be subject to offset by certain of the clinical and marketing milestone payments payable to Aurinia as follows: (a) the payments to the former Ciclofilin shareholders pursuant to (ii) above would be offset by payment to Aurinia of CAD $450,000, and (b) the payments to the former Ciclofilin shareholders pursuant to (iii) above would be subject to offset by payment to Aurinia of up to CAD $2,000,000. In addition to the above clinical and milestone payments, the Aurinia Agreement provides for the following additional contingent payment obligations: (x) a royalty of 2.5% on net sales of CRV431 which is uncapped, (y) a royalty of 5% on license revenue from CRV431 and (z) a payment equal to 30% of the proceeds from a Liquidity Event (as defined in the Purchase and Sale Agreement) with respect to Ciclofilin, of which

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

approximately $150,000 plus interest will be paid to Aurinia. The maximum obligation under both (y) and (z) is CAD $5,000,000.

On June 17, 2019, we submitted an IND to the FDA to support initiation of our CRV431 NASH clinical development program in the United States and received approval in July 2019. We completed dosing of CRV431 in our multiple ascending dose ("MAD") clinical trial in September 2020.

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 our interim financial information. The consolidated balance sheet as of December 31, 2019 was derived from the audited annual consolidated financial statements but does not include all disclosures required by U.S. 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, 2019 contained in our Annual Report on Form 10-K.

Principles of Consolidation

The accompanying condensed consolidated financial statements include our accounts and the accounts of our subsidiaries, Contravir Research Inc. and Hepion Research Corp, which conduct their operations in Canada. All intercompany balances and transactions have been eliminated in consolidation.

Correction of Immaterial Errors

In connection with the preparation of our unaudited condensed consolidated financial statements as of and for the period ended September 30, 2020 and 2019, we determined that a revision was required to correct misstatements associated with the classification of certain income tax balances and misstatements related to certain of our income tax disclosures as of and for the year ended December 31, 2019. This resulted in corrections to both the December 31, 2019 consolidated financial statements and certain income tax note disclosures.

We corrected the consolidated financial statement presentation as follows: (a) a reclassification of $174,949 for our Canadian deferred tax asset and a corresponding increase of $174,949 to the deferred tax asset valuation allowance (and corresponding correction to income tax disclosure) netting to $0; (b) a reclassification and true ups of $178,941 of prepaid taxes related to our Canadian subsidiary; (c) adjustments to reclassify balances from our Canadian deferred tax asset as an offset to our unrecognized tax position (and corresponding correction to income tax disclosure) in the net amount of $357,566 (inclusive of an opening balance tax withholding accrual); (d) the accrual of a withholding tax and related penalties and interest of $250,255 and corresponding impact to income taxes related to our Canadian subsidiary (adjusted through beginning of year accumulated deficit and stockholders' equity); (e) reclassifications of $390,270 to correct Canadian deferred tax balances that were incorrectly netted with U.S. deferred tax balances; and (f) the related impact to income tax expense for the establishment of the deferred tax asset valuation allowance and other Canadian tax true-ups in the total net amount of $318,640.

We also corrected certain amounts in the income tax note disclosure related to the following: (a) an overstatement of $324,172 to the Stock Compensation & Other deferred tax asset; (b) an understatement of $162,619 in the Federal NOL; (c) an understatement of $37,406 in the State NOL; (d) an overstatement of research and development credits of $143,361; and (d) Corresponding corrections in the net amount of $122,762 were also made in Deferred tax asset valuation allowance within the disclosures in the associated income tax disclosure of deferred tax assets and liabilities.

The above corrections had no impact on the previously reported amounts of consolidated cash flows from operating, investing, or financing activities. We assessed the materiality of the misstatements both quantitatively and qualitatively and determined the correction of these errors to be immaterial to all prior consolidated financial statements taken as a whole and, therefore, amending previously filed reports to correct the errors was not required.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

The following tables present the amounts as reported, net correction adjustments, and corrected amounts for items affected by the corrections for the year ended December 31, 2019:

	Year ended December 31, 2019		
	As reported	Net adjustments	To be reported
Accumulated deficit - beginning of year	$ (76,463,932)	$ (250,255)	$ (76,714,187)
Total stockholders' equity - beginning of year	$ 1,975,051	$ (250,255)	$ 1,724,796
Other assets	$ 127,939	$ 178,941	$ 306,880
Total assets	$ 20,432,607	$ 178,941	$ 20,611,548
Accrued expenses	$ 493,636	$ 357,566	$ 851,202
Total current liabilities	$ 1,251,889	$ 357,566	$ 1,609,455
Deferred tax liability	$ 18,752	$ 390,270	$ 409,022
Total liabilities	$ 4,247,015	$ 747,836	$ 4,994,851
Accumulated deficit	$ (83,182,630)	$ (568,895)	$ (83,751,525)
Total stockholders' equity	$ 16,185,592	$ (568,895)	$ 15,616,697
Total liabilities and stockholders' equity	$ 20,432,607	$ 178,941	$ 20,611,548
Income taxes	$ 1,227,322	$ (318,640)	$ 908,682
Net loss	$ (6,718,698)	$ (318,640)	$ (7,037,338)
Net loss attributable to common shareholders	$ (12,161,645)	$ (318,640)	$ (12,480,285)
Net loss per common share - basic and diluted	$ (5.95)	$ —	$ (6.11)

The following tables present the amounts as reported, net correction adjustments, and corrected amounts for note disclosures affected by the corrections for the year ended December 31, 2019:

	Year ended December 31, 2019		
	As reported	Net adjustments	To be reported
Federal net operating loss (“NOL”)	$ 16,650,007	$ 162,619	$ 16,812,626
State NOL	2,401,609	37,406	2,439,015
Research and development credits	1,493,666	(143,361)	1,350,305
Lease liability	242,234	—	242,234
Stock compensation & other	1,213,339	(324,172)	889,167
Deferred tax asset valuation allowance	(20,823,235)	(122,762)	(20,945,997)
Total deferred tax asset	1,177,620	(390,270)	787,350
Deferred tax liability (In-Process R&D)	(957,000)	—	(957,000)
Right-of-use asset	(239,372)	—	(239,372)
Total deferred tax liability	(1,196,372)	—	(1,196,372)
Net deferred tax liability	$ (18,752)	$ (390,270)	$ (409,022)

In addition, certain disclosures of gross NOLs that are included in the Income Tax Note disclosure in our 2019 Annual Report on Form 10-K are updated as follows to reflect changes to the 2019 gross NOLs and an update to the uncertain tax position as a result of the addition corrections above.

As of December 31, 2019 and 2018, we had U.S. federal and state net operating loss carryforwards of $107.3 million and $102.8 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2037. We also had federal and state research and development tax credit carry forwards of approximately $1.2 million as of December 31, 2019, which will begin to expire in December 2027.

We had an unrecognized tax position of $283,600, a corresponding accrual for penalties and interest in the amount of $148,400, as a component of income tax expense, accrued through December 31, 2019 and an unrecognized

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tax position of $185,400 and a corresponding accrual for penalties and interest of $64,800, respectively, as of December 31, 2018. There are no amounts included in the unrecognized tax benefit at December 31, 2019 that will impact the effective rate if recognized. We expect that the entire amount of the unrecognized tax benefit to be reduced to $0 in the next 12 months.

Going Concern

As of September 30, 2020, we had $13.7 million in cash, we had an accumulated deficit of $99.1 million, and we had working capital of $10.4 million. For the nine months ended September 30, 2020, cash used in operating activities was $11.6 million, and for the three and nine months ended September 30, 2020, we had a net loss of $6.2 million and $15.4 million, respectively. We have not generated revenue to date and have incurred substantial losses and negative cash flows from operations since our inception. We have historically funded our operations through issuances of convertible debt, common stock and preferred stock. We expect to continue to incur 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.

These condensed consolidated financial statements have been prepared under the assumption that we will 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 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. These condensed consolidated 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. 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 business. If we are unable to raise additional capital when required or on acceptable terms, we 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 we would otherwise seek to develop or commercialize on unfavorable terms.

COVID-19 Pandemic

On January 30, 2020, the World Health Organization (“WHO”) announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the “COVID-19 outbreak”) and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation and its impact on our financial condition, liquidity, operations, suppliers, industry, and workforce.

While we have not experienced delays to date, We may experience delays in the conduct of clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. The COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidate. The evolving COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in our CRV431 clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical

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trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial, related to the COVID-19 pandemic, or in obtaining sufficient supplies of clinical trial materials. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change and we do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. Although we cannot estimate the length or gravity of the impact of the COVID-19 outbreak nor estimate the potential impact to our fiscal year 2020 financial statements at this time, if the pandemic continues, it could have a material adverse effect on our results of future operations, financial position, liquidity, and capital resources, and those of the third parties on which we rely in fiscal year 2020.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), as amended on June 5, 2020 by the Paycheck Protection Program ("PPP"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. On April 13, 2020, we were granted a loan (the "Loan") from JPMorgan Chase Bank, N.A. in the aggregate amount of $176,585, pursuant to the PPP under Division A, Title I of the CARES Act. We are continuing to evaluate and examine the impacts the CARES Act may have on our business, results of operations, financial condition or liquidity.

The Loan, which was in the form of a Note dated April 13, 2020 issued by us, matures on April 13, 2022 and bears interest at a rate of 0.98% per annum, payable monthly commencing on November 13, 2020. The Note may be prepaid by us at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, rent and utilities. We intend to use the entire Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. We believe that we have properly satisfied all eligibility requirements for the PPP loan and we intend to comply with the loan forgiveness provisions in the legislation; however, there can be no assurance that we will obtain full forgiveness of the loan based on the legislation. The PPP Loan is reflected in the condensed consolidated balance sheet as long-term debt based upon the terms and conditions of the Loan agreement.

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.

Our significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2019 included in our Form 10-K. Since the date of such consolidated financial statements, there have been no changes to our significant accounting policies.

Cash

As of September 30, 2020 and December 31, 2019, cash was $13.7 million and $13.9 million, respectively, consisting 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. We have never experienced losses related to these balances.

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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 our 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 us. Unobservable inputs are inputs that reflect our 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 we can 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 us 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.

Financial instruments consist of cash and accounts payable, long-term debt, derivative instruments — warrants 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 and contingent consideration, which were marked to market at the end of each reporting period. See Note 5 for additional information of the fair value of the derivative liabilities. We recorded contingent consideration from the 2016 acquisition of Ciclofilin, which is required to be carried at fair value. See Note 6 for additional information on the fair value of the contingent consideration.

Derivative Financial Instruments

We have 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 the 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 5 for additional information.

The fair value of the warrants, issued in connection with the October 2015, April 2016, and April 2017 common stock offerings were deemed to be derivative instruments due to certain contingent put features, 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 5) are deemed to be derivative instruments since if we do not maintain an effective registration statement, we are obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside our control. 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.

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The fair value of warrants was affected by changes in inputs to the Black-Scholes option pricing model including our 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, 2020 and December 31, 2019, the fair value of all warrants was $30,831 and $5,623, respectively, which are classified as a long-term derivative liability on our condensed consolidated balance sheets.

Property, equipment and depreciation

As of September 30, 2020 and December 31, 2019, we had $45,476 and $57,166, respectively, of property and equipment, consisting primarily of lab equipment, 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 expense for the three months ended September 30, 2020 and 2019 was $7,204 and $7,268, respectively, and was $20,933 and $20,196 for the nine months ended September 30, 2020 and 2019, respectively. Expenditures for repairs and maintenance are charged to operations as incurred. We will periodically evaluate whether current events or circumstances indicate that the carrying value of our depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at September 30, 2020 or December 31, 2019.

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 our fourth quarter, and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

In January 2017, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2017-04, Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment, which eliminates Step 2 from the goodwill impairment test. The annual, or interim, goodwill impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit should be considered when measuring the goodwill impairment loss, if applicable.

The amendments also eliminate the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. We adopted ASU 2017-04 on January 1, 2020, and the adoption of this standard did not have a material effect on our condensed consolidated financial statements.

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. As a result of the COVID-19 pandemic, we performed a qualitative assessment of goodwill and determined that it was not more likely than not that the fair value of our reporting was less than its carrying value. There was no impairment of goodwill for the nine months ended September 30, 2020 and 2019.

IPR&D acquired in a business combination is capitalized as indefinite-lived assets on our 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 our 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

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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 our programs, we could incur significant charges in the period in which the impairment occurs.

As a result of the COVID-19 pandemic, we performed a qualitative assessment of IPR&D and determined that it was not more likely than not that the asset was impaired. There was no impairment of IPR&D for the nine months ended September 30, 2020 and 2019.

Income Taxes

We account for income taxes under the asset and liability method. We recognize 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 carryforwards. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which we expect to recover or settle those temporary differences. We recognize 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. We reduce the measurement of a deferred tax asset, if necessary, by a valuation allowance if it is more likely than not that we will not realize some or all of the deferred tax asset. We account 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 April 2019, we transferred New Jersey 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 consolidated statement of operations. We received approval for the sale of net operating losses through participation in the New Jersey Technology Business Tax Certificate Transfer (NOL) Program. We continue to maintain a full valuation allowance for our U.S net deferred tax assets. The current period income tax expense is related to our foreign operations.

Contingencies

In the normal course of business, we are subject to loss contingencies, such as legal proceedings and claims arising out of our 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”), we record accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. In accordance with this guidance, we do 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

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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.

We do not currently have any commercial biopharmaceutical products and do not expect to have such for several years, if at all. Accordingly, our research and development costs are expensed as incurred. While certain of our research and development costs may have future benefits, our policy of expensing all research and development expenditures is predicated on the fact that we have 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, 2020 and December 31, 2019, we had prepaid research and development costs of $0.5 million and $0.4 million, 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, we issue stock options with only service-based vesting conditions and record the expense for 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 estimated expected stock volatility is based on the historical volatility of our own traded stock price. The expected term of 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 we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

Foreign Exchange

The functional currency of Hepion Pharmaceuticals, Inc. and ContraVir Research Inc. is the U.S. dollar. The functional currency of Hepion Research Corp. is the Canadian dollar. Our 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, 2020 and December 31, 2019.

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 consolidated statements of operations. The impact of foreign exchange gains (losses) was immaterial at September 30, 2020 and December 31, 2019.

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. Our chief operating decision maker views our operations and manages the business in one segment.

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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 attributable to common stockholders by the weighted-average common shares outstanding during the period.

4. Recent Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12). This guidance will be effective for us in the first quarter of 2021 on a prospective basis, and early adoption is permitted. We are currently evaluating the impact of the new guidance on our condensed consolidated financial statements.

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. We adopted this standard on January 1, 2020 and the impact that this guidance had on our condensed consolidated financial statements was immaterial.

5. Stockholders' Equity and Derivative Liability — Warrants

Series A Convertible Preferred Stock

On October 14, 2014, our Board of Directors authorized the sale and issuance of up to 1,250,000 shares of Series A Convertible Preferred Stock (the "Series A"). All shares of the Series A were issued between October 2014 and February 2015. Each share of the Series A is convertible at the option of the holder into the number of shares of common stock determined by dividing the stated value of such share by the conversion price that is subject to adjustment. As of September 30, 2020, there were 85,581 shares outstanding. During the nine months ended September 30, 2020, no shares of the Series A were converted.

Series C Convertible Preferred Stock Issuance

On July 3, 2018, we completed a rights offering pursuant to our effective registration statement on Form S-1. We offered for sale units in the rights offering and each unit sold in connection with the rights offering consisted of 1 share of our Series C Convertible Preferred Stock, or Series C, and common stock warrants (the "Rights Offering"). 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. As of September 30, 2020, there were 1,817 shares outstanding. During the nine months ended September 30, 2020, 10 shares of the Series C were converted into 92 shares of our common stock.

Common Stock and Warrant Offering

On October 7, 2015, we 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 our prior shelf registration statement on Form S-3. The shares of common stock and warrants were issued separately on October 13, 2015. The warrants were 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.

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

If we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property ("Fundamental Transaction"), then we 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, we have 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 our condensed consolidated 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. "Refer to Note 6".

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our 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 our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. 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, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Price of Hepion common stock	$ 3.11	$ 5.36
Expected warrant term (years)	0.03 years	0.78 years
Risk-free interest rate	0.22 %	1.66 %
Expected volatility	136 %	72 %
Dividend yield	—	—

On April 4, 2016, we closed a public offering of 8,803 shares of our 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 our prior shelf registration statement on Form S-3. The warrants were 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 us were $7.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately $0.7 million. If the warrants were exercised in full, we would receive additional proceeds of approximately $4.2 million.

If we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property ("Fundamental Transaction"), then we 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, we have 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 our condensed consolidated 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. "Refer to Note 6".

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our 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

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valuation involves using inputs such as the fair value of our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. 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, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Price of Hepion common stock	$ 3.11	$ 5.36
Expected warrant term (years)	0.51 years	1.26 years
Risk-free interest rate	0.22 %	1.66 %
Expected volatility	126 %	75 %
Dividend yield	—	—

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 our 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 us were $12.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately $0.5 million. If the warrants were exercised in full, we would receive additional proceeds of approximately $7.5 million.

If we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property (“Fundamental Transaction”), then we 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, we have 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 our condensed consolidated statement of operations and comprehensive loss. Upon the issuance of these warrants, the fair value of approximately $4.0 million was recorded as derivative financial instruments liability-warrants. “Refer to Note 6”.

The fair value of these liability classified warrants were estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our 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 our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. 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, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Price of Hepion common stock	$ 3.11	$ 5.36
Expected warrant term (years)	1.56 years	2.31 years
Risk-free interest rate	0.22 %	1.66 %
Expected volatility	116 %	69 %
Dividend yield	—	—

The warrants, issued in connection with the July 2018 Rights Offering are deemed to be derivative instruments since if we do not maintain an effective registration statement, we are obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside

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of our control. 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. Other than for the fair value of common stock, we developed our 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 our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. 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, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Price of Hepion common stock	$ 3.11	$ 5.36
Expected warrant term (years)	2.75 years	3.50 years
Risk-free interest rate	0.22 %	1.66 %
Expected volatility	118 %	65 %
Dividend yield	—	—

The following table sets forth the components of changes in our derivative financial instruments liability balance for the nine months ended September 30, 2020:

Date	Description	Number of Warrants Outstanding	Derivative Instrument Liability
December 31, 2019	Balance of derivative financial instruments liability	107,998	$ 5,623
	Change in fair value of warrants for the nine months ended September 30, 2020	—	25,208
September 30, 2020	Balance of derivative financial instruments liability	107,998	$ 30,831

Common Stock Offering

On February 12, 2020, we entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley FBR, Inc., as agent (“B. Riley FBR”), pursuant to which we may offer and sell, from time to time, through B. Riley FBR, shares of our common stock, par value $0.0001 per share (the “Common Stock”), having an aggregate offering price of up to $7,000,000 (the “Shares”).

The offer and sale of the Shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-229534) filed by us with the Securities and Exchange Commission (the “SEC”) on February 6, 2019, as amended on February 13, 2019, and declared effective by the SEC on February 19, 2019, as supplemented by a prospectus supplement dated February 12, 2020 and filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”). Also, on March 27, 2020, we filed a prospectus supplement to the Form S-3 (File No. 333-229534) pursuant to which we may offer and sell an additional $4.6 million.

As of September 30, 2020, under the Sales Agreement we sold 5,262,806 shares of our common stock resulting in net proceeds of $11.2 million from the “at the market offerings”.

Pursuant to the Sales Agreement, B. Riley FBR may sell the Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers’ transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with B. Riley FBR. B. Riley FBR will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

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6. Fair Value Measurements

The following table presents our liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy at September 30, 2020 and December 31, 2019.

Description	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, 2020:				
Contingent consideration	$ 2,560,000	$ —	$ —	$ 2,560,000
Derivative liabilities related to warrants	$ 30,831	$ —	$ —	$ 30,831
As of December 31, 2019:				
Contingent consideration	$ 2,430,000	$ —	$ —	$ 2,430,000
Derivative liabilities related to warrants	$ 5,623	$ —	$ —	$ 5,623

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities- warrants in our condensed consolidated statement of operations. See Note 5 for a rollforward of the derivative liability for the nine months ended September 30, 2020. 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, we review 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.

Contingent consideration was recorded for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and our 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. 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 and in the fourth quarter of 2018, 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, 2020, 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, 2020.

	Acquisition-related Contingent Consideration
Liabilities:	
Balance at December 31, 2019	$ 2,430,000
Change in fair value recorded in earnings	130,000
Balance at September 30, 2020	$ 2,560,000

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7. Indefinite-lived Intangible Assets and Goodwill

IPR&D

Our IPR&D asset consisted of the following at:

	Indefinite-lived Intangible Asset
CRV431 balance at December 31, 2019	$ 3,190,000
Change during the nine months ended September 30, 2020	—
CRV431 balance at September 30, 2020	$ 3,190,000

No impairment losses were recorded on IPR&D during the nine months ended September 30, 2020 and 2019.

Goodwill

The table below provides a roll-forward of our goodwill balance:

	Amount
Goodwill balance at December 31, 2019	$ 1,870,924
Changes during the nine months ended September 30, 2020	—
Goodwill balance at September 30, 2020	$ 1,870,924

No impairment losses were recorded to goodwill during the nine months ended September 30, 2020 and 2019.

8. Accrued Liabilities

Accrued expenses consisted of the following:

	September 30, 2020	December 31, 2019
Payroll and related costs	$ 540,510	$ 346,244
Research and development	1,293,875	12,075
Legal fees	26,856	2,354
Accrued taxes	522,075	431,923
Other	817	58,606
Total accrued expenses	$ 2,384,133	$ 851,202

9. Accounting for Share-Based Payments

On June 3, 2013, we 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. At our annual meeting of stockholders on July 30, 2020, we received shareholder approval to increase the number of shares issuable under the Plan to 2,500,000. As of September 30, 2020, we had 35,229 shares available for grant.

We classify stock-based compensation expense in our condensed consolidated statement of operations in the same way the award recipient's payroll costs are classified or in which the award recipients' service payments are classified. We recorded stock-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
General and administrative	$ 750,168	$ 10,369	$ 1,066,796	$ 31,107
Research and development	240,509	6,760	326,738	20,661
Total stock-based compensation expense	$ 990,677	$ 17,129	$ 1,393,534	$ 51,768

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A summary of stock option activity under the Plan is presented as follows:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2019	41,271	$ 3.24 -$ 2,452.80	$ 194.83	$ 43,182	8.42 years
Granted	2,423,500	$ 1.63 -$ 3.72	$ 2.50	$ 2,071,270	
Forfeited	—	$ — -$ —	$ —	$ —	
Cancelled	—	$ — -$ —	$ —	$ —	
Balance outstanding, September 30, 2020	2,464,771	$ 1.63 -$ 2,452.80	$ 5.96	$ 2,042,540	9.64 years
Vested awards and those expected to vest at September 30, 2020	2,367,095	$ 3.24 -$ 2,452.80	$ 6.10	$ 1,965,890	9.64 years
Vested and exercisable at September 30, 2020	23,940	$ 3.24 -$ 2,452.80	$ 357.31	$ —	7.45 years

There were 20,639 options granted to employees during the nine months ended September 30, 2019. The total fair 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 our common stock for those stock options that had exercise prices lower than the fair value of our common stock.

As of September 30, 2020, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was $7.0 million to be recognized over a weighted-average remaining vesting period of approximately 2.3 years.

The following weighted-average assumptions are used in the Black-Scholes valuation model to estimate fair value of stock option awards when granted to employees.

	Nine Months Ended September 30,	
	2020	2019
Stock price	$ 2.50	$ 3.24
Risk-free interest rate	0.34 %	1.85 %
Dividend yield	—	—
Expected volatility	126.3 %	76.5 %
Expected term (in years)	6.0	6.0

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 our stock options.

Dividend yield— We have not paid any dividends on our common stock since inception and do not anticipate paying dividends on our common stock in the foreseeable future.

Expected volatility—We base expected volatility on the trading price of our common stock.

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, which 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

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options in accordance with ASC 718. We will use the simplified method until we have 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, we have "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, we determined that we had sufficient history of issuing stock options and decreased our estimated forfeiture rate from 10%, which was based on the historical experience of our former parent, to 3%, which is our actual historical forfeiture rate. The forfeiture rate was 10% through the end of the 3rd fiscal quarter ended March 31, 2016 and was the 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, 2020 and 2019. We 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.

10. Loss per Share

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 accretion of beneficial conversion feature and other discount on this instrument for the periods in which the preferred stock is outstanding.

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Basic and diluted net (loss) income per common share	**2020**	**2019**	**2020**	**2019**
Numerator:				
Net loss	$ (6,231,542)	$ (1,819,683)	$ (15,398,239)	$ (4,824,292)
Preferred stock deemed dividend	(5,287)	(8,460)	(5,287)	(5,444,826)
Net loss attributable to common stockholders	$ (6,236,829)	$ (1,828,143)	$ (15,403,526)	$ (10,269,118)
Denominator:				
Weighted average common shares outstanding	9,025,139	3,453,628	7,294,790	1,532,927
Net loss per share of common stock—basic and diluted	$ (0.69)	$ (0.53)	$ (2.11)	$ (6.70)

The following outstanding securities at September 30, 2020 and 2019 have been excluded from the computation of basic and diluted weighted shares outstanding, as they would have been anti-dilutive:

	Nine Months Ended September 30,	
	2020	**2019**
Common shares issuable upon conversion of Series A preferred stock	3,184	3,184
Common shares issuable upon conversion of Series C preferred stock	16,747	16,987
Stock options	2,464,771	9,010
Warrants – liability classified	107,998	107,997
Warrants – equity classified	2,428,568	2,733,076
Total	5,021,268	2,870,254

The liability and equity classified warrants disclosed above have been excluded from the computation of basic and diluted earnings per share because the exercise price of the warrants exceeds the average market price of our common stock for the period they were outstanding.

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11. Commitments and Contingencies

Contractual Obligations

In August 2014, we entered into a lease for corporate office space in Edison, New Jersey. In December 2017, we 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. In May 2018, we entered into a 3-year lease for office equipment to be used at our corporate office space in Edison, New Jersey. In October 2019, we entered into a 3-year lease for office and research laboratory space in Edmonton, Canada. Prior to signing this lease, the space was previously on a month to month basis.

Legal Proceedings

We are involved in legal proceedings of various types. Significant judgment is required to determine both the likelihood and the estimated amount of a loss related to such matters. Additionally, while any litigation contains an element of uncertainty, we have at this time no reason to believe that the outcome of such proceedings or claims will have a material adverse effect on our condensed consolidated financial condition or results of operations.

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 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 and equipment), and (2) the customer has the right to control the use of the identified asset.

Operating leases where we are the lessee are included under the caption "Right of Use 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 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, we recognized an operating lease liability of $0.8 million based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of $0.8 million. As of September 30, 2020, the ROU assets were $0.6 million, the current lease liabilities were $0.3 million, and the non-current lease liabilities were $0.4 million. The discount rate used to account for our operating leases under ASC 842 is our estimated incremental borrowing rate of 6.5%.

Rent expense for the three months ended September 30, 2020 and 2019 was $0.1 million and $46,346, respectively, and $0.2 million and $0.2 million for the nine months ended September 30, 2020 and 2019, respectively.

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The weighted average remaining term of our noncancelable operating leases is 2.38 years. Future minimum rental payments under our noncancelable operating leases at September 30, 2020 is as follows:

2020	$ 71,016
2021	285,932
2022	270,313
2023	53,902
2024 and thereafter	—
Total	681,163
Present value adjustment	(47,397)
Lease liability at September 30, 2020	$ 633,766

Employment Agreements

We 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, termination without cause or retirement, occur.

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 as of and for the year ended December 31, 2019 filed with the United States Securities and Exchange Commission ("SEC"). 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.

Impact of COVID-19

On January 30, 2020, the World Health Organization ("WHO") announced a global health emergency because of a new strain of coronavirus originating in Wuhan, China (the "COVID-19 outbreak") and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO classified the COVID-19 outbreak as a pandemic, based on the rapid increase in exposure globally.

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on our financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation and its impact on our financial condition, liquidity, operations, suppliers, industry, and workforce.

While we have not experienced delays to date, we may experience delays in the conduct of clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. The COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidate. The evolving COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in our CRV431 clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial, related to the COVID-19 pandemic, or in obtaining sufficient supplies of clinical trial materials. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change and we do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. Although we cannot estimate the length or gravity of the impact of the COVID-19 outbreak nor estimate the potential impact to our fiscal year 2020 financial statements at this time, if the pandemic continues, it could have a material adverse effect on our results of future operations, financial position, liquidity, and capital resources, and those of the third parties on which we rely in fiscal year 2020.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), as amended on June 5, 2020 by the Paycheck Protection Program ("PPP"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. On April 13, 2020, we were granted a loan (the "Loan") from JPMorgan Chase Bank, N.A. in the aggregate amount of $176,585, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act. We are continuing to evaluate and examine the impacts the CARES Act may have on our business, results of operations, financial condition or liquidity.

The Loan, which was in the form of a Note dated April 13, 2020 issued by us, matures on April 13, 2022 and bears interest at a rate of 0.98% per annum, payable monthly commencing on November 13, 2020. The Note may be prepaid by us at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, rent and utilities. We intend to use the entire Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. We believe we have properly satisfied all eligibility requirements for the PPP loan and we intend to comply with the loan forgiveness provisions in the legislation; however, there can be no assurance that we will obtain full forgiveness of the loans based on the legislation. The PPP Loan is reflected in the condensed consolidated balance sheet as long-term debt based upon the terms and conditions of the Loan agreement.

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 liver fibrosis have 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. 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.

ARTIFICAL INTELLIGENCE (AI)

We have created a proprietary AI platform called, "AI-POWR™ to optimize the outcomes of our current clinical programs and to potentially identify novel indications for CRV431 and possibly identify new targets and new drug molecules to broaden our pipeline.

AI-POWR™ is our acronym for **A**rtificial **I**ntelligence-**P**recision Medicine; **O**mics that include genomics, proteomics, metabolomics, transcriptomics, and lipidomics; **W**orld database access; and **R**esponse and clinical outcomes. AI-POWR™ allows for the selection of novel drug targets, biomarkers, and appropriate patient populations. AI-POWR™ is used to identify responders from big data sources using our multi-omics approach, while modelling inputs and scenarios to increase response rates. The components of AI-POWR™ include access to publicly available databases,

and in-house genomic and multi-omic big data, processed via machine learning algorithms. AI outputs allow for improved response outcomes through enhanced patient selection, biomarker selection and drug target selection. We believe AI outputs will help identify responders *a priori* and reduce the need for large sample sizes through study design enrichment.

We intend to use AI-POWR™ to help identify which patients will best respond to CRV431 for treatment of NASH patients, currently in a Phase 2a clinical trial. It is anticipated that applying this proprietary platform to our drug development program will ultimately save time, resources and money. In so doing, we believe that AI-POWR™ is a risk-mitigation strategy that should reap benefits all the way through from clinical trials to commercialization.

We believe that NASH is a very heterogenous disease and we need to have a better understanding of interactions between changes to proteins, genes, lipids, and metabolites, to name a few, induced by both drugs and disease. All of this is further complicated by variable drug concentrations, patient traits and temporal factors. AI-POWR™ is designed to address many of these typical challenges, as we believe we can use our proprietary platform to shorten development timelines and increase the delta between placebo and treatment groups. AI-POWR™ will be used to drive our ongoing Phase 2a NASH program and identify additional potential indications for CRV431 to expand our footprint in the cyclophilin inhibition therapeutic space.

FINANCIAL OPERATIONS OVERVIEW

From inception through September 30, 2020, we have an accumulated deficit of $99.1 million and we have not generated any revenue from operations. We 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 February 12, 2020, we entered into an At Market Issuance Sales Agreement (the “Sales Agreement”) with B. Riley FBR, Inc., as agent (“B. Riley FBR”), pursuant to which we may offer and sell, from time to time, through B. Riley FBR, shares of our common stock, par value $0.0001 per share (the “Common Stock”), having an aggregate offering price of up to $7,000,000 (the “Shares”).

The offer and sale of the Shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-229534) filed by us with the Securities and Exchange Commission (the “SEC”) on February 6, 2019, as amended on February 13, 2019, and declared effective by the SEC on February 19, 2019, as supplemented by a prospectus supplement dated February 12, 2020 and filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”). Also, on March 27, 2020, we filed a prospectus supplement to the Form S-3 (File No. 333-229534) pursuant to which we may offer and sell an additional $4.6 million.

As of September 30, 2020, under the Sales Agreement we sold 5,264,806 shares of our common stock resulting in net proceeds of $11.2 million from the “at the market offerings”

Pursuant to the Sales Agreement, B. Riley FBR may sell the Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act, including sales made by means of ordinary brokers’ transactions, including on The Nasdaq Capital Market, at market prices or as otherwise agreed with B. Riley FBR. B. Riley FBR will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the Shares from time to time, based upon instructions from us, including any price or size limits or other customary parameters or conditions we may impose.

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

Our condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and

expenses, income taxes and related disclosures. On an ongoing basis, we evaluate our estimates and assumptions. Our actual results may differ from these estimates under different assumptions or conditions.

During the nine months ended September 30, 2020, there were no significant changes to our critical accounting policies and estimates as described in the financial statements contained in the Annual Report on Form 10-K for the year ended December 31, 2019.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of September 30, 2020.

RECENT ACCOUNTING PRONOUNCEMENTS

Please refer to Note 4 of Notes to Condensed Consolidated 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 could remain an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the first public sale of equity securities in October 2015, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior December 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

On December 31, 2020, our status as an emerging growth company will end. 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 on December 31, 2020, 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.

We expect to qualify as a "smaller reporting company" for the foreseeable future.

RESULTS OF OPERATIONS

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

	Three Months Ended September 30,		
	2020	2019	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	3,782,505	846,453	2,936,052
General and administrative	2,448,489	1,064,081	1,384,408
Loss from operations	(6,230,994)	(1,910,534)	(4,320,460)
Other income (expense):			
Change in fair value of debt	—	(22,197)	22,197
Interest expense	(16,159)	(15,354)	(805)
Change in fair value of derivative instruments – warrants and contingent consideration	(46,433)	128,402	(174,835)
Loss before income taxes	(6,293,586)	(1,819,683)	(4,473,903)
Income tax (expense) benefit	62,044	—	62,044
Net loss	$ (6,231,542)	$ (1,819,683)	$ (4,411,859)

We had no revenues during the three months ended September 30, 2020 and 2019, respectively, 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, 2020 and 2019 was $3.8 million and $0.8 million, respectively. The $3.0 million increase was primarily due to an increase of $1.6 million for costs related to drug supply and various ongoing studies, a $1.1 million increase in consulting and outside service costs related to various ongoing studies, and a $0.2 million increase in stock-based compensation costs.

General and administrative expenses for the three months ended September 30, 2020 and 2019 was $2.4 million and $1.1 million, respectively. The increase of $1.3 million is primarily related to an increase of $0.7 million in stock-based compensation costs, a $0.1 million increase in insurance costs, and a $0.3 million increase in professional fees and consulting costs.

Net loss for the three months ended September 30, 2020 was $6.2 million, which was the result of the operating expenses discussed above. Net loss for the three months ended September 30, 2019 was $1.8 million, which was the result of the operating expenses discussed above offset by income of $0.1 million resulting from the change in fair value of derivative instruments related to our warrants and contingent consideration.

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

	Nine Months Ended September 30, 2020	2019	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	9,370,176	2,120,152	7,250,024
General and administrative	5,823,169	3,407,650	2,415,519
Loss from operations	(15,193,345)	(5,527,802)	(9,665,543)
Other income (expense):			
Change in fair value of debt	—	(175,992)	175,992
Interest expense	(16,159)	(555,441)	539,282
Change in fair value of derivative instruments – warrants and contingent consideration	(155,208)	473,929	(629,137)
Loss before income taxes	(15,364,712)	(5,785,306)	(9,579,406)
Income tax (expense) benefit	(33,527)	961,014	(994,541)
Net loss	$ (15,398,239)	$ (4,824,292)	$ (10,573,947)

We had no revenues during the nine months ended September 30, 2020 and 2019, respectively, 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, 2020 and 2019 was $9.4 million and $2.1 million, respectively. The $7.3 million increase was primarily due to an increase of $3.2 million for costs related to drug supply and various ongoing studies, a $1.0 million increase attributable to the phase 1 and phase 2 studies related to CRV431, a $2.2 million increase in consulting and outside services costs, and a $0.3 million increase in stock-based compensation costs.

General and administrative expenses for the nine months ended September 30, 2020 and 2019 was $5.8 million and $3.4 million, respectively. The $2.4 million increase was primarily related to an increase in insurance costs of $0.2 million, an increase of $1.0 million in stock-based compensation costs, a $0.3 million increase for consulting services, and a $0.3 million increase in professional fees.

Net loss for the nine months ended September 30, 2020 was $15.4 million, which was the result of the operating expenses discussed above, and a loss of $0.2 million for the change in fair value of derivative instruments related to our warrants and contingent consideration. Net loss for the nine months ended September 30, 2019 was $4.8 million, which was the result of the operating expenses discussed above, a loss of $0.2 million for the change in fair value of debt, a $0.6 million loss for interest expense, which was offset by income of $0.5 million resulting from the change in fair value of derivative instruments related to our warrants and contingent consideration, and $1.0 million for income tax benefit.

Liquidity and Capital Resources

As of September 30, 2020, we had working capital of $10.4 million compared to working capital of $12.8 million as of December 31, 2019. The decrease of $2.4 million in working capital is primarily related to a decrease in cash of $0.2 million and an increase in accounts payable and accrued expenses of $2.0 million.

Cash Flows

The following table summarizes our cash flows for the following periods:

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (11,639,794)	$ (5,124,878)
Investing activities	(9,243)	(45,336)
Financing activities	11,437,399	17,201,731
Net (decrease) increase in cash	$ (211,638)	$ 12,031,517

As of September 30, 2020, we had $13.7 million in cash. Net cash used in operating activities was $11.6 million for the nine months ended September 30, 2020 consisting primarily of our net loss of $15.4 million. Changes in working capital accounts had a positive impact of $2.2 million on cash primarily for an increase in accounts payable and accrued expenses.

Net cash used in operating activities was $5.1 million for the nine months ended September 30, 2019 consisting primarily of our net loss of $4.8 million offset by non-cash operating activities of $0.3 million. Changes in working capital accounts had a negative impact of $0.6 million on cash.

Net cash used in investing activities during the nine months ended September 30, 2020 and 2019 was immaterial in both periods.

Net cash provided by financing activities was $11.4 million for the nine months ended September 30, 2020 due primarily to the issuance of common stock, net of issuance costs.

Net cash provided by financing activities was $17.2 million for the nine months ended September 30, 2019 due primarily to the issuance of preferred stock for $10.1 million, $2.1 million for the exercise of warrants and $5.8 million for the issuance of common stock.

Operating and Capital Expenditure Requirements

As of September 30, 2020, we had an accumulated deficit of $99.1 million and expect to incur a significant increase in 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.

The condensed consolidated financial statements as of September 30, 2020 have been prepared under the assumption that we will continue as a going concern within one year after the financial statements are issued. 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.

On October 29, 2020, we filed a Form S-1 Registration Statement under the Securities Act of 1933 with the Securities and Exchange Commission to offer additional shares of our common stock in order to raise funds for future research projects. 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 been volatile and may remain difficult for the foreseeable future. These developments may 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

Please refer to Note 11 of Notes to Condensed Consolidated Financial Statements in this Quarterly Report on Form 10-Q for a description of our contractual obligations and commitments.

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 September 30, 2020, 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.

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, 2020 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 the following:

- We assessed our company wide accounting resource requirements and as a result have hired, and are in the process of hiring additional experienced accounting personnel, and taken steps to improve the overall efficiency of our accounting and reporting processes. We will continue to regularly monitor our accounting resource sufficiency, our internal controls processes and procedures, and we may undertake additional measures as deemed necessary to fully remediate the control deficiencies.
- We have implemented several software solutions including software for reporting of stock-based awards and software related to public company reporting to improve our financial reporting process.
- We are 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.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

The information presented below updates the Risk Factors disclosed in our annual report on Form 10-K for the year ended December 31, 2019 and should be read in conjunction with the risk factors and other information disclosed in our 2019 Annual Report on Form 10-K that could have a material effect on our business, financial condition and results of operations.

ITEM 6. EXHIBITS

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEPION PHARMACEUTICALS, INC. (Registrant)

Date: 11/16/2020

By: /s/ ROBERT FOSTER
Robert Foster
Chief Executive Officer
(Principal Executive Officer)

Date: 11/16/2020

By: /s/ JOHN CAVAN
John Cavan
Chief Financial Officer

EXHIBIT 31.1

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 16, 2020

/s/ Robert Foster
Robert Foster
Chief Executive Officer and Director
(Principal Executive Officer)

EXHIBIT 31.2

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 16, 2020

/s/ John Cavan
John Cavan
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HEPION PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2020
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, 2020 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 16, 2020

/s/ Robert Foster
Robert Foster
Chief Executive Officer and Director
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
HEPION PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2020
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, 2020 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 16, 2020

/s/ John Cavan
John Cavan
Chief Financial Officer