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, 2025

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	OTC QB

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, 2025, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $0.9 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 March 11, 2026 was 11,620,317.

Documents Incorporated by Reference:

Parts of the registrant's Proxy Statement for the Registrant's 2026 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, 2025.

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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:

- **our ability to raise substantial additional capital to continue as a going concern and fund our planned operations in the near term;**
- **estimates regarding our expenses, use of cash, timing of future cash needs and anticipated capital requirements;**
- **success in retaining, or changes required in, our officers, key employees or directors;**
- **our public securities' potential liquidity and trading;**
- **our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;**
- **our plans to pursue research and development of other future product candidates;**
- **the potential advantages of our product candidates and those being developed;**
- **the rate and degree of market acceptance and clinical utility of our product candidates;**
- **the success of our collaborations and partnerships with third parties;**
- **our estimates regarding the potential market opportunity for our product candidates;**
- **our sales, marketing and distribution capabilities and strategy;**
- **our ability to establish and maintain arrangements for manufacture of our product candidates;**
- **our ability to compete with companies currently marketing or engaged in the development of treatments for indications that our product candidates are designed to target; and**
- **our intellectual property position, including the strength and enforceability of our intellectual property rights.**

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, 2025 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

Hepion Pharmaceuticals, Inc. (we, our, or us) is a medical diagnostic 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.

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 May 9, 2025, we entered into a license agreement ("License Agreement") with New Day Diagnostics LLC ("New Day") pursuant to which we in-licensed certain diagnostic tests for celiac disease, respiratory multiplex (Covid/Influenza A/B and RSV), helicobacter pylori ("H. pylori") and hepatocellular carcinoma ("HCC"). The celiac, respiratory multiplex and H. pylori tests have CE marks and are eligible to be sold in the European Union ("EU") and certain eligible markets that accept the CE mark, with the notable exception of the United States at the present time. Pursuant to the License Agreement, we paid $525,000 in cash to New Day along with $270,629 in shares of our common stock. In addition, we agreed to pay New Day up to $17.15 million upon achievement of certain regulatory, sales and reimbursement milestones. Further, we will pay New Day royalty rates in the upper single to low double digits based on net sales.

We accounted for this transaction as an asset acquisition. The total consideration of $815,045, including the $19,146 of transaction fees, was allocated between purchased in-process research and development and Intangibles for the assets with CE mark in the EU. The portion allocated to in-process research and development was $412,299 and it was expensed upon the completion of the transaction, as research and development cost. We did not recognize any contingent consideration (milestone payments) given the low probability of meeting those targets. Royalties will be recognized when earned.

In accordance with ASC 360-10-35-21, a long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. We tested the asset for impairment during the reporting period, noting there were triggering events related to delayed timing to market resulting in an adverse effect on estimated cashflow over the next two years. Given that the license agreement requires both parties to agree to renewal after the initial two years, we projected the estimated cashflows for the first two years for the assets available for sales in eligible markets, noting the projected cashflow will not be enough to recover the allocated cost in the first two years of the license agreement. The total impairment loss recorded was $402,746. Therefore, the total cost related to the New Day licensing agreement was expensed.

On May 26, 2025, we entered into a patent and associated assets acquisition agreement (the "Agreement") with Panetta Partners Limited ("Panetta") whereby Panetta purchased from us all patent assets, knowhow, clinical trial data and drug product relating to Rencofilstat (formerly CRV431) for a nominal amount. There was no gain or loss resulting from this transaction. Panetta also assumed all contingent consideration obligations to the predecessor company's shareholders. Pursuant to the Agreement, Panetta agreed to provide a contingent value right ("CVR") to our stockholders to receive one or more contingent payments upon the achievement of certain milestones as set forth below:

a) a payment of US$500,000 on the regulatory approval by the US Food and Drug Administration of the first new drug application for Rencofilstat (formerly CRV431)
b) a further payment of US$1,000,000 on first instance of net sales of an approved drug product containing Rencofilstat (a "*Licensed Product*") exceeding US$350,000,000; and
c) a further payment of US$3,000,000 on first instance of net sales of a Licensed Product exceeding US$750,000,000.

We did not recognize any contingent consideration given the high uncertainty of achieving these milestones.

On February 25, 2026, we entered into an intellectual property license agreement with Cirna Diagnostics, LLC ("**Cirna**") pursuant to which we licensed certain liver disease diagnostic assets from Cirna. We will pay an upfront payment of $50,000 as well as certain patent expenses, up to $2,350,000 in milestone payments, up to $4,500,000 in sales milestone payments and a royalty payment on net sales in the low single digits.

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.

Government Regulation

The design, development, manufacture, testing and sale of our products in the U.S. are subject to regulation by numerous governmental authorities, principally the FDA, and corresponding state and local regulatory agencies.

FDA Regulation

Medical Devices

Generally, the products we develop must be cleared by the FDA before they are marketed in the United States. Before and after approval, authorization, or clearance in the United States, our products are subject to extensive regulation by the FDA, as well as by other regulatory bodies. FDA regulations govern, among other things, the development, testing, manufacturing, labeling, safety, storage, recordkeeping, market clearance, authorization or approval, advertising and promotion, import and export, marketing and sales, and distribution of medical devices, including IVDs. IVDs are a type of medical device and include reagents and instruments used in the diagnosis or detection of diseases, conditions or infections, including, without limitation, the presence of certain chemicals or other biomarkers. Predictive, prognostic and screening tests can also be IVDs.

In the United States, medical devices are subject to varying degrees of regulatory control and are classified in one of three classes depending on the extent of controls the FDA determines are necessary to reasonably ensure their safety and effectiveness:

- Class I: general controls, such as labeling and adherence to quality system regulations;
- Class II: special controls, premarket notification (often referred to as a 510(k)), specific controls such as performance standards, patient registries, post-market surveillance, additional controls such as labeling and adherence to quality system regulations; and
- Class III: special controls and requires a premarket approval ("PMA").

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a de novo application, or approval of a premarket approval (PMA).

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our initial product is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

510(k) clearance, a company must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Classification

Devices of a new type that FDA has not previously classified based on risk are automatically classified into Class III by operation of section 513(f)(1) of the FDCA, regardless of the level of risk they pose. To avoid requiring PMA review of low- to moderate-risk devices classified in Class III by operation of law, Congress enacted section 513(f)(2) of the FDCA. This provision allows FDA to classify a low- to moderate-risk device not previously classified into Class I or II. After de novo authorization, an authorized device may be used as a predicate for future devices going through the 510(k) process.

Clinical Trials

Clinical trials are often required for a de novo authorization. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Sponsors of applicable clinical trials of devices also are required to register with www.clinicaltrials.gov, a public database of clinical trial information. Information related to the device, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration. Although the FDA's Quality System Regulation (QSR) does not fully apply to investigational devices, the requirement for controls on design and development does apply.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Once we have a commercialized product, our manufacturing processes will be required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- refusal to grant export approval for our products; or
- criminal prosecution.

Federal and State Fraud and Abuse Laws

We are subject to federal fraud and abuse laws such as the federal Anti-Kickback Statute (AKS), the federal prohibition against physician self-referral (Stark Law), the Eliminating Kickbacks in Recovery Act (EKRA), and the federal False Claims Act (FCA). We are also subject to similar state and foreign fraud and abuse laws.

The AKS (Social Security Act § 1128B(b)) prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce such person to refer an individual, or to purchase, lease, order, arrange for, or recommend purchasing, leasing or ordering, any item or service that may be reimbursable, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. There are a number of statutory exceptions and regulatory safe harbors to the AKS that provide protection from AKS liability to arrangements that fully satisfy the applicable requirements.

EKRA (18 USC § 220) prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in return for the referral of a patient to, or in exchange for an individual using the services of certain entities, including laboratories, if the services are covered by a health care benefit program. The term "health care benefit program" is broadly defined such that EKRA extends to referrals reimbursed by both governmental and commercial third-party payers. EKRA includes a number of statutory exceptions that provide protection from EKRA liability if the applicable requirements are met.

The Stark Law (Social Security Act § 1877) generally prohibits, among other things, clinical laboratories and other so-called "designated health services" entities from billing Medicare for any designated health services when the physician ordering the service, or any member of such physician's immediate family, has a financial relationship, such as a direct or indirect investment interest in or compensation arrangement with the billing entity, unless the arrangement meets an exception to the prohibition. The Stark Law also prohibits physicians from making such referrals to a designated health services entity. There are also similar state laws that apply where Medicaid and/or commercial payers are billed.

The FCA (31 USC § 3729) imposes penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the government that are false or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to such a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. This statute also permits a private individual acting as a "qui tam" whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false claim or statement for penalties assessed.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payer knows or should know is likely to influence the beneficiary to order or receive a reimbursable item or service from a particular provider, practitioner, or supplier, and contracting with an individual or entity that the person knows or should know is excluded from participation in a federal health care program. In addition, federal criminal statutes created by the Health Insurance Portability and Accountability Act (HIPAA) prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition to these federal laws, there are often similar state anti-kickback and false claims laws that typically apply to arrangements involving reimbursement by a state-funded Medicaid or other health care program. Often, these laws closely follow the language of their federal law counterparts, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial payers.

A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other healthcare providers, and, in some states, marketing expenditures. In addition, some state statutes impose outright bans on certain manufacturer gifts to physicians or other health care professionals. Some of these laws, referred to as "aggregate spend" or "gift" laws, carry substantial fines if they are violated.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs and extensive annual trainings for all of our employees and contractors. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Anti-Corruption

The FCPA and similar international bribery laws make it unlawful for persons or entities to make payments to foreign government officials to assist in obtaining and maintaining business. Specifically, the anti-bribery provisions of the FCPA prohibit any offer, payment, promise to pay, or authorizing the payment of money or anything of value to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to a foreign official to do or omit to do an act in violation of his or her duty, or to secure any improper advantage in order to assist in obtaining or retaining business for or with, or directing business, to any person. In addition to the anti-bribery provisions of the FCPA, the statute also contains accounting requirements designed to operate in tandem with the anti-bribery provisions. Covered companies are required to make and keep books and records that accurately and fairly reflect the transactions of the company and devise and maintain an adequate system of internal accounting controls. With our international operations through our third-party partnerships, we could incur significant fines and penalties, as well as criminal liability, if we fail to comply with either the anti-bribery or accounting requirements of the FCPA, or similar international bribery laws. Even an unsuccessful challenge of our compliance with these laws could cause us to incur adverse publicity and significant legal and related costs.

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, 2025, we had two 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.

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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, 2025 and 2024, we had an accumulated deficit of $246.1 million, and $237.8 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, 2025 and 2024, we raised net proceeds of approximately $8.2 million and $4.3 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. 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. Absent further funding, we currently expect to run out of available cash resources during the third quarter of 2026. As a result of our lack of cash resources, we have slowed the timeline of our clinical trial work to preserve cash resources in the near-term. If we fail to obtain additional financing, we likely will be forced to abandon such activities entirely and file for bankruptcy protection, with the possible loss of such properties or assets (including the license to our core technology). Based on our explorations to date, we do not expect that any other strategic alternatives, such as a potential sale of the Company or its assets or other restructuring efforts, will be available to us in the near-term. As a result, any inability to obtain additional financing in the near-term, including a material amount of financing over the next 2-3 years, would likely result in a material adverse effect on our business, results of operations, cash flow, financial condition and prospects and cause our stockholders to receive little or no return on their shares of common stock.

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.

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.

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.

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.

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

If 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.

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.

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

We conduct our business in a heavily regulated industry, and changes in regulations or violations of regulations may, directly or indirectly, reduce our revenue, adversely affect our results of operations and financial condition and harm our business.

The life sciences industry is highly regulated, and the regulatory environment in which we and our collaborators operate may change significantly and adversely to us in the future. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation, federal and state laws relating to:

- laboratory testing, including CLIA and state laboratory licensing laws;
- the development, testing, use, distribution, promotion and advertising of research services, kits, clinical diagnostics and pharmaceutical therapies, including certain LDTs, and related services, which are regulated by the FDA under the FDCA and the FTC;
- test ordering, documentation of tests ordered, billing practices and claims payment under CMS and the HHS OIG enforcing those laws and regulations;
- cellular therapies, medical device and *in vitro* diagnostic clearance, marketing authorization or approval;
- laboratory anti-mark-up laws;
- the handling and disposal of medical and hazardous waste;
- fraud and abuse laws such as the False Claims Act, the AKS, EKRA, and the Stark Law;
- Occupational Safety and Health Administration rules and regulations;
- HIPAA and other federal and state data privacy and security laws;
- federal and state genetic information laws, such as the Genetic Information Nondiscrimination Act ("GINA") and similar state laws; and
- coverage and restrictions on coverage and reimbursement for clinical diagnostics and pharmaceutical therapies and Medicare, Medicaid, other governmental payors and private insurers reimbursement levels.

In particular, the laws, regulations and policies governing the marketing of RUO products, LDTs and clinical diagnostic tests and services are extremely complex and are subject to interpretation by the courts and governmental agencies. Our failure to comply could lead to civil or criminal penalties, exclusion from participation in state and federal health care programs, or prohibitions or restrictions on our laboratories' ability to provide or receive payment for our services. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position, or that a private party could file suit under the qui tam provisions of the federal False Claims Act or a similar state law. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations, and other private third-party payors.

The insurance coverage and reimbursement status of newly approved products, in a new category of diagnostics and therapeutics, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for current or future products could limit our ability, and that of our collaborators, to fully commercialize our products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford the clinical diagnostic tests and therapeutics that we and our collaborators plan to develop and sell. In addition, because our clinical diagnostics and some of our potential therapeutic products will represent new approaches to the research, diagnosis, detection and treatment of diseases, we cannot accurately estimate how our products and services, and those jointly created with our collaborators, would be priced, whether reimbursement could be obtained or any potential revenue generated. Sales of our products will depend substantially, both domestically and internationally, on the extent to which the costs of our products and services are paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize some of our products or services. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products or services. If we adopt a self-pay strategy with respect to any products or services, we may experience similar difficulties in the establishment or maintenance of sufficiently high pricing. Changes in the reimbursement landscape may occur, which are outside of our control, and may impact the commercial viability of our products and services.

There is significant uncertainty related to the insurance coverage and reimbursement of newly cleared, authorized or approved products and services. In the U.S., many significant decisions about reimbursement for new diagnostics and medicines are typically made by CMS, an agency within the HHS, and its contractors. CMS and its contractors decide whether and to what extent a new diagnostic or medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS policies to a substantial degree. It is difficult to predict what CMS and its contractors will decide with respect to reimbursement for novel products and services such as ours. Additionally, reimbursement agencies in Europe may be more conservative than CMS. These inherent limitations could affect our ability to realize revenues from our clinical products.

Outside the U.S., the reimbursement process and timelines vary significantly. Certain countries, including a number of member states of the EU, set prices and make reimbursement decisions for diagnostics and pharmaceutical products, or medicinal products, as they are commonly referred to in the EU, with limited participation from the marketing authorization or Conformité Européene ("CE") mark holders, or may take decisions that are unfavorable to the authorization or CE mark holder where they have participated in the process. We cannot be sure that such prices and reimbursement decisions will be acceptable to us or our collaborators. If the regulatory authorities in these foreign jurisdictions set prices or make reimbursement criteria that are not commercially attractive for us or our collaborators, our revenues and the potential profitability of our products and services in those countries would be negatively affected.

An increasing number of countries, including the U.S. and the EU, are pursuing initiatives to attempt to control the healthcare budget by focusing cost-cutting efforts on medicinal products, and to a lesser extent, medical devices, provided under their state-run healthcare systems. Additionally, some countries require approval of the sale price of a product before it can be marketed or mandatory discounts or profit caps may be applied. Further, after the sale price is approved, it remains subject to review during the product lifecycle. In many countries, the pricing review period begins after marketing or product licensing approval is granted or the CE mark is obtained. As a result, we or our collaborators might obtain marketing approval for a product or service in a particular country, but then may experience delays in the reimbursement approval or be subject to price regulations that would delay the commercial launch of our product or service, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of that product or service in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the U.S. and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for newly cleared, authorized or approved devices and medicines and, as a result, they may not cover or provide adequate payment for our clinical diagnostics or the cellular therapies to be sold by us or our collaborators. For example, the U.S. government introduced the Lower Drug Costs Now Act of 2019 to reduce the cost of drugs. This blueprint contains certain measures that HHS is already working to implement. In addition, the No Surprises Act ("NSA") took effect in January 2022. One of the goals of the NSA is to protect patients from "surprise" medical bills resulting from gaps in coverage for services provided by out-of-network providers, such as laboratories, related to patient visits at in-network facilities. The NSA limits the amount out-of-network laboratories may charge a patient for laboratory services ordered during an in-network facility visit and establishes an independent dispute resolution process for determining the amount of reimbursement for the laboratory service in the event that the laboratory and insurer cannot agree on a rate. To the extent the NSA limits the price charged for our diagnostic products or cellular therapeutics, the commercial viability of those products may be adversely affected.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological program pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, which are, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures on our clinical diagnostics and cellular therapies sold by us and our collaborators due to the trend toward value-based pricing and coverage, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Changes in law relating to health insurance coverage and payment may adversely affect our business.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. clinical diagnostic and biopharmaceutical industries. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and medical devices, including laboratory kits, and promoted a new Medicare Part D coverage gap discount program.

Some of the provisions of the ACA have been subject to judicial and Congressional challenges. It is also unclear how regulatory provisions and sub-regulatory guidance, both of which fluctuate continually, may affect interpretation and implementation of the ACA and its practical effects on our business. In addition, changes in the number of patients that can look to third-party payment to help afford our products and services may affect the demand for these products and services.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase downward pressure on drug and device pricing. Such reforms could have an adverse effect on anticipated revenues from our products and services, including those that we jointly develop with our collaborators, and may affect our overall financial condition and ability to develop or obtain regulatory clearance, authorization or approval for our products and services.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and clear, authorize or approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory and policy changes. In addition, government funding of agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and devices to be reviewed and cleared, authorized or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We must maintain compliance with marketing authorization requirements of the FDA and equivalent foreign and state regulatory authorities for our products and services whose sale is subject to their authority and failure to maintain compliance with FDA requirements may prevent or delay the marketing of our products and services.

Even after we have obtained marketing authorization we must comply with the scope of that clearance, authorization or approval. Failure to comply with those limitations or the additional, extensive and ongoing post-marketing obligations imposed by the FDA or other regulatory requirements of other regulatory agencies, such as the Clinical Laboratory Evaluation Program for New York State, could result in unanticipated compliance expenditures, a range of administrative enforcement actions, injunctions and criminal prosecution. FDA post-market obligations include, among other things, compliance with the FDA QSR, establishing registration and device listings, labeling requirements, reporting of certain adverse events and malfunctions, and reporting of certain recalls. In addition, circumstances may arise that cause us to recall equipment used in connection with our products and services. Such recalls could have an adverse effect on our ability to provide those products and services, which in turn would adversely affect our financial condition. Our collaborators will also be required to maintain FDA clearance and possibly also other authorizations or approvals for the products and services that we jointly develop. Any failure by us or our collaborators to maintain such clearance, authorization or approval could impair or cause a delay in our ability to profit from these collaborations.

For each product we are developing that requires FDA premarket review or equivalent regulatory approval, the FDA or other regulatory authority may not grant clearance, authorization or premarket approval and failure to obtain necessary approvals for our future products and services would adversely affect our ability to grow our business.

Before we begin to manufacture, label and market additional clinical diagnostic products for commercial diagnostic use in the U.S., we may be required to obtain either clearance, marketing authorization or approval from the FDA and state regulatory authorities with jurisdiction over such products, unless an exemption applies or, in the case of the FDA, it exercises its enforcement discretion and refrains from enforcing its requirements. For example, the FDA currently refrains from enforcing its medical device requirements with respect to LDTs, which the FDA considers to be a type of in vitro diagnostic test that is designed, manufactured and used within a single properly licensed laboratory.

The process of obtaining PMA from the FDA is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. Conversely, in the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally marketed "predicate" device in order for the product to be cleared for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics or if it has different technological characteristics as the predicate device, the proposed device must be as safe and effective as, and not raise different questions of safety or effectiveness than, the predicate device. Clinical data is sometimes required to support substantial equivalence. For lower-risk devices that would otherwise automatically be placed into Class III, which require a PMA because no predicate device is available and the devices do not fall within an existing 510(k)-exempt classification, an applicant may submit a de novo request to down classify the device into Class II or Class I, which would not require a PMA. In the de novo process, the FDA must determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of a device, which is low to moderate risk and has no predicate. In other words, the applicant must justify the "down-classification" to Class I or II for a new product type that would otherwise automatically be placed into Class III, but is lower risk. Clinical data may be required. For laboratory tests for which FDA clearance, authorization or approval is required, the FDA may also require data to support analytical and clinical validity.

The 510(k), de novo and PMA processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies. The FDA's 510(k) clearance pathway usually takes from three to nine months from submission, but it can take longer for a novel type of product. The FDA's de novo classification pathway usually takes from six to 12 months, but for many applicants can take up to 18 months or more.

The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory clearances, authorizations or approvals would have a material adverse effect on our business, financial condition and prospects.

The FDA can delay, limit or deny clearance, authorization or approval of a device for many reasons, including:

- the inability to demonstrate to the satisfaction of the FDA that the products are safe or effective for their intended uses;
- the disagreement of the FDA with the design, conduct or implementation of the clinical trials or the analysis or interpretation of data from preclinical studies, analytical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical studies, analytical studies and clinical trials may be insufficient to support clearance, authorization or approval, where required;
- the inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the FDA, may recommend against approval of a PMA or other application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee makes a favorable recommendation, the FDA may still not approve the product;
- the FDA may identify deficiencies in our marketing application;
- the FDA may identify deficiencies in our or our collaborators' manufacturing processes, facilities or analytical methods;
- the potential for policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance, authorization or approval; and
- the FDA or foreign regulatory authorities may audit clinical trial data and conclude that the data is not sufficiently reliable to support a PMA.

There are numerous FDA personnel assigned to review different aspects of marketing submissions, which can present uncertainties based on their ability to exercise judgment and discretion during the review process. During the course of review, the FDA may request or require additional data and information, and the development and provision of these data and information may be time-consuming and expensive. The process of obtaining regulatory clearances, authorizations or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances, authorizations or approvals on a timely basis, or at all for our products in development. If we are unable to obtain clearance, authorization or approval for any products for which we plan to seek clearance, authorization or approval, our business may be harmed.

Modifications to our products with FDA clearance may require new FDA clearances, authorizations or approvals, or may require us to cease marketing or recall the modified clinical diagnostic products or future clinical products until clearances are obtained.

Any modification to a 510(k)-cleared device that significantly affects its safety or effectiveness, or that constitutes a major change in its intended use, could require a new 510(k) clearance, a new de novo authorization or approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances, authorizations or approvals are necessary.

For any product approved pursuant to a PMA, we would be required to seek supplemental approval for many types of modifications to the approved product. The FDA requires manufacturers in the first instance to determine whether a PMA supplement or other regulatory filing is needed or whether the change may be reported via the PMA Annual Report, but may disagree with a company's assessment.

If the FDA disagrees with our determination, which it may not review until we submit an annual report or the FDA conducts an inspection or other inquiry, and requires us to seek new clearances, authorizations or approvals for modifications to our previously cleared, authorized or approved clinical diagnostic products for which we have concluded new clearances, authorizations or approvals are unnecessary, we may be required to cease marketing or distribution of these clinical diagnostic products or to recall the modified products until we obtain clearance, authorization or approval. We may also be subject to enforcement action, including, among other things, significant regulatory fines or penalties.

Our employees, consultants and collaborators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and those of our collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent improper marketing, fraud, misconduct, kickbacks, bribery, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees and suppliers, but it is not always possible to identify and deter misconduct. In addition, our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such investigations or actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. We currently have a compliance program in accordance with the elements of an effective program outlined by the HHS OIG, which could help mitigate damages, but cannot prevent all misconduct. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, suffer adverse publicity and reputational harm, and have the attention of management diverted in defending ourselves against any of these claims or investigations.

Future Medicare payment rates are uncertain.

In January 2020, CMS revised the National Coverage Determination ("NCD") for molecular diagnostic laboratory testing services utilizing a NGS methodology, which includes our clinical diagnostic products, for Medicare beneficiaries with advanced cancer. CMS revised the NCD to extend specific coverage for germline (inherited) testing. CMS stated that it is continuing to make other technical, clarifying and conforming changes in the NCD manual and they are also clarifying the existing policy related to diagnostic tests for Somatic (Acquired) Cancer. If CMS were to make material revisions to policy, this could potentially impact the scope of clonoSEQ coverage.

Under Medicare Part B, payment for most diagnostic laboratory tests is made under the Clinical Laboratory Fee Schedule ("CLFS"), which assigns payment amounts to tests based on billing codes. Under the Protecting Access to Medicare Act of 2014 ("PAMA"), certain laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or Medicare's Physician Fee Schedule are required to report to CMS every three years, or annually for "advanced diagnostic laboratory tests," commercial payor payment rates and volumes for tests they perform and that are assigned specific billing codes. PAMA has special provisions relating to "advanced diagnostic laboratory tests," as defined by the statute, and these provisions affect the rate-setting at the time of launch and the periodicity of rate reporting and revision. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. If, in the future, clonoSEQ or any of our tests are assigned a specific code we would be required to report commercial payor payment data on those tests. Payments for tests billed under miscellaneous codes are determined by the MACs, which also have discretion to change those payment rates.

CMS uses the data reported by laboratories to calculate a payment rate for each CLFS test, other than those coded with miscellaneous codes and certain others, based on the volume-weighted median of the private payor rates. These rates apply for three years, except that payment rates for advanced diagnostic laboratory tests apply for one year. If we offer tests with specific codes, this apparatus will apply. Under these circumstances, Medicare's payment rates would be determined by the rates we and other laboratories, if any, with tests that share the specific codes we use, obtain from commercial payors. In that case, if we are unable to obtain and maintain adequate reimbursement rates from commercial payors, this may adversely affect our Medicare rates.

In some circumstances, our tests may be furnished to hospital inpatients and paid by Medicare under different rules. For example, when a specimen is obtained from a patient who is at the time classified by Medicare as a hospital inpatient, Medicare would not make a separate payment for the test and we would have to look to the hospital for payment. We do not know how often this will occur or whether hospitals will resist paying us for our tests. In this situation, Medicare coverage would be determined by the MAC for the jurisdiction where the hospital is located, which may not cover our tests.

Our products, and those jointly developed with our collaborators, may in the future be subject to product or service recalls. A recall of products or services, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our or our collaborators' products or services, could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products or services that are subject to FDA regulation. Manufacturers may, under their own initiative, recall a product or service if any deficiency is found. The FDA requires that certain corrections and removals, including recalls intended to reduce a health risk, be reported to the FDA within ten working days of initiating such correction or removal. For reportable corrections and removals, companies are required to make additional periodic submissions to the FDA after initiating the recall, and often engage with the FDA on their recall strategy prior to initiating the recall. A government-mandated or voluntary recall by us, one of our distributors or our collaborators could occur as a result of an unacceptable health risk, component failures, failures in laboratory processes, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products or services or those jointly developed with our collaborators would divert managerial and financial resources and adversely affect our reputation, results of operations and financial condition. We may also be subject to liability claims, be required to bear other costs or take other actions that may negatively impact our future sales and our ability to generate profits. Companies are also required to maintain certain records of corrections and removals, even if these do not require reporting to the FDA. We or our collaborators may initiate voluntary recalls involving our commercialized products or services in the future that we determine do not require FDA notification. If the FDA disagrees with our determinations, they may require us to report those actions as recalls. A future recall announcement by us or our collaborators could harm our reputation with customers and negatively affect our results of operations and financial condition. In addition, the FDA or other agency could take enforcement action for failing to report the recalls when they were conducted.

If we or our collaborators initiate a recall, including a correction or removal, for one of our commercialized products or services, issue a safety alert, or undertake a field action or recall to reduce a health risk, this could lead to increased scrutiny by the FDA, other governmental and regulatory enforcement bodies, and our or our collaborators' customers regarding the quality and safety of our products and services, and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports could be used against us by competitors and cause customers to delay purchase decisions or cancel orders, which would harm our reputation.

Any additional commercialized products or any future products that obtain regulatory clearance, authorization, approval, accreditation or licensure will remain subject to regulatory scrutiny and our failure to maintain our regulatory clearances, authorizations, approvals, accreditations or licensures could adversely affect our reputation, business and results of operations.

Even if we or our collaborators obtain regulatory clearance, authorization, approval, accreditation or licensure in a jurisdiction for our products and services, the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our products and services, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance of our or our collaborators' manufacturing and distribution. Advertising for certain devices and labeling, including promotional labeling, for all devices must comply with FDA requirements. In addition, device advertising and promotion may also be subject to other federal and state laws. For example, the FDA shares jurisdiction over the regulation of device advertising with the FTC. Advertising for devices characterized as restricted by the FDA is subject to specified FDA requirements, while advertising for non-restricted devices is regulated by the FTC.

If we or our collaborators fail to comply with applicable regulatory requirements following clearance, authorization, approval, accreditation or licensure of any of our products and services, a regulatory agency may:

- initiate an inspection of our or our collaborators' facilities;
- issue an untitled or warning letter asserting that we or our collaborators are in violation of law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory clearance, authorization or approval, or revoke a license or accreditation;
- suspend any ongoing clinical studies;
- delay or refuse clearance, authorization or approval of a pending regulatory submission or supplement submitted by us or our collaborators;
- impose restrictions on our or our collaborators' cleared, authorized, approved, accredited or licensed products or services;
- seize or recall the product or service;
- partially suspend or entirely shut down our or our collaborators' manufacturing or laboratory operations;
- issue advisories or other field actions;
- impose operating restrictions;
- refuse to allow us or our collaborators to enter into supply contracts, including government contracts; or
- refer matters to the DOJ or other enforcement or regulatory bodies.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our and our collaborators' ability to commercialize any cleared, authorized or approved products and services and generate revenues.

If any of our diagnostic products or services cause or contribute to a death or serious injury, or malfunction in certain ways, we will be required to report such death, serious injury or malfunction under applicable medical device reporting regulations, and such events can result in voluntary corrective actions or agency enforcement actions.

Under FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or one of our similar devices were to recur. If such a death, serious injury or malfunction were to occur, and we or our collaborators are unable to demonstrate that the adverse events were caused by factors other than our or our collaborator's products and services, regulatory authorities could order us to cease further development of, or deny clearance, authorization or approval of, any of our or our collaborators' products and services for any or all targeted indications. Even if we and our collaborators are able to demonstrate that any serious adverse events are not related to our products and services, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we or our collaborators elect, or are required, to delay, suspend or terminate any clinical trial of any product in development, the commercial prospects of such product in development may be harmed and our ability to generate product revenues may be delayed or eliminated. Any of these occurrences may harm our and our collaborators' ability to identify and develop future products and services, and may significantly harm our business, financial condition, result of operations and prospects.

We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations may have an adverse effect on our business.

Healthcare providers, physicians, hospitals and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and services for which we may obtain clearance, authorization or approval. Our current and future arrangements with healthcare providers, physicians, hospitals and third-party payors, and our sales, marketing and educational activities related to our products and services, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations at the federal and state level that may constrain our business or financial arrangements, and the relationships through which we market, sell and distribute our products and services. In addition, our operations are also subject to various federal and state fraud and abuse, physician payment transparency, and privacy and security laws, including, without limitation:

The AKS, which prohibits, among other things, persons and entities, including clinical laboratories, from knowingly and willfully soliciting, receiving, offering or paying remuneration, whether directly or indirectly, overtly or covertly, in case or in kind, to induce or reward or in return for either the referral of an individual or the purchase, lease, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. The AKS has been interpreted broadly to apply to, among other things, arrangements between clinical laboratories and prescribers and purchasers of our tests. The term "remuneration" expressly includes kickbacks, bribes or rebates and has been broadly interpreted to include anything of value, including gifts, discounts, waivers of payment, ownership interests and any goods or services provided at less than their fair market value. There are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, however, these exceptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exception or safe harbor may be subject to scrutiny. The failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct *per se* illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of the facts and circumstances to determine whether one purpose of the remuneration in the arrangement was to induce referrals or generate business that is payable by a federal healthcare program. A violation of the AKS may be grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the False Claims Act. Moreover, certain AKS safe harbors currently protecting rebates paid by device manufacturers to third parties and other arrangements between device manufacturers and third parties may later be modified or repealed pursuant to a pending regulatory proposal, which could require us to revisit or modify our business practices. Our practices may not meet all of the criteria for safe harbor protection from AKS liability in all cases. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate any AKS provisions to have committed a violation. In addition, renumeration may not be offered or provided to beneficiaries under the monetary penalty law provision prohibiting inducements to beneficiaries.

Section 8122 of the SUPPORT Act, EKRA, which establishes an all-payor anti-kickback prohibition that extends to arrangements with recovery homes, clinical laboratories and clinical treatment facilities. EKRA includes a number of statutory exceptions, and directs agencies to develop further exceptions. Current EKRA exceptions in some cases reference, and in others differ from, the AKS safe harbors. Significantly, the EKRA prohibitions apply to the soliciting or receipt of remuneration for any referrals to recovery homes, clinical treatment facilities or clinical laboratories, whether or not related to the treatment of substance use disorders. Further, the EKRA prohibitions cover the payment or offer of remuneration to induce a referral to, or in exchange for, an individual using the services of such providers. EKRA creates additional risk that relationships with referral sources could be problematic.

Federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment to, or approval by, the federal government that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the federal government. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. In addition, AKS violations implicate the False Claims Act. Conduct that results in a False Claims Act violation may also implicate various federal criminal statutes.

The Criminal Health Care Fraud Statute, which imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge or specific intent to violate the Criminal Health Care Fraud Statute.

The Stark Law, which is directed at "self-referral," prohibits, with certain exceptions, referrals for certain DHS, including laboratory services, that are covered by Medicare and Medicaid by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. Because the Stark Law is a strict liability statute, proof of specific intent to violate the law is not a required element of a violation. Any person who engages in a scheme to circumvent the Stark Law's referral prohibition may be subject to significant fines for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to Medicare or Medicaid in violation of the Stark Law is subject to civil monetary penalties applied to each bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs, and those claims are considered false claims for which the parties to the arrangement may be liable under the False Claims Act. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals. The Stark Law also places an annual cap on the amount of non-monetary compensation, which consists of meal spend and educational items, that a company can spend on a physician in the aggregate. We occasionally enter into financial relationships, usually compensation relationships, such as a consulting arrangement, with physicians who refer patients for testing. If these arrangements do not meet the Stark Law's requirements, any claims submitted to Medicare or Medicaid could violate the law and put both the physician referral source and us at risk.

The administrative simplification provisions of HIPAA, as amended and supplemented by HITECH, impose, among other things, obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information ("PHI") held by certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, and their respective business associates. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal court to enforce the federal HIPAA regulation and seek attorneys' fees and costs associated with pursuing federal civil actions. The HHS Office for Civil Rights ("OCR") has increased its focus on compliance and continues to train state attorneys general for enforcement purposes.

GINA, which restricts employers and health insurance companies from requiring or using the results of genetic tests in specific contexts and does not provide a private right of action. A number of states have also adopted laws regarding genetic tests, some aligned with GINA and some with broader applicability, including granting broader rights to individuals and imposing strict obligations on organizations to safeguard genetic data and the results of any such testing.

The Physician Payments Sunshine Act created under the ACA, and its implementing regulations, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with certain exceptions, to annually report to HHS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The Physician Payments Sunshine Act has been extended to payments and transfers of value to physician assistants, nurse practitioners and other mid-level healthcare providers for payments and other transfers of value made to these practitioners. In addition, certain state and local laws may impose additional transparency and healthcare compliance requirements on medical device manufacturers, as well as certain restrictions or limits on interactions with healthcare professionals.

The FTCA, which the FTC interprets to require taking appropriate steps to secure consumers' personal information and considers the failures to do so to constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Health information is considered sensitive data that merits stronger safeguards, and the FTC's guidance for appropriately securing consumers' personal information is consistent with what is required by the HIPAA Security Rule. Many states have passed comprehensive privacy laws, some states, most notably Massachusetts and Nevada, also have adopted laws requiring the implementation of security measures to protect personal information, and all 50 states and the District of Columbia, Puerto Rico and Guam, have adopted breach notification laws.

Analogous state laws and regulations, such as state anti-kickback, self-referral and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and in some cases even in self-pay scenarios. In addition, some state laws require life sciences companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to impose transparency requirements or restrictions on marketing activities.

Various state, federal and foreign laws and regulations govern our ability to communicate, prospect, advertise and market our products and services through email, phone, text messages, facsimile and online methods.

Because of the breadth of these laws and the narrowness of the exceptions and safe harbors available under them, it is possible that certain of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of the ongoing interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert management's attention from our business.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in government healthcare programs, injunctions, private *qui tam* actions brought by individual whistleblowers in the name of the government and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

We will need to increase the size of our organization.

As of December 31, 2025, 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.

Risks Related to Our Common Stock

Our common stock is a "penny stock," which may make it more difficult for investors to sell their shares of common stock due to suitability requirements.

Our common stock is considered to be a "penny stock." The Commission has adopted Rule 15g-9 under the Exchange Act, which generally defines "penny stock" to be any equity security that has a market price (as defined) less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. The price of our common stock is significantly less than $5.00 per share and, currently we do not qualify for an exception. This designation imposes additional sales practice requirements on broker-dealers who sell to persons other than established customers and accredited investors. The penny stock rules require a broker-dealer buying our securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities given the increased risks generally inherent in penny stocks. These rules may restrict the ability and/or willingness of brokers or dealers to buy or sell our common stock, either directly or on behalf of their clients, may discourage potential stockholders from purchasing our common stock, or may adversely affect the ability of stockholders to sell their shares.

Our common stock is currently traded on the OTC QB Market, which may have an unfavorable impact on our stock price and liquidity.

Our common stock is currently quoted on the OTC QB Markets. The OTC QB Markets is significantly more limited market than the national securities exchanges such as the New York Stock Exchange, or Nasdaq stock exchange, and there are lower financial or qualitative standards that a company must meet to have its stock quoted on the OTC QB Markets. OTC QB Markets is an inter-dealer quotation system much less regulated than the major exchanges, and trading in our common stock may be subject to abuses, volatility and shorting, which may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. The Financial Industry Regulatory Authority ("FINRA") has adopted rules that require a broker-dealer to have reasonable grounds for believing an investment is suitable for that customer when recommending an investment to a customer. FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for some customers and may make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may result in a limited ability to buy and sell our stock.

Financial Industry Regulatory Authority ("FINRA") sales practice requirements may also limit a stockholder's ability to buy and sell our common stock, which could depress the price of our common stock.

FINRA has adopted rules that require a broker-dealer to have reasonable grounds for believing that the investment is suitable for that customer before recommending an investment to a customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives, and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. Thus, the FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares of common stock, have an adverse effect on the market for our shares of common stock, and thereby depress our price per share of common stock.

Since our common stock is currently quoted on the OTC QB Markets our stockholders may face significant restrictions on the resale of our common stock due to state "blue sky" laws and the sale of common stock in this offering is subject to state "blue sky" laws.

Each state has its own securities laws, often called "blue sky" laws, which (i) limit sales of securities to a state's residents unless the securities are registered in that state or qualify for an exemption from registration, and (ii) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must also be registered in that state. Since our common stock is currently quoted on the OTC QB Markets, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as the market-makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our securities to be limited, as you may be unable to resell your common stock without the significant expense of state registration or qualification.

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, 2025, 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, 2025, 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. 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 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 Chief Executive Officer and Financial Controller are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Chief Executive and Financial Controller oversee 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 Chief Executive 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 March 11, 2026, 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, 2025.

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	5,822	$ 356.90	3,451

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 medical diagnostic 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.

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.

On May 9, 2025, we entered into a license agreement (the "License Agreement") with New Day Diagnostics LLC ("New Day") pursuant to which we in-licensed certain diagnostic tests for celiac disease, respiratory multiplex (Covid/Influenza A/B and RSV), helicobacter pylori ("H. pylori") and hepatocellular carcinoma ("HCC"). The celiac, respiratory multiplex and H. pylori tests have CE marks and are eligible to be sold in the European Union ("EU") and certain eligible markets that accept the CE mark, with the notable exception of the United States at the present time.

Pursuant to the License Agreement, we paid $525,000 in cash to New Day along with $200,000 in shares of our common stock. In addition, we have agreed to pay New Day up to $17.15 million upon achievement of certain regulatory, sales and reimbursement milestones. In addition, we will pay New Day royalty rates in the upper single to low double digits based on net sales.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2025, we have an accumulated deficit of $246.1 million, and we have not generated any revenue from operations. We expect to incur additional losses to perform further research and development activities and 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.

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RESULTS OF OPERATIONS

Comparison of the Years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	445,512	11,847,348	(11,401,836)
General and administrative	3,315,433	7,499,230	(4,183,797)
Asset impairment loss	402,746	—	402,746
Loss from operations	(4,163,691)	(19,346,578)	(15,182,887)
Other income (expense):			
Interest expense	(24,406)	(1,247,313)	1,222,907
Write-off related party note receivable	—	(600,000)	600,000
Change in fair value of contingent consideration and derivative financial instruments	(4,089,753)	7,599,263)	(11,689,016)
Inducement expense	—	(2,567,044)	2,567,044
Loss before income taxes	(8,277,850)	(16,161,672)	7,883,822
Income tax benefit	—	2,969,252	(2,969,252)
Net loss	$ (8,277,850)	$ (13,192,420)	$ (4,914,570)

We had no revenues during the years ended December 31, 2025 and 2024, 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, 2025 and 2024 were $0.4 million and $11.8 million, respectively. The decrease of $11.4 million was primarily due to a $10.6 million decrease in clinical trial costs and drug development primarily for our phase 2b study (which includes a partial offset of $0.4 million in expense related to purchased in-process research and development from the New Day asset acquisition), a $0.5 million decrease in employee compensation costs due to reduced headcounts and a $0.4 million decrease in consulting and outside services.

General and administrative expenses for the years ended December 31, 2025 and 2024 amounted to $3.3 million and $7.5 million, respectively. The decrease of $4.2 million is primarily due to a $0.7 million decrease in employee compensation costs, $0.8 million decrease in stock-based compensation costs, $0.4 million decrease in consulting and outside services, $1.7 million decrease in professional fees, $0.2 million in rent, $0.1 million decrease in software and support, and $0.1 million decrease in insurance expense.

Asset impairment loss for the years ended December 31, 2025 and 2024 were $0.4 million and $0 million, respectively. The increase of $0.4 million was primarily impairment expense related to the asset acquired in the license agreement. We tested the asset for impairment during the reporting period, noting there were triggering events related to delayed timing to market resulting in an adverse effect on estimated cashflow over the next two years. Given that the license agreement requires both parties to agree to renewal after the initial two years, we projected the estimated cashflows for the first two years for the assets available for sales in eligible markets, noting the projected cashflow will not be enough to recover the allocated cost in the first two years of the license agreement, resulting in an impairment loss.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations through December 31, 2025 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 in the United States. However, with the assets related to the New Day licensing agreement, there are three products that have CE marks and are eligible to be sold in the European Union ("EU") and certain eligible markets that accept the CE mark, with the notable exception of the United States at the present time but we cannot guarantee when and how much revenue will be generated from those products. 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, 2025, we had an accumulated deficit of $246.1 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 the development of acquired assets 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, 2025 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,	
	2025	**2024**
Net cash provided by (used in):		
Operating activities	$ (3,271,520)	$ (18,216,303)
Investing activities	(132,117)	(600,000)
Financing activities	4,825,291	4,349,707

As of December 31, 2025, we had a working capital of $2.8 million compared to working capital deficit of $1.5 million as of December 31, 2024. The increase of $4.3 million in working capital is primarily due to $8.2 million in net proceeds received from equity issuance offset by the $3.4 million related to settlement of a note payable, and the Company's other operating costs for the 12 months ended December 31, 2025.

Operating Activities:

As of December 31, 2025, we had $1.8 million in cash. Net cash used in operating activities was $3.3 million for the year ended December 31, 2025 consisting primarily of our net loss of $8.3 million, adjusted non-cash charges of $4.5 million, including $0.4 million for asset impairment, and $4.1 million in change in fair value of derivative warrants. Changes in working capital accounts had a negative impact of $0.4 million on cash primarily due to an increase in accounts payable, accrued expenses and prepaid expenses.

As of December 31, 2024, we had $0.4 million in cash. Net cash used in operating activities was $18.3 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.

Investing Activities:

Net cash used in investing activities was $0.1 million for the year ended December 31, 2025 related to the acquisition of licenses from New Day Diagnostics. Net cash used in investing activities was $0.6 million for the year ended December 31, 2024 related to the to the loan Pharma Two B.

Financing Activities:

Net cash provided by financing activities was $4.8 million for the year ended December 31, 2025, due primarily to $8.3 million proceeds received from common stock and warrant, net of issuance costs offset by $3.4 million payment on notes payable.

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

CRITICAL ACCOUNTING ESTIMATE

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 derivative financial instruments-warrants, has the greatest potential impact on our consolidated financial statements. We evaluate this estimate 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 Derivative Financial Instruments- Warrants

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. To calculate the fair value of the 2025 warrants, we performed a back solve at inception that contemplated a Discount for Lack of Marketability (DLOM) and dilution adjustments. Refer to Note 4.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2025.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2025 and 2024, 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, 2025 and 2024, 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.

January 2025 Common Stock and Warrant Transaction – Refer to Note 4 to the financial statements

Critical Audit Matter Description

On January 23, 2025, the Company completed a 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, generating total gross cash proceeds of $9.0 million. 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 Company accounted for Series A and Series B warrants as liability awards and the Pre-Funded Warrant as permanent equity.

The company estimated the fair value at issuance using a Black-Scholes option pricing model. This method of valuation involves using inputs such as the fair value of the common stock, historical volatility, the contractual term of the warrants, risk-free interest rates and dividend yields. The Company then performed a back solve that contemplated a discount for lack of marketability and dilution adjustments. At issuance, the Company recorded liabilities for the initial fair values of $1.3 million for the Series A warrants and $5.4 million for the Series B warrants.

The principal consideration for our determination that the evaluation of this 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 warrants issued (2) the fair values of the warrants given the sensitivity of the underlying significant assumptions specifically the discount for lack of marketability and dilution adjustments. 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 the warrants as liability or equity instruments.
- We involved our fair value specialist who assisted in evaluating the reasonableness of management's valuation methodology and the significant assumptions used in the valuation models, including the discount for lack of marketability and dilution adjustments.
- 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
March 11, 2026

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash	$ 1,828,062	$ 406,408
Prepaid expenses	1,241,890	1,207,329
Total current assets	3,069,952	1,613,737
Total assets	$ 3,069,952	$ 1,613,737
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 167,810	$ 220,202
Accrued expenses	77,507	23,684
Notes payable, current	54,066	2,900,000
Total current liabilities	299,383	3,143,886
Derivative financial instruments—warrants	103,022	333,189
Total liabilities	402,405	3,477,075
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, 2025 and 2024, 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, 2025 and 2024.	839,320	839,320
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 11,620,317 and 139,168 shares issued and outstanding at December 31, 2025 and 2024, respectively.	1,162	14
Additional paid-in capital	247,060,568	234,252,981
Accumulated other comprehensive income (loss)	8,345	8,345
Accumulated deficit	(246,097,656)	(237,819,806)
Total stockholders' equity	2,667,547	(1,863,338)
Total liabilities and stockholders' equity	$ 3,069,952	$ 1,613,737

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,	
	2025	**2024**
Revenues	$ —	$ —
Costs and expenses:		
Research and development	445,512	11,847,348
General and administrative	3,315,433	7,499,230
Asset impairment loss	402,746	—
Total operating expenses	4,163,691	19,346,578
Loss from operations	(4,163,691)	(19,346,578)
Other income (expense):		
Interest expense, net	(24,406)	(1,247,313)
Write-off related party note receivable	—	(600,000)
Change in fair value of contingent consideration and derivative financial instruments	(4,089,753)	7,599,263)
Inducement expense	—	(2,567,044
Loss before income taxes	(8,277,850)	(16,161,672)
Income tax benefit (expense)	—	2,969,252
Net loss	$ (8,277,850)	$ (13,192,420)
Weighted average common shares outstanding:		
Basic and diluted	9,409,375	122,894
Net loss per common share: (see Note 11)		
Basic and diluted	$ (0.88)	$ (107.35)

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,	
	2025	2024
Net loss	$ (8,277,850)	$ (13,192,420)
Other comprehensive income (loss):		
Foreign currency translation	—	87,124
Total other comprehensive income (loss)	—	87,124
Comprehensive loss	$ (8,277,850)	$ (13,105,296)

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 Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
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)
Net loss	—	—	—	—	—	—	—	—	(8,277,850)	(8,277,850)
Stock-based compensation expense	—	—	—	—	—	—	20,783	—	—	20,783
Issuance of restricted stock units	—	—	—	—	1,000	—	—	—	—	—
Issuance of common stock and pre-funded warrants, net	—	—	—	—	553,846	55	2,086,537	—	—	2,086,592
Issuance of common stock in connection with stock split	—	—	—	—	60,860	6	(6)	—	—	—
Conversion of 2025 Series B warrants into common stock	—	—	—	—	10,173,402	1,018	10,429,713	—	—	10,430,731
Issuance of common stock in connection with license agreement	—	—	—	—	692,041	69	270,560	—	—	270,629
Balance at December 31, 2025	85,581	855,808	1,688	839,320	11,620,317	1,162	$247,060,568	8,345	$(246,097,656)	$ 2,667,547

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (8,277,850)	$ (13,192,420)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	20,783	791,645
Asset impairment loss	402,746	—
Depreciation	—	30,758
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	4,089,753	(5,579,263)
Change in fair value of contingent consideration	—	(2,020,000)
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	1,431	(4,545,565
Right of use asset	—	212,878
Operating lease liability	—	(209,020)
Prepaid expenses and other assets	491,617	1,858,823
Net cash used in operating activities	(3,271,520)	(18,216,303)
Cash flows from investing activities:		
Investment in license agreement	(132,117)	—
Investment in related party receivable	—	(600,000)
Net cash used in investing activities	(132,117)	(600,000)
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants, net	9,000,000	1,849,707
Equity issuance costs	(802,597)	—
Proceeds from equity and debt issuance under SPA, net of discount	—	2,500,000
Payments on notes payable	(3,372,112)	
Net cash (used in) provided by financing activities	4,825,291	4,349,707
Effect of exchange rates on cash	—	87,124
Net increase (decrease) in cash	1,421,654	(14,379,472)
Cash at beginning of period	406,408	14,785,880
Cash at end of period	$ 1,828,062	$ 406,408
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ 17,765	$ —
Supplementary disclosure of non-cash financing activities:		
Issuance of Note Payable for payment of prepaid expense	$ 526,178	$ —
Inducement expense for issuance of Series B-1 and B-2 warrants	$ —	2,821,399
Cashless Exercise of 2025 Series B Warrants	$ 10,430,732	—
Issuance of common stock in connection with license agreement	$ 270,629	—

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 medical diagnostic 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.

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 May 9, 2025, Hepion Pharmaceuticals, Inc., a Delaware corporation (the "Company"), entered into a license agreement ("License Agreement") with New Day Diagnostics LLC ("New Day") pursuant to which the Company in-licensed certain diagnostic tests for celiac disease, respiratory multiplex (Covid/Influenza A/B and RSV), helicobacter pylori ("H. pylori") and hepatocellular carcinoma ("HCC"). The celiac, respiratory multiplex and H. pylori tests have CE marks and are eligible to be sold in the European Union ("EU") and certain eligible markets that accept the CE mark, with the notable exception of the United States at the present time. Pursuant to the License Agreement, the Company paid $525,000 in cash to New Day along with $270,629 in common stock of the Company. In addition, the Company has agreed to pay New Day up to $17.15 million upon achievement of certain regulatory, sales and reimbursement milestones. In addition, the Company will pay New Day royalty rates in the upper single to low double digits based on net sales.

The Company accounted for this transaction as an asset acquisition. The total consideration of $815,045, including the $19,146 of transaction fees, was allocated between purchased in-process research and development and Intangibles for the assets with CE mark in the EU. The portion allocated to in-process research and development was $412,299 and it was expensed upon the completion of the transaction, as research and development cost. We did not recognize any contingent consideration (milestone payments) given the low probability of meeting those targets. Royalties will be recognized when earned.

In accordance with ASC 360-10-35-21, a long-lived asset (asset group) shall be tested for recoverability whenever events or changes in circumstances indicate that its carrying amount may not be recoverable. We tested the asset for impairment during the reporting period, noting there were triggering events related to delayed timing to market resulting in an adverse effect on estimated cashflow over the next two years. Given that the license agreement requires both parties to agree to renewal after the initial two years, we projected the estimated cashflows for the first two years for the assets available for sales in eligible markets, noting the projected cashflow will not be enough to recover the allocated cost in the first two years of the license agreement. The total impairment loss recorded was $402,746. Therefore, the total cost related to the New Day licensing agreement was expensed.

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

On May 26, 2025, Hepion Pharmaceuticals, Inc., a Delaware corporation (the "Company"), entered into a patent and associated assets acquisition agreement (the "Agreement") with Panetta Partners Limited ("Panetta") whereby Panetta purchased from the Company all patent assets, knowhow, clinical trial data and drug product relating to Rencofilstat (formerly CRV431) for a nominal amount. There was no gain or loss resulting from this transaction. Panetta also assumed all contingent consideration obligations to the predecessor company's shareholders. Pursuant to the Agreement, Panetta has agreed to provide a contingent value right ("CVR") to the stockholders of the Company to receive one or more contingent payments upon the achievement of certain milestones as set forth below:

a) a payment of US$500,000 on the regulatory approval by the US Food and Drug Administration of the first new drug application for Rencofilstat (formerly CRV431)
b) a further payment of US$1,000,000 on first instance of net sales of an approved drug product containing Rencofilstat (a "*Licensed Product*") exceeding US$350,000,000; and
c) a further payment of US$3,000,000 on first instance of net sales of a Licensed Product exceeding US$750,000,000.

We did not recognize any contingent consideration given the high uncertainty of achieving these milestones.

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 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, 2025, we had $1.8 million in cash, an accumulated deficit of $246.1 million, and working capital of $2.8 million. For the year ended December 31, 2025, cash used in operating activities was $3.3 million and we had a net loss of $8.3 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.

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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 estimate is the fair value of derivative financial instruments.

Cash

As of December 31, 2025 and 2024, the amount of cash was $1.8 million and $0.4 million, respectively, consisting of checking accounts held at a U.S. commercial bank. 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.

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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.

Property, equipment and depreciation

As of December 31, 2025 and 2024, we had $0 of property and equipment. 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 years 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, 2025 or December 31, 2024.

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.

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
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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, 2025 and 2024, we had prepaid research and development costs of $0 million.

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, 2025 and 2024, 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.

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Foreign Exchange

The functional currency of Hepion Pharmaceuticals, Inc. and ContraVir Research Inc. is the U.S. dollar. The functional currency of Hepion Research Corp. is the Canadian dollar. Assets and liabilities of Hepion Research Corp. are translated into U.S. dollars using period-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a separate component of shareholders' equity. The amount of currency translation adjustment was de minimis at December 31, 2025 and 2024. 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 loss was trivial and $0.1 million for the years ended December 31, 2025 and 2024, 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 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 is regularly provided with consolidated expense information and 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.

In December 2023, the Financial Accounting Standards Board (FASB) issued an Accounting Standard Update (ASU) requiring enhancements to disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. The Company adopted this standard prospectively in the consolidated financial statements for the year ended December 31, 2025. Refer to Note 10 for the revised disclosures.

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).

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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 5).

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, 2025, there were 85,581 shares outstanding. During the years ended December 31, 2025 and 2024, 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, 2025, there were 1,688 shares outstanding. There were no conversions for the years ended December 31, 2025 and 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
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Common Stock and Warrant Offering

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 as of December 31, 2025 and 2024.

	Series A Warrants	
	December 31, 2025	December 31, 2024
Stock price	$ 0.06	$ 23.50
Expected warrant term (years)	3.1 years	4.1 years
Risk-free interest rate	3.64%	4.3%
Expected volatility	171.05%	90.1%
Dividend yield	—	—

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	Series B-1 Warrants		Series B-2 Warrants	
	December 31 2025	December 31, 2024	December 31, 2025	December 31, 2024
Stock price	$ 0.06	$ 23.50	$ N/A	$ 23.50
Expected warrant term (years)	3.1 years	4.1 years	N/A	0.6 year
Risk-free interest rate	3.64%	4.3%	N/A	4.2%
Expected volatility	171.05%	90.1%	N/A	92.6%
Dividend yield	—	—	—	—

The following assumptions were used to measure the Series B Warrants upon modification and the Series B-1 and B-2 at issuance in conjunction with the warrant inducement on February 16, 2024.

	Series A Warrants		Series B Warrants	
	Pre-Modification	Post-Modification	Pre-Modification	Post-Modification
Stock price	$ 128.00	$ 128.00	$ 128.00	128.00
Expected warrant term (years)	4.6 years	5.0 years	1.1 years	n/a
Risk-free interest rate	4.3%	4.3%	4.9%	n/a%
Expected volatility	111.0%	116.0%	143.0%	n/a%
Dividend yield	—	—	—	—

	Series B-1 Warrants	Series B-2 Warrants
	February 16, 2024	February 16, 2024
Stock price	$ 128.00	$ 128.00
Expected warrant term (years)	5.0 years	1.5 years
Risk-free interest rate	4.3%	4.8%
Expected volatility	116.0%	130.0%
Dividend yield	—	—

As of December 31, 2025, the Series B-2 warrants had expired.

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.

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The Company accounted for Series A and Series B warrants as liability awards and the Pre-Funded Warrant as a permanent equity, using an allocation of 75% for the liability and 25% for the equity components. A total of $2.3 million was recorded to permanent equity for the common stock and pre-funded warrants. The Series A and Series B Warrants were recorded at fair value on the date of issuance, and remeasured at fair value at the balance sheet date, with changes in fair value recorded to earnings. The Series A and Series B Warrant liabilities were assessed to be $1.3 million and $5.4 million, respectively, on the day of the transaction. As of December 31, 2025, a total of 10,173,402 Series B warrants were exercised and converted into common shares. As of December 31, 2025, none of the Series A warrants have been exercised, and the fair value of the Series A warrant liability was $0.1 million. The total number of unexercised Series A warrants as of December 31, 2025 was 3,443,461. All the pre-funded warrants were exercised as of March 31, 2025.

As part of the transaction, the Company incurred equity issuance costs of $0.8 million related to advisory and legal fees directly attributable to the issuance of the common stock from the Series A and Series B Warrant Agreement, which were allocated at $0.2 million and $0.6 million against additional paid-in-capital and warrant liability (expensed to change in fair value), respectively.

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 10,173,402 common shares.

As of April 4, 2025 all of the Series B warrants were exercised into 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.

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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 2025 Series A and Series B Warrants.

	2025 Series A Warrants	
	December 31, 2025	January 23, 2025
Stock price	$ 3.22	$ 10.00
Expected warrant term (years)	4.2 years	5.17 years
Risk-free interest rate	3.64%	4.12%
Expected volatility	151.25%	114.0%
Dividend yield	—	—

The Series B Warrants are exercisable on a cashless basis for a quantity equal to three times the gross quantity of shares underlying the warrants, and there is no exercise price associated with a cashless exercise (including no exercise price incorporated into the calculation of shares issuable under the cashless exercise). To calculate the fair value, we performed a back solve at inception that contemplated a DLOM and dilution adjustments. The fair value of the Series B warrants as of January 23, 2025 was $5.4 million.

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"). In addition, on April 15, 2025, we received written notice from Nasdaq indicating that Nasdaq believes we are a "public shell" and that the continued listing of our securities was no longer warranted.

On March 25, 2025, we requested a hearing, which hearing was held on April 29, 2025. On May 9, 2025, the Company received written notice (the "Notice") from the Office of General Counsel of The Nasdaq Stock Market ("Nasdaq") indicating that the Nasdaq Hearings Panel has determined to delist the Company's shares from Nasdaq due to the Company's failure to meet Nasdaq's continued listing standards. The Notice indicated that trading in the Company's shares of common stock on Nasdaq was suspended effective at the open of trading on Tuesday, May 13, 2025. On June 25, 2025, the Company successfully completed the process of transitioning to the OTCQB Venture Market.

The following table sets forth the components of changes in our derivative financial instruments liability balance for the year ended December 31, 2025 and 2024.

Date	Number of Warrants Outstanding	Derivative Instrument Liability
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
Issuance of 2025 Series A warrants	3,443,461	1,348,441
Issuance of 2025 Series B warrants	10,173,402	5,360,673
Exercise of 2025 Series B warrants	(10,173,402)	(10,430,731)
Change in fair value of warrants**	—	3,491,450
Expiration of Series B-2 warrants	(14,706)	—
Balance of derivative liability at December 31, 2025	3,477,775	$ 103,022

* 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.

** The total change in fair value of warrants excludes the expense of $0.6 million of issuance cost.

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, 2025 and 2024.

		Fair Value Measurement at Reporting Date Using		
Description	Fair value	(Level 1)	(Level 2)	(Level 3)
As of December 31, 2025:				
Derivative liabilities related to warrants	$ 103,022	$ —	$ 103,022	$ —
As of December 31, 2024:				
Derivative liabilities related to warrants	$ 333,189	$ —	$ 333,189	$ —

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 Condensed Consolidated Financial Statements

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, 2025 and 2024. 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.

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. As of December 31, 2024, the fair value of the contingent consideration was $0 because the projected milestones upon which the liability was based will not be achieved, and as of December 31, 2025, the contingency no longer exists, as the assets were acquired by Panetta (See Note 1).

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

	Acquisition-related Contingent Consideration
Liabilities:	
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 $2.9 million notes payable was paid off on January 23, 2025.

On March 15, 2025, the Company entered into a one-year Directors and Officers Liability Insurance agreement for $656,178. The Company made a down payment of $130,000, with the remaining balance financed with a third-party over the following ten months at an annual percentage rate of 7.30%. Beginning April 2025, the Company will make 10 monthly payments of $54,394, with the last payment expected to be made in January 2026. At the end of December 31, 2025, the outstanding balance on this note payable was approximately $54,066.

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

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.

8. Accrued Liabilities

At December 31, 2025 and December 31, 2024, the other accrued expenses was made up of accrued interest on note payable resulting from the Securities Purchase Agreement (the “SPA”) entered into in July 2024 (Refer to Note 4).

9. 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.

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 10,000 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. The RSUs vested in March 2025.

In addition, during the year ended December 31, 2024, the Company granted 6,800 options with a term of 2 to 10 years that were vested upon issuance. There were no grants during the year ended December 31, 2025. As of December 31, 2025, we had 3,451 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,	
	2025	**2024**
General and administrative	$ 20,783	$ 791,645
Research and development	—	—
Total stock-based compensation expense	$ 20,783	$ 791,645

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, 2024	7,813	$ 382.00	$ —	8.75 years
Forfeited	(1,991)	$ 457.45	$ —	
Balance outstanding, December 31, 2025	5,822	$ 356.90	$ —	5.15 years
Awards outstanding, vested awards and those expected to vest at December 31, 2025	5,822	$ 356.90	$ —	5.15 years
Vested and exercisable at December 3, 2025	5,822	$ 356.90	$ —	5.15 years

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

As of December 31, 2025, there was no unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures.

10. 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 $8.3 million and $16.2 million for the years ended December 31, 2025 and 2024, respectively, and was generated entirely in the United States and Canada.

The income tax expense consisted of the following:

	As of December 31,	
	2025	2024
Current Expense		
Federal	$ —	$ —
State	—	2,969,252
Foreign	—	—
Total Current Expense	$ —	$ 2,969,252
Deferred Expense		
Federal	—	—
State	—	—
Foreign	—	—
Total Deferred Expense	$ —	$ —
Income tax benefit (expense)	$ —	$ 2,969,252

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. There was no income tax benefit for the year ended December 31, 2025.

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,	
	2025	2024
Federal NOL	$ 26,324,337	$ 22,892,219
State NOL	5,854,047	4,237,665
Research and development credits	1,676,973	1,643,510
IRC 174 capitalization	11,273,792	15,282,658
Fixed Assets	4,430	4,430
Intangibles	113,212	—
Stock compensation & other	242,474	523,652
Total	45,489,265	44,584,134
Deferred tax asset valuation allowance	(45,489,265)	(44,584,134)
Total deferred tax asset	—	—

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

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, 2025 and 2024.

The valuation allowance did not significantly change and increased by $0.9 million for the years ended December 31, 2025 and 2024, respectively, due primarily to the generation of net operating losses during these periods.

As of December 31, 2025 and 2024, we had U.S. federal operating loss carryforwards of $131.2 million and $113.2 million, respectively, and state net operating loss carryforwards of $64.9 million and $46.9 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 research and development tax credit carry forwards of approximately $1.7 million as of December 31, 2025, 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.

The reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate for income from continuing operations reflecting the requirements of ASU 2023-09, as adopted prospectively, is as follows:

	Year Ended December 31, 2025	
	Amount	**% of Pre-Tax Income**
U.S. statutory income tax rate	(1,723,225)	21.0%
State income taxes, net of federal benefit(a)	(292,653)	3.6%
Tax Credits		
Research and development credits	(30,000)	0.4%
Nontaxable or nondeductible items		
Warrant Issuance	858,848	(10.5)%
Other		
Return to Provision adjustments	(3,463)	0.0%
Deferred Tax adjustments	285,363	(3.5)%
Changes in valuation allowance	905,130	(11.0)%
Effective tax rate	—	0.0%

(a)For the year ended December 31, 2025, state taxes in New Jersey made up the majority (greater than 50% of the tax effect).

A reconciliation of income tax benefit computed at the statutory federal income tax rate to income taxes, prior to the adoption of ASU 2023-09, reflected in the consolidated financial statements is as follows:

	2024
U.S. statutory income tax rate	21.0%
State income taxes, net of federal benefit	9.1%
Sale of New Jersey tax benefits	18.4%
Research and development credits	3.2%
Contingent consideration and warrants	6.6%
Return to Provision adjustments	(7.9)%
Deferred Tax adjustments	(31.6)%
Other	0.1%
Valuation allowance	(0.5)%
Effective tax rate	18.4%

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.

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

11. 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	**2025**	**2024**
Numerator:		
Net loss	$ (8,277,850)	$ (13,192,420)
Denominator:		
Weighted average common shares outstanding	9,409,375	122,894
Net loss per share of common stock—basic and diluted	$ (0.88)	$ (107.35)

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, 2025 and 2024 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,	
	2025	**2024**
Common shares issuable for:		
Series A preferred stock	3	3
Series C preferred stock	16	16
Restricted Stock Units	—	1,000
Stock options	5,822	7,813
Warrants – liability classified	34,314	49,020
Warrants – equity classified	1,105	1,795
2025 Series A warrants	3,443,461	—
Total	3,484,721	59,647

The strike price for the equity classified warrants is $2,500 each and the expiration date is in February 2026.

12. 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.

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, 2025, 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, 2025 and 2024 was $0 and $0.2 million, respectively, which included a de minimis amount for a short-term lease.

There were no future minimum rental payments under operating leases at December 31, 2025.

Employment Agreements

We have an employment agreement with one employee which require the funding of a specific level of payments, if certain events, such as a change in control, or termination without cause occur The agreement was entered into subsequent to the balance sheet date.

13. Subsequent Event

On February 25, 2026, we entered into an intellectual property license agreement with Cirna Diagnostics, LLC ("**Cirna**") pursuant to which we licensed certain liver disease diagnostic assets from Cirna. We will pay an upfront payment of $50,000 as well as certain patent expenses, up to $2,350,000 in milestone payments, up to $4,500,000 in sales milestone payments and a royalty payment on net sales in the low single digits.

Dr. Tim Block, who is a board member of the Company, is a member of Cirna.

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 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 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, 2025. 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, 2025. 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, 2025, our 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, the Company's control environment was ineffective as they 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 risk assessment, information & communication, and monitoring components of COSO along with certain control activities including both business process controls and information technology general controls.

- Lack of proper design and implementation of controls over formal review, approval, and evaluation of non-core, complex accounting transactions.

- Lack of proper design and implementation of certain controls over the income tax provision and management's review of the income tax provision. The Company utilized a third-party to assist in the preparation of the tax provision. Specifically, the Company 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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Based on that evaluation, our principal executive officer/principal financial officer concluded there were no such changes, except as noted above, during the quarter ended December 31, 2025.

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 2025 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 2025 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 2025 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 2025 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 2025 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)

Table of Contents

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).
10.4#	License Agreement dated May 9, 2025 by and between Hepion Pharmaceuticals, Inc. and New Day Diagnostics LLC (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on May 19, 2025)
10.5#	Intellectual Property License Agreement dated February 25, 2026 by and between Cirna Diagnostics, LLC and Hepion Pharmaceuticals, Inc.
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 (incorporated by reference to Exhibit 19.1 to Form 10-K filed on April 8, 2025)
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Form 10-K filed on April 8, 2025)
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.
# Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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: March 11, 2026

HEPION PHARMACEUTICALS, INC.

By: */s/ KAOUTHAR LBIATI*
Kaouthar Lbiati
Chief Executive Officer/Chief Financial Officer and Director
(Principal Executive Officer and Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, Kaouthar Lbiati, 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/ KAOUTHAR LBIATI Kaouthar Lbiati	Chief Executive Officer/Chief Financial Officer, Director (Principal Executive Officer and Financial Officer)	March 11, 2026
/s/ MICHAEL PURCELL Michael Purcell	Director	March 11, 2026
/s/ TIMOTHY BLOCK Timothy Block	Director	March 11, 2026