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

FORM 10-K

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

For the year ended December 31, 2024

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)

55 Madison Ave, Suite 400- PMB# 4362, Morristown, New Jersey 07960
(Address of Principal Executive Offices)

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	HEPA	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2024, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $5.9 million based on the last reported sale price of the registrant's common stock.

The number of shares of the registrant's Common Stock outstanding as of April 8, 2025 was 10,975,276.

Documents Incorporated by Reference:

Parts of the registrant's Proxy Statement for the Registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2024.

TABLE OF CONTENTS

		Page
Cautionary Note Regarding Forward-Looking Statements		3
	PART I	
Item 1.	Business	5
Item 1A.	Risk Factors	15
Item 1B.	Unresolved Staff Comments	40
Item 1C.	Cybersecurity	40
Item 2.	Properties	41
Item 3.	Legal Proceedings	41
Item 4.	Mine Safety Disclosures	41
	PART II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	42
Item 6.	[Reserved]	42
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	42
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	48
Item 8.	Financial Statements and Supplementary Data	49
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	70
Item 9A.	Controls and Procedures	70
Item 9B.	Other Information	71
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	71
	PART III	
	Certain information called for by Part III (Items 10, 11, 12, 13 and 14) has been omitted as Registrant intends to file with the Securities and Exchange Commission not later than 120 days after the close of its fiscal year a definitive Proxy Statement pursuant to Regulation 14A.	72
	PART IV	
Item 15.	Exhibits and Financial Statement Schedules	73
Item 16.	Form 10-K Summary	74
SIGNATURES		75

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. Any statements in this Annual Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement. We do not assume any obligation to update forward-looking statements as circumstances change and thus you should not unduly rely on these statements.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to:

- Market conditions;
- Our capital position;
- Our ability to compete with larger better financed pharmaceutical companies;
- Our uncertainty of developing marketable products;
- Our ability to develop and commercialize our products;
- Our ability to obtain regulatory approvals;
- Our ability to maintain and protect intellectual property rights;
- The inability to raise additional future financing and lack of financial and other resources;
- Our ability to control product development costs;
- We may not be able to attract and retain key employees;
- We may not be able to compete effectively;
- We may not be able enter into new strategic collaborations;
- Changes in government regulation affecting product candidates could increase our development costs;
- Our involvement in patent and other intellectual property litigation could be expensive and could divert management's attention;
- The possibility that there will be no market acceptance for our products; and
- Changes in third-party reimbursement policies could adversely affect potential future sales of any of our products that are approved for marketing.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements, which speak only as of the date of this Annual Report. We assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements contained in this Annual Report. All written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

All share amounts included in this Annual Report have been retroactively adjusted to reflect a 1-for-50 reverse stock split, which took effect on March 17, 2025.

Risk Factor Summary

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Business

We have incurred losses since inception, anticipate that we will incur continued losses for the foreseeable future indicating the possibility that we may not be able to operate in the future.

We, and our collaborators, must comply with extensive government regulations in order to advance our product candidates through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

Risks Relating to the Commercialization of our Product Candidates

We may delay or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

If we fail to enter into collaborations, license agreements or other transactions with third parties to accelerate the development of our product candidates, we will bear the risk of developmental failure.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those we develop through collaborations, our revenues and potential for profitability will be harmed.

Risks Related to Our Intellectual Property

If we are unable to adequately protect or expand our intellectual property related to our current or future product candidates, our business prospects could be harmed.

If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates.

Our failure to successfully discover, acquire, develop, and market additional product candidates or approved products would impair our ability to grow.

Risks Related to Government Regulation

Even if our product candidate receives regulatory approval, it may still face future development and regulatory difficulties.

Health care reform measures and other recent legislative initiatives could adversely affect our business.

Risks Related to Our Common Stock

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Our management determined that our disclosure controls and procedures and internal controls were ineffective as of December 31, 2024 and if they continue to be ineffective could result in material misstatements in our financial statements.

Certain provisions in our certificate of incorporation and by-laws, and of Delaware law, may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company headquartered in Morristown, New Jersey, previously focused on the development of drug therapy for treatment of chronic liver diseases. Our cyclophilin inhibitor, rencofilstat (formerly CRV431), was being developed to offer benefits to address multiple complex pathologies related to the progression of liver disease.

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.

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.

In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs. We incurred a one-time restructuring charge of approximately $0.7 million in the fourth quarter of 2023. Additionally, we initiated a process to explore a range of strategic and financing alternatives focused on maximizing stockholder value within the current financial environment and NASH drug development landscape.

On April 19, 2024, we announced that we have begun wind-down activities in our ASCEND- NASH clinical trial. We did not have access to sufficient funding to complete the study, as designed. The wind-down activities were implemented to halt further clinical activities other than those which would allow for an orderly and patient safety manner that would meet the minimum FDA requirements for safely closing a clinical trial. All clinical trial activities were completed and the trial was closed in August 2024.trial.

On July 19, 2024, we along with Pharma Two B Ltd., a company organized under the laws of the State of Israel ("Parent"), and Pearl Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Parent ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other things, on the terms and subject to the conditions set forth therein, Merger Sub will merge with and into us (the "Merger"), pursuant to which we would survive the Merger as an indirect wholly owned subsidiary of Parent.

Concurrently with the Merger, on July 19, 2024, we entered into a Securities Purchase Agreement (the "SPA") with certain purchasers pursuant to which we sold an aggregate of $2.9 million in principal amount of our Original Issue Discount Senior Unsecured Nonconvertible Notes (the "Notes"). The Notes are due on the earlier of: (i) December 31, 2024, (ii) the date of the closing of the Merger, (iii) the date that the Merger is terminated pursuant to the terms of the Merger Agreement, or (iv) such earlier date as the Notes are required or permitted to be repaid as provided in the Note, as may be extended at the option of the holder of the Note as described in the Note.

On December 10, 2024, Parent informed us that Nasdaq would not exclude our historical losses from its burn rate calculation and as a result on December 10, 2024, we and Pharma Two B and Pearl entered into an agreement to terminate the Merger Agreement (the "Termination Agreement"). Pursuant to the Termination Agreement, the Merger Agreement was terminated.

On January 23, 2025, we consummated a best efforts registered offering for 73,222 shares of common stock, Pre-Funded Warrants to purchase 480,624 shares of common stock, Series A Warrants to purchase 553,846 shares of common stock and Series B Warrant to purchase 553,846 shares of common stock for gross proceeds of $9,000,000. A portion of the net proceeds was used to repay the Notes along with accrued interest.

Rencofilstat

Rencofilstat is a therapeutic drug candidate that binds and inhibits the function of a specific class of isomerase enzymes called cyclophilins that mainly regulate protein folding. 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 the scientific literature to have therapeutic effects in a variety of experimental models, including liver disease models. In preclinical *in vitro* and/or *in vivo* experiments conducted to date rencofilstat decreased liver fibrosis, liver inflammation, liver tumor burden, and titers of HBV, HCV, HDV, and HIV-1. Importantly, reduction in liver fibrosis by rencofilstat was observed *in vivo* in several experimental models and studies of NASH and liver fibrosis. Findings to date suggest that rencofilstat might treat certain inciting agents of liver disease such as hepatitis viruses and also the ensuing disease processes resulting from those agents such as fibrosis.

Cyclophilins are pleiotropic enzymes that play a role in injury and steatosis through mechanisms including cell death occurring through mitochondrial transition pore permeability (cyclophilin D). Inhibition of cyclophilin D, therefore, may play an important role in protection from cell injury and death. Cyclophilin A binding to CD147 is known to play a role in inflammation, cyclophilin B plays a role in fibrosis through collagen production, and cyclophilins also play a role in cirrhosis and cancer (e.g., cell proliferation and metastasis). Cyclophilin inhibition with rencofilstat, therefore, may play an important role in reducing liver disease.

To date, we have completed a number of separate preclinical animal efficacy studies of rencofilstat to assess antifibrotic activity. These studies were conducted by independent laboratory collaborations at, for example, The Scripps Research Institute (San Diego, CA), SMC Corporation (Tokyo, Japan), and Physiogenex S.A.S. (France), Each of these studies demonstrated consistent and significant reductions in fibrosis in mice and rats. Rencofilstat was also tested in *ex vivo* Precision Cut Liver Slices and in Precision Cut Lung Slices obtained from human donors. Again, rencofilstat demonstrated an antifibrotic effect in human tissue that was consistent with the animal study findings. These studies provide support of advancing rencofilstat into clinical trials for NASH, and potentially additional indications where fibrosis plays a role.

On June 10, 2016, we entered into an agreement with Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) to acquire 100% of the issued and outstanding shares of common stock of Ciclofilin. The transaction was accounted for as a business combination (in accordance with Accounting Standards Codification (“ASC”) 805, *Business Combinations*) and, as such, the Ciclofilin assets acquired, and liabilities assumed were recorded at their respective fair values as of the effective date of the executed agreement. The transaction had been accounted for using the acquisition method of accounting, which required that assets acquired, and liabilities assumed be recognized at their fair values as of the acquisition date. The acquisition consisted of cash consideration and certain milestone payments (contingent consideration).

The Merger Agreement was amended on January 14, 2022 primarily for the following: (i) upon receipt of Phase II positive data from the first Phase II clinical trial of rencofilstat in NASH patients which has been achieved: (1) such number of validly issued, fully paid and non-assessable shares of our common stock equal to 7.5% of the issued and outstanding of our common stock on the Closing Date as defined in the original agreement, which 4,317 were issued in March 2022, and (2) a payment of $2.0 million to Ciclofilin shareholders, including a payment to our CEO of $0.8 million and other Hepion employees of $0.2 million, which such payment being made in January 2022, (ii) a payment of $1.0 million upon the positive read out of the first planned interim futility analysis of a Phase IIb clinical trial of rencofilstat in NASH patients, supporting the continuation of the Phase IIb trial, (iii) a payment of $5.0 million upon initiation of the first Phase III trial of rencofilstat in patients, where initiation occurs with first patient in the study dosed with study medication, (iv) a payment of $5.0 million upon the filing and acceptance by the U.S. Food and Drug Administration of the first new drug application for CPI-431-32; and (v) a payment of $8.0 million upon the regulatory approval by the U.S. Food and Drug Administration of the first new drug application for rencofilstat.

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

On November 19, 2021, we submitted an IND to the FDA to support initiation of a rencofilstat clinical development program in the United States for the treatment of HCC and received approval on December 17, 2021.

On November 30, 2021, the FDA granted Fast Track designation for our lead drug candidate, rencofilstat, for the treatment of NASH. The FDA Fast Track designation allows sponsors to gain access to expedited drug approval reviews for medical conditions that are serious and potentially life-threatening, and where there is an unmet medical need. The program is also designed to facilitate drug development by making provisions for more frequent meetings with the FDA to discuss drug development plans, and Fast Track designation can lead to Accelerated Approval and/or Priority Review eligibility if certain criteria are met.

On June 20, 2022, the FDA granted Orphan Drug Designation to rencofilstat, a liver-targeting, orally administered, novel cyclophilin inhibitor, for the treatment of HCC. The FDA Orphan Drug Designation program provides orphan status to drugs or biologics intended for the prevention, diagnosis, or treatment of diseases that affect fewer than 200,000 people in the United States. Sponsors of medicines that are granted Orphan Drug Designation are entitled to certain incentives, including tax credits for qualified clinical trials, prescription drug user-fee exemptions, and potential seven-year marketing exclusivity upon FDA approval.

Intellectual Property

Patents and other proprietary intellectual rights are crucial in our business and establishing and maintaining these rights are essential to justify the development of our product candidate. We have sought, and intend to continue to seek, patent protection for our inventions and rely upon patents, trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain a competitive advantage for our product candidate. In order to protect these rights, know-how and trade secrets, we typically require employees, consultants, collaborators and advisors to enter into confidentiality agreements with us, generally stating that they will not disclose any confidential information about us to third parties for a certain period of time and will otherwise not use confidential information for anyone's benefit but ours.

As patent applications in the U.S. are maintained in secrecy until patents are published or issued, unless earlier publication is required under applicable law or in connection with patents filed under the Patent Cooperation Treaty ("PCT") or as publication of discoveries in the scientific or patent literature often lags behind the actual discoveries, we cannot be certain that we or our licensors were the first to make the inventions described in our pending patent applications or that we or our licensors were the first to file patent applications for such inventions. Furthermore, the patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions, and therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability cannot be predicted.

Pursuant to the terms of the Uruguay Round Agreements Act, patents filed on or after June 8, 1995 have a term of 20 years from the date of filing, somewhat irrespective of the period of time it may take for the patent to ultimately issue. This may shorten the period of patent protection afforded to our products as patent applications in the biopharmaceutical sector often take considerable time to issue. Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing data exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were used to support the marketing application for the drug. The Drug Price Competition and Patent Term Restoration Act of 1984 also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding New Drug Application ("NDA") plus the period of time between the filing of the NDA and FDA approval, with a five-year maximum patent extension. We cannot be sure that we will be able to take advantage of either the patent term extension or marketing data exclusivity provisions of this law.

On June 13, 2016, we completed our merger with Ciclofilin Pharmaceuticals, Inc. ("CPI") acquiring all its outstanding equity interests. We acquired Ciclofilin's lead asset, CPI-431-32, which we renamed rencofilstat, strengthens our liver disease portfolio and is currently in preclinical development for the treatment of liver fibrosis. On February 14, 2014, CPI, through its wholly owned subsidiary, had entered into a Purchase and Sale Agreement to acquire Aurinia Pharmaceuticals Inc. ("Aurinia") entire interest in rencofilstat. There was no upfront consideration. There are future milestone payments of up to CAD $2.9 million, which are to be paid within 30 days of achieving such milestone. In addition to the milestone payments, future payment obligations (in Canadian Dollars "CAD") include a royalty of 2.5% of net sales. The amount payable under the foregoing royalty obligation is uncapped.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we have taken security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees, and consultants. Our employees and consultants also sign agreements requiring that they assign to us their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment with us and not to disclose or misuse our confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable in terms acceptable to us, or at all.

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and currently have no plans to invest in or build such capabilities internally.

Manufacturing

We do not own or operate any facilities in which we can formulate and manufacture our product candidates.

Pharmaceutical Pricing and Reimbursement

In the U.S. and most foreign markets, any revenue associated with the sale of our product candidate, if approved for sale, will depend largely upon the availability of reimbursement from third-party payers. Third-party payers include various government health authorities such as The Centers for Medicare and Medicaid Services ("CMS"), which administers Medicare and Medicaid in the U.S., managed-care providers, private health insurers and other organizations. Third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may ultimately not be considered cost-effective, and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to support a profitable operation or generate an appropriate return on our investment in product development.

The U.S. and foreign governments periodically propose and pass legislation designed to reduce the cost of healthcare and pharmaceutical products. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before our product candidate is ever approved for sale. In addition, the adoption of new legislation could further limit reimbursement for pharmaceuticals. Further, an increasing emphasis on managed care in the U.S. has and will continue to increase the pressure on pharmaceutical pricing. The marketability of our products may suffer if the government and other third-party payers fail to provide adequate coverage and reimbursement rates for our product candidate.

Regulatory Matters

Overview

The preclinical and clinical testing, manufacture, labeling, storage, distribution, promotion, sale, export, reporting and record-keeping of drug products and product candidates are subject to extensive regulation by numerous governmental authorities in the U.S., principally the FDA and corresponding state agencies, and regulatory agencies in foreign countries.

Non-compliance with applicable regulatory requirements can result in, among other things, total or partial suspension of the clinical development of a product candidate, manufacturing and marketing, failure of the FDA or similar regulatory agency in other countries to grant marketing approval, withdrawal of marketing approvals, fines, injunctions, seizure of products and criminal prosecution.

U.S. Regulatory Approval

Pursuant to FDA regulations, we are required to successfully undertake a long and rigorous development process before our product candidate can be marketed or sold in the U.S. This regulatory process typically includes the following steps:

- the completion of satisfactory preclinical studies under the FDA's Good Laboratory Practices, or GLP, regulation;

- the submission and acceptance of an IND that must be reviewed by the FDA or Clinical Trial Application that must be reviewed by similar regulatory agencies in other countries and become effective before human clinical trials may begin;

- obtaining the approval of an Institutional Review Board, or IRB, or Ethics Committee, or EC, at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;

- the successful completion of a series of adequate and well- controlled human clinical trials to establish the safety, potency, efficacy and purity of any product candidate for its intended use, which conform to the FDA's good clinical practice, or GCP, regulations;

- the development and demonstration of manufacturing processes that conform to FDA-mandated current Good Manufacturing Practices, or cGMPs; and

- the submission to, and review and approval by, the FDA of a New Drug Application, or NDA, or a Biologic License Application, or BLA, prior to any commercial sale or shipment of a product.

Successfully completing this development process requires a substantial amount of time and financial resources. We cannot assure you that this process will result in the granting of an approval for our product candidate on a timely basis, if at all, or that we will have sufficient financial resources to see the process for our product candidate through to completion.

Preclinical Studies

Preclinical studies generally include laboratory, or in vitro, evaluation of a product candidate, its chemistry, formulation, stability, and toxicity, as well as certain in vivo animal studies to assess a product's potential safety and biologic activity. We must submit the results of these preclinical studies, together with other information, including manufacturing records, analytical data and proposed clinical trial protocols, to the FDA as part of an IND, which must be reviewed and become effective before we may begin any human clinical trials. An IND generally becomes effective approximately 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises material concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. If our product candidate is placed on clinical hold, we may be required to resolve any outstanding issues to the satisfaction of the FDA before we could begin, or continue, clinical trials of such product candidate. Preclinical studies supportive of an IND generally take a year or more to complete, and there is no guarantee that an IND based on those studies will become effective, allowing human clinical testing to begin.

Certain preclinical studies must be conducted in compliance with the FDA's GLP regulations and the U.S. Department of Agriculture's Animal Welfare Act. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring such studies to be conducted again.

Clinical Trials

This clinical trial phase of drug development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, biologic activity, efficacy and dosage of an investigational new drug product in humans, as well as the ability to produce the drug substance and drug product in accordance with the FDA's cGMP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the activity or efficacy of the product candidate. Each clinical trial protocol must be submitted to the FDA as part of the IND prior to beginning the trial. Each trial and the clinical protocol must be reviewed, approved and conducted under the auspices of an IRB and, with limited exceptions, requires the patient's informed consent to participate in the trial. Sponsors, investigators, and IRBs also must satisfy extensive GCPs, including regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial, and reporting any serious adverse events on a timely basis. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk.

Clinical trials to support an NDA for marketing approval are typically conducted in three sequential phases: Phase 1, 2 and 3, with Phase 4 clinical trials often conducted after marketing approval has been granted. The FDA may require sponsors to conduct Phase 4 clinical trials to study certain safety issues or other patient populations. Data from these activities are compiled in an NDA or a BLA for submission to the FDA requesting approval to market the drug. These phases may be compressed, may overlap, or may be omitted in some circumstances.

- Phase 1:After an IND becomes effective, Phase 1 human clinical trials can begin. A product candidate is typically introduced either into healthy human subjects or in some cases, patients with the medical condition for which the product candidate is intended to be used. Generally, the purpose of a Phase 1 trial is to assess a product candidate's safety and the ability of the human body to tolerate it at different dose levels. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase 1 trials typically evaluate these aspects of the investigational drug in both single doses, as well as multiple doses.

- Phase 2:During Phase 2 clinical trials, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dose tolerance and determine the optimal dose for a subsequent Phase 2 or Phase 3 trial. Phase 2 trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that is not treated with the product candidate but either receives a placebo or a drug already on the market for the same indication. Typically, two or more Phase 2 studies will be conducted for a product candidate prior to advancing to Phase 3.

- Phase 3:If and when one or more Phase 2 trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety profile, one or more Phase 3 trials may be undertaken to further demonstrate or confirm the clinical efficacy and safety of the investigational drug in an expanded patient population, with the goal of evaluating its overall risk-benefit relationship. Phase 3 trials are generally designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase 3 trials is typically a prerequisite to the filing of an NDA or BLA for a product candidate.

In the case of product candidates being developed for serious or life- threatening diseases, Phase 1 trials may be conducted in patients with the respective disease rather than in healthy volunteers. These studies may provide initial evidence of activity or efficacy traditionally obtained in Phase 2 clinical trials, and therefore these trials may be referred to as Phase 1/2 or Phase 1b clinical trials.

A company may request an "end-of-Phase 2 Meeting" with the FDA to assess the safety of the dose regimen to be studied in the Phase 3 clinical trial, to evaluate the planned design of a Phase 3 trial, and to identify any additional information that will be needed to support an NDA. If a Phase 3 clinical trial has been the subject of discussion at an "end- of-Phase 2 Meeting," the trial sponsor may be eligible for a Special Protocol Assessment ("SPA"), by the FDA, a process by which the FDA, at the request of the sponsor, will evaluate the trial protocol and issues relating to the protocol within 45 days to assess whether it is deemed to be adequate to meet the scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of a Phase 3 clinical trial intended to form the primary basis of an efficacy claim in an NDA or BLA, the FDA may reduce the understanding to writing. The SPA, however, is not a guarantee of product approval by the FDA, or approval of any permissible claims about the product.

Throughout the various phases of clinical development, samples of the product candidate made in different batches are tested for stability to establish any shelf-life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed. Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical development that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate further evaluation or trials based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the subject or patient. The FDA, the sponsor, or an IRB may suspend or terminate a clinical trial at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk. The FDA can also request additional clinical trials be conducted as a condition to product approval or advancement to the next stage of development. Additionally, new government requirements may be established that could delay or prevent regulatory approval of products under development. Furthermore, IRBs, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials in their respective institutions at any time for a variety of reasons, including safety issues. A Data Safety Monitoring Board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk.

Clinical trials performed outside the U.S. under an IND must meet the same requirements that apply to studies conducted in the U.S. The FDA may accept a foreign clinical study not conducted under an IND only if the study is well- designed, well-conducted, performed by qualified investigators, and conforms to the ethical principles contained in the Declaration of Helsinki, or with the laws and regulations of the country in which the research was conducted, whichever provides greater protection of the human subjects.

Certain information about clinical trials, including a description of the study, participation criteria, location of study sites, and contact information, is required to be sent to the National Institutes of Health, ("NIH") for inclusion in a publicly accessible database that is available at www.clinicaltrials.gov. Sponsors also are subject to certain state laws imposing requirements to make publicly available certain information on clinical trial results. In addition, the Food and Drug Administration Amendments Act of 2007 directed the FDA to issue regulations that will require sponsors to submit to the NIH the results of all controlled clinical studies, other than Phase 1 studies.

New Drug and Biologics License Applications

If and when we believe that all the requisite clinical trials for a product candidate have been completed with satisfactory and supporting clinical data, we must submit an NDA or BLA to the FDA in order to obtain approval for the marketing and sale of a product candidate in the U.S. Among many other items, an NDA or BLA typically includes the results of all preclinical and toxicology studies and human clinical trials and a description of the manufacturing process and quality control methods. The FDA must approve the NDA or BLA prior to the marketing and sale of the related product. The FDA may deny an NDA or BLA if it believes all applicable regulatory criteria are not satisfied, or it may require additional data, including clinical, toxicology, safety, or manufacturing data prior to approval. The FDA has 60 days from its receipt of an NDA or BLA to review the application to ensure that it is sufficiently complete for a substantive review before accepting it for filing. The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be amended with the additional information. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee.

An NDA or BLA can receive either standard or priority review. A product candidate representing a potentially significant improvement in the treatment, prevention or diagnosis of a life threatening or serious disease may receive a priority review. In addition, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses that provide meaningful therapeutic benefit over existing treatments may also receive accelerated approval on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing Phase 4 clinical trials. Priority review and accelerated approval do not change the standards for approval but may expedite the approval process.

If the results of the FDA's evaluation of the NDA or BLA, and inspection of manufacturing facilities and clinical sites are favorable, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA or BLA approval, the FDA may require post-approval testing, including Phase 4 trials, and surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

If the FDA determines that it cannot approve the application in its present form, it generally issues what is referred to as a complete response letter. A complete response letter will describe all the specific deficiencies that the agency has identified in an application that must be met in order to secure final approval of the NDA or BLA. If and when those conditions are met to the FDA's satisfaction, the FDA will typically re-review the application and possibly issue an approval letter. However, even after submitting this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. It can take several years for the FDA to approve an NDA or BLA once it is submitted, and the actual time required for any product candidate to be approved may vary substantially, depending upon the nature, complexity, and novelty of the product candidate.

We cannot assure you that the FDA, or any other similar regulatory agency in another country, will grant approval for our product candidate on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval.

Post-Approval Regulations

If and when a product candidate receives regulatory approval to be marketed and sold, the approval is typically limited to a specific clinical indication or use. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown safety problems with a product may result in restrictions on its use, or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP regulations, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. We cannot be certain that we, or our present or future contract manufacturers or suppliers, will be able to comply with cGMP regulations and other FDA regulatory requirements.

Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities for our current and future product candidates, failure of the FDA to grant approval for marketing of such product candidate, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves our product candidate, we, or our collaborators if applicable, and our contract manufacturers must provide the FDA with certain updated safety, efficacy, and manufacturing information. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs, or other post-approval changes may necessitate additional FDA review and approval. We rely, and expect to continue to rely, on third parties for the formulation and manufacture of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct.

The labeling, advertising, promotion, marketing and distribution of an approved drug or biologic product must also comply with FDA and Federal Trade Commission ("FTC") requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions, and criminal prosecution.

The FDA's policies may change in the future and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidate. Moreover, increased attention to the containment of health care costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad, or the impact such changes could have on our business.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and in some circumstances the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

From time to time, legislation is drafted, introduced, and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will change or what the impact of such changes, if any, may be.

Foreign Regulatory Approval

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the U.S. is similar to that required in Europe, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure*. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein, and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.

- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

- *National authorization procedures.* There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:

  Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Human Capital

The human capital objectives we focus on in managing our business include attracting, developing, and retaining key personnel. Our employees are critical to the success of our organization, and we are committed to supporting our employees' professional development. We believe our management team has the experience necessary to effectively implement our growth strategy and continue to drive shareholder value. We provide competitive compensation and benefits to attract and retain key personnel, while also providing a safe, inclusive and respectful workplace. In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs, which included a reduction in personnel in the first quarter of 2024.

As of December 31, 2024, we had no employees.

Corporate Information

We were incorporated under the laws of the State of Delaware in May 2013. Our principal executive offices are located at 55 Madison Ave, Suite 400- PMB #462, Morristown, New Jersey.

Available Information

Our annual report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings with the United States Securities and Exchange Commission, or the SEC, and all amendments to these filings, are available, free of charge, on our website at www.Hepion.com as soon as reasonably practicable following our filing of any of these reports with the SEC. You can also obtain copies free of charge by contacting our Investor Relations department at our office address listed above. The public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Room 1580, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy, and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information posted on or accessible through these websites are not incorporated into this filing.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report, including our consolidated financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have incurred losses since inception, anticipate that we will incur continued losses for the foreseeable future indicating the possibility that we may not be able to operate in the future.

For the years ended December 31, 2024 and 2023, we had an accumulated deficit of $237.8 million, and $224.6 million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, initiate new clinical trials, acquire or license technologies, advance other product candidates into clinical development, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. For the years ended December 31, 2024 and 2023, we raised net proceeds of approximately $4.3 million and $4.5 million, respectively, through the sale of notes payable, common stock and warrants, to fund our future operations.

The consolidated financial statements included in this Annual Report on Form 10-K 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 consolidated financial statements without additional capital becoming available.

Our ability to raise additional funds is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying consolidated financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment in our company.

We expect future product candidates to be in the early stages of development and commercial viability remains subject to the successful outcome of current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

In the near-term, failure to successfully advance the development of our product candidates may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have these product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have these product candidates successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our product candidates must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development, or they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;

- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. Several companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application, or NDA or a biologics license application, or BLA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Our product candidates will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that our product candidates will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidates to be commercialized by us or collaborators for at least several years.

Our product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidates to obtain regulatory approval to further advance clinical development or to market them. Even if our product candidates demonstrate biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the results of preclinical studies or clinical trials for our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business.

In order to further advance the development of, and ultimately receive regulatory approval to sell, our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities (including an Institutional Review Board or Ethical Committee) or IRB or EC, not authorizing us to commence or conduct a clinical trial at a prospective trial site;

- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting patients or participants dropping out of our clinical trials at a higher rate than we anticipated;
- our third-party contractors, upon whom we rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks;
- IRBs, ECs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidate demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of an NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidates may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete clinical trials of our product candidates and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials.

We, and our collaborators, must comply with extensive government regulations in order to advance our product candidates through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

The product candidates that we, or our collaborators, may develop require regulatory approval to advance through clinical development and to ultimately be marketed and sold and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety,efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biopharmaceutical products.

Our product candidates are also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidates' safety and efficacy before they can be approved for the targeted indications. Our product candidates have not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidate based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA's or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidate through clinical development, and ultimately commercialize them, may:

- adversely impact our ability to raise sufficient capital to fund the development of our product candidate;
- adversely affect our ability to further develop or commercialize our product candidate;
- diminish any competitive advantages that we or our collaborators may have or attain; and
- adversely affect the receipt of potential milestone payments and royalties from the sale of our products or product revenues.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including:

- delays, suspension or termination of clinical trials related to our products;
- refusal by regulatory authorities to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.

We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidate for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidate. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including:

- the progress of the development of our product candidates;
- the number of product candidates we pursue;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- general market conditions for offerings from biopharmaceutical companies;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and
- our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidate or marketing territories. Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidate will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if the FDA believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidate. If we adopt an alternative brand name, we will lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidates for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect, it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidate may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial, or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidate, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that our existing product candidate or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

Our product candidate could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidate, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

We have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for our product candidate, and we cannot be certain that our product candidate will be successful in clinical trials or receive regulatory approval. Further, our product candidate may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidate, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidate, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidate are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval and to commercialize our product candidate, directly or with a collaborator, worldwide including the United States, the European Union and other additional foreign countries which we have not yet identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidate, and we cannot predict success in these jurisdictions.

We may be required to suspend or discontinue clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any of our product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidate and could result in the FDA or other regulatory authorities denying further development or approval of our product candidate for any or all targeted indications. Ultimately, our product candidate may prove to be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients' privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidate in the United States and we will not generate any revenue.

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre- clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years, and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for our product candidate currently under development. Any approvals we may obtain may not cover all the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidate for the claimed intended uses. Following any regulatory approval of our product candidate, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidate in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from.

Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies, and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidate, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidate. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully identify and develop key points of product differentiations from currently available therapies;
- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidate.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed shingles drugs, we may never generate meaningful revenue.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidate in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidate, we may not be able to commercialize our product candidate which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidate in international markets.

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If the manufacturers upon whom we intend to rely on fail to produce our product candidates, in the volumes that we require on a timely basis or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate.

We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of rencofilstat, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We continue to pursue active pharmaceutical ingredients, or API, and drug product supply agreements with other manufacturers. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and good manufacturing practices or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary to produce our product candidate.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We are responsible for ensuring that each of our contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers our product candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

While we will oversee compliance by our contract manufacturers, ultimately, we will not have control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety our product candidates is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of our product candidates, entail higher costs or result in us being unable to effectively commercialize our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

If our any of our product candidates are approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidates in larger quantities. We may not be able to successfully increase the manufacturing capacity for our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high-quality manufacturing. Our failure to achieve and maintain these high-quality manufacturing standards in collaboration with our third-party manufacturers, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We intend to rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce bulk APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements to produce these materials. If our manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidates would be delayed, which may significantly impact our ability to develop the product candidates. If we or our manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If any of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on several factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidates that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidates, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our product.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed product.

If third-party contract manufacturers upon whom we intend to rely on to formulate and manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers expose us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidate;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidate. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated current good marketing practices or cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidate could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Due to regulatory restrictions inherent in an IND, NDA or BLA, various steps in the manufacture of our product candidates may need to be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of our product candidate. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidate.

Our industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative products, which could harm our business.

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, rencofilstat or any other product candidate we may develop, would compete against existing therapies or other product candidate in various stages of clinical development that we believe may potentially become available in the future.

Developing a pharmaceutical product candidate is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that could compete with our product candidate have substantially more resources than we have, and much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substances and drug products, and marketing and sales. Our competitors may be more successful than we are in obtaining FDA or other regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' drugs or product candidates may be more effective, have fewer negative side effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any drug we, or our potential collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidate obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we or our collaborators will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidate does not demonstrate any competitive advantages over existing drugs, new drugs or product candidate, we or our future collaborators may terminate the development or commercialization of our product candidate at any time.

We anticipate that our product candidate if successfully developed and approved, will compete directly or indirectly with existing drugs, some of which are generic. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on competing patented drugs.

We also face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biopharmaceutical companies, and for attracting investigators and clinical sites capable of conducting our preclinical studies and clinical trials. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are safer, more effective, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required regulatory approvals and commercialize their products before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that could delay the ability of competitors to market certain products. We cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our collaborators, will be able to compete successfully with our competitors' existing products or products under development.

We do not currently have any internal drug discovery capabilities, and therefore we are dependent on in-licensing or acquiring development programs from third parties in order to obtain additional product candidates.

If in the future we decide to further expand our pipeline, we will be dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our future product candidate in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. Such insurance coverage may not protect us against any or all the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss.

Our research activities, through third parties, involve the controlled use of certain hazardous materials and medical waste. Notwithstanding the regulations controlling the use and disposal of these materials, as well as the safety procedures we undertake, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge or exposure, we may be held liable for any resulting damages, which may exceed our financial resources and have an adverse effect on our business.

Our operations could be disrupted if our information systems fail, if we are unsuccessful in implementing necessary upgrades or if we are subject to cyber-attacks.

Our business depends on the efficient and uninterrupted operation of our computer and communications systems and networks, hardware and software systems and our other information technology. We collect and maintain information, which includes confidential and proprietary information as well as personal information regarding our collaborators and employees, in digital form. Data maintained in digital form is subject to risk of malware, computer viruses, computer hacking, acts of data theft, phishing, other cyber-attacks and employee error or malfeasance, which are increasing in frequency and sophistication. In July 2019, one of our employees was victim to a phishing incident, to which we have taken certain actions in response to and to which we do not anticipate significant disruption to our business or future prospects. Despite our efforts to monitor and safeguard our systems to prevent data compromise, the possibility of data compromise cannot be eliminated entirely, and risks associated with intrusion, tampering, and theft remain. In addition, we may not have sufficient insurance coverage with respect to system failures or cyber-attacks. A failure of our systems, or an inability to successfully expand the capacity of these systems, or an inability to successfully integrate new technologies into our existing systems could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

Business disruptions could seriously harm future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party manufacturers, CROs and other contractors and consultants, could be subject to pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Any disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

The occurrence of regional epidemics or a global pandemic, have had and may continue to have an adverse effect on how we and our CROs, CMOs, and other contractors, consultants and third parties are operating our businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID-19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses of our CROs, CMOs, and other contractors, consultants and third parties. To the extent that the pandemic harms our business and results of operations, many of the other risks described in this Part I, Item 1A of this report may be heightened.

In addition, we rely on a third-party manufacturer to manufacture API for our product candidate. Any disruption in production or inability of our manufacturer to produce or ship adequate quantities to meet our needs, whether as a result of a natural disaster or other causes (such as the COVID-19 pandemic), could impair our ability to operate our business on a day-to-day basis and to continue our research and development of our product candidate. In addition, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or political unrest in areas in which we do business. Any recall of the manufacturing lots or similar action regarding our API used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidate and impair our competitive position.

Risks Relating to the Commercialization of our Product Candidate.

We may delay or terminate the development of our product candidates at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of our product candidate, we may delay, suspend or terminate the future development of our product candidates at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidates is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidates, or otherwise fail to establish marketing and sales capabilities, we may not be able to successfully commercialize our products.

We currently have no infrastructure to support the commercialization of our product candidates, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if our product candidates are successfully developed and ultimately approved for sale, our future profitability will depend largely on our ability to access or develop suitable marketing and sales capabilities. We anticipate that we will need to establish relationships with other companies, through license and collaborations agreements, to commercialize our product candidate in the U.S. and in other countries around the world. To the extent that we enter into these license and collaboration agreements, or marketing and sales arrangements with other companies to sell, promote or market our products in the U.S. or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, will depend largely on their efforts, which may not be successful. In the event we develop a sales force and marketing capabilities, this may result in us incurring significant costs before the time that we may generate any significant product revenues. We may not be able to attract and retain qualified third parties or marketing or sales personnel or be able to establish marketing capabilities or an effective sales force.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those we develop through collaborations, our revenues and potential for profitability will be harmed.

In the U.S. and most foreign markets, our product revenues, and therefore the inherent value of our product candidate, will depend largely upon the reimbursement rates established by third-party payers for such product candidate or products. Such third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. These third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products, services and pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs or pharmaceutical products. Further, the comparative effectiveness of new compounds over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by these payers to establish reimbursement rates. We may also need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. We cannot assure you that any products we successfully develop will be reimbursed in part, or at all, by any third-party payers in any countries.

Domestic and foreign governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical drugs. In some foreign markets, governmental agencies control prescription drugs' pricing and profitability. In the U.S. significant changes in federal health care policy have been recently approved and will mostly likely result in reduced reimbursement rates in the future. We expect that there will continue to be federal and state proposals to implement more governmental control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products domestically. Cost control initiatives could decrease the price that we receive for our product candidate that may be approved for sale in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidate is approved for sale, which could further limit or eliminate reimbursement rates for our product candidate.

If any product candidate that we develop independently or through collaborations is approved but does not gain meaningful acceptance in its intended market, we are not likely to generate significant revenues or become profitable.

Even if our product candidate is successfully developed and we or a collaborator obtain the requisite regulatory approvals to commercialize it in the future, it may not gain market acceptance or utilization among physicians, patients or third-party payers. The degree of market acceptance that our product candidate may achieve will depend on several factors, including:

- the therapeutic efficacy or perceived benefit of the product relative to existing therapies, if they exist;
- the timing of market approval and existing market for competitive drugs;
- the level of reimbursement provided by payers to cover the cost of the product to patients;
- the net cost of the product to the user or payer;
- the convenience and ease of administration of our product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, prevalence and severity of negative side effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA.

There can be no assurance that physicians will choose to prescribe or administer our product, if approved, to the intended patient population. If our product does not achieve meaningful market acceptance, or if the market for our product proves to be smaller than anticipated, we may not generate significant revenues or ever become profitable.

Even if we or a collaborator achieve market acceptance for our product, we may experience downward pricing pressure on the price of our product due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

Pressure from social activist groups and future government regulations, whose goal it is to reduce the cost of drugs, particularly in less developed nations, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our product in the future.

We may be unable to successfully develop a product candidate that is the subject of collaboration if our collaborator does not perform, terminates our agreement, or delays the development of our product candidate.

We expect to continue to enter into and rely on license and collaboration agreements or other business arrangements with third parties to further develop and/or commercialize our existing and future product candidates. Such collaborators or partners may not perform as agreed upon or anticipated, fail to comply with strict regulations, or elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement. For example, if an existing or future collaborator does not devote sufficient time and resources to our collaboration arrangement, we may not realize the full potential benefits of the arrangement, and our results of operations may be adversely affected.

A majority of the potential revenue from existing and future collaborations will likely consist of contingent payments, such as payments for achieving development or regulatory milestones and royalties payable on the sales of approved products. The milestone and royalty revenues that we may receive under these collaborations will depend primarily upon our collaborator's ability to successfully develop and commercialize our product candidate. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly involved in the development or commercialization of our product candidate and, accordingly, will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or other internal programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;
- do not have sufficient resources necessary to fully support the product candidates through clinical development, regulatory approval and commercialization;
- are unable to obtain the necessary regulatory approvals; or
- may re-evaluate the importance and their support for developing our product candidate pipeline due to a change in management, business operations or financial strategy.

In addition, a collaborator may decide to pursue the development of a competitive product candidate developed outside of our collaboration with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the collaborative arrangement, or other licensing agreement terms. If a collaboration partner fails to develop or effectively commercialize our product candidate for any of these reasons, we may not be able to replace them with another partner willing to develop and commercialize our product candidate under similar terms, if at all. Similarly, we may disagree with a collaborator as to which party owns newly or jointly developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the collaboration, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate.

Risks Related to Our Intellectual Property

If we are unable to adequately protect or expand our intellectual property related to our future product candidates, our business prospects could be harmed.

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights. Therefore, any issued patents that we own or otherwise have intellectual property rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate. The degree of future protection for our proprietary intellectual property rights is uncertain because issued patents and other legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors:

- we or our licensors may not have been the first to discover the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;
- our or our licensors' pending patent applications may not result in issued patents;
- our or our licensors' issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and
- third parties may develop intellectual property around our or our licensors' patent claims to design competitive intellectual property and ultimately product candidates that fall outside the scope of our or our licensors' patents.

Because of the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before our product candidate can be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following approval and commercialization. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of life-saving drugs. Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property.

We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies we own or have licensed, or otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide competitive advantages to us. We cannot assure you as to the degree of protection that will be afforded by any of our issued or pending patents, or those licensed by us.

If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate". The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, United States Patent and Trademark Office, or USPTO, interference proceedings and related legal and administrative proceedings, both in the U.S. and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the U.S. are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to our product candidate may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding in the USPT office, or similar proceedings in other countries to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPTO or a foreign patent office may grant patent rights to our product candidate or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidate, or be prevented from developing, manufacturing and commercializing our product candidate at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successful product candidate or approved drug. If we or our collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts of our technical and management personnel will be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidate in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

We cannot be sure that any patents will be issued or that patents licensed to us will be issued from any of our patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the U.S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is obtainable, or prior to us filing patent applications on inventions we may make from time to time. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a third-party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We are pursuing various therapeutic opportunities through our pipeline. We may spend several years completing our development of any current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- inability to motivate key employees of any acquired businesses; and
- assumption of known and unknown liabilities.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Risks Related to Government Regulation

Even if our product candidates receive regulatory approval, it may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or impose ongoing requirements for potentially costly post-approval studies. Our product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval to commercialize it outside of the United States.

In the future, we may seek to commercialize our product candidates in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of our product candidate and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

We intend to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates.

We intend to enter into agreements with third-party contract research organizations, or CROs, under which we will delegate to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

We will need to increase the size of our organization.

As of December 31, 2024, we do not have any full time employees. In December 2023, our board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs, which included a reduction in force. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage development efforts effectively;
- manage our clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidate may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third- party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidate reimbursed by government or third-party payers. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly- approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures and other recent legislative initiatives could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care and to lower drug prices. In the United States, comprehensive health care reform legislation has been enacted by the Federal government and we expect that there will continue to be a number of federal and state proposals to implement government control over the pricing of prescription pharmaceuticals. In addition, increasing emphasis on reducing the cost of health care in the United States will continue to put pressure on the pricing and reimbursement of prescription pharmaceuticals. Moreover, in some foreign jurisdictions, pricing of prescription pharmaceuticals is already subject to government control. Additionally, other federal and state legislation impose obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the drug product provided to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding distribution of the drug product. Further, under this legislation, manufacturers will have drug product investigation, quarantine, disposition, notification and purchaser license verification responsibilities related to counterfeit, diverted, stolen and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Additionally, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was signed into law, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our drug products and potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures, or imports, specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021 the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form.

Further, prior to the United States Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequestration. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, increased the statute of limitations period for the government to recover overpayments to providers from 3 to 5 years.

Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, which ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, the Centers for Medicare & Medicaid Services, or CMS, issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement.

Also, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the United States Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2023 to January 1, 2026. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. No legislation or administrative actions have been finalized to implement these principles. In addition, Congress is considering drug pricing as part of other reform measures. It is unclear whether these or similar policy initiatives will be implemented in the future. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. In particular, it is possible that additional governmental action is taken in response to the COVID-19 pandemic. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain sustained profitability or commercialize our drugs, particularly since the majority of our current revenue is derived from federal healthcare programs, including Medicare and Medicaid.

We are currently unable to predict what additional legislation or regulation, if any, relating to the health care industry may be enacted in the future or what effect recently enacted federal legislation or any such additional legislation or regulation would have on our business. The pendency or approval of such proposals or reforms could result in a decrease in our stock price or limit our ability to raise capital or to enter into collaboration agreements for the further development and commercialization of our product.

Our clinical activities involve the handling of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our clinical activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, storage, handling and disposal of these hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or if we fail to comply with such laws and regulations, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations or impose sanctions, such as fines, and we could be held liable for any resulting damages or liabilities. We do not currently maintain hazardous materials insurance coverage.

Risks Related to Our Common Stock

Our common stock may be delisted if we fail to comply with continued listing standards.

If we fail to meet any of the continued listing standards of The Nasdaq Capital Market, our common stock could be delisted from The Nasdaq Capital Market. These continued listing standards include specifically enumerated criteria, such as:

- a $1.00 minimum closing bid price;
- stockholders' equity of $2.5 million;
- 500,000 shares of publicly-held common stock with a market value of at least $1 million;
- 300 round-lot stockholders; and
- compliance with Nasdaq's corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq's discretionary authority.

If we fail to comply with Nasdaq's continued listing standards, we may be delisted and our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board, or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Finally, delisting of our common stock could result in our common stock becoming a "penny stock" under the Exchange Act.

On September 3, 2024, we received written notice from Nasdaq indicating that the bid price for our Common Stock for the last 30 consecutive business days, had closed below the minimum $1.00 per share and, as a result, we were not in compliance with the $1.00 minimum bid price requirement for the continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until March 3, 2025, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Common Stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days during this 180 day period. If we are not in compliance by March 3, 2025, we may qualify for a second 180 calendar day compliance period. On March 5, 2025, Nasdaq informed us that we qualified for a second 180 calendar day compliance period until September 1, 2025. If we fail to regain compliance during the second compliance period, then Nasdaq will notify us of its determination to delist our Common Stock, at which point we would have an option to appeal the delisting determination to a Nasdaq hearings panel.

On November 20, 2024, we received written notice from Nasdaq indicating that since our Form 10-Q for the period ended September 30, 2024 reported a stockholders' deficit of ($406,685) and we did not meet the alternatives of minimum of $35 million market value of listed securities or net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years (the "Listing Rule"), we no longer complied with the Listing Rule. Under the Listing Rule, we have 45 days to submit a plan to regain compliance. On January 3, 2025, we submitted a plan to regain compliance. On March 5, 2025, Nasdaq informed us that we comply with the Listing Rule for stockholder's equity. However, if we fail to evidence compliance upon filing our next periodic report for the period ending March 31, 2025, we may be subject to delisting, which may be appealed to a hearings panel.

On March 18, 2025, we received written notice from Nasdaq indicating that the bid price for our common stock, for the last 10 consecutive business days, had closed below $0.10 per share and, as a result, we are subject to the provisions contemplated under Listing Rule 5810(c)(3)(A)(iii) (the "Low Priced Stocks Rule").

As such, unless we request an appeal of Nasdaq's determination to delist our common stock from The Nasdaq Capital Market by March 25, 2025 and pay Nasdaq a hearing fee of $20,000, our common stock will be delisted from The Nasdaq Capital Market at the opening of business on March 27, 2025. On March 25, 2025, we requested a hearing and we are awaiting a hearing date. No guarantee can be provided that we will be successful in the appeal and that our common stock will continue to be listed on The Nasdaq Capital Market.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessment of the effectiveness of our internal control over financial reporting. As of December 31, 2024, our management has determined that we had material weaknesses in our control environment and in the period end financial close and reporting process. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly.

The market price of our common stock may be volatile and adversely affected by several factors.

The market price of our common stock could fluctuate significantly in response to various factors and events, including:

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results;
- catastrophic weather and/or global disease outbreaks, such as the COVID-19 pandemic; and
- whether an active trading market in our common stock is maintained.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

The stock market in general has recently experienced relatively large price and volume fluctuations, particularly in response to the COVID-19 outbreak. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines.

U.S. federal income tax reform could adversely affect us.

On December 22, 2017, the "Tax Cuts and Jobs Act" (TCJA) was signed into law that significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. The tax reform has not caused a material impact to our projection of minimal cash taxes or to our net operating losses as of December 31, 2024, the date of these consolidated financial statements. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This Annual Report on Form 10-K does not discuss any such tax legislation or the manner in which it might affect purchasers of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Certain provisions in our certificate of incorporation and by-laws, and of Delaware law, may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

Our certificate of incorporation, by-laws and Delaware law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirers to negotiate with our board of directors rather than to attempt a hostile takeover. These provisions include, among others:

- the inability of our stockholders to call a special meeting;
- rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings;
- the right of our board to issue preferred stock without stockholder approval;
- the ability of our directors, and not stockholders, to fill vacancies on our board of directors.

Delaware law also imposes some restrictions on mergers and other business combinations between us and any holder of 15% or more of our outstanding common stock.

We believe these provisions will protect our stockholders from coercive or otherwise unfair takeover tactics by requiring potential acquirers to negotiate with our board of directors and by providing our board of directors with more time to assess any acquisition proposal. These provisions are not intended to make our company immune from takeovers. However, these provisions will apply even if the offer may be considered beneficial by some stockholders and could delay or prevent an acquisition that our board of directors determines is not in the best interests of our company and our stockholders. These provisions may also prevent or discourage attempts to remove and replace incumbent directors.

Future sales and issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plan could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of rencofilstat. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We presently do not intend to pay cash dividends on our common stock.

We expect that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk management and strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards.

Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with an IT consultant who reports to our Interim CEO/Chief Financial Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with IT and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants, or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our Interim Chief Executive/Chief Financial Officer is primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Interim Chief Executive/Chief Financial Officer oversees our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above. The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our Interim Chief Executive/Chief Financial Officer and IT consultant provide periodic briefings to the audit committee regarding our company’s cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 55 Madison Ave, Suite 400- PMB #462, Morristown, New Jersey, 07960.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become a party to various legal actions and complaints arising in the ordinary course of business. In addition to commitments and obligations in the ordinary course of business, we are subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. It is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the Nasdaq Capital Market under the ticker symbol "HEPA".

Holders of Record

As of April 8, 2025, there were 659 holders of record of our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Equity Compensation Plan Information

The following table summarizes information about our equity compensation plans as of December 31, 2024.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity Compensation Plans Approved by Stockholders	7,813	$ 382	1,460

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are a biopharmaceutical company headquartered in Morristown, New Jersey, that was previously focused on the development of drug therapy for treatment of chronic liver diseases. Our cyclophilin inhibitor, rencofilstat (formerly CRV431), was being developed to offer benefits to address multiple complex pathologies related to the progression of liver disease.

We were 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 reinforced rencofilstat's direct antifibrotic mode of action and increase our confidence level that we anticipated observing fibrosis reductions in our 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 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.

In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs. We incurred a one-time restructuring charge of approximately $0.7 million in the fourth quarter of 2023. Additionally, we initiated a process to explore a range of strategic and financing alternatives focused on maximizing stockholder value within the current financial environment and NASH drug development landscape.

On April 19, 2024, we announced that we have begun wind-down activities in our ASCEND- NASH clinical trial. We did not have access to sufficient funding to complete the study, as designed. The wind-down activities were implemented to halt further clinical activities other than those which would allow for an orderly and patient safety manner that would meet the minimum FDA requirements for safely closing a clinical trial. All clinical trial activities were completed and the trial was closed in August 2024.

On July 19, 2024, we along with Pharma Two B Ltd., a company organized under the laws of the State of Israel ("Parent"), and Pearl Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Parent ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other things, on the terms and subject to the conditions set forth therein, Merger Sub will merge with and into us (the "Merger"), pursuant to which we would survive the Merger as an indirect wholly owned subsidiary of Parent.

Concurrently with the Merger, on July 19, 2024, we entered into a Securities Purchase Agreement (the "SPA") with certain purchasers pursuant to which we sold an aggregate of $2.9 million in principal amount of our Original Issue Discount Senior Unsecured Nonconvertible Notes (the "Notes"). The Notes are due on the earlier of: (i) December 31, 2024, (ii) the date of the closing of the Merger, (iii) the date that the Merger is terminated pursuant to the terms of the Merger Agreement, or (iv) such earlier date as the Notes are required or permitted to be repaid as provided in the Note, as may be extended at the option of the holder of the Note as described in the Note.

On December 10, 2024, Parent informed us that Nasdaq would not exclude our historical losses from its burn rate calculation and as a result on December 10, 2024, we and Pharma Two B and Pearl entered into an agreement to terminate the Merger Agreement (the "Termination Agreement"). Pursuant to the Termination Agreement, the Merger Agreement was terminated.

On January 23, 2025, we consummated a best efforts registered offering for 73,222 shares of common stock, Pre-Funded Warrants to purchase 480,624 shares of common stock, Series A Warrants to purchase 553,846 shares of common stock and Series B Warrant to purchase 553,846 shares of common stock for gross proceeds of $9,000,000. A portion of the net proceeds was used to repay the Notes along with accrued interest.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2024, we have an accumulated deficit of $237.8 million and we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities and for ongoing administrative expenses, and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

RECENT ACCOUNTING PRONOUNCEMENTS

For detailed information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 3, "Recent Accounting Pronouncements" in the accompanying Notes to Consolidated Financial Statements.

RESULTS OF OPERATIONS

Comparison of the Years ended December 31, 2024 and 2023:

	Year Ended December 31,		
	2024	2023	Change
Revenues	$ —		$ —
Costs and Expenses:			
Research and development	11,847,348	35,639,656	(23,792,308)
General and administrative	7,499,230	9,618,298	(2,119,068)
Asset impairment loss	—	3,190,000	(3,190,000)
Loss from operations	(19,346,578)	(48,447,954)	(29,101,376)
Other income (expense):			
Interest expense	(1,247,313)	(9,465)	(1,237,848)
Write-off related party note receivable	(600,000)	—	600,000
Change in fair value of contingent consideration and derivative financial instruments	7,599,263	(877,645)	8,476,908
Inducement expense	(2,567,044)	—	(2,567,044)
Loss before income taxes	(16,161,672)	(49,335,064)	(23,829,360)
Income tax benefit	2,969,252	409,022	2,560,230
Net loss	$ (13,192,420)	$ (48,926,042)	$ (21,269,130)

We had no revenues during the years ended December 31, 2024 and 2023, 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 years ended December 31, 2024 and 2023 were $11.8 million and $35.6 million, respectively. The decrease of $23.8 million was primarily due to a $18.5 million decrease in clinical trial costs and drug development primarily for our phase 2b study, a $2.9 million decrease in employee compensation costs due to reduced headcounts and a $1.0 million decrease in stock-based compensation costs. Also, there is a decrease of $0.7 million due to the absence of the one-time restructuring charge related to the strategic restructuring plan implemented in Q4 2023.

General and administrative expenses for the years ended December 31, 2024 and 2023 amounted to $7.5 million and $9.6 million, respectively. The decrease of $2.1 million is primarily due to a $1.4 million decrease in employee compensation costs, and a $0.7 million decrease in stock-based compensation costs.

For the year ended December 31, 2023, we incurred an impairment to our in-process research and development asset of $3.2 million. Our in-process research and development asset was impaired in 2023 due to the slowdown of our Phase2b study, the delayed timeline of our clinical trials and our removal of Hepatitis B as a second indication to focus solely on Rencofilstat.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations through December 31, 2024 primarily through the issuance of convertible preferred stock, warrants, the issuance and sale of shares of our common stock, and subsequent issuances of shares of our common stock through at-the market offerings.

On January 23, 2025, we consummated a best efforts registered offering for 73,222 shares of common stock, Pre-Funded Warrants to purchase 480,624 shares of common stock, Series A Warrants to purchase 553,846 shares of common stock and Series B Warrant to purchase 553,846 shares of common stock for gross proceeds of $9,000,000. A portion of the net proceeds was used to repay the Notes along with accrued interest.

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 December 31, 2024, we had an accumulated deficit of $237.8 million. We expect to continue to incur significant losses for the foreseeable future.

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 additional financing and a failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our 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 candidates derived from these technologies. We believe that we will continue to expend substantial resources for the foreseeable future in connection with our anticipated acquisition of an asset in connection with our strategic alternatives strategy. In addition, other unanticipated costs may arise.

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 consolidated financial statements as of December 31, 2024 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 to fund operations. 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 (i) acquire new product candidates; or (ii) 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:

	Year Ended December 31,	
	2024	**2023**
Net cash provided by (used in):		
Operating activities	$ (18,216,303)	$ (40,888,878)
Investing activities	(600,000)	(14,304)
Financing activities	4,349,707	4,494,950

As of December 31, 2024, we had a working capital deficit of $1.5 million compared to working capital of $12.2 million as of December 31, 2023. The decrease of $13.7 million in working capital is primarily related to cash spend related to our wind-down activities and operating costs, offset by $3.0 million in proceeds received from sales of our state NOLs.

Operating Activities:

As of December 31, 2024, we had $0.4 million in cash. Net cash used in operating activities was $18.2 million for the year ended December 31, 2024 consisting primarily of our net loss of $13.2 million, adjusted for an increase in non-cash charges of $5.3 million, primarily for stock-based compensation, amortization of debt discount, write-off of the loan to Pharma Two B and warrant related inducement expense, partially offset by $7.6 million in change in fair value of contingent consideration and the change in fair value of derivative warrants. Changes in working capital accounts had a negative impact of $2.7 million on cash primarily due to an increase in accounts payable, accrued expenses and prepaid expenses.

As of December 31, 2023, we had $14.8 million in cash. Net cash used in operating activities was $40.9 million for the year ended December 31, 2023 consisting primarily of our net loss of $48.9 million, adjusted for an increase in non-cash charges of $4.9 million primarily for stock-based compensation, impairment of our in-process research and development asset, and the change in fair value of derivative warrants. Changes in working capital accounts had a positive impact of $3.0 million on cash primarily due to a decrease in prepaid expenses.

Investing Activities:

Net cash used in investing activities during the year ended December 31, 2024 and 2023 was $600,000 and de minimis, respectively. The $600,000 used in investing activity during the year ended December 31, 2024 related to the loan to Pharma Two B.

Financing Activities:

Net cash provided by financing activities was $4.4 million and $4.5 million for the year ended December 31, 2024 and 2023, respectively, primarily due to the exercise of warrants (induced), and the equity and debt issuance under a Securities Purchase Agreement, in 2024 .and the issuance of common stock and warrants in 2023.

CRITICAL ACCOUNTING ESTIMATES

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles ("GAAP") in the United States of America. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the assumptions and estimates associated with fair value of financial instruments, income taxes, contingencies, research and development, in-process research and development, and share-based payments have the greatest potential impact on our consolidated financial statements. We evaluate these estimates on an ongoing basis. Actual results could differ from those estimates under different assumptions or conditions, and any differences could be material. For further information on all of our significant accounting policies, see Note 3 of the Notes to the Consolidated Financial Statements under Item 8 of this Annual Report on Form 10-K.

Fair Value of Financial Instruments

Financial instruments consist of cash, accounts payable, contingent consideration and derivative financial instruments. 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 and derivatives. We record contingent consideration and our derivative financial instruments at fair value at the end of each reporting period.

Contingent consideration was related to the acquisition of Ciclofilin and recorded on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash, upon the achievement of certain milestones and in 2016 was estimated based on a probability-weighted discounted cash flow model. For the year ended December 31, 2023, significant assumptions used to calculate the fair value of the contingent consideration included the discount rate, projected milestone achievement dates, and the probability of success. For the year ended December 31, 2024, the fair value of the contingent consideration is zero as management concluded the milestones will not be achieved.

Derivative financial instruments are related to the issuance of warrants accounted for as a liability. The Black-Scholes model, which uses significant assumptions including risk-free interest rate, volatility, stock price and expected term to calculate fair value.

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. Income tax expense for the years ended December 31, 2024 and 2023 are related to our foreign operations. For the year ended December 31, 2024, we received $3.0 million in proceeds from sales of our state NOLs related to prior years under the State of New Jersey's Technology Business Tax Certificate Transfer Program.

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 December 31, 2024 and 2023, we had prepaid research and development costs of $0 million and $2.5 million, respectively.

In-Process Research and Development

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

The annual, or interim if (events or changes in circumstances indicate that it is more likely than not that the asset is impaired), 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 during the three months ended December 31, 2023, our IPR&D asset was impaired due to the slowdown of our Phase 2b clinical trial delaying the potential approval of Rencofilstat, which also resulted in lower revenue and profit projections. We also discarded Hepatitis B as a second indication due to costs and to focus solely on NASH. The full $3.2 million IPR&D asset was impaired at December 31, 2023.

Share-based payments

ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"), requires companies to measure the cost of employee and non-employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Generally, we issue stock options with only service-based vesting conditions and record the expense for awards using the straight-line method (see Note 9 to the consolidated financial statements). We account for awards granted to employees that are in excess of what is available to grant as a liability and is recorded at fair value each reporting period in the consolidated financial statements.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The estimated expected stock volatility is based on the historical volatility of our common stock. The expected term of stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2024.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (Grassi & Co., CPAs, P.C.; Jericho, New York; PCAOB ID#606)	50
Consolidated Balance Sheets	51
Consolidated Statements of Operations	52
Consolidated Statements of Comprehensive Loss	53
Consolidated Statements of Changes in Stockholders' Equity	54
Consolidated Statements of Cash Flows	55
Notes to the Consolidated Financial Statements	56

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Hepion Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Hepion Pharmaceuticals, Inc. (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company's significant operating losses and negative cash flows from operations since inception raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Warrant Inducement Transaction – Refer to Note 4 to the financial statements

Critical Audit Matter Description

On February 16, 2024, the Company entered into an agreement with a current warrant holder to exercise the outstanding Series B Warrants (the "Inducement"). Pursuant to the terms of the Inducement, the holder agreed to exercise the Series B Warrant in full and purchase a total of 980,393 shares of common stock at a reduced price of $2.10 per share, generating total gross cash proceeds of $2,058,825.

In connection with the Inducement, the Company agreed to amend the terms of the October 2023 Series A common stock purchase warrant held by a purchaser in the offering to reduce the exercise price thereof to $1.91 per share and to extend the expiration date to February 2029. All of the other terms of the October 2023 Series A common stock purchase warrant will remain unchanged. Additionally, the Company issued to the investor unregistered Series B-1 Warrants to purchase up to an aggregate of 735,295 shares of common stock and Series B-2 Warrants to purchase up to an aggregate of 735,295 shares of common stock. The Series B-1 and Series B-2 Warrants will have an exercise price of $1.91 per share, will be exercisable immediately following the date of issuance and will expire in 5 years and 1.5 years, respectively.

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. This method of valuation involves using inputs such as the fair value of our common stock, historical volatility, the contractual term of the warrants, risk-free interest rates and dividend yields.

In connection with the Inducement, the Company recognized total inducement expense of $2,567,044 during the year ended December 31, 2024.

The principal consideration for our determination that the evaluation of the inducement transaction was a critical audit matter is the high degree of subjectivity and judgment by management in determining (1) the accounting conclusions related to the treatment of new warrants issued and the prior warrants modified in the context of the inducement transaction and (2) the fair values of the warrants given the sensitivity of the underlying significant assumptions specifically the expected volatility. Auditing these elements involved especially challenging and subjective auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skill or knowledge needed.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures performed to address this critical audit matter included the following, among others:

- We evaluated the appropriateness of management's accounting conclusions related to the treatment of new warrants issued and the prior warrants modified in the context of the inducement transaction.
- We involved our fair value specialist who assisted in evaluating the reasonableness of management's valuation methodology and significant assumptions in the valuation model, including the expected volatility.
- We evaluated the competency and objectivity of management's expert engaged to perform the valuation.

/s/ GRASSI & CO., CPAs, P.C.

We have served as the Company's auditor since 2023.
Jericho, New York
April 8, 2025

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash	$ 406,408	$ 14,785,880
Prepaid expenses	1,207,329	2,701,960
Total current assets	1,613,737	17,487,840
Property and equipment, net	—	29,487
Right-of-use assets	—	212,878
Other assets	—	364,192
Total assets	$ 1,613,737	$ 18,094,397
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 220,202	$ 2,348,829
Accrued expenses	23,684	2,439,351
Operating lease liabilities, current	—	115,916
Notes payable, current	2,900,000	—
Short-term portion of contingent consideration	—	386,000
Total current liabilities	3,143,886	5,290,096
Contingent consideration, non-current	—	1,634,000
Operating lease liabilities, non-current	—	93,104
Derivative financial instruments—warrants	333,189	3,796,390
Total liabilities	3,477,075	10,813,590
Commitments and contingencies (see Note 12)		
Stockholders' equity:		
Series A convertible preferred stock, stated value $10 per share, 85,581 shares issued and outstanding at December 31, 2024 and 2023, respectively.	855,808	855,808
Series C convertible preferred stock, stated value $1,000 per share, 1,688 shares issued and outstanding at December 31, 2024 and 2023.	839,320	839,320
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 139,168 and 96,375 shares issued and outstanding at December 31, 2024 and 2023, respectively.	14	10
Additional paid-in capital	234,252,981	230,291,834
Accumulated other comprehensive income (loss)	8,345	(78,779)
Accumulated deficit	(237,819,806)	(224,627,386)
Total stockholders' equity	(1,863,338)	7,280,807
Total liabilities and stockholders' equity	$ 1,613,737	$ 18,094,397

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

	Year Ended December 31,	
	2024	**2023**
Revenues	$ —	$ —
Costs and expenses:		
Research and development	11,847,348	35,639,656
General and administrative	7,499,230	9,618,298
Asset impairment loss	—	3,190,000
Total operating expenses	19,346,578	48,447,954
Loss from operations	(19,346,578)	(48,447,954)
Other income (expense):		
Interest expense, net	(1,247,313)	(9,465)
Write-off related party note receivable	(600,000)	—
Change in fair value of contingent consideration and derivative financial instruments	7,599,263	(877,645)
Inducement expense	(2,567,044)	—
Loss before income taxes	(16,161,672)	(49,335,064)
Income tax benefit (expense)	2,969,252	409,022
Net loss	$ (13,192,420)	$ (48,926,042)
Weighted average common shares outstanding:		
Basic and diluted	122,894	79,416
Net loss per common share: (see Note 11)		
Basic and diluted	$ (107.35)	$ (616.07)

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Comprehensive Loss

	Year Ended December 31,	
	2024	**2023**
Net loss	$ (13,192,420)	$ (48,926,042)
Other comprehensive income (loss):		
Foreign currency translation	87,124	11,389
Total other comprehensive income (loss)	87,124	11,389
Comprehensive loss	$ (13,105,296)	$ (48,914,653)

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity

	Preferred Stock Series A		Preferred Stock Series C		Common Stock		Additional Paid in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance at December 31, 2022	85,581	855,808	1,801	840,320	76,230	8	223,951,313	(90,168)	(175,701,344)	49,855,937
Net loss	—	—	—	—	—	—	—	—	(48,926,042)	(48,926,042)
Other comprehensive loss	—	—	—	—	—	—	—	11,389	—	11,389
Stock-based compensation expense	—	—	—	—	—	—	1,340,311	—	—	1,340,311
Stock-based liability awards converted to equity	—	—	—	—	—	—	2,983,006	—	—	2,983,006
Issuance of common stock in connection with stock split	—	—	—	—	536	—	—	—	—	—
Conversion of preferred stock to common	—	—	(113)	(1,000)	1	—	1,000	—	—	—
Issuance of common stock, net	—	—	—	—	8,000	1	39	—	—	40
Warrant exercises	—	—	—	—	11,608	1	2,016,165	—	—	2,016,166
Balance at December 31, 2023	85,581	$855,808	1,688	$839,320	96,375	$ 10	$230,291,834	$ (78,779)	$(224,627,386)	$ 7,280,807
Net loss	—	—	—	—	—	—	—	—	(13,192,420)	(13,192,420)
Other comprehensive income/loss	—	—	—	—	—	—	—	87,124	—	87,124
Stock-based compensation expense	—	—	—	—	—	—	791,645	—	—	791,645
Warrant exercises, net	—	—	—	—	13,088	1	2,300,688	—	—	2,300,689
Issuance of shares in abeyance	—	—	—	—	6,520	1—	(1)	—	—	—
Issuance of common stock	—	—	—	—	23,185	2	868,815	—	—	868,817
Balance at December 31, 2024	85,581	$855,808	1,688	$839,320	139,168	$ 14	$234,252,981	$ 8,345	$(237,819,806)	$ (1,863,338)

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (13,192,420)	$ (48,926,042)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	791,645	1,340,311
Depreciation	30,758	67,131
Amortization of debt discount	1,268,817	—
Inducement expense	2,567,044	—
Write-off related party note receivable	600,000	—
Change in fair value of derivative instrument-warrants	(5,579,263)	1,317,646
Change in fair value of contingent consideration	(2,020,000)	(440,000)
Change in deferred tax liability	—	(409,022)
Impairment of in-process research and development	—	3,190,000
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	(4,545,565)	302,919
Right of use asset	212,878	89,825
Operating lease liability	(209,020)	(96,712)
Prepaid expenses and other assets	1,858,823	2,675,066
Net cash used in operating activities	(18,216,303)	(40,888,878)
Cash flows from investing activities:		
Purchase of property and equipment	—	(14,304)
Investment in related party receivable	(600,000)	—
Net cash used in investing activities	(600,000)	(14,304)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants, net of issuance costs	—	4,494,950
Proceeds from exercise of warrants, net	1,849,707	—
Proceeds from equity and debt issuance under SPA, net of discount	2,500,000	—
Net cash (used in) provided by financing activities	4,349,707	4,494,950
Effect of exchange rates on cash	87,124	5,024
Net decrease in cash	(14,379,472)	(36,403,208)
Cash at beginning of period	14,785,880	51,189,088
Cash at end of period	$ 406,408	$ 14,785,880
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ —
Supplementary disclosure of non-cash financing activities:		
Conversion of Series C convertible preferred stock	$ —	$ 1,000
Inducement expense for issuance of Series B-1 and B-2 warrants	2,821,399	—
Stock-based liability awards reversed to additional paid-in capital	—	2,983,006
Operating lease asset additions	—	252,118

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

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

1. Business Overview

Hepion Pharmaceuticals, Inc. (we, our, or us) is a biopharmaceutical company headquartered in Morristown, New Jersey, that was previously focused on the development of drug therapy for treatment of chronic liver diseases. Our cyclophilin inhibitor, rencofilstat (formerly CRV431), was being developed to offer benefits to address multiple complex pathologies related to the progression of liver disease.

We were 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 reinforced rencofilstat's direct antifibrotic mode of action and increase our confidence level that we anticipated observing fibrosis reductions in our 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 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.

In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs. We incurred a one-time restructuring charge of approximately $0.7 million in the fourth quarter of 2023. Additionally, we initiated a process to explore a range of strategic and financing alternatives focused on maximizing stockholder value within the current financial environment and NASH drug development landscape.

On April 19, 2024, we announced that we have begun wind-down activities in our ASCEND- NASH clinical trial. We did not have access to sufficient funding to complete the study, as designed. The wind-down activities were implemented to halt further clinical activities other than those which would allow for an orderly and patient safety manner that would meet the minimum FDA requirements for safely closing a clinical trial. All clinical trial activities were completed and the trial was closed in August 2024.

On July 19, 2024, we along with Pharma Two B Ltd., a company organized under the laws of the State of Israel ("Parent"), and Pearl Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Parent ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other things, on the terms and subject to the conditions set forth therein, Merger Sub will merge with and into us (the "Merger"), pursuant to which we would survive the Merger as an indirect wholly owned subsidiary of Parent.

Concurrently with the Merger, on July 19, 2024, we entered into a Securities Purchase Agreement (the "SPA") with certain purchasers pursuant to which we sold an aggregate of $2.9 million in principal amount of our Original Issue Discount Senior Unsecured Nonconvertible Notes (the "Notes"). The Notes are due on the earlier of: (i) December 31, 2024, (ii) the date of the closing of the Merger, (iii) the date that the Merger is terminated pursuant to the terms of the Merger Agreement, or (iv) such earlier date as the Notes are required or permitted to be repaid as provided in the Note, as may be extended at the option of the holder of the Note as described in the Note.

On December 10, 2024, Parent informed us that Nasdaq would not exclude our historical losses from its burn rate calculation and as a result on December 10, 2024, we and Pharma Two B and Pearl entered into an agreement to terminate the Merger Agreement (the "Termination Agreement"). Pursuant to the Termination Agreement, the Merger Agreement was terminated.

2. Basis of Presentation

Basis of presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The accompanying 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 consolidated financial statements on Form 10-K 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.

On March 17, 2025, we effected a reverse stock split of our voting common stock at a ratio of one-for-fifty (the "Reverse Stock Split"). When the Reverse Stock Split became effective, every fifty (50) shares of our issued and outstanding Common Stock immediately prior to the effective time was automatically reclassified into one (1) share of Common Stock, without any change in the par value per share. The Reverse Stock Split reduced the number of shares of Common Stock issuable upon the exercise or vesting of its outstanding stock options and warrants in proportion to the ratio of the Reverse Stock Split and causes a proportionate increase in the conversion and exercise prices of such stock options and warrants. In addition, the number of shares reserved for issuance under our equity compensation plans immediately prior to the effective time was reduced proportionately. The Reverse Stock Split did not change the total number of authorized shares of Common Stock or preferred stock.

Going Concern

As of December 31, 2024, we had $0.4 million in cash, an accumulated deficit of $237.8 million, and working capital deficit of $1.5 million. For the year ended December 31, 2024, cash used in operating activities was $18.2 million and we had a net loss of $13.2 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 the issuance of convertible preferred stock, warrants, the issuance and sale of shares of our common stock, and subsequent issuances of shares of our common stock through at-the market offerings. Our ability to continue operations after our current cash resources are exhausted depends on future events outside of our control, including our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. If adequate additional funds are not available when required, management may need to curtail planned operations to conserve cash until sufficient additional capital can be raised. There can be no assurances that such a plan would be successful.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

These 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 consolidated financial statements without additional capital becoming available to us. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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) seek collaborators for our product candidates on terms that are less favorable than might otherwise be available; or (ii) relinquish or otherwise dispose of rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize on unfavorable terms.

On January 23, 2025, we consummated a "best efforts" public offering of 553,846 shares of common stock (or pre-funded warrants in lieu thereof) with each share of common stock (or pre-funded warrant) accompanied by (i) a series A common warrant to purchase one (1) common share at an exercise price of $20.00 per share and (ii) a series B common warrant to purchase one (1) common share at an exercise price of $20.00 per share. The gross proceeds of the public offering were approximately $9.0 million before deducting placement agent fees and offering expenses and were used to repay certain indebtedness and for general corporate purposes, including working capital, operating expenses and capital expenditures. Refer to Note 14.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of 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 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 most significant estimates include fair value of financial instruments, share-based compensation and contingent consideration.

Cash

As of December 31, 2024 and 2023, the amount of cash was $0.4 million and $14.8 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.
- Level 3—Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

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, contingent consideration and derivative financial instruments. Cash and accounts payable are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature. Contingent consideration and derivative financial instruments are 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 and derivative financial instruments.

Property, equipment and depreciation

As of December 31, 2024 and 2023, we had $0 and $29,487, respectively, of property and equipment, consisting primarily of lab equipment, computer equipment, and furniture and fixtures. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the depreciable assets are 3 to 7 years. Expenditures for repairs and maintenance are charged to operations as incurred. We will periodically evaluate whether current events or circumstances indicate that the carrying value of our depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at December 31, 2024 or December 31, 2023.

In-Process Research & Development

In accordance with ASC Topic 350, *Intangibles — Goodwill and Other* ("ASC Topic 350"), goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually, in our fourth quarter, and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

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

The annual, or interim if (events or changes in circumstances indicate that it is more likely than not that the asset is impaired), 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 performed a quantitative assessment of IPR&D for the year ended December 31, 2023 and concluded that our IPR&D asset was impaired due to the slowdown of our Phase 2b clinical trial delaying the potential approval of Rencofilstat, which also resulted in lower revenue and profit projections. We also discarded Hepatitis B as a second indication due to costs and to focus solely on NASH. The full $3.2 million IPR&D asset was impaired at December 31, 2023.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

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 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 believe that additional ownership changes have likely occurred since that time as a result of equity offerings and other changes in the ownership of our stock. 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 December 31, 2024 and 2023, we had prepaid research and development costs of $0 million and $2.5 million, respectively.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Share-based payments

ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"), requires companies to measure the cost of employee and non-employee services received in exchange for the award of equity instruments based on the estimated fair value of the award at the date of grant. The expense is to be recognized over the period during which an employee is required to provide services in exchange for the award. Generally, we issue stock options with only service-based vesting conditions and record the expense for awards using the straight-line method (see Note 10). We account for awards granted to employees that are in excess of what is available to grant as a liability recorded at fair value each reporting period in the consolidated financial statements. ASC 718 allows for the election of forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. For the years ended December 31, 2024 and 2023, we determined that 3% is our forfeiture rate based on historical experience. We will continue to analyze the forfeiture rate on at least an annual basis or when there are any identified triggers that would justify immediate review.

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 gain was $0.1 million and de minimis for the years ended December 31, 2024 and 2023, 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 gains was $0.1 million and $0.1 million for the years ended December 31, 2024 and 2023, 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 (CODM), 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. The Company reports its segment information to reflect the manner in which the CODM reviews and assesses performance. The Company's Interim Chief Executive Officer has the responsibility as the CODM and reviews and assesses the performance of the Company as a whole.

The primary financial measures used by the CODM to evaluate performance and allocate resources is consolidated net loss. The CODM uses consolidated net loss to evaluate the performance of the Company's ongoing operations and as part of the Company's internal planning and forecasting processes.

Net loss per share

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

Recent Accounting Pronouncements

On January 1, 2024, the Company adopted Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280).* The new guidance improves reportable segment disclosures primarily through enhanced disclosures about significant segment expenses and by requiring current annual disclosures to be provided in interim periods. The new guidance is to be applied retrospectively to all prior periods presented unless impracticable to do so. As the guidance requires only additional disclosure, there are no effects of this standard on the Company's financial position, results of operations or cash flows. This adoption did not have a material impact on the consolidated financial statements.

4. Stockholders' Equity

On July 19, 2024, Hepion Pharmaceuticals, Inc., a Delaware corporation (the "Company"), Pharma Two B Ltd., a company organized under the laws of the State of Israel ("Parent"), and Pearl Merger Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Parent ("Merger Sub"), entered into an Agreement and Plan of Merger to which, among other things, on the terms and subject to the conditions set forth therein, Merger Sub will merge with and into the Company (the "Merger"), with the Company surviving the Merger as an indirect wholly owned subsidiary of Parent. Merger Sub is a newly incorporated Delaware corporation and a wholly owned, direct subsidiary of P2B HoldCo, Inc., a Delaware corporation ("Holdco"). Holdco is a wholly owned, direct subsidiary of P2B Topco, Inc., a Delaware corporation ("Topco"). Topco is a wholly owned, direct subsidiary of Parent. Each of Merger Sub, Holdco and Topco were formed for purposes of consummating the transactions contemplated by the Merger Agreement and the other Transaction Agreements (as defined in the Merger Agreement).

Concurrently with the Merger, on July 19, 2024, the Company entered into a Securities Purchase Agreement (the "SPA") with certain purchasers pursuant to which the Company sold an aggregate of $2.9 million in principal amount of the Company's Original Issue Discount Senior Unsecured Nonconvertible Notes (the "Notes"). In addition, pursuant to the SPA, the Company issued to the purchasers an aggregate 23,185 shares of Common Stock (see Note 6).

The Merger was expected to be consummated in the fourth quarter of 2024, however, on December 11, 2024, the Company announced the termination of the Merger Agreement, as Pharma Two B informed the Company that Nasdaq will not exclude historical losses of the Company from its burn rate calculation.

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 December 31, 2024, there were 85,581 shares outstanding. During the years ended December 31, 2024 and 2023, 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 89 common stock warrants that expired in July 2023. As of December 31, 2024, there were 1,688 shares outstanding. During the year ended December 31, 2023, 113 shares of the Series C were converted into 1 shares of our common stock. There were no conversions for the year ended December 31, 2024. 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 $0.0092 per share (subject to adjustments upon the occurrence of certain dilutive events).

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

Common Stock and Warrant Offering

On September 28, 2023, we entered into a securities purchase agreement with an institutional investor for the purchase and sale of 8,000 shares of our common stock (or common stock equivalents in lieu thereof) at a purchase price of $255.00 per share and pre-funded warrants to purchase up to 11,608 shares at a offering price of $254.50 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 19,608 shares of common stock and Series B Warrants to purchase up to an aggregate of 19,608 shares of common stock. The Series A and Series B Warrants will have an exercise price of $242.50 per share, will be exercisable immediately following the date of issuance and will expire in 5 years and 1.5 years, respectively. The closing of the registered direct offering and the concurrent private placement was on October 3, 2023. We received gross proceeds of $5.0 million, before deducting the underwriting discount and other offering expenses of approximately $0.5 million that was recorded as general and administrative costs in our consolidated statement of operations. All of the pre-funded warrants were exercised in the fourth quarter of 2023.

We used the guidance in ASC 480, Distinguishing Liabilities from Equity, ("ASC 480"), ASC 815-40, Derivatives and Hedging ("ASC 815-40") and ASC 260, Earnings Per Shares ("ASC 260") to determine the accounting classification for the warrants.

Based on this evaluation, we determined that the Warrants are not indexed to our own stock and are precluded from being classified within equity. Therefore, the Warrants were classified as a liability on the balance sheet, initially recorded at fair value, and then subsequently will be carried at fair value with changes in fair value recognized in the income statement.

Upon the issuance of the warrants, the fair value of the warrants was determined to be approximately $8.9 million resulting in no residual to allocate to equity and, further, with the excess of the fair value over the proceeds received was recorded as a day one loss of $3.9 million that was recorded to "Change in fair value of contingent consideration and derivative financial instruments" in the consolidated statement of operations.

On February 16, 2024, the Company entered into an agreement with a current warrant holder to exercise the outstanding Series B Warrants (the "Series B Warrant Agreement"). Pursuant to the terms of the Series B Warrant Agreement, the holder agreed to exercise the Series B Warrant in full and purchase a total of 19,608 shares of common stock at a reduced price of $105.00 per share, generating total gross cash proceeds of $2,058,825.

The Company accounted for this transaction as a modification and settlement of the Series B Warrant liability. As such, the Company first recognized a gain of $286,007 as a result of the change in fair value of the Series B Warrant immediately prior to the modification. As the modified Series B Warrant was immediately exercisable, the post-modification fair value was determined to be the intrinsic value of the Series B Warrant at the date of the modification. Therefore, the change in fair value on the date of the modification prior to the modification compared to the fair value on the date of the modification after the modification, but prior to exercise was determined to be $601,224, which was recorded as an inducement charge, within other expenses in the Company's consolidated statement of operations. The Company then subsequently reclassified the liability into equity upon settlement.

As part of the transaction, the Company incurred equity issuance costs of $209,118 related to advisory and legal fees directly attributable to the issuance of the common stock from the Series B Warrant Agreement, which were recorded against additional paid-in-capital.

In connection with the offering, the Company agreed to amend, effective upon the closing of this offering, the terms of the October 2023 Series A common stock purchase warrant held by a purchaser in the offering to reduce the exercise price thereof to $95.50 per share and to extend the expiration date to February 2029. All of the other terms of the October 2023 Series A common stock purchase warrant will remain unchanged.

The Company accounted for this transaction as a modification of the Series A Warrant liability. As such the Company first recognized a gain of $669,466 as a result of the change in fair value of the Series A Warrant immediately prior to the modification. As a result of the modification, the change in fair value on the date of the modification prior to the modification compared to the fair value on the date of the modification after the modification, but prior to exercise was an fair value of $346,869, which was recorded as an inducement expense, due to the modification being a result of the Series B Warrant Agreement, and is recorded within the Company's consolidated statement of operations.

Additionally, as part of the Series B Warrant Agreement, we issued to the investor unregistered Series B-1 Warrants to purchase up to an aggregate of 14,706 shares of common stock and Series B-2 Warrants to purchase up to an aggregate of 14,706 shares of common stock, collectively the "New Warrant Shares". The Series B-1 and Series B-2 Warrants will have an exercise price of $95.50 per share, will be exercisable immediately following the date of issuance and will expire in 5 years and 1.5 years, respectively. The grant date value of the New Warrant Shares issued of $2,821,000 was recorded as inducement expense within other expenses in the Company's consolidated statement of operations.

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. This method of valuation involves using inputs such as the fair value of our common stock, historical volatility, the contractual term of the warrants, risk-free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 2 measurement (see Note 5). The following assumptions were used to measure the Series A and Series B Warrants at modification and to remeasure the liability as of December 31, 2024 and December 31, 2023 and to measure Series B-1 and B-2 at issuance and to remeasure the liability as of December 31, 2024.

	Series A Warrants	
	December 31, 2024	December 31, 2023
Stock price	$ 23.50	$ 162.00
Expected warrant term (years)	4.1 years	4.5 years
Risk-free interest rate	4.3%	3.9%
Expected volatility	90.1%	116.6%
Dividend yield	—	—

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

	Series B Warrants		
	Pre-Modification February 16, 2024	Post-Modification February 16, 2024	December 31, 2023
Stock price	$ 128.00	$ 128.00	$ 162.00
Expected warrant term (years)	1.1 years	n/a	1.5 years
Risk-free interest rate	4.9%	n/a	4.6%
Expected volatility	143.0%	n/a	122.1%
Dividend yield	—	—	—

	Series B-1 Warrants		Series B-2 Warrants	
	February 16, 2024	December 31, 2024	February 16, 2024	December 31, 2024
Stock price	$ 128.00	$ 23.50	$ 128.00	$ 23.50
Expected warrant term (years)	5.0 years	4.1 years	1.5 years	0.6 year
Risk-free interest rate	4.3%	4.3%	4.8%	4.2%
Expected volatility	116.0%	90.1%	130.0%	92.6%
Dividend yield	—	—	—	—

The following table sets forth the components of changes in our derivative financial instruments liability balance for the year ended December 31, 2024 and 2023.

Date	Number of Warrants Outstanding	Derivative Instrument Liability
Balance of derivative liability at December 31, 2022	—	—
Issuance of Series A, Series B and Pre-funded warrants	50,824	8,889,100
Exercise of warrants	(11,608)	(2,016,166)
Change in fair value of warrants	—	**(3,076,544)**
Balance of derivative liability at December 31, 2023	39,216	$ 3,796,390
Issuance of Series B-1 and Series B-2 warrants *	29,412	2,821,399
Modification of Series A warrants *	—	346,869
Modification of Series B warrants *	—	(601,224)
Exercise of Series B warrants	(19,608)	(450,982)
Change in fair value of warrants	—	(5,579,263)
Balance of derivative liability at December 31, 2024	49,020	$ 333,189

* In connection with issuance of Series B-1 and B-2 warrants and modification of Series A and Series B warrants, the Company recognized total inducement expense of $2,567,044 during the year ended December 31, 2024.

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 December 31, 2024 and 2023.

	Fair Value Measurement at Reporting Date Using			
Description	Fair value	(Level 1)	(Level 2)	(Level 3)
As of December 31, 2024:				
Contingent consideration	$ —	$ —	$ —	$ —
Derivative liabilities related to warrants	$ 333,189	$ —	$ 333,189	—
As of December 31, 2023:				
Contingent consideration	$ 2,020,000	$ —	$ —	$ 2,020,000
Derivative liabilities related to warrants	$ 3,796,390	$ —	$ 3,796,390	$ —

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities- warrants in our consolidated statement of operations. See Note 4 for a rollforward of the derivative liability for years ended December 31, 2024 and 2023. The financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we review the assets and liabilities that are subject to ASC 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

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.

At December 31, 2024 and 2023, the assumptions we used to calculate the fair value were as follows:

	Assumptions	
	December 31, 2024	December 31, 2023
Discount rate	n/a	11.5%
Stock price	n/a	n/a
Projected milestone achievement dates	n/a	Mar 2023 — Sep 2030
Probability of success of milestone achievements	0%	13% — 40%

As of June 30, 2024, $0 was recorded as a current liability and as non-current liability based upon management's best estimate using the latest available information. Management reviewed and updated the assumptions at June 30, 2024 and reduced the contingent consideration to $0 because the projected milestones upon which the liability was based will not be achieved. There was no change in the assumptions at December 31, 2024, and therefore the liability was $0.

The following table presents the change in fair value of the contingent consideration for the years ended December 31, 2024 and 2023.

	Acquisition-related Contingent Consideration
Liabilities:	
Balance at December 31, 2022	$ 2,460,000
Change in fair value recorded in earnings	(440,000)
Balance at December 31, 2023	2,020,000
Change in fair value recorded in earnings	(2,020,000)
Balance at December 31, 2024	$ —

6. Notes Payable

Concurrently with the Merger, on July 19, 2024, the Company entered into a Securities Purchase Agreement (the "SPA") with certain purchasers pursuant to which the Company sold an aggregate of $2.9 million in principal amount of the Company's Original Issue Discount Senior Unsecured Nonconvertible Notes (the "Notes"). The Notes are due on the earlier of: (i) December 31, 2024, (ii) the date of the closing of the Merger, (iii) the date that the Merger is terminated pursuant to the terms of the Merger Agreement, or (iv) such earlier date as the Notes are required or permitted to be repaid as provided in the Note, as may be extended at the option of the holder of the Note as described in the Note. The principal amount of the note was discounted by $400,000 (discount rate of 13.8%), fees and expenses. The Company allocated the proceeds of the $2,500,000 received in exchange for the Notes and common shares in accordance with their relative fair values, which was 65% and 35%, respectively. The difference between the allocated proceeds and the face value was treated as debt discount.

On December 11, 2024, the Company announced that it had entered into a termination agreement with Pharma Two B Ltd. which terminates the merger agreement between the two parties that was previously entered into on July 19, 2024. The termination of the merger triggered the notes to become due and payable, and began accruing interest at 14%. The accrued and unpaid interest was $23,684 as of December 31, 2024.

Subsequent to December 31, 2024, the notes payable was paid off with proceeds from the 2025 financing - see Note 14 Subsequent Events.

	December 31, 2024
Principal	$ 2,900,000
Discount	(1,268,817)
Amortization of debt discount	1,268,817
Net carrying amount	$ 2,900,000

7. Related Party Transaction

As part of the July 19, 2024 Securities Purchase Agreement discussed in Note 6, the Company provided a $600,000 loan to Pharma Two B from the net proceeds from the transaction. The outstanding principal under this promissory note will be paid to, together with accrued interest, on the earlier of: (i) December 31, 2024 and (ii) the date that the Business Combination is terminated pursuant to the terms of the Merger Agreement. In the event the Business Combination is consummated, the outstanding principal amount under this promissory note, together with all accrued interest, shall be deemed to be paid in full and this note shall automatically be terminated and Pharma Two B shall have no further obligations hereunder. All payments shall be applied, first, to interest and then to principal, and the principal amount of this note may be prepaid in whole or in part at any time without penalty, in which event interest shall cease to accrue on the portion of the principal so prepaid.

On December 11, 2024, the Company announced that it had entered into a termination agreement with Pharma Two B Ltd. which terminates the merger agreement between the two parties that was previously entered into on July 19, 2024.

We were subsequently notified that Pharma Two B has filed for insolvency proceedings with the court and therefore are unable to fulfil its financial obligations regarding the loan payable. As a result, we have written off the receivable from Pharma Two B.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

8. 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)	December 31, 2024	December 31, 2023
Equipment	3.0 years	$ 358,548	$ 346,770
Furniture and fixtures	7.0 years	62,183	62,183
Less: Accumulated depreciation		(420,732)	(379,466)
		$ —	$ 29,487

Depreciation expense for the years ended December 31, 2024 and 2023 was de minimis and $0.1 million, respectively.

9. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2024	2023
Research and development	$ —	$ 1,268,560
Professional fees	—	319,157
Other	23,684	851,634
Total accrued expenses	$ 23,684	$ 2,439,351

At December 31, 2023, Other accrued expenses includes approximately $0.7 million for restructuring costs. In December 2023, the board of directors approved a strategic restructuring plan to preserve capital by reducing operating costs. The restructuring costs of approximately $0.7 million are related to severance amounts due to members of our clinical team and were recorded to research and development costs in the consolidated statement of operations at December 31, 2023. As part of this process, we formally communicated the termination of employment to 6 employees and terminated none of the employees during 2023. We incurred further restructuring costs of less than $0.1 million during the year ended December 31, 2024. As of December 31, 2024, the restructuring plan was completed and there were no additional accruals.

10. Accounting for Share-Based Payments

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. In April 2023, with the approval of the 2023 Plan, these awards are no longer accounted for as liability-classified and the cumulative liability of $3.0 million was recorded to additional paid-in capital.

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. On March 6, 2024 pursuant to the 2023 Plan, we granted 1,000 RSUs with a fair value of $114.50 per share, which vest upon the earlier of (i) one year after date of grant or (ii) change of control of the Company. In addition, during the three months ended March 31, 2024, the Company granted 6,800 options with a term of 2 to 10 years that were vested upon issuance. Subsequent to the grant of these options, we had 1,460 awards available for grant from the 2023 Plan.

We classify stock-based compensation expense in our 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:

	Year Ended December 31,	
	2024	2023
General and administrative	$ 791,645	$ 1,456,692
Research and development	—	960,223
Total stock-based compensation expense	$ 791,645	$ 2,416,915

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

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

	Number of Options	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2023	7,835	$ 2,429.00	$ —	5.17 years
Granted	6,800	$ 128.00	$ —	
Forfeited	(6,821)	$ 2,357.00	$ —	
Balance outstanding, December 31, 2024	7,813	$ 382.00	$ —	8.75 years
Awards outstanding, vested awards and those expected to vest at December 31, 2024	7,813	$ 382.00	$ —	8.75 years
Vested and exercisable at December 31, 2024	7,793	$ 381.50	$ —	8.75 years

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

	Year Ended December 31, 2024
Stock price	$ 128.00
Risk-free interest rate	4.29 - 4.64 %
Dividend yield	—
Expected volatility	116.7%
Expected term (in years)	2.0 years - 6.0 years

The total fair value of awards vested during the year ended December 31, 2024 and 2023 was $0.7 million and $2.7 million, respectively.

As of December 31, 2023, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was $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 Consolidated Financial Statements

Forfeitures—ASC 718 allows for the election of forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. For the years ended December 31, 2024 and 2023, we determined that 3% is our forfeiture rate based on historical experience. We will continue to analyze the forfeiture rate on at least an annual basis or when there are any identified triggers that would justify immediate review.

11. Income Taxes

We provide for income taxes under ASC 740, *"Income Taxes"* ("ASC 740"). Under ASC 740, the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

Our loss before income taxes was $16.2 million and $49.3 million for the years ended December 31, 2024 and 2023, respectively, and was generated entirely in the United States and Canada.

Income tax benefit for the year ended December 31, 2024 was $3.0 million and was related to the sale of our state NOLs related to prior years under the State of New Jersey's Technology Business Tax Certificate Transfer Program. Income tax benefit for the year ended December 31, 2023 was $0.4 million was related to the impairment of our IPR&D asset.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes.

The significant components of our deferred tax assets are comprised of the following:

	As of December 31,	
	2024	**2023**
Federal NOL	$ 22,892,219	$ 19,036,151
State NOL	4,237,665	4,588,524
Research and development credits	1,643,510	3,042,677
IRC 174 capitalization	15,282,658	15,068,767
Lease liability	—	58,756
Fixed Assets	75,714	—
Stock compensation & other	523,652	2,812,248
Total	44,584,134	44,607,123
Deferred tax asset valuation allowance	(44,584,134)	(44,544,637)
Total deferred tax asset	—	62,486
In-Process R&D	—	—
Right-of-use asset	—	(62,486)
Total deferred tax liability	—	(62,486)
Net deferred tax liability	$ —	$ -

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses since inception, we have concluded that it is more likely than not that the benefit of our deferred tax assets will not be realized. Accordingly, we have provided a valuation allowance for all deferred tax assets as of December 31, 2024 and 2023.

The valuation allowance did not significantly change and increased by $13.4 million for the years ended December 31, 2024 and 2023, respectively, due primarily to the generation of net operating losses during these periods.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

A reconciliation of income tax benefit computed at the statutory federal income tax rate to income taxes as reflected in the consolidated financial statements is as follows:

	Year Ended December 31,	
	2024	2023
U.S. statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	9.1%	6.4%
Sale of New Jersey tax benefits	18.4%	—
Research and development credits	3.2%	2.9%
Contingent consideration and warrants	6.6%	(0.1)%
Foreign tax differential	0.1%	(1.7)%
Return to Provision adjustments	(7.9)%	—
Deferred Tax adjustments	(31.6)%	—
Other	0.0%	0.5%
Valuation allowance	(0.5)%	(29.8)%
Effective tax rate	18.4%	(0.8)%

As of December 31, 2024 and 2023, we had U.S. federal and state net operating loss carryforwards of $160.1 million and $148.0 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2037. We also had federal and state research and development tax credit carryforwards of approximately $1.6 million as of December 31, 2024, which will begin to expire in December 2027.

Under the provisions of the Internal Revenue Code, the NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service ("IRS") 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 and concluded that we have experienced ownership changes since inception that we believe under Section 382 and 383 of the Code will result in limitations on our ability to use certain pre-ownership change NOLs and credits, which have been removed from the table above. We believe that additional ownership changes have likely occurred since that time as a result of subsequent equity offerings and other changes in the ownership of our stock. 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.

We file income tax returns in the United States, Canada and various state jurisdictions. Our federal income tax returns for the years 2018 and forward, and state income returns for the years 2017 and forward remain subject to examination by the IRS and state authorities. Our tax returns in Canada are also subject to examination.

We have approximately $2.2 million of undistributed earnings in Canada, which we continue to reinvest indefinitely, and therefore no withholding taxes related to its repatriation has been recorded.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

12. Loss per Share

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.

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

	Year Ended December 31,	
Basic and diluted net loss per common share	**2024**	**2023**
Numerator:		
Net loss	$ (13,192,420)	$ (48,926,042)
Denominator:		
Weighted average common shares outstanding	122,894	79,416
Net loss per share of common stock—basic and diluted	$ (107.35)	$ (616.07)

In connection with series B warrants exercise (see Note 4), 6,520 warrants that were exercised during the quarter ended March 31, 2024 were not yet issued as common stock and are held by the Company in abeyance, were included in the Company's calculation of basic and diluted loss per share. The shares of common stock held by the Company in abeyance are considered outstanding for the purposes of computing earnings per share, as these shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

The 6,520 warrants that were exercised during the quarter ended March 31, 2024 were issued as common stock in June 2024.

The following outstanding securities at December 31, 2024 and 2023 have been excluded from the computation of basic and diluted weighted shares outstanding, as they would have been anti-dilutive given the net loss in both periods:

	December 31,	
	2024	**2023**
Common shares issuable for:		
Series A preferred stock	3	3
Series C preferred stock	16	16
Restricted Stock Units	1,000	—
Stock options	7,813	7,835
Warrants – liability classified	49,020	39,216
Warrants – equity classified	1,795	4,220
Total	59,647	51,290

The strike prices for the equity classified warrant ranges from $1,875- $2,500 each and the expiration dates are in 2025 and 2026.

13. 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. As of December 2024, we had paid all outstanding rent on the lease, terminated the lease and vacated the office.

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 leased this space on a month-to-month basis until December 31, 2023.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Notes to Consolidated Financial Statements

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

Operating leases where we are the lessee are included under the caption "Right of Use Assets" ("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 December 31, 2023, the ROU assets were $0.2 million, the current lease liabilities were $0.1 million, and there were $0.1 million non-current lease liabilities. An estimated incremental borrowing rate of 14.9% was used in to account for the second amendment of the Edison Lease. For the first amendment of the Edison Lease, an incremental borrowing rate 6.50% was used. As of December 31, 2024, there were no ROU and lease liabilities as we had paid all outstanding rent on the lease, terminated the lease and vacated the office.

Rent expense for the years ended December 31, 2024 and 2023 was $0.2 million and $0.3 million, respectively, which included a de minimis amount for a short-term lease.

For the years ended December 31, 2024 and 2023, the weighted average remaining term of our noncancelable operating leases is 0 year and 1.58 years, respectively.

There were no future minimum rental payments under operating leases at December 31, 2024.

Employment Agreements

We do not have any employment agreements with employees which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur.

14. Subsequent Events

On January 23, 2025, we consummated a "best efforts" public offering of 553,846 shares of common stock (or pre-funded warrants in lieu thereof) with each share of common stock (or pre-funded warrant) accompanied by (i) a series A common warrant to purchase one (1) common share at an exercise price of $20.00 per share and (ii) a series B common warrant to purchase one (1) common share at an exercise price of $20.00 per share. The exercise periods for the Series A and B warrants are five years and two and half years, respectively. The Series B warrants have an alternate cashless exercise of one warrant for three common shares.

The combined offering price of each share of common stock together with the accompanying Series A and Series B common warrants is $16.250, and the combined offering price of each pre-funded warrant, all of which were exercised as of April 2, 2025, together with the accompanying series A and series B common warrants is $16.245. The gross proceeds of the public offering were approximately $9.0 million before deducting placement agent fees and offering expenses and were used to repay certain indebtedness ($2.9M note payable) and expected to be used for general corporate purposes, including working capital, operating expenses and capital expenditures.

The Series B warrants contained certain volume weighted average price provisions that reset the exercise price to a minimum floor price of $3.21 and also resets the number of warrants to 3,406,390 which are exercisable into 10,219,170 common shares. As of April 2, 2025 all of the Series B warrants were exercised into 10,219,170 of common shares at a weighted average reset price of $3.27. Since the Series B warrants were exercised on a cashless basis, there were no proceeds to the company. No Series A warrants were exercised, however the reset provisions increased the amount of Series A warrants such that 3,443,461 are outstanding at an exercise price of $3.21.

On March 17, 2025, we effected a reverse stock split of our voting common stock at a ratio of one-for-fifty (the "Reverse Stock Split"). When the Reverse Stock Split became effective, every fifty (50) shares of our issued and outstanding Common Stock immediately prior to the effective time was automatically reclassified into one (1) share of Common Stock, without any change in the par value per share. The Reverse Stock Split reduced the number of shares of Common Stock issuable upon the exercise or vesting of its outstanding stock options and warrants in proportion to the ratio of the Reverse Stock Split and causes a proportionate increase in the conversion and exercise prices of such stock options and warrants. In addition, the number of shares reserved for issuance under our equity compensation plans immediately prior to the effective time was reduced proportionately. The Reverse Stock Split did not change the total number of authorized shares of Common Stock or preferred stock.

On March 18, 2025, we received written notice from Nasdaq indicating that the bid price for our common stock, for the last 10 consecutive business days, had closed below $0.10 per share and, as a result, we are subject to the provisions contemplated under Listing Rule 5810(c)(3)(A)(iii) (the "Low Priced Stocks Rule").

As such, unless we request an appeal of Nasdaq's determination to delist our common stock from The Nasdaq Capital Market by March 25, 2025 and pay Nasdaq a hearing fee of $20,000, our common stock will be delisted from The Nasdaq Capital Market at the opening of business on March 27, 2025. On March 25, 2025, we requested a hearing and we are awaiting a hearing date. No guarantee can be provided that we will be successful in the appeal and that our common stock will continue to be listed on The Nasdaq Capital Market.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING FINANCIAL DISCLOSURE

None.

ITEM 9A. 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 December 31, 2024, our Interim Principal Executive Officer/ Principal Financial Officer has concluded that, due to the material weaknesses in our internal control over financial reporting noted below, our disclosure controls and procedures were not effective.

Management's Report on Internal Controls Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of our interim principal executive/principal financial officer and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with accounting principles generally accepted in the United States of America. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and board of directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission in *Internal Control — Integrated Framework (2013)*. In connection with this assessment, we identified material weaknesses in internal control over financial reporting as of December 31, 2024. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Based on that evaluation, as of December 31, 2024, our interim principal executive officer/principal financial officer concluded that our internal controls and procedures are not effective, and that we have material weaknesses in our control environment and period end financial close and reporting process as described below. We expect to continue to have material weaknesses if we are not able to raise capital in the future to add additional personnel and implement additional internal control procedures.

- Due to cost-cutting measures implemented during 2023 and completed in 2024, our control environment was ineffective because we did not maintain a sufficient complement of personnel to execute controls as designed including the absence of proper segregation of duties. Such impacted controls include indirect controls affecting the risk assessment and monitoring components of COSO along with certain control activities

- We identified a material weakness in our internal controls related to the proper design and implementation of control over formal review, approval, and evaluation of non-core, complex accounting transactions.

- We identified a material weakness in internal control related to the proper design and implementation of certain controls over 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 need to raise additional capital in order to add additional personnel and implement additional internal control procedures.

If we are able to raise additional capital, we plan on implementing several remedial actions to improve our internal controls, including:

- We will need to increase personnel in the future in order to have proper segregation of duties.

- 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.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to exemptions provided to issuers that are non-accelerated filers as defined in Section 2(a) of the Securities Act of 1933.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our interim principal executive officer/principal financial officer concluded there were no such changes, except as noted above, during the quarter ended December 31, 2024.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding our directors, executive officers and corporate governance will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item regarding security ownership of certain beneficial owners and management will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships, Related Person Transactions and Director Independence.

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2024 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accounting fees and services will be included in our 2024 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Hepion Pharmaceuticals, Inc. appearing on page 49 of this report.

(b) (2) Financial Statement Schedules

The schedules required to be filed by this item have been omitted because of the absence of conditions under which they are required, or because the required information is included in the consolidated financial statements or the notes thereto.

(b) EXHIBITS

Exhibit Number	Exhibit Description
3.1(a)	Certificate of Incorporation of Hepion Pharmaceuticals, Inc. (filed as Exhibit 3.1 to the Company's registration statement on Form 10-12G which was filed with the Securities and Exchange Commission on August 8, 2013 and incorporated herein by reference).
3.1(b)	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Hepion Pharmaceuticals, Inc. filed with the Secretary of State of the State of Delaware on October 14, 2014 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 2014 and incorporated herein by reference).
3.1(c)	Certificate of Designation, Preferences and Rights of the Series B Convertible Preferred Stock of Hepion Pharmaceuticals, Inc. filed with the Secretary of State of the State of Delaware on December 18, 2014 (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2014 and incorporated herein by reference).
3.1(d)	Certificate of Amendment of Certificate of Incorporation of Hepion Pharmaceuticals, Inc. dated May 25, 2018 (filed as Exhibit 3.1 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on May 29, 2018 and incorporated herein by reference).
3.1(e)	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (filed as Exhibit 3.1 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on July 5, 2018 and incorporated herein by reference).
3.1(f)	Certificate of Designation of Preference, Rights and Limitations of Series D Convertible Preferred Stock filed with the Secretary of the State of Delaware on April 26, 2019 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on May 8, 2019).
3.1(g)	Certificate of Designation of Preference, Rights and Limitations of Series E Convertible Preferred Stock, filed with the Secretary of the State of Delaware on June 18, 2019 (incorporated by reference to Exhibit 3.1 to Form 8-K filed June 20, 2019)
3.1(h)	Certificate of Amendment to the Certificate of Incorporation, dated May 28, 2019 (incorporated by reference to Exhibit 3.1 to Form 8-K filed May 31, 2019)
3.1(i)	Certificate of Amendment to the Certificate of Incorporation, dated July 18, 2019 (incorporated by reference to Exhibit 3.1 to Form 8-K filed July 23, 2019)
3.1(j)	Certificate of Designation of Series F Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed November 4, 2022)
3.1(k)	Certificate of Designation of Series G Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed November 4, 2022)
3.1(l)	Certificate of Amendment to Certificate of Designation of Series F Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.3 to Form 8-K filed November 4, 2022)
3.1(m)	Certificate of Amendment to Certificate of Designation of Series F Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.4 to Form 8-K filed November 4, 2022)
3.2(a)	By-Laws of Hepion Pharmaceuticals, Inc. (filed as Exhibit 3.2 to the Company's registration statement on Form 10-12G which was filed with the Securities and Exchange Commission on August 8, 2013 and incorporated herein by reference).
3.2(b)	Amendment to the By-Laws of Hepion Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed August 23, 2021)

4.1	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.6 to Form 10-K filed with the Securities and Exchange Commission on May 14, 2020 and incorporated herein by reference).
4.2	Form of Series A Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed on October 3, 2023).
3	Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed on October 3, 2023).
4.4	Form of Series B-1 Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on February 16, 2024).
4.5	Form of Series B-2 Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed on February 16, 2024).
4.6	Form of Amendment No. 1 to Series A Warrant (incorporated by reference to Exhibit 10.2 to Form 8-K filed on February 16, 2024).
10.1	10/1/2023 Omnibus Equity Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement filed on April 28, 2023)
10.2	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on October 3, 2023).
10.3	Form of Warrant Inducement Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 16, 2024).
14.1	Code of Business Conduct and Ethics (filed as Exhibit 14.1 to the Company's Transition Report on Form 10-KT filed with the Securities and Exchange Commission on March 26, 2018 and incorporated herein by reference)
19.1	Insider Trading Policy
21.1	List of Subsidiaries
23.1	Consent of Grassi & Co., CPAs, P.C., Independent Registered Public Accounting Firm
24	Power of Attorney (included on signature page hereto)
31.1	Certification of Chief Executive 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.
97.1	Clawback Policy(incorporated by reference to Exhibit 97.1 to Form 10-K filed on April 16, 2024).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: April 8, 2025

HEPION PHARMACEUTICALS, INC.
By: /s/ JOHN BRANCACCIO
John Brancaccio
Interim Chief Executive Officer/Chief Financial Officer and Director
(Interim Principal Executive Officer and Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, John Brancaccio, and each of them acting individually, as his attorney-in-fact, with full power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JOHN BRANCACCIO John Brancaccio	Interim Chief Executive Officer/Chief Financial Officer, Director (Interim Principal Executive Officer and Financial Officer)	April 8, 2025
/s/ MICHAEL PURCELL Michael Purcell	Director	April 8, 2025
/s/ TIMOTHY BLOCK Timothy Block	Director	April 8, 2025
/s/KAOUTHAR LBIATI Kaouthar Lbiati	Director	April 8, 2025

Exhibit 19.1

HEPION PHARMACEUTICALS, INC.

INSIDER TRADING POLICY

and Guidelines with Respect to
Certain Transactions in Company Securities

This Policy provides guidelines to employees, officers and directors of Hepion Pharmaceuticals, Inc. (the "Company") with respect to transactions in the Company's securities.

Applicability of Policy

This Policy applies to all transactions in the Company's securities, including common stock, options for common stock and any other securities the Company may issue from time to time, such as preferred stock, warrants and convertible debentures, as well as to derivative securities relating to the Company's stock, whether or not issued by the Company, such as exchange-traded options. It applies to all officers of the Company, all members of the Company's Board of Directors, and all employees of, and consultants and contractors to, the Company and its subsidiaries who receive or have access to Material Nonpublic Information (as defined below) regarding the Company. This group of people, members of their immediate families, and members of their households are sometimes referred to in this Policy as "Insiders". This Policy also applies to any person who receives Material Nonpublic Information from any Insider.

Any person who possesses Material Nonpublic Information regarding the Company is an Insider for so long as the information is not publicly known. Any employee can be an Insider from time to time, and would at those times be subject to this Policy.

Statement of Policy

General Policy

It is the policy of the Company to oppose the unauthorized disclosure of any nonpublic information acquired in the work-place and the misuse of Material Nonpublic Information in securities trading.

Specific Policies

1. Trading on Material Nonpublic Information. No director, officer or employee of, or consultant or contractor to, the Company, and no member of the immediate family or household of any such person, shall engage in any transaction involving a purchase or sale of the Company's securities, including any offer to purchase or offer to sell, during any period commencing with the date that he or she possesses Material Nonpublic Information concerning the Company, and ending at the close of business on the second Trading Day following the date of public disclosure of that information, or at such time as such nonpublic information is no longer material. As used herein, the term "Trading Day" shall mean a day on which national stock exchanges and the National Association of Securities Dealers, Inc. Automated Quotation System (NASDAQ) are open for trading.

2. Disclosure of Information to Others. The Company is required under Regulation FD of the federal securities laws to avoid the selective disclosure of Material Nonpublic Information. The Company has established procedures for releasing material information in a manner designed to achieve broad public dissemination of the information immediately upon its release. You may not, therefore, disclose information to anyone outside the Company, including family members and friends, other than in accordance with those procedures. You also may not discuss the Company or its business in an internet "chat room" or similar internet-based forum.

3. Confidentially of Nonpublic Information. Nonpublic information relating to the Company is the property of the Company and the unauthorized disclosure of such information is forbidden.

Potential Criminal and Civil Liability and/or Disciplinary Action

1. Liability for Insider Trading. Insiders may be subject to penalties of up to $1,000,000 and up to ten years in jail for engaging in transactions in the Company's securities at a time when they have knowledge of nonpublic information regarding the Company.

2. Liability for Tipping. Insiders may also be liable for improper transactions by any person (commonly referred to as a "tippee") to whom they have disclosed nonpublic information regarding the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in the Company's securities. The Securities and Exchange Commission (the "SEC") has imposed large penalties even when the disclosing person did not profit from the trading. The SEC, the stock exchanges and the National Association of Securities Dealers, Inc. use sophisticated electronic surveillance techniques to uncover insider trading.

3. Possible Disciplinary Actions. Employees of the Company who violate this Policy shall also be subject to disciplinary action by the Company, which may include ineligibility for future participation in the Company's equity incentive plans or termination of employment.

Trading Restrictions

1. Prohibition on Trading During Quarterly Blackout Periods.

To ensure compliance with this Policy and applicable federal and state securities laws, the Company has adopted a policy that prohibits persons listed on Exhibit B or C from buying or selling the Company's securities during a regular quarterly "blackout" period (unless they have established a pre-arranged trading plan that complies with Rule 10b5-1 promulgated under the Securities Exchange Act of 1934 (the "Exchange Act")). Each blackout period begins on the 20th day of the last month of the fiscal quarter and continues until the end of the second full trading day after the public release of quarterly results.

It should be noted that trading on dates that are outside of the quarterly blackout periods will not relieve any one from liability if in possession of Material Nonpublic Information concerning the Company. Although the Company may from time to time recommend the suspension of trading by directors, officers, employees and others because of developments known to the Company and not yet disclosed to the public, each person is individually responsible at all times for compliance with the prohibitions against insider trading. Trading in the Company's securities should not be considered a "safe harbor", and all directors, officers and other persons should use good judgment at all times.

2. Preclearance of Trades. No person listed on Exhibit B or C is to purchase, sell, or otherwise engage in transactions in securities of the Company without obtaining prior clearance of the transaction by the Insider Trading Compliance Officer. The proposed transaction will be reviewed for compliance with applicable regulatory requirements.

The Company may also find it necessary, from time to time, to require compliance with the preclearance process from certain employees, consultants and contractors other than and in addition to those persons listed on Exhibit B and C.

3. Rule 10b5-1 trading programs. The SEC has adopted a rule that permits insiders to trade in certain circumstances where it is clear that inside information was not a factor in the decision to trade. Rule 10b5-1 provides that an individual who buys or sells securities while aware of Material Nonpublic Information does not violate Rule 10b-5 if the buying or selling is in conformity with a binding contract, instruction or written plan that was put into place at a time when the individual was not aware of Material Nonpublic Information. Establishing such a pre-arranged trading plan provides an opportunity for an Insider to limit his or her potential insider trading liability. When trading arrangements are prearranged, it becomes clearer to the investing public (and potential plaintiffs) that the Insider's purchases and sales are not being prompted by his or her knowledge of current developments within the Company, or such person's feelings about the Company's prospects.

The Company permits its directors and officers to set up Rule 10b5-1 trading programs. However, great care must be exercised in relying on new Rule 10b5-1, for the following reasons:

In order to meet the requirements of Rule 10b5-1, binding contracts, instructions and written plans must: (i) lock in the amount, price and dates of future trades; (ii) provide a formula or algorithm for determining future trades; or (iii) delegate discretion for determining amount, price and dates to a third party *precisely* as provided under the rule.

The ability to modify provisions once locked in is limited, and modification or termination of arrangements is risky.

Although Rule 10b5-1 may help directors and officers avoid liability under Rule 10b-5, it does not eliminate other relevant securities law requirements and prohibitions. Therefore, buying and selling in reliance on Rule 10b5-1 must also be designed to comply with the reporting and short-swing profit rules under Section 16 of the Exchange Act, the limitations on insider selling imposed by Rule 144 under the Securities Act, the prohibition on trading during administrative blackouts under 401(k) or other retirement plans, and, in some cases, certain other securities law requirements.

The liability avoidance provisions of Rule 10b5-1 are affirmative defenses. If the government can prove that an individual was aware of material, nonpublic information at the time of a purchase or sale, the burden of proving that trading was pursuant to an adequate contract, instruction or written plan will be on the individual. Compliance must be well documented and capable of proof in court.

4. Procedures for Establishing Rule 10b5-1 Trading Programs. If an officer or director wishes to establish an arrangement designed to comply with Rule 10b5-1, he or she must follow the procedures listed below:

- Arrangements must be in the form of a *written* contract.
- The contract must be reviewed and approved in advance by the Company's Insider Trading Compliance Officer.
- The contract must be entered into when the officer or director is not in possession of any Material Nonpublic Information and not subject to any blackout.
- The contract must either:

  (i) Specify the amount of securities to be purchased or sold (i.e., a set number of shares or a set dollar amount) and the price and date on which the securities are to be purchased or sold;

  (ii) Include a written formula or algorithm, for determining the amount of securities to be purchased or sold and the price and date of their purchase or sale; or

  (iii) Effectively delegate to a third party who does not have access to any Inside Information all power to determine how, when or whether to effect purchases or sales.

- The officer or director will not be permitted to cancel or make any changes to the contract when in possession of any Material Nonpublic Information or during any blackout period.
- Cancellations or amendments must be approved in advance by the Company's Insider Trading Compliance Officer and must be in writing.

Please be aware that the Company will likely be required to publicly disclose any trading plan adopted by an officer or director. Additionally, the Company will need to establish a procedure with whomever is handling the 10b5-1 transactions to ensure:

- Prompt filing of a Form 4 after each transaction takes place; and
- Compliance with SEC Rule 144 at the time of any sale.

Most sophisticated brokers, investment bankers and advisors have developed standard documentation for Rule 10b5-1 trading plans. If this type of plan is adopted, we strongly recommend the officer or director work with a brokerage firm that is experienced in these matters. **In order to ensure compliance with Rule 10b5-1, please remember that any trading plan or amendment must be submitted to the Company's Insider Trading Compliance Officer for review and approval in advance of entering the plan or amendment.**

5. Trading Restrictions during "Retirement Plan" Administrative Blackout Periods. Persons listed on Exhibits B or C are prohibited from trading in any Company securities during administrative blackout periods under 401(k) and similar retirement plans (unless such persons have established a pre-arranged trading plan that complies with Rule 10b5-1 promulgated under the Exchange Act). Any profits realized from a prohibited transaction are recoverable by the Company, including through a shareholder derivative-type action, without regard to intent. In addition, unlike Section 16 of the Exchange Act, no matching transaction within the blackout period is required in order to impose the disgorgement penalty. The Company's Insider Trading Compliance Officer will advise you whenever an administrative blackout is imposed with respect to the Company's 401(k) or other retirement plans.

6. Individual Responsibility. Every officer, director and employee has the individual responsibility to comply with this Policy against insider trading. An Insider may, from time to time, have to forego a proposed transaction in the Company's securities even if he or she planned to make the transaction before learning of the Material Nonpublic Information and even though the Insider believes he or she may suffer an economic loss or forego anticipated profit by waiting.

Applicability of Policy to Inside Information Regarding Other Companies

This Policy and the guidelines described herein also apply to Material Nonpublic Information relating to other companies, including the Company's customers, vendors or suppliers ("business partners"), when that Material Nonpublic Information is obtained in the course of employment with, or other services performed on behalf of, the Company. Civil and criminal penalties, and termination of employment, may result from trading on Inside Information regarding the Company's business partners. All employees should treat Material Nonpublic Information about the Company's business partners with the same care required with respect to information related directly to the Company.

Definition of Material Nonpublic Information

It is not possible to define all categories of material information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important to an investor in making an investment decision regarding the purchase or sale of the Company's securities.

While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information may include:

- Financial results
- Projections of future earnings or losses
- News of a pending or proposed merger
- News of the disposition of a subsidiary
- Impending bankruptcy or financial liquidity problems
- Gain or loss of a substantial customer or supplier
- Changes in dividend policy
- New product announcements of a significant nature
- Significant news about potential products
- Significant product defects or modifications
- Significant pricing changes
- Stock splits
- New equity or debt offerings
- Acquisitions
- Significant litigation exposure due to actual or threatened litigation
- Major changes in senior management.

Either positive or negative information may be material.

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public.

Certain Exceptions

For purposes of this Policy, the Company considers that the exercise of stock options for cash under the Company's stock option plans or the purchase of shares under the Company's employee stock purchase plan (but not the sale of any such shares) is exempt from this Policy, since the other party to the transaction is the Company itself and the price does not vary with the market but is fixed by the terms of the option agreement or the plan.

Additional Information - Directors and Officers

Directors and officers of the Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Securities Exchange Act of 1934, as amended. The practical effect of these provisions is that officers and directors who purchase and sell the Company's securities within a six-month period must disgorge all profits to the Company whether or not they had knowledge of any Material Nonpublic Information. Under these provisions, and so long as certain other criteria are met, neither the receipt of an option under the Company's option plans, nor the exercise of that option nor the receipt of stock under the Company's employee stock purchase plan is deemed a purchase under Section 16; however, the sale of any such shares is a sale under Section 16 and the purchase and sale must be reported on Form 4. Moreover, no officer or director may ever make a short sale of the Company's stock. The Company has provided, or will provide, separate memoranda and other appropriate materials to its officers and directors regarding compliance with Section 16 and its related rules.

Certifications

All Company officers, directors, employees and consultants will be required to certify in writing their understanding of and intent to comply with the Insider Trading Policy. In addition, Company officers, directors, employees and consultants may be required to certify their compliance with the Insider Trading Policy on an annual basis.

Inquiries

Please direct your questions as to any of the matters discussed in this Policy to the Company's Insider Trading Compliance Officer.

Certification

The undersigned, employee, officer, director or consultant of Hepion Pharmaceuticals, Inc. and/or related corporations, hereby certifies that he/she has carefully read and understands and agrees to comply with the Company's Insider Trading Policy and Guidelines with Respect to Certain Transactions in Company Securities, a copy of which was distributed to the undersigned along with this Certification.

Date: _____

_____
(Signature)

_____
(Print Name)

_____
(Department)

Exhibit B

OFFICERS AND DIRECTORS SUBJECT TO SECTION 16

1. Directors:

ALL

2. Officers:

Name	Current Position

Exhibit C

OTHER EMPLOYEES/CONSULTANTS SUBJECT TO PRE-CLEARANCE PROCEDURES

Name	Current Position

Exhibit 21.1

LIST OF SUBSIDIARIES

Name	State or Other Jurisdiction of Incorporation
ContraVir Research, Inc.	Delaware
Hepion Research Corp.	Canada

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in Registration Statements on Form S-1 (No. 333-275231, 333-280752 and 333-284052), and Form S-8 (Nos. 333-273269, 333-252188, 333-203867, 333-215662 and 333-234728) of our report dated April 8, 2025 relating to the consolidated financial statements of Hepion Pharmaceuticals, Inc. appearing in this Annual Report (Form 10-K) as of and for the years ended December 31, 2024 and 2023. Our report includes an explanatory paragraph regarding the existence of substantial doubt about the Company's ability to continue as a going concern.

/s/ GRASSI & CO., CPAs, P.C.
Jericho, New York
April 8, 2025

Exhibit 31.1

Certification of Principal Executive Officer and Principal Financial Officer of Hepion Pharmaceuticals, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, John Brancaccio, certify that:

1. I have reviewed this Annual Report on Form 10-K 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)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant 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 my 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: April 8, 2025

/s/ JOHN BRANCACCIO
John Brancaccio
Interim Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive and Financial Officer)

Exhibit 32.1

Certification Of
Principal Executive and Financial Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 Of The Sarbanes-Oxley Act Of 2002

In connection with the Annual Report of Hepion Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Brancaccio, Interim Chief Executive Officer and Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: April 8, 2025

/s/ JOHN BRANCACCIO
John Brancaccio
Interim Chief Executive Officer and Interim Chief Financial Officer
(Principal Executive and Financial Officer)