Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2023

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 X	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 6, 2023 was 4,337,682.

HEPION PHARMACEUTICALS, INC.
FORM 10-Q

TABLE OF CONTENTS

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 consolidated financial statements as of and for the year ended December 31, 2022 contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 10, 2023. 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.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 19,284,080	$ 51,189,088
Prepaid expenses and other current assets	1,985,356	5,306,985
Total current assets	21,269,436	56,496,073
Property and equipment, net	41,087	81,620
Right-of-use assets	242,507	50,585
In-process research and development	3,190,000	3,190,000
Other assets	260,078	426,174
Total assets	$ 25,003,108	$ 60,244,452
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,006,221	$ 2,665,896
Accrued expenses	2,907,565	4,799,983
Operating lease liabilities, current	112,282	53,614
Short-term portion of contingent consideration	376,430	366,229
Total current liabilities	6,402,498	7,885,722
Contingent consideration	1,903,570	2,093,771
Deferred tax liability	409,022	409,022
Operating lease liabilities, non-current	129,261	—
Total liabilities	8,844,351	10,388,515
Commitments and contingencies (see Note 11)		
Stockholders' equity:		
Series A convertible preferred stock, stated value $10 per share, 85,581 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	855,808	855,808
Series C convertible preferred stock, stated value $1,000 per share, 1,800 and 1,801 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	839,320	840,320
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 3,838,289 and 3,811,481 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	384	381
Additional paid-in capital	228,124,931	223,950,940
Accumulated other comprehensive loss	(93,928)	(90,168)
Accumulated deficit	(213,567,758)	(175,701,344)
Total stockholders' equity	16,158,757	49,855,937
Total liabilities and stockholders' equity	$ 25,003,108	$ 60,244,452

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues	$ —	$ —	$ —	$ —
Cost and expenses:				
Research and development	8,518,520	5,740,122	30,196,848	25,753,211
General and administrative	2,146,045	2,725,204	7,842,512	8,091,780
Goodwill impairment loss	—	—	—	1,870,924
Total operating expenses	10,664,565	8,465,326	38,039,360	35,715,915
Loss from operations	(10,664,565)	(8,465,326)	(38,039,360)	(35,715,915)
Other income (expense):				
Interest expense	(2,381)	(2,265)	(7,054)	(7,652)
Change in fair value of contingent consideration	140,000	(80,000)	180,000	334,992
Loss before income taxes	(10,526,946)	(8,547,591)	(37,866,414)	(35,388,575)
Income tax benefit (expense)	—	—	—	—
Net loss	$ (10,526,946)	$ (8,547,591)	$ (37,866,414)	$ (35,388,575)
Weighted-average common shares outstanding:				
Basic and diluted	3,838,289	3,811,481	3,825,523	3,811,469
Net loss per common share: (see Note 10)				
Basic and diluted	$ (2.74)	$ (2.24)	$ (9.90)	$ (9.28)

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (10,526,946)	$ (8,547,591)	$ (37,866,414)	$ (35,388,575)
Other comprehensive loss:				
Foreign currency translation	(6,277)	(60,368)	(3,760)	(90,335)
Total other comprehensive loss	(6,277)	(60,368)	(3,760)	(90,335)
Comprehensive loss	$ (10,533,223)	$ (8,607,959)	$ (37,870,174)	$ (35,478,910)

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

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 other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	85,581	$ 855,808	1,801	$ 840,320	3,811,481	$ 381	$ 223,950,940	$ (90,168)	$ (175,701,344)	$ 49,855,937
Net loss	—	—	—	—	—	—	—	—	(13,259,921)	(13,259,921)
Other comprehensive income (loss)	—	—	—	—	—	—	—	19,353	—	19,353
Stock-based compensation expense	—	—	—	—	—	—	537,123	—	—	537,123
Conversion of Series C to common	—	—	(1)	(1,000)	1	—	1,000	—	—	—
Balance at March 31, 2023	85,581	855,808	1,800	839,320	3,811,482	381	224,489,063	(70,815)	(188,961,265)	37,152,492
Net loss	—	—	—	—	—	—	—	—	(14,079,547)	(14,079,547)
Other comprehensive income (loss)	—	—	—	—	—	—	—	(16,836)	—	(16,836)
Stock-based compensation expense	—	—	—	—	—	—	333,954	—	—	333,954
Stock-based liability awards converted to equity	—	—	—	—	—	—	2,983,006	—	—	2,983,006
Issuance of common stock in connection with stock split	—	—	—	—	26,807	3	(3)	—	—	—
Balance at June 30, 2023	85,581	855,808	1,800	839,320	3,838,289	384	227,806,020	(87,651)	(203,040,812)	26,373,069
Net loss	—	—	—	—	—	—	—	—	(10,526,946)	(10,526,946)
Other comprehensive income (loss)	—	—	—	—	—	—	—	(6,277)	—	(6,277)
Stock-based compensation expense	—	—	—	—	—	—	318,911	—	—	318,911
Balance at September 30, 2023	85,581	$ 855,808	1,800	$ 839,320	3,838,289	$ 384	$ 228,124,931	$ (93,928)	$ (213,567,758)	$ 16,158,757

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

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 other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	85,581	$ 855,808	1,806	$ 845,320	3,811,263	$ 381	$ 224,794,789	$ —	$ (133,501,295)	$ 92,995,003
Net loss	—	—	—	—	—	—	—	—	(6,929,685)	(6,929,685)
Other comprehensive income (loss)	—	—	—	—	—	—	—	9,146	—	9,146
Stock-based compensation expense	—	—	—	—	—	—	556,610	—	—	556,610
Conversion of Series C to common	—	—	(5)	(5,000)	2	—	5,000	—	—	—
Issuance of common stock, net	—	—	—	—	216	—	5,008	—	—	5,008
Balance at March 31, 2022	85,581	855,808	1,801	840,320	3,811,481	381	225,361,407	9,146	(140,430,980)	86,636,082
Net loss	—	—	—	—	—	—	—	—	(19,911,299)	(19,911,299)
Other comprehensive income (loss)	—	—	—	—	—	—	—	(39,113)	—	(39,113)
Stock-based compensation expense	—	—	—	—	—	—	634,651	—	—	634,651
Balance at June 30, 2022	85,581	855,808	1,801	840,320	3,811,481	381	225,996,058	(29,967)	(160,342,279)	67,320,321
Net loss	—	—	—	—	—	—	—	—	(8,547,591)	(8,547,591)
Other comprehensive income (loss)	—	—	—	—	—	—	—	(60,368)	—	(60,368)
Stock-based compensation expense	—	—	—	—	—	—	546,580	—	—	546,580
Balance at September 30, 2022	85,581	$ 855,808	1,801	$ 840,320	3,811,481	$ 381	$ 226,542,638	$ (90,335)	$ (168,889,870)	$ 59,258,942

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (37,866,414)	$ (35,388,575)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,189,988	2,320,793
Depreciation	54,866	58,985
Change in fair value of contingent consideration	(180,000)	(334,992)
Impairment of goodwill	—	1,870,924
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,430,993	1,849,760
Right of use asset	50,585	203,448
Operating lease liability	(54,578)	(211,414)
Prepaid expenses and other assets	3,487,456	(532,599)
Net cash used in operating activities	(31,887,104)	(30,163,670)
Cash flows from investing activities:		
Purchases of property and equipment	(13,956)	—
Proceeds from disposal of property and equipment	—	2,266
Net cash (used in) provided by investing activities	(13,956)	2,266
Cash flows from financing activities:		
Contingent consideration milestone payment	—	(2,000,000)
Net cash used in financing activities	—	(2,000,000)
Effect of exchange rates on cash	(3,948)	(42,370)
Net decrease in cash	(31,905,008)	(32,203,774)
Cash at beginning of period	51,189,088	91,348,967
Cash at end of period	$ 19,284,080	$ 59,145,193
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ 941
Supplementary disclosure of non-cash financing activities:		
Conversion of Series C convertible preferred stock	$ 1,000	$ 5,000
Issuance of common stock in conjunction with milestone payment	—	5,008
Stock-based liability awards reversed to additional paid-in capital	2,983,006	—
Operating lease asset additions	242,507	—

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

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 drug therapy for treatment of chronic liver diseases. This therapeutic approach targets fibrosis, inflammation, and shows potential for the treatment of hepatocellular carcinoma ("HCC") associated with non-alcoholic steatohepatitis ("NASH"), viral hepatitis, and other liver diseases. Our cyclophilin inhibitor, rencofilstat (formerly CRV431), is being developed to offer benefits to address multiple complex pathologies related to the progression of liver disease.

We are developing rencofilstat as our lead molecule. Rencofilstat is a compound that binds and inhibits the function of a specific class of isomerase enzymes called cyclophilins that regulate protein folding, in addition to other activities. Many closely related isoforms of cyclophilins exist in humans. Cyclophilins A, B, and D are the best characterized cyclophilin isoforms. Inhibition of cyclophilins has been shown in scientific literature to have therapeutic effects in a variety of experimental models, including liver disease models.

We have completed a number of Phase 1 and Phase 2 clinical trials. In May 2023, we announced that our Phase 2a study ("ALTITUDE-NASH") met its primary endpoint by demonstrating improved liver function and was well tolerated after four months of treatment with once daily oral rencofilstat administered to NASH subjects with stage 3 or greater fibrosis. All additional secondary efficacy and safety endpoints were also met. These observations provide further evidence that builds on previous findings from a shorter 28-day Phase 2a ("AMBITION") trial. Taken together, the AMBITION and ALTITUDE-NASH trials reinforce rencofilstat's direct antifibrotic mode of action and increase our confidence level that we anticipate observing fibrosis reductions in our ongoing 12-month Phase 2b ("ASCEND-NASH") clinical trial.

In June 2023, we announced that the Data and Safety Monitoring Board ("DSMB") met to review the current data for the ASCEND-NASH 2b study and has issued a "study may proceed without modification" clearance. This, the first planned DSMB meeting, occurred on schedule, and all labs, electrocardiogram's, adverse events, and protocol deviations were reviewed, focusing on any potential safety signals from the placebo-controlled trial.

2. Basis of Presentation

Basis of Presentation

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, 2022, 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, 2022, contained in our Annual Report on Form 10-K filed with the SEC on April 10, 2023.

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.

Reverse Stock Split

On May 3, 2023, our Board of Directors declared a 1-for-20 reverse stock split of the outstanding shares of our common stock in order to satisfy requirements for the continued listing of our common stock on Nasdaq. The reverse stock split was effective May 11, 2023. All applicable share and per share information in these condensed consolidated financial statements on Form 10-Q have been adjusted retrospectively to give effect to the reverse stock split for all periods presented. The reverse stock split did not reduce the number of authorized shares of common stock and did not alter the par value.

Going Concern

As of September 30, 2023, we had $19.3 million in cash, an accumulated deficit of $213.6 million, and working capital of $14.9 million. For the nine months ended September 30, 2023, cash used in operating activities was $31.9 million and we had a net loss of $37.9 million. 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 rencofilstat. 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. The 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 our current product candidate 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.

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, 2022, included in our Annual Report on 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, 2023 and December 31, 2022, cash was $19.3 million and $51.2 million, respectively, consisting of checking accounts held at U.S. and Canadian commercial banks. At certain times, our cash balances with any one financial institution may exceed Federal Deposit Insurance Corporation insurance limits. We believe it mitigates our risk by depositing our cash balances with high credit, quality financial institutions. We have never experienced losses related to these balances.

Fair Value of Financial Instruments

Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and 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.

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

- 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, accounts payable, 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 contingent consideration, which is recorded at fair value at the end of each reporting period. We recorded contingent consideration from the 2016 acquisition of Ciclofilin, which is required to be carried at fair value. See Note 5 for additional information on the fair value of the contingent consideration.

Property, equipment and depreciation

As of September 30, 2023 and December 31, 2022, we had $41,087 and $0.1 million, respectively, of property and equipment, consisting primarily of lab equipment, computer equipment, and furniture and fixtures. There were no adjustments to the carrying value of property and equipment at September 30, 2023 or December 31, 2022.

In-Process Research & Development

The annual, or interim (if events or changes in circumstances indicate that it is more likely than not that the asset is impaired), In-Process Research and Development ("IPR&D") impairment test is performed by comparing the fair value of the asset to the asset's carrying amount. When testing indefinite-lived intangibles for impairment, we may assess qualitative factors for its indefinite-lived intangibles to determine whether it is more likely than not that the asset is impaired. Alternatively, we may bypass this qualitative assessment for our indefinite-lived intangible asset and perform the quantitative impairment test that compares the fair value of the indefinite-lived intangible asset with the asset's carrying amount. 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.

We concluded that no triggering event occurred during the three months ended September 30, 2023. However, economic conditions could result in reductions in our future projected cash flows used to estimate fair value which could indicate an impairment.

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.

We continue to maintain a full valuation allowance for our U.S and foreign net deferred tax assets.

Under the provisions of the Internal Revenue Code, the net operating loss (NOL) and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986, respectively, as well as similar state tax provisions. This could limit the amount of tax attributes that we can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The utilization of these NOLs is subject to limitations based on past and future changes in our ownership pursuant to Section 382. We completed a Section 382 study of transactions in our stock through December 31, 2021

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

and concluded that we have experienced ownership changes since inception that we believe under Section 382 and 383 of the Internal Revenue Code will result in limitations on our ability to use certain pre-ownership change NOLs and credits. We are not aware of any ownership changes in 2023 or 2022. In addition, we may experience subsequent ownership changes as a result of future equity offerings or other changes in the ownership of our stock, some of which are beyond our control. As a result, the amount of the NOLs and tax credit carryforwards presented in our consolidated financial statements could be further limited. Similar provisions of state tax law may also apply to limit the use of accumulated state tax attributes.

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 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, 2023 and December 31, 2022, we had prepaid research and development costs of $1.4 million and $4.7 million, respectively.

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. Assets and liabilities of Hepion Research Corp. 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 $93,928 and $90,168 at September 30, 2023 and December 31, 2022, respectively. 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 general and administrative expense within the consolidated statements of operations. The impact of foreign exchange losses (gains) was $59,432 and $27,601 for the three months ended September 30, 2023 and 2022, respectively, and was $115,527 and $(4,917) for the nine months ended September 30, 2023 and 2022, respectively.

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.

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

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.

Recent Accounting Pronouncements

There are no recent accounting pronouncements that will have a material effect on our condensed consolidated financial statements for the nine months ended September 30, 2023.

4. Stockholders' Equity

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, 2023, there were 85,581 shares outstanding. During the nine months ended September 30, 2023 and 2022, no shares of the Series A were converted. If we sell common stock or equivalents at an effective price per share that is lower than the conversion price, the conversion price may be reduced to the lower conversion price. The Series A will be automatically convertible into common stock in the event of a fundamental transaction as defined in the offering.

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 4,446 common stock warrants that expired in July 2023. As of September 30, 2023, there were 1,800 shares of Series C outstanding. During the nine months ended September 30, 2023, 1 share of the Series C was converted into 1 share of our common stock and during the nine months ended September 30, 2022, 5 shares of the Series C were converted into 2 shares of our common stock. Each share of Series C is convertible into common stock at any time at the option of the holder thereof at the conversion price then in effect. The conversion price for the Series C is determined by dividing the stated value of $1,000 per share by $0.08 per share (subject to adjustments upon the occurrence of certain dilutive events).

5. 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, 2023 and December 31, 2022.

		Fair Value Measurement at Reporting Date Using		
Description	**Fair value**	**(Level 1)**	**(Level 2)**	**(Level 3)**
As of September 30, 2023:				
Contingent consideration	$ 2,280,000	$ —	$ —	$ 2,280,000
As of December 31, 2022:				
Contingent consideration	$ 2,460,000	$ —	$ —	$ 2,460,000

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.

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

At September 30, 2023 and December 31, 2022, the assumptions we used to calculate the fair value were as follows:

	Assumptions	
	September 30, 2023	December 31, 2022
Discount rate	11.0%	8.5%
Projected milestone achievement dates	Mar 2024 — Jun 2029	Dec 2023 — Dec 2028
Probability of success of milestone achievements	13 % — 40%	13 % — 40%

As of September 30, 2023, $1,903,570 was classified as a non-current liability based upon management's best estimate using the latest available information. Management reviewed the assumptions and for the nine months ended September 30, 2023, the only change made was to the milestone achievement dates.

The following table presents the change in fair value of the contingent consideration for the nine months ended September 30, 2023.

	Acquisition-related Contingent Consideration
Liabilities:	
Balance at December 31, 2022	$ 2,460,000
Change in fair value recorded in earnings	48,434
Balance at March 31,2023	2,508,434
Change in fair value recorded in earnings	(88,434)
Balance at June 30, 2023	2,420,000
Change in fair value recorded in earnings	(140,000)
Balance at September 30, 2023	$ 2,280,000

6. Property and Equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method, based on useful lives as follows:

	Estimated Useful Life (in years)	September 30, 2023	December 31, 2022
Equipment	3 years	$ 340,133	$ 326,382
Furniture and fixtures	7 years	62,183	62,183
Less: Accumulated depreciation		(361,229)	(306,945)
		$ 41,087	$ 81,620

Depreciation expense for the three months ended September 30, 2023 and 2022 was $18,500 and $17,726, respectively, and was $54,866 and $58,985 for the nine months ended September 30, 2023 and 2022, respectively.

7. Indefinite-lived Intangible Assets

IPR&D

Our IPR&D asset consisted of the following at:

	Indefinite-lived Intangible Asset
Rencofilstat balance at December 31, 2022	$ 3,190,000
Change during the nine months ended September 30, 2023	—
Rencofilstat balance at September 30, 2023	$ 3,190,000

No impairment losses were recorded on IPR&D during the nine months ended September 30, 2023 and 2022.

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

8. Accrued Liabilities

Accrued liabilities consisted of the following:

	September 30, 2023	December 31, 2022
Payroll and related costs	$ 945,029	$ 838,683
Stock-based compensation	—	1,906,401
Research and development	1,752,939	1,716,035
Professional fees	35,322	246,664
Other	174,275	92,200
Total accrued expenses	$ 2,907,565	$ 4,799,983

9. Accounting for Share-Based Payments

In April 2023, our board of directors approved the 2023 Omnibus Equity Incentive Plan (the 2023 Plan), which became effective in June 2023 upon stockholder approval. The 2023 Plan allows for the grant of up to 500,000 awards for the purpose of attracting, motivating and retaining employees (including officers), non-employee directors and non-employee consultants. At September 30, 2023, there were no awards granted from the 2023 Plan.

On June 3, 2013, we adopted the 2013 Equity Incentive Plan (the 2013 Plan), which expired in June 2023 and we are no longer making grants under it. Stock options granted under the 2013 Plan typically vest after three years of continuous service from the grant date and will have a contractual term of ten years. We granted options during the three months ended June 30, 2022 and 2021, and at the time that these grants were made, we did not have any options available for grant under the Plan. We accounted for these option grants as liability-classified awards requiring us to measure the fair value of the awards each reporting period since there were not enough shares available at the time of the grant. With the approval of the 2023 Plan, these awards are no longer accounted for as liability-classified and the cumulative liability of $2,983,006 was recorded to additional paid-in capital.

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,	
	2023	2022	2023	2022
General and administrative	$ 189,380	$ 350,990	$ 1,360,097	$ 1,561,574
Research and development	129,531	265,845	906,495	759,219
Total stock-based compensation expense	$ 318,911	$ 616,835	$ 2,266,592	$ 2,320,793

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

A summary of stock option activity under the 2013 Plan and 2023 Plan is presented as follows:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Team
Balance outstanding, December 31, 2022	444,749	$ 13.80 - $ 40,320.00	$ 46.20	$ —	8.13 years
Granted	—	$ — - $ —	$ —	$ —	
Adjustment for stock split	47	$ — - $ —	$ —	$ —	
Exercised	—	$ — - $ —	$ —	$ —	
Forfeited	(5,073)	$ 34.00 - $ 74.40	$ 34.05	$ —	
Cancelled	(14,691)	$ 32.60 - $ 11,648.00	$ 40.31	$ —	
Balance outstanding, September 30, 2023	425,032	$ 13.80 - $ 40,320.00	$ 47.51	$ —	7.08 years
Awards outstanding, vested awards and those expected to vest at September 30, 2023	424,345	$ 13.80 - $ 40,320.00	$ 47.54	$ —	7.07 years
Vested and exercisable at September 30, 2023	369,385	$ 13.80 - $ 40,320.00	$ 49.76	$ —	6.98 years

The total fair value of awards vested during the nine months ended September 30, 2023 and 2022 was $2.6 million and $4.3 million, respectively.

As of September 30, 2023, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was $0.5 million to be recognized over a weighted-average remaining vesting period of approximately 0.7 years.

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

	Nine Months Ended September 30,	
	2023	2022
Stock price	$ —	$ 13.80
Risk-free interest rate	— %	4.02 %
Dividend yield	—	—
Expected volatility	— %	115.4 %
Expected term (in years)	0.0	6.0

Stock price—The stock price used is the closing price of our common stock on the day prior to the grant date.

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.

SAB No. 110, *Share-Based Payment*, ("SAB No. 110") expresses the views of the Staff of the SEC with respect to extending the use of the simplified method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with ASC 718. 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.

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

10. Loss per Share

Basic and diluted net loss per common share was determined by dividing net loss by the weighted-average common shares outstanding during the period.

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 per common share:	**2023**	**2022**	**2023**	**2022**
Numerator:				
Net loss	$ (10,526,946)	$ (8,547,591)	$ (37,866,414)	$ (35,388,575)
Denominator:				
Weighted average common shares outstanding	3,838,289	3,811,481	3,825,523	3,811,469
Net loss per share of common stock—basic and diluted	$ (2.74)	$ (2.24)	$ (9.90)	$ (9.28)

The following outstanding securities at September 30, 2023 and 2022 have been excluded from the computation of basic and diluted weighted shares outstanding, as they would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Common shares issuable for:				
Series A preferred stock	159	159	159	159
Series C preferred stock	829	830	829	830
Stock options	425,032	444,749	425,032	444,749
Warrants – equity classified	210,979	215,559	210,979	215,559
Total	636,999	661,297	636,999	661,297

The 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.

11. Commitments and Contingencies

Legal Proceedings

We are involved in various legal proceedings. 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 consolidated financial condition or results of operations.

Leases

In July 2014, we entered into a lease for corporate office space in Edison, New Jersey ("Edison Lease"). In July 2017, we entered into the first amendment to the Edison Lease expanding the office footprint and extending the Edison Lease for an approximate 5-year period that ended on March 31, 2023. In August 2023, we signed a second amendment to the Edison Lease in which we reduced our corporate office space and extended the lease for a period of 2.3 years ending July 31, 2025.

In October 2019, we entered into a 3-year lease for office and research laboratory space in Edmonton, Canada, which expired on September 30, 2022 and we are leasing this space on a month-to-month basis. We are currently negotiating with the landlord for a new lease agreement.

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.

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

Operating leases where we are the lessee are included under the caption "Right of Use Assets" ("ROU") on our 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 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.

As of September 30, 2023, our ROU asset was $0.2 million, the current lease liability was $0.1 million, and the long-term lease liability was $0.1 million. The discount rate used to account for our operating leases under ASC 842 is our estimated incremental borrowing rate of 14.9%.

Rent expense for the three months ended September 30, 2023 and 2022 was a credit of $49,217 and $0.1 million, respectively, and was $0.2 million and $0.3 million for the nine months ended September 30, 2023 and 2022, respectively. At September 30, 2023, the weighted average remaining term of our noncancelable operating leases is 1.84 years.

Future minimum rental payments under our noncancelable operating lease at September 30, 2023 is as follows:

Remainder of 2023	$	40,631
2024		137,605
2025		84,000
2026		—
2027 and thereafter		—
Total		262,236
Present value adjustment		(20,693)
Lease liability at September 30, 2023	$	241,543

12. Subsequent Events

On October 31, 2023, we filed an S-1 registration statement with the Securities and Exchange Commission to offer up to 1,960,786 shares of our common stock consisting of (a) up to an aggregate of 980,393 shares of our common stock that are issuable upon exercise of warrants exercisable for one share of our common stock at an exercise price of $4.85 per share for a term of five years from the date of issuance (the "Series A Warrants"), and (b) up to an aggregate of 980,393 shares of our common stock that are issuable upon exercise of warrants exercisable for one share of our common stock at an exercise price of $4.85 per share for a term of eighteen months from the date of issuance (the "Series B Warrants").

On September 28, 2023, we entered into a securities purchase agreement with an institutional investor for the purchase and sale of 980,393 shares of our common stock (or common stock equivalents in lieu thereof) at a purchase price of $5.10 per share and pre-funded warrants to purchase up to 580,393 shares at a offering price of $5.09 in a registered direct offering priced at-the-market under Nasdaq rules. In addition, in a concurrent private placement, we issued to the investor unregistered Series A Warrants to purchase up to an aggregate of 400,000 shares of common stock and Series B Warrants to purchase up to an aggregate of 400,000 shares of common stock. The Series A and Series B Warrants will have an exercise price of $4.85 per share, will be exercisable immediately following the date of issuance and will expire in five years and one and a half years, respectively. The closing of the registered direct offering and the concurrent private placement was on October 3, 2023.

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, 2022 filed with the United States Securities and Exchange Commission ("SEC") on April 10, 2023. Accordingly, to the extent that this Report contains forward-looking statements regarding the financial condition, operating results, business prospects or any other aspect of us, please be advised that our actual financial condition, operating results and business performance may differ materially from that projected or estimated by us in forward-looking statements, and you should not unduly rely on such statements.

Business Overview

We are a biopharmaceutical company headquartered in Edison, New Jersey, focused on the development of drug therapy for treatment of chronic liver diseases. This therapeutic approach targets fibrosis, inflammation, and shows potential for the treatment of hepatocellular carcinoma ("HCC") associated with non-alcoholic steatohepatitis ("NASH"), viral hepatitis, and other liver diseases. Our cyclophilin inhibitor, rencofilstat (formerly CRV431), is being developed to offer benefits to address multiple complex pathologies related to the progression of liver disease.

We are developing rencofilstat as our lead molecule. Rencofilstat is a compound that binds and inhibits the function of a specific class of isomerase enzymes called cyclophilins that regulate protein folding, in addition to other activities. Many closely related isoforms of cyclophilins exist in humans. Cyclophilins A, B, and D are the best characterized cyclophilin isoforms. Inhibition of cyclophilins has been shown in scientific literature to have therapeutic effects in a variety of experimental models, including liver disease models.

We have completed a number of Phase 1 and Phase 2 clinical trials. In May 2023, we announced that our Phase 2a study ("ALTITUDE-NASH") met its primary endpoint by demonstrating improved liver function and was well tolerated after four months of treatment with once daily oral rencofilstat administered to NASH subjects with stage 3 or greater fibrosis. All additional secondary efficacy and safety endpoints were also met. These observations provide further evidence that builds on previous findings from a shorter 28-day Phase 2a ("AMBITION") trial. Taken together, the AMBITION and ALTITUDE-NASH trials reinforce rencofilstat's direct antifibrotic mode of action and increase our confidence level that we anticipate observing fibrosis reductions in our ongoing 12-month Phase 2b ("ASCEND-NASH") clinical trial.

In June 2023, we announced that the Data and Safety Monitoring Board ("DSMB") met to review the current data for the ASCEND-NASH 2b study and has issued a "study may proceed without modification" clearance. This, the first planned DSMB meeting, occurred on schedule, and all labs, electrocardiogram's, adverse events, and protocol deviations were reviewed, focusing on any potential safety signals from the placebo-controlled trial.

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 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 typically 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 clinical symptoms and therefore are unaware that they have it. Once NASH is diagnosed, it is a major health concern as the liver often becomes fibrotic and puts individuals at increased risk of developing cirrhosis and other complications. Individuals with advanced liver fibrosis have a 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, including the USA, and NASH is quickly becoming the most common reason for individuals requiring a liver transplant 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 currently there are no drugs that are specifically approved to treat the disease.

HCC is a major type of liver cancer, accounting for approximately 85% – 90% of all cases. NASH, hepatitis viral infections, and alcohol consumption are all major causes of HCC. Globally, over 700,000 people die each year from liver cancer which is second only to lung cancer among all cancer-related deaths. The high mortality is due to the fact that only around half of all people who develop HCC (in developed countries) receive the diagnosis early enough to have an opportunity for therapeutic intervention. Additionally, recurrence rates are high, and current treatment options remain limited.

HCC is a type of cancer in which the tissue microenvironment plays a major role in its development. In most cases HCC is preceded by significant, long-term damage to liver cells, inflammation, and fibrosis. One-third of people with cirrhosis, a very advanced stage of liver disease, will eventually progress to HCC. The chronic injury to the liver leads to many genetic mutations that eventually lead to transformation of cells and formation of tumors. The noxious tissue microenvironment also promotes cancer by altering the function of immune cells and endothelial cells which form tumor-supporting blood vessels. These various events underscore the importance of halting liver injury and scarring as early and effectively as possible to prevent cancer development.

Artificial Intelligence (AI)

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

AI-POWR™ is our acronym for Artificial Intelligence - Precision Medicine; Omics that include genomics, proteomics, metabolomics, transcriptomics, and lipidomics; World database access; and Response 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 processed via machine learning algorithms. We believe AI outputs will 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 NASH patients will best respond to Rencofilstat. 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. The AI-POWR™ platform is continually updated with in-house and published data to further refine the accuracy of the neural network.

We believe that NASH is a heterogenous disease, and we need to have a better understanding of interactions among proteins, genes, lipids, metabolites, and other disease variables to help predict disease progression, regression, and responses to Rencofilstat. All of this is further complicated by variable drug concentrations, patient traits and temporal factors. AI-POWR™ is designed to address many of the typical challenges in drug development, 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 Phase 2b Ascend-NASH program and identify additional potential indications for Rencofilstat to expand our footprint in the cyclophilin inhibition therapeutic space.

FINANCIAL OPERATIONS OVERVIEW

From our inception in May 2013 through September 30, 2023, we have an accumulated deficit of $213.6 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.

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 ESTIMATES

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, 2023, there were no significant changes to our critical accounting estimates from those described in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in the Annual Report on Form 10-K for the year ended December 31, 2022.

RECENT ACCOUNTING PRONOUNCEMENTS

Please refer to Note 3 of Notes to Condensed Consolidated Financial Statements, Recent Accounting Pronouncements, in this Quarterly Report on Form 10-Q.

RESULTS OF OPERATIONS

Comparison of the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	8,518,520	5,740,122	2,778,398
General and administrative	2,146,045	2,725,204	(579,159)
Loss from operations	(10,664,565)	(8,465,326)	(2,199,239)
Other income (expense):			
Interest expense	(2,381)	(2,265)	(116)
Change in fair value of contingent consideration	140,000	(80,000)	220,000
Loss before income taxes	(10,526,946)	(8,547,591)	(1,979,355)
Income tax benefit (expense)	—	—	—
Net loss	$ (10,526,946)	$ (8,547,591)	$ (1,979,355)

We had no revenues during the three months ended September 30, 2023 and 2022, 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, 2023 and 2022 was $8.5 million and $5.7 million, respectively. The increase of $2.8 million was primarily due to a $3.5 million increase in clinical trial costs primarily for our phase 2b study, offset by a $0.5 million decrease in drug development costs, and a $0.2 million decrease in consulting and outside services.

General and administrative expenses for the three months ended September 30, 2023 and 2022 was $2.1 million and $2.7 million, respectively. The decrease of $0.6 million was primarily due to a decrease of $0.2 million for stock-based compensation expense and a decrease of $0.3 million in consulting costs.

Comparison of the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
	2023	2022	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	30,196,848	25,753,211	4,443,637
General and administrative	7,842,512	8,091,780	(249,268)
Goodwill impairment loss	—	1,870,924	(1,870,924)
Loss from operations	(38,039,360)	(35,715,915)	(2,323,445)
Other income (expense):			
Interest expense	(7,054)	(7,652)	598
Change in fair value of derivative instruments – warrants and contingent consideration	180,000	334,992	(154,992)
Loss before income taxes	(37,866,414)	(35,388,575)	(2,477,839)
Income tax (expense) benefit	—	—	—
Net loss	$ (37,866,414)	$ (35,388,575)	$ (2,477,839)

We had no revenues during the nine months ended September 30, 2023 and 2022, 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, 2023 and 2022 was $30.2 million and $25.8 million, respectively. The increase of $4.4 million was primarily due to an increase of $13.6 million in clinical trial costs for our phase 2b study and an increase in compensation costs of $0.4 million due to an increase in headcount. This was offset by a decrease of $9.2 million in drug development costs as prior year cost were high due to ramp up of our phase 2b study and a $0.6 million decrease in consulting costs.

General and administrative expenses for the nine months ended September 30, 2023 and 2022 was $7.8 million and $8.1 million, respectively. The decrease of $0.3 million was primarily for a decrease of $0.7 million in consulting costs as well as a decrease of $0.2 million in insurance costs. This was offset by an increase of $0.4 million increase in compensation costs, a $0.2 million increase in professional fees and a $0.1 million increase in travel costs.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations through September 30, 2023 primarily through the issuance of convertible preferred stock, the issuance of convertible debt, and issuances of shares of our common stock through firm commitment, registered direct and at-the market offerings.

Future Funding Requirements

We have no products approved for commercial sale. To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of our product candidate. As a result, we are not profitable and have incurred losses in each period since our inception in 2013. As of September 30, 2023, we had an accumulated deficit of $213.6 million. We expect to continue to incur significant losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- pursue the clinical and preclinical development of our current product candidate;
- leverage our technologies to advance product candidates into preclinical and clinical development;
- seek regulatory approvals for our product candidate that successfully complete clinical trials, if any;
- attract, hire and retain additional clinical, quality control and scientific personnel;
- establish our manufacturing capabilities through third parties and scale-up manufacturing to provide adequate supply for clinical trials and commercialization;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;

- expand and protect our intellectual property portfolio;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- acquire or in-license other product candidates and technologies; and
- incur additional legal, accounting and other expenses in operating our business, including ongoing costs associated with operating as a public company.

Even if we succeed in commercializing our product candidate, we will continue to incur substantial research and development and other expenditures to potentially develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional financing and a failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our non-replicating and replicating technologies and our product candidate derived from these technologies. Preclinical studies and clinical trials and additional research and development activities will require substantial funds to complete. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the development of our current product candidates and programs as well as any future product candidates we may choose to pursue, as well as the gradual gaining of control over our required manufacturing capabilities and other corporate uses. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current and future product candidate and programs, and of conducting preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidate that we may pursue;
- the stability, scale and yields during the manufacturing process as we scale-up production and formulation of our product candidate for later stages of development and commercialization;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals and developing our ability to establish sales and marketing capabilities, if any, for our current and future product candidates we develop if clinical trials are successful;
- our ability to establish and maintain collaborations, strategic licensing or other arrangements and the financial terms of such agreements;
- the cost of commercialization activities for our current and future product candidates that we may develop, whether alone or with a collaborator;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, our future products, if any; and

A change in the outcome of any of these or other variables with respect to the development of any of our current and future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will need additional funds to meet operational needs and capital requirements associated with such operating plans.

The condensed consolidated financial statements as of and for the nine months ended September 30, 2023 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 accumulated deficit and our recurring and expected continuing losses from operations, we have concluded there is substantial doubt in our ability to continue as a going concern without additional capital becoming available to attain

further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will be required to raise additional capital to continue the development and commercialization of our current product candidate 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, delay, scale back or discontinue the development and/or commercialization of one or more product candidates; 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 relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize on unfavorable terms.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (31,887,104)	$ (30,163,670)
Investing activities	(13,956)	2,266
Financing activities	—	(2,000,000)

As of September 30, 2023, we had working capital of $14.9 million compared to working capital of $48.6 million as of December 31, 2022. The decrease of $33.7 million in working capital is primarily related to our cash spend for the nine months ended September 30, 2023.

Operating Activities:

As of September 30, 2023, we had $19.3 million in cash. Net cash used in operating activities was $31.9 million for the nine months ended September 30, 2023 consisting primarily of our net loss of $37.9 million. Changes in non-cash operating activities was $1.1 million, primarily for stock-based compensation. Changes in working capital accounts had a positive impact of $4.9 million on cash primarily for a decrease in prepaid expenses and other assets of $3.5 million and an increase in accounts payable and accrued expenses of $1.4 million.

Net cash used in operating activities was $30.2 million for the nine months ended September 30, 2022 consisting primarily of our net loss of $35.4 million. Changes in non-cash operating activities was $3.9 million, primarily for stock-based compensation, goodwill impairment and the change in fair value of the contingent consideration. Changes in working capital accounts had a positive impact of $1.3 million on cash primarily for an increase in accounts payable and accrued expenses of $1.8 million offset by an increase in prepaid expenses of $0.5 million.

Investing Activities:

Net cash used in investing activities was nominal for the nine months ended September 30, 2023 and 2022.

Financing Activities:

There was no cash provided by or used in financing activities for the nine months ended September 30, 2023.

Net cash used in financing activities was $2.0 million for the nine months ended September 30, 2022 for the contingent consideration milestone payment per the Ciclofilin acquisition merger agreement.

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, 2023, our Principal Executive Officer and Principal Financial Officer have concluded that that we have material weaknesses in our control environment and period end financial close and reporting process as described below and therefore our disclosure controls and procedures were not effective.

- During 2022, we identified a material weakness in our internal controls related to the proper design and implementation of controls over formal review, approval, and evaluation of non-core, complex accounting transactions.
- During 2022, we identified a material weakness in internal control related to the proper design and implementation of certain controls over our income tax provision and management's review of the income tax provision. We utilize a third-party to assist in the preparation of our tax provision. Specifically, we did not sufficiently design and implement controls related to the completeness and accuracy of certain aspects of the tax provision and the completeness and accuracy income tax disclosures.

Remediation of Material Weaknesses

We are committed to the remediation of the material weaknesses described above, as well as the continued improvement of our internal control over financial reporting. We plan on implementing several remedial actions to improve our internal controls, including:

- We are utilizing the services of external consultants for non-routine and\or technical accounting issues as they arise.
- Expanding and improving our review process for complex accounting transactions. We plan to further improve this process by enhancing access to accounting literature, identification of third-party professionals with whom to consult regarding complex accounting applications and consideration of additional staff with the requisite experience and training to supplement existing accounting professionals.
- Management, with the assistance of a third party, will perform an evaluation of the processes and procedures around our tax provision processes, internal control design gaps, and recommend process enhancements.
- Implementing enhancements and process improvements, including the design and implementation of well-defined controls and related control attributes regarding income tax provision and income tax disclosures.
- Developing a detailed timeline of the tax provision calculation, to ensure that sufficient time is allocated to complete the process as designed.

As we continue our evaluation and improve our internal control over financial reporting, management may identify and take additional measures to address control deficiencies. We cannot assure you that we will be successful in remediating the material weaknesses in a timely manner.

Changes in Internal Control over Financial Reporting

Except as noted above, there have been no changes in our internal controls over financial reporting during the three months ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2022.

ITEM 5. Other Information

During the three months ended September 30, 2023, no director or officer adopted or terminated any Rule 10b5-1 trading arrangement, and/or any non-Rule 10b5-1 trading arrangement (as such terms are defined pursuant to Item 408(a) of Regulation S-K).

ITEM 6. EXHIBITS

4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 filed on Form 8-K on October 3, 2023)
4.2	Form of Series A Warrant (incorporated by reference to Exhibit 4.2 filed on Form 8-K on October 3, 2023)
4.3	Form of Series B Warrant (incorporated by reference to Exhibit 4.3 filed on Form 8-K on October 3, 2023)
10.1	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 filed on Form 8-K on October 3, 2023)
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-the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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
104	Cover Page Interactive Data File (formatted as Inline XBRL in Exhibit 101)

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: 11/20/2023 By: /s/ ROBERT FOSTER
Robert Foster
Chief Executive Officer
(Principal Executive Officer)

Date: 11/20/2023 By: /s/ JOHN CAVAN
John Cavan
Chief Financial Officer
(Principal Financial and Accounting 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 20, 2023

/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 20, 2023

/s/ John Cavan

John Cavan
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
HEPION PHARMACEUTICALS, INC.
FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023
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, 2023 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 20, 2023

/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, 2023
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, 2023 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 20, 2023

/s/ John Cavan
John Cavan
Chief Financial Officer
(Principal Financial and Accounting Officer)