

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the year ended December 31, 2019

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

(State or Other Jurisdiction of
Incorporation or Organization)

46-2783806

(I.R.S. Employer
Identification No.)

399 Thornall Street, First Floor

Edison, New Jersey

(Address of Principal Executive Offices)

08837

(Zip Code)

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

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

Title of each class

Common Stock, par value \$0.0001 per share

Name of each exchange on which registered

The Nasdaq Capital Market

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

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

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

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

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

As of June 30, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's voting stock held by non-affiliates was approximately \$14.4 million based on the last reported sale price of the registrant's common stock on June 30, 2019.

The number of shares of the registrant's Common Stock outstanding as of May 14, 2020 was 9,025,061.

Documents Incorporated by Reference:

None

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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:

- Market conditions;
- Our capital position;
- Our ability to compete with larger better financed pharmaceutical companies;
- Our uncertainty of developing marketable products;
- Our ability to develop and commercialize our products;
- Risks associated with delays, increased costs and funding shortages caused by the COVID-19 pandemic;
- Our ability to obtain regulatory approvals;
- Our ability to maintain and protect intellectual property rights;
- The inability to raise additional future financing and lack of financial and other resources;
- Our ability to control product development costs;
- We may not be able to attract and retain key employees;
- We may not be able to compete effectively;
- We may not be able enter into new strategic collaborations;
- Changes in government regulation affecting our product candidate could increase our development costs;
- Our involvement in patent and other intellectual property litigation could be expensive and could divert management’s attention;
- The possibility that there will be no market acceptance for our products; and
- Changes in third-party reimbursement policies could adversely affect potential future sales of any of our products that are approved for marketing.

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

Statement Regarding COVID-19-Related Filing Delay

Hepion Pharmaceuticals, Inc. has relied on the U.S. Securities and Exchange Commission’s March 25, 2020, Order [Rel. No. No. 34-88465] to postpone filing this Annual Report. The reasons for our postponement are set out fully in our March 30, 2020, Form 8-K, which is incorporated here by reference. In particular, COVID-19 has caused severe disruptions in travel and transportation and limited access to our facilities resulting in limited support from our staff.

PART I

ITEM 1. BUSINESS

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

Overview

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

NASH is the form of liver disease that is triggered by what has come to be known as the “Western diet”, characterized especially by high-fat, high-sugar, and processed foods. Among the effects of a prolonged Western diet is fat accumulation in liver cells (steatosis) which is described as non-alcoholic fatty liver disease (“NAFLD”) and can predispose cells to injury. NAFLD may evolve into NASH when the fatty liver begins to progress through stages of cell injury, inflammation, fibrosis, and carcinogenesis. People who develop NASH often have additional predisposing conditions such as diabetes and hypertension, but the exact biochemical events that trigger and maintain the progression are not well known. Many people in the early stages of disease do not have significant symptoms and therefore do not know that they have it. NASH becomes evident and a major concern when the liver becomes fibrotic and puts the individual at increased risk of developing cirrhosis and other complications. Individuals with advanced liver fibrosis have significantly higher risk of developing liver cancer, although cancer may also arise in some patients before significant hepatitis or fibrosis. NASH is increasing worldwide at an alarming rate due to the spread of the Western diet, obesity, and other related conditions. Approximately 4-5% of the global population is estimated to have NASH, and that proportion is higher in the USA. It is predicted that NASH will become the leading reason for individuals requiring a liver transplant in the USA as early as 2020. Considering the serious outcomes linked to advancing NASH, the economic and social burden of the disease is enormous. There are no simple blood tests to diagnose or track the progression of NASH, and no drugs are approved to specifically treat the disease.

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

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

Viral hepatitis may be linked to one or more viruses including hepatitis A, B, C, D, or E. Hepatitis B virus (“HBV”) is one of many hepatitis viruses that selectively infect human liver cells and can establish persistent infections under certain conditions. Chronic infections, especially by HBV, HCV, and HDV, cause progressive liver inflammation, fibrosis, cirrhosis, and cancer. Collectively, these infections represent one of the 3 major triggers of progressive liver disease (NAFLD/NASH and alcohol being the others).

An HBV vaccine is available that, if administered *prior to* HBV infection, assists the body in neutralizing the virus and blocking infection. However, vaccination is not efficacious for people who are already infected with HBV, and the vaccine has not been historically available to everyone. As a result, an estimated 240 million people worldwide have chronic HBV infection. Anti-HBV medications are used widely by chronically infected individuals but usually are only effective in decreasing viral replication and viremia (virus in the blood), and NOT in eradicating HBV from the liver. This is because HBV, unlike HCV, has evolved clever ways of persisting in liver cells and evading the immune system. Thus, despite vaccines and anti-viral medications, chronic HBV infection remains a huge global health problem. Chronic HBV infection is the leading cause of hepatocellular carcinoma, which kills around 350,000 people per year. A similar number of people die each year from cirrhosis and other complications arising from HBV.

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

CRV431

CRV431 is a novel drug candidate designed to target a class of proteins called cyclophilins, of which there are many isoforms. Cyclophilins play a role in health and in the pathogenesis of certain diseases and are known as peptidyl prolyl isomerases. The isomerase activity plays an important role in several biological processes including, for example, folding of proteins to confer certain 3-dimensional configurations. Additionally, specific host cyclophilins (e.g., cyclophilin A, B, C, D) play a role in the pathogenesis of many diseases, including liver disease and viral hepatitis.

Cyclophilins are pleiotropic enzymes that play a role in injury and steatosis through mechanisms including cell death occurring through mitochondrial pore permeability (cyclophilin D). Inhibition of cyclophilin D, therefore, may play an important role in protection from cell death. Cyclophilin A binding to CD147 is known to play a role in inflammation, cyclophilin B plays a role in fibrosis through collagen production, and cyclophilins also play a role in cirrhosis and cancer (e.g., cell proliferation and metastasis). Cyclophilin inhibition with CRV431, therefore, may play an important role in reducing liver disease.

Important risk factors for development of liver disease include viral hepatitis (HBV, HCV, HDV), alcohol, and non-alcoholic fatty liver disease and the more aggressive form called non-alcoholic steatohepatitis. The life cycle of certain viruses, including for example, HBV, HIV, and hepatitis C virus (“HCV”) infections are dependent on host proteins (cyclophilins) for the role they play in the virus life cycle and propagation of the virus. CRV431 has been developed to inhibit the role of host cyclophilins and therefore interfere in viral propagation. CRV431 does not directly target the virus and, as such, should be less susceptible to drug resistance, borne from viral mutations.

Thus far, *in vitro* testing of CRV431 has been conducted in-house and in collaboration with external groups including for example, the Scripps Research Institute (Scripps). Data in various cell lines of either transfected or infected HBV demonstrates nanomolar efficacy (EC50 values) and micromolar toxicity (CC50 values). The selective index (“SI”), therefore, is wide and suggests that CRV431 presents a viable clinical drug candidate for the treatment of viral infections, including HBV. Additional testing in a transgenic mouse model of HBV indicated that CRV431 reduced HBV DNA in the liver and HBsAg in serum. CRV431 is orally active and appears to be well tolerated.

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

On June 17, 2019, we submitted an IND to the FDA to support initiation of our CRV431 NASH clinical development program in the United States and received approval in July 2019. We completed the first segment of a Phase 1 multiple ascending dose clinical trial in December 2019.

TXL

TXL is a novel lipid acyclic nucleoside phosphonate that is designed to deliver high intracellular concentrations of the active antiviral agent tenofovir diphosphate. TXL’s novel structure results in decreased circulating levels of tenofovir (TFV), lowering systemic exposure and thereby reducing the potential for renal side effects. We have completed Phase 1 and Phase 2 clinical trials in healthy volunteers and HBV patients, demonstrating an efficacious agent with favorable safety and tolerability profile.

After a thorough review of the business opportunity of TXL and the available resources of the Company to continue development of TXL, the Company made the decision to terminate the License Agreement by and between us and Chimerix, dated December 17, 2014.

On April 2, 2019, we delivered a notification to Chimerix of its intention to terminate the License Agreement by and between us and Chimerix, dated December 17, 2014. The termination of the License Agreement became effective on June 1, 2019. Pursuant to the License Agreement, Chimerix granted Hepion rights for the development and commercialization of TXL. Upon the effectiveness of the termination of the License Agreement on June 1, 2019, Chimerix reacquired all worldwide rights to TXL.

Hepion made the decision to terminate the License Agreement following its decision to no longer pursue development of TXL, and to focus its resources and development programs on further advancing CRV431.

Intellectual Property

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

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

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

On June 13, 2016 we completed our merger with Ciclofilin Pharmaceuticals, Inc. ("CPI") acquiring all its outstanding equity interests. Ciclofilin's lead asset, CPI-431-32, which we renamed CRV431, strengthens our liver disease portfolio and is currently in preclinical development for the treatment of liver fibrosis and in development against hepatitis B virus (HBV). On February 14, 2014, CPI, through its wholly owned subsidiary, had entered into a Purchase and Sale Agreement to acquire Aurinia Pharmaceuticals Inc. ("Aurinia") entire interest in CRV431. There was no upfront consideration. There are future milestone payments of up to CAD \$2.9 million, which are to be paid within 30 days of achieving such milestone. In addition to the milestone payments, future payment obligations (in Canadian Dollars "CAD") include a royalty of 2.5% of net sales. The amount payable under the foregoing royalty obligation is uncapped.

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

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

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

Sales and Marketing

We currently do not have any commercialization or sales and marketing capabilities, and currently have no plans to invest in or build such capabilities internally. Currently, we anticipate partnering or collaborating with, or licensing certain rights to, other larger pharmaceutical or biopharmaceutical companies to support the development of our antiviral product candidate through late-stage clinical development and, if successful, commercialization. However, we may decide not to license any development and commercialization rights to our product candidate in the future.

Manufacturing

We do not own or operate any facilities in which we can formulate and manufacture our product candidate. We intend to rely on contract manufacturers to produce all materials required to conduct preclinical studies and clinical trials under current good manufacturing practices (“cGMP”), with management and oversight of these activities by our management team. We have identified alternate sources of supply and other contract manufacturers that can produce materials for our preclinical and clinical trial requirements on a timely basis. However, if an existing or future contract manufacturer fails to deliver on schedule, or at all, it could delay or interrupt the development process for our product candidate and affect our operating results and estimated timelines.

We intend to use contract manufacturers to produce clinical trial material for use in the clinical trials of CRV431.

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.

We, and our existing collaborators, intend to obtain coverage and reimbursement from these third-party payers for any of our products that may be approved for sale; however, we cannot assure you that we will be successful in obtaining adequate coverage, reimbursement, or pricing, if any.

Regulatory Matters

Overview

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

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

U.S. Regulatory Approval

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

- the completion of satisfactory preclinical studies under the FDA's Good Laboratory Practices, or GLP, regulation;
- the submission and acceptance of an IND that must be reviewed by the FDA or Clinical Trial Application that must be reviewed by similar regulatory agencies in other countries and become effective before human clinical trials may begin;
- obtaining the approval of an Institutional Review Board, or IRB, or Ethics Committee, or EC, at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials;
- the successful completion of a series of adequate and well- controlled human clinical trials to establish the safety, potency, efficacy and purity of any product candidate for its intended use, which conform to the FDA's good clinical practice, or GCP, regulations;
- the development and demonstration of manufacturing processes that conform to FDA-mandated current Good Manufacturing Practices, or cGMPs; and
- the submission to, and review and approval by, the FDA of a New Drug Application, or NDA, or a Biologic License Application, or BLA, prior to any commercial sale or shipment of a product.

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

Preclinical Studies

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

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

Clinical Trials

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

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

- *Phase 1:* After an IND becomes effective, Phase 1 human clinical trials can begin. A product candidate is typically introduced either into healthy human subjects or in some cases, patients with the medical condition for which the product candidate is intended to be used. Generally, the purpose of a Phase 1 trial is to assess a product candidate's safety and the ability of the human body to tolerate it at different dose levels. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase 1 trials typically evaluate these aspects of the investigational drug in both single doses, as well as multiple doses.
- *Phase 2:* During Phase 2 clinical trials, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dose tolerance and determine the optimal dose for a subsequent Phase 2 or Phase 3 trial. Phase 2 trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that is not treated with the product candidate but either receives a placebo or a drug already on the market for the same indication. Typically, two or more Phase 2 studies will be conducted for a product candidate prior to advancing to Phase 3.
- *Phase 3:* If and when one or more Phase 2 trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety profile, one or more Phase 3 trials may be undertaken to further demonstrate or confirm the clinical efficacy and safety of the investigational drug in an expanded patient population, with the goal of evaluating its overall risk-benefit relationship. Phase 3 trials are generally designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase 3 trials is typically a prerequisite to the filing of an NDA or BLA for a product candidate.

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

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

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

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

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

New Drug and Biologics License Applications

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

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

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

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

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

Post-Approval Regulations

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

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

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

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

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

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

Foreign Regulatory Approval

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

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

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

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

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

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

- *Centralized procedure.* The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Union. This procedure results in a single marketing authorization issued by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- *National authorization procedures.* There are also two other possible routes to authorize medicinal products in several countries, which are available for investigational drug products that fall outside the scope of the centralized procedure:
- *Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of medicinal products that have not yet been authorized in any European Union country and that do not fall within the mandatory scope of the centralized procedure.
- *Mutual recognition procedure.* In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Employees

As of December 31, 2019, we had 12 employees. Our relations with our employees are satisfactory.

Corporate Information

We were incorporated under the laws of the State of Delaware in May 2013. Our principal executive offices are located at 399 Thornall Street, First Floor, Edison, New Jersey. Our telephone number is (732) 902-4000. We also maintain a research laboratory in Edmonton, Canada

Available Information

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

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report, including our 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.

As of the years ended December 31, 2019 and 2018, we had an accumulated deficit of \$83.2 million, and \$76.5 million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, continue our 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. Primarily as a result of our losses incurred to date, our expected continued future losses, and limited cash balances, management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has also included in its report an explanatory paragraph regarding this uncertainty. Our ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

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

We 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 candidate or continue our development programs.

We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidate 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 candidate, 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 candidate;
- 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 candidate.

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.

Our product candidate CVRV431 is in the early stages of development and its 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 candidate, our business will be materially harmed.

In the near-term, failure to successfully advance the development of our product candidate 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 candidate through preclinical studies and clinical trials, have our product candidate approved for sale by the FDA or regulatory authorities in other countries, and ultimately have our product candidate 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 candidate, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidate.

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

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

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

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

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

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidate to obtain regulatory approval to further advance clinical development or to market them. Even if our product candidate demonstrates biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. In preclinical studies and clinical trials were conducted to date, our product candidate has demonstrated an acceptable safety profile, although these studies and trials have involved a small number of subjects or patients over a limited period of time. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the results of preclinical studies or clinical trials for our product candidate, 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 candidate, 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 a 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 candidate 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 candidate 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.

If approved and commercialized, CRV431 intends to compete with numerous therapies for the treatment of NASH that are currently in development. To our knowledge, other potential competitors are in both later and earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for CRV431.

As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidate.

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

The product candidate that we, or our collaborators, are developing 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 candidate is 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 candidate has 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 candidate we are developing or 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 have limited experience in the development of small molecule antiviral product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.

Our product candidate, CRV431 is a chemical compound, also referred to as small molecules. We have limited experience in the discovery, development and manufacturing of these small molecule antiviral compounds. In order to successfully develop our product candidate, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of several responsibilities and key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidate. Therefore, our success depends in part on our ability to retain highly qualified key management personnel, and directors to develop, implement and execute our business strategy, operate the Company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidate, we need to retain or attract certain personnel, consultants or advisors with experience in the drug development activities of small molecules that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems. We are highly dependent upon our senior management and scientific staff, particularly Dr. Robert Foster, our Chief Executive Officer. The loss of services of Dr. Foster or our other member of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidate.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such personnel among biotechnology, pharmaceutical and other companies. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key managers or employees or are unable to attract and retain qualified key personnel, directors, advisors or consultants, the development of our product candidate could be delayed or terminated, and our business may be harmed.

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

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

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

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

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

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

We may experience delays in clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial, related to the COVID-19 pandemic, or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidate versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidate may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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 candidate.

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

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

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

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidate in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies, and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

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

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

If approved and commercialized, CRV431 intends to compete with at numerous therapies for the treatment of NASH that are currently in development. To our knowledge, other potential competitors are in both later and earlier stages of development. If potential competitors are successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for CRV431.

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

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

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

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

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

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

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidate in international markets. However, we have not decided how to commercialize our product candidate 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 candidate 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 candidate entirely on our own. If we are unable to enter into a marketing arrangement for our product candidate in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

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

We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of CRV431, however, could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

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

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

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

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

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

To date, our product candidate has been manufactured in small quantities for preclinical studies and clinical trials. If our product candidate is approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidate in larger quantities. We may not be able to increase successfully the manufacturing capacity for our product candidate 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 increase successfully 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 candidate requires 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 candidate may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidate.

We rely on the third-party manufacturers of our product candidate to purchase from third-party suppliers the materials necessary to produce bulk APIs, and our product candidate 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 candidate would be delayed, which may significantly impact our ability to develop the product candidate. 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 candidate, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

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

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

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, CRV431 or any other product candidate we may develop, would compete against existing therapies or other product candidates in various stages of clinical development that we believe may potentially become available in the future.

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

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

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

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

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

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

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our clinical trials in the amount of \$10.0 million. 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.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidate and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidate. The evolving COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in our CRV431 clinical trials for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency and clinical trial staff can no longer get to the clinic. Such facilities and offices may also be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services related to CRV431. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

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 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.

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

Risks Relating to the Commercialization of our Product Candidate

We may delay or terminate the development of 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.

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 one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate 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 collaborations, license agreements or other transactions with third parties to accelerate the development of our product candidate, we will bear the risk of developmental failure.

We plan to seek out-licensing opportunities as a way to accelerate the development of our product candidate. There is no guarantee that we will enter into a future transaction on favorable terms, or at all, or that discussions will initiate or progress on our desired timelines. Completing transactions of this nature is difficult and time-consuming. Potentially interested parties may decline to re-engage or may terminate discussions based upon their assessment of our competitive, financial, regulatory or intellectual property position or for any other reason. Furthermore, we may choose to defer consummating a transaction relating to our product candidate until additional clinical data are obtained. If we decide to not actively pursue a transaction until we have additional clinical data, we and our stockholders will bear the risk that our product candidate fails prior to any future transaction.

If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidate, 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 candidate, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if our product candidate is 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 any of our product candidates 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.

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.

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.

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

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

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

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

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

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

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

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

We will need to increase the size of our organization.

We are a small company with 12 employees as of December 31, 2019. To continue our clinical trials and commercialize our product candidate, 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. Over the next 12 months depending on the progress of our planned clinical trials and capital raising efforts, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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

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

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

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

Healthcare reform measures could hinder or prevent our product candidate's commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been several legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. This law will substantially change the way healthcare is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains several provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2018 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the PPACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the PPACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how these decisions, subsequent appeals and other efforts to challenge, repeal or replace the PPACA will affect the law or our business. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain PPACA qualified health plans and health insurance issuers under the PPACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress may consider other legislation to repeal or replace elements of the PPACA.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed products. Other third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidate that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

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

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

Risks Related to Our Common Stock

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, 2019 and 2018, and if they continue to be ineffective could result in material misstatements in our financial statements.

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, 2019 and 2018, 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.

If we fail to comply with the continued minimum closing bid requirements of the Nasdaq Capital Market LLC (“Nasdaq”) or other requirements for continued listing, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

On August 29, 2018, we received a written notice (the “Notice”) from the Nasdaq Stock Market LLC (“Nasdaq”) that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), (the “Rule”) as the minimum bid price of our common stock had been below \$1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had until February 25, 2019, to regain compliance with the minimum bid price requirement. On February 27, 2019, we received a letter from Nasdaq indicating that, based upon our continued non-compliance with the minimum bid price requirement as well as the fact that we have not yet held an annual meeting of shareholders within twelve months of the end of our fiscal year end, our common stock would be subject to delisting unless we timely request a hearing before a Nasdaq Hearings Panel (the “Panel”). Additionally, on March 18, 2019, we received an additional letter from Nasdaq notifying us that we failed to comply with the minimum \$2.5 million stockholders' equity requirement for continued listing under Nasdaq Listing Rule 5550(b) (the "Stockholders' Equity Rule"). Nasdaq indicated that this matter served as an additional basis for delisting our securities from Nasdaq and that the Panel will consider this matter. We requested a hearing before the Panel, which was held on April 11, 2019. On May 3, 2019, the Panel notified us that they accepted our compliance plan and granted us an extension until August 26, 2019 to regain compliance with the above noted criteria. On May 31, 2019 we implemented a reverse stock split of our outstanding common stock. Our common stock began trading on a split-adjusted basis on June 3, 2019.

A delisting of our common stock from The Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

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 recent COVID-19 pandemic; and
- whether an active trading market in our common stock develops and 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, 2019, the date of these financial statements. Our net deferred tax assets and liabilities were adjusted, and the impact of \$0.5 million was recognized as an income tax benefit during the first quarter of 2018. 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. For more information, see “Description of Our Capital Stock—Anti-takeover Effects of Certain Provisions of Hepion Certificate of Incorporation, By-laws and the DCGL.”

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 are an “emerging growth company” and as a result of our reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could remain an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the first public sale of equity securities in October 2015, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the prior December 31st, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of CRV431. 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 2. PROPERTIES

Our corporate headquarters are located in approximately 6,400 square feet of leased space at 399 Thornall Street, First Floor, Edison, New Jersey, 08837.

We have approximately 2,200 square feet of leased office and laboratory space located at 2011-94 Street, NW, Suite 102, Edmonton, AB, CANADA, T6N 1H1.

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. On October 30, 2019, Dark Arts Consulting, Inc. filed a complaint against us, in the Supreme Court of the State of New York, Nassau County, for breach of contract and related causes of action premised on allegations of non-payment of a technology services agreement. We had the action removed to the United States District Court, Eastern District of New York, on December 18, 2019. On December 26, 2019 we filed a pre-motion letter seeking leave to file a motion to dismiss the action. The Court referred the case to mediation on January 27, 2020. We reached a mutually agreeable settlement during the mediation meeting that occurred on March 11, 2020, which was not material to our financial position.

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**

On July 23, 2019, our common stock, which traded on the NASDAQ Capital Market, ceased trading under the ticker symbol “CTRV” and commenced trading on the NASDAQ Capital Market under the ticker symbol “HEPA”.

Holders of Record

As of February 28, 2020, there were 204 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, 2019.

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	41,271	\$ 194.83	0

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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 and our 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.

Business Overview

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

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

We are developing CRV431 as our lead molecule. CRV431 is a cyclophilin inhibitor that targets specific isomerases that play an important role in protein folding in health and in disease. To date, in vivo studies in several animal models of fibrosis and HCC have repeatedly and consistently demonstrated that CRV431 reduces fibrosis scores and overall liver tumor burden. Other models including in vitro and ex vivo (human precision cut liver slices) have similarly demonstrated the anti-fibrotic effects of CRV431. We have completed a Single Ascending Dose ("SAD") phase 1 human clinical study with CRV431 demonstrating safety, tolerability, and pharmacokinetics ("PK"). We are now in the midst of conducting a Multiple Ascending Dose ("MAD") phase 1 human clinical trial investigating safety, tolerability, and PK of CRV431.

CRV431

CRV431 is a novel drug candidate designed to target a class of proteins called cyclophilins, of which there are many isoforms. Cyclophilins play a role in health and in the pathogenesis of certain diseases and are known as peptidyl prolyl isomerases. The isomerase activity plays an important role in several biological processes including, for example, folding of proteins to confer certain 3-dimensional configurations. Additionally, specific host cyclophilins (e.g., cyclophilin A, B, C, D) play a role in the pathogenesis of many diseases, including liver disease and viral hepatitis.

Cyclophilins are pleiotropic enzymes that play a role in injury and steatosis through mechanisms including cell death occurring through mitochondrial pore permeability (cyclophilin D). Inhibition of cyclophilin D, therefore, may play an important role in protection from cell death. Cyclophilin A binding to CD147 is known to play a role in inflammation, cyclophilin B plays a role in fibrosis through collagen production, and cyclophilins also play a role in cirrhosis and cancer (e.g., cell proliferation and metastasis). Cyclophilin inhibition with CRV431, therefore, may play an important role in reducing liver disease.

Important risk factors for development of liver disease include the presence of non-alcoholic fatty liver disease and the more aggressive form called non-alcoholic steatohepatitis (NASH). Additional risk factors for the development of liver disease includes the presence of viral hepatitis (HBV, HCV, HDV), and alcohol consumption.

We have conducted four separate studies of CRV431 in a mouse NASH model. This model utilized streptozotocin in combination with a high fat diet to create NASH, with fibrosis occurring in eight to twelve weeks. By approximately 20 weeks of age, mice began to develop hepatocellular carcinoma (HCC).

In our first study, conducted by an independent laboratory in Japan, non-alcoholic fatty liver disease (NAFLD) activity scores (NAS) were assessed. NAS, a composite score of steatosis, inflammation, and ballooning of the liver, was determined when either five or 20 mg/kg once daily treatment with CRV431 was administered by oral gavage. In this first study, CRV431 was administered for only three weeks which did not result in a statistically significant decline in NAS. In a second independent study conducted at Scripps Research Institute, CRV431 was administered for six weeks at a dose of 50 mg/kg/day orally. A third study conducted at Scripps wherein CRV431 was administered for 11 weeks demonstrated a statistically significant decline in NAFLD activity scores, whereas the six-week study did not. A fourth study conducted at Scripps was undertaken to investigate fibrosis and HCC.

Each of these same four studies also examined fibrosis scores, as measured by Sirius red staining for collagen. Except for the lowest dose tested in Japan, which was only 5 mg/kg/day of CRV431, all four studies demonstrated that CRV431 resulted in a statistically significant reduction of fibrosis, compared to vehicle control, whether the study drug was given for 3, 6, 10 or 11-weeks once daily by oral gavage. Significant reductions in fibrosis scores were observed at both 20 and 50 mg/kg/day.

In longer-term experiments in the NASH mouse model, CRV431 dosing began on week 20, for a period of 10 weeks. Hepatocellular carcinoma (HCC) begins to develop at about 20 weeks in this model. CRV431 was administered by oral gavage at 50 mg/kg/day. Our results indicated that CRV431 significantly ($p=0.02$) reduced tumor burden (number and size of nodules) compared with vehicle control mice. This score reflected a tumor burden reduction of about 52%. Altogether, the most robust and consistent CRV431 effects in the NASH model were reductions in fibrosis and cancerous nodules.

Our Phase 1 single ascending dose study was performed in healthy volunteers administered CRV431 orally at doses of 75, 225, 375, and 525 mg. This study design was a randomized, partially blinded, placebo-controlled trial to evaluate the safety, tolerability, and PK of CRV431. A total of 6 subjects were given CRV431 in each of the four dosing cohorts. An additional 2 subjects were given placebo in each of these cohorts, so that a total of 24 subjects received CRV431 and a total of 8 subjects received placebo.

The T_{max} occurred generally at about one hour. As expected, corresponding C_{max} values increased with increasing dose. Systemic exposures, as determined by AUC were linear ($r^2 = 0.914$) up to 375 mg, but AUCs (systemic exposures) did not appreciably change from 375 mg to 525 mg. Terminal elimination half-life was approximately 100 hours.

In the Phase 1 study of CRV431, there were no severe adverse events (SAEs). The adverse events (AEs) reported were mild to moderate in nature and were almost all not related to study drug. There were no Grade 3 or 4 lab abnormalities, and all vital signs and ECGs remained normal.

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

On June 17, 2019, we submitted an IND to the FDA to support initiation of our CRV431 NASH clinical development program in the United States and received approval in July 2019. We completed the first segment of a Phase 1 multiple ascending dose clinical trial in December 2019.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2019, we have an accumulated deficit of approximately \$83.2 million. From inception through December 31, 2019, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

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

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

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

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

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

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

Recent Developments

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

The offer and sale of the Shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-229534) filed by us with the Securities and Exchange Commission (the "SEC") on February 6, 2019, as amended on February 13, 2019, and declared effective by the SEC on February 19, 2019, as supplemented by a prospectus supplement dated February 12, 2020 and filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act").

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

As of March 18, 2020, we sold 2,311,867 shares of our common stock resulting in net proceeds of \$6.8 million under the Sales Agreement.

Under the Sales Agreement, the Company may offer and sell an additional \$4.6 million under a prospectus supplement to the Form S-3 (File No. 333-229534) dated March 27, 2020 that was filed with the SEC pursuant to the Securities Act. As of April 30, 2020, we sold an additional 2,950,939 shares of our common stock resulting in net proceeds of \$4.5 million under the Sales Agreement. As of April 30, 2020, the Company sold a total of 5,262,806 shares and received total proceeds of \$11.3 million from the "at the market offerings".

CRITICAL ACCOUNTING POLICIES

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of these 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 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.

While our significant accounting policies are more fully described in Note 3 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

Going Concern

As of the year ended December 31, 2019, we had \$13.9 million in cash. Net cash used in operating activities was \$7.6 million for the year ended December 31, 2019. Net loss for the year ended December 31, 2019 was \$7.0 million. As of December 31, 2019, we had an accumulated deficit of \$83.2 million. As of December 31, 2019, we had working capital of \$13.1 million, whereas on December 31, 2018 we had working capital of \$0.1 million. We expect to incur a significant increase in operating losses for the next several years as we expand our research, development and clinical trials of CRV143. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our 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 concluded there is substantial doubt in our ability to continue as a going concern within one year after the financial statements are issued without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

Fair Value of Financial Instruments

Financial instruments consist of cash, accounts payable, convertible notes, contingent consideration and derivative instruments. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature, except for convertible notes, contingent consideration and derivative instruments. We adopted the fair value measurement for our convertible notes, which is updated each reporting period and we mark to market our contingent consideration and derivative instruments at the end of each reporting period.

A lattice-based model is used to estimate the fair value of the Secured Convertible Note. The lattice model utilizes a “decision tree” whereby future movement in our common stock price is estimated based on a volatility factor. We classified the fair value of the Secured Convertible Note as a Level 3 measurement due to the lack of observable market data. The lattice model requires the development and use of assumptions including our stock price volatility returns, an appropriate risk-free interest rate, default intensity rate and expected recovery rate given default.

Contingent consideration was related to the acquisition of Ciclofilin and recorded on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of \$19.60. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin,) and we paid a related milestone payment of \$1,000,000 and issued 1,439 shares of our common stock with a fair value of \$55,398, representing 2.5% of our issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders.

Derivative financial instruments

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

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

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

The fair value of warrants was affected by changes in inputs to the Black-Scholes option pricing model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2019 and 2018, the fair value of such warrants was approximately \$5,623 and \$0.4 million, respectively, which are classified as a long-term derivative liability on the Company's balance sheets.

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 the deferred tax asset. We account for uncertain tax positions by recognizing the financial statement effects of a tax position only when, based upon technical merits, it is "more-likely-than-not" that the position will be sustained upon examination. Potential interest and penalties associated with unrecognized tax positions are recognized in income tax expense.

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

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. We, in accordance with this guidance, does not recognize gain contingencies until realized.

Research and Development

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

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, 2019 and 2018, we had prepaid research and development costs of \$0.4 million and \$41,514, respectively.

Goodwill and In-Process Research & Development

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

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

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. There was no impairment of goodwill for the years ended December 31, 2019 and 2018.

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

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

There was no impairment of IPR&D for the years ended December 31, 2019 and 2018.

Share-based payments

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

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

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2019.

RECENT ACCOUNTING PRONOUNCEMENTS

For detailed information regarding recently issued accounting pronouncements and the expected impact on our consolidated financial statements, see Note 4, “Recent Accounting Pronouncements” in the accompanying Notes to Consolidated Financial Statements.

JOBS Act

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

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

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

We may take advantage of these provisions up to the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement or such earlier time that we are no longer an emerging growth company. We could remain an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the first public sale of equity securities in October 2015, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the prior December 31st, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

RESULTS OF OPERATIONS

Comparison of the Years ended December 31, 2019 and 2018:

	Years ended		Change
	December 31, 2019	December 31, 2018	
Revenues	\$ —	\$ —	\$ —
Costs and Expenses:			
Research and development	3,184,082	7,593,715	(4,409,633)
General and administrative	4,586,003	7,000,444	(2,414,441)
Loss from operations	(7,770,085)	(14,594,159)	(6,824,074)
Other income (expense):			
Change in fair value of debt	(179,652)	(108,942)	(70,710)
Interest on debt	(554,998)	(339,158)	(215,840)
Change in fair value of derivatives instruments – warrants and contingent consideration	558,715	5,056,964	(4,498,249)
Loss before income taxes	(7,946,020)	(9,985,295)	2,039,275
Income tax benefit	1,227,322	536,000	691,322
Net loss	<u>\$ (6,718,698)</u>	<u>\$ (9,449,295)</u>	<u>\$ 2,730,597</u>

We had no revenues during the years ended December 31, 2019 and 2018, 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, 2019 and 2018 amounted to \$3.2 million and \$7.6 million, respectively. The \$4.4 million decrease was primarily due to a decrease of \$3.4 million for costs attributable to the decision to discontinue clinical development of TXL and Valnivudine, a \$1.2 million decrease in employee-related compensation costs due to lower headcount, offset by a \$0.3 million increase attributable to the execution and the completion of the phase 1 study related to CRV431.

General and administrative expenses for the years ended December 31, 2019 and 2018 amounted to \$4.6 million and \$7.0 million, respectively. The decrease of \$2.4 million was primarily due to a \$1.4 million decrease in employee-related costs due to lower headcount, a \$0.2 million decrease in stock compensation costs, and a \$0.6 million decrease in professional fees.

During the years ended December 31, 2019 and 2018, we recorded an income tax benefit of \$1.2 million and \$0.5 million, respectively. The change is primarily related to our state tax benefit of \$1.0 million offset by changes related to foreign taxes in 2019 and an adjustment for the utilization of indefinite deferred tax liabilities in 2018 that did not occur in 2019.

Net loss for the year ended December 31, 2019 was \$6.7 million, which was the result of the operating expenses discussed above, a loss of \$0.2 million for the change in fair value of debt, a \$0.6 million loss for interest expense, which was offset by income of \$0.6 million resulting from the change in fair value of derivative instruments related to our warrants. Net loss for the year ended December 31, 2018 was \$9.4 million, which was the result of the operating expenses discussed above, a loss of \$0.1 million for the change in fair value of debt, a \$0.3 million loss for interest expense, which was offset by income of \$5.1 million resulting from the change in fair value of derivative instruments related to our warrants.

Liquidity and Capital Resources

As of December 31, 2019, we had working capital of \$13.1 million compared to working capital of \$0.1 million as of December 31, 2018. The increase of \$13.0 million in working capital is primarily related to an increase in cash and cash equivalents of \$11.1 million and a decrease in convertible debt of \$1.4 million.

Cash Flows

The following table summarizes our cash flows for the year ended December 31, 2019 and 2018:

	Year ended December 31, 2019	Year ended December 31, 2018
Net cash (used in) provided by:		
Operating activities	\$ (7,565,059)	\$ (15,646,027)
Investing activities	(51,469)	900
Financing activities	18,707,071	12,523,539
Net increase (decrease) in cash	<u>\$ 11,090,543</u>	<u>\$ (3,121,588)</u>

As of December 31, 2019, we had \$13.9 million in cash. Net cash used in operating activities was \$7.6 million for the year ended December 31, 2019 consisting of our net loss of \$6.7 million, adjusted for non-cash charges primarily of \$0.5 million for the change in the debt discount recorded as interest expense and \$0.2 million for the change in fair value of our debt. This was offset by \$0.6 million for the changes in fair value of derivative instruments and contingent consideration and \$0.3 million for the change in deferred taxes. Changes in working capital accounts had a negative impact of \$0.8 million on cash.

Net cash used in operating activities was approximately \$15.6 million for the year ended December 31, 2018. Cash was consumed from continuing operations by the net loss of \$9.4 million, and non-cash items consisting mainly of the changes in fair value of derivative instruments totaling \$5.3 million. Changes in working capital accounts had a negative impact of \$1.0 million on cash.

Net cash used in investing activities during the year ended December 31, 2019 and December 31, 2018 of was immaterial in both periods.

Net cash provided by financing activities was \$18.7 million for the year ended December 31, 2019 due primarily to the issuance of common stock, net of issuance costs in our April and June 2019 offerings of \$7.7 million, proceeds from issuance of preferred stock and warrants of \$10.0 million, and proceeds from the exercise of warrants of \$2.1 million. This was offset by the repayment of convertible debt of \$1.1 million.

Net cash provided by financing activities was \$12.5 million for the year ended December 31, 2018 due primarily to the issuance of common stock in our May and July 2018 offerings of \$1.6 million, proceeds from issuance of preferred stock and warrants of \$10.4 million, proceeds from debt financing of \$2.0 million, and offset by the repayment of convertible debt of \$1.3 million.

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

The offer and sale of the Shares will be made pursuant to a shelf registration statement on Form S-3 and the related prospectus (File No. 333-229534) filed by us with the Securities and Exchange Commission (the "SEC") on February 6, 2019, as amended on February 13, 2019, and declared effective by the SEC on February 19, 2019, as supplemented by a prospectus supplement dated February 12, 2020 and filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act").

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

As of March 18, 2020, we sold 2,311,867 shares of our common stock resulting in net proceeds of \$6.8 million under the Sales Agreement.

Under the Sales Agreement, the Company may offer and sell an additional \$4.6 million under a prospectus supplement to the Form S-3 (File No. 333-229534) dated March 27, 2020 that was filed with the SEC pursuant to the Securities Act. As of April 30, 2020, we sold an additional 2,950,939 shares of our common stock resulting in net proceeds of \$4.5 million under the Sales Agreement. As of April 30, 2020, the Company sold a total of 5,262,806 shares and received total proceeds of \$11.3 million from the "at the market offerings".

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

On April 25, 2019 we announced the pricing of a public offering with total gross proceeds of approximately \$2,140,000 before deducting placement agent fees and other offering expenses payable by us that closed on April 29, 2019. The securities offered by us consist of (i) Class A Units each consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock at a combined price of \$8.40 per Class A Unit, and (ii) Class B Units each consisting of one share of Series D Convertible Preferred Stock, with a stated value of \$1,000 per share, and convertible into 119 shares of Common Stock per share of Series D Convertible Preferred Stock, and Warrants to purchase 119 shares of Common Stock, at a combined price of \$1,000 per Class B Unit. The aggregate number of shares of Common Stock issued to the Class A Units and issued upon conversion of the Series D Convertible Preferred Stock was 254,762. The aggregate number of Warrants issued in the offering was 254,762. The Warrants have an exercise price of \$8.40, are exercisable upon issuance and expire five years from the date of issuance. A total of 555,377 warrants were exercised during the year ended December 31, 2019 resulting in proceeds of approximately \$2.1 million.

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

Operating and Capital Expenditure Requirements

As of December 31, 2019, we had an accumulated deficit of \$83.2 million and expect to incur a significant increase in operating losses for the next several years as we expand our research, development and clinical trials of CRV431. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

The consolidated financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern within one year after the financial statements are issued. Due to our recurring and expected continuing losses from operations, we have concluded there is substantial doubt in our ability to continue as a going concern without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

At this time, there is significant uncertainty relating to the trajectory of the novel coronavirus outbreak and impact of related responses. The continued spread of the outbreak could materially harm our business, results of operations, and financial condition. Due to this uncertainty and plans outside of management’s control, we may not be able to achieve and implement such plans within one year after the date that the financial statements are issued to address the substantial doubt that exists.

Contractual Obligations and Commitments

We have a long-term contractual cash obligation as of December 31, 2019, comprised of our debt with IRT and our debt debenture with an investor (see Note 5). The following table summarizes this obligation:

Contractual Obligations	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Lease obligations	\$ 889,029	\$ 274,825	\$ 560,302	\$ 53,902	\$ —
Total contractual obligations	\$ 889,029	\$ 274,825	\$ 560,302	\$ 53,902	\$ —

We have recorded contingent consideration for the acquisition of Ciclofilin on June 10, 2016 as well as executed several license agreements, as discussed in Note 7 and Note 13 to the consolidated financial statements, respectively. We have not included the contingent consideration payments or accrued milestone and royalty payments associated with licensing as management cannot reasonably estimate if or when they will occur. In connection with the June 2016 merger agreement with Ciclofilin, we are obligated to pay Aurinia Pharmaceuticals, Inc. royalties at a low single-digit percentage related to sales of CRV 431 post approval by the FDA.

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

Leases

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

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

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

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

The Company adopted ASC 842 in the first quarter of 2019 using an alternative modified retrospective approach, in which prior periods will not be restated. As a result of the adoption, as of January 1, 2019, the Company recognized an operating lease liability of \$773 thousand based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of \$764 thousand. As of December 31, 2019, the lease liabilities are \$610 thousand, of which \$192 thousand is current and \$418 thousand is non-current. The ROU assets are \$601 thousand. The discount rate used to account for the Company’s operating leases under ASC 842 is the Company’s estimated incremental borrowing rate of 6.5%.

Rent expense related to the Company’s operating leases was \$283,050 and \$289,504 for the years ended December 31, 2019 and 2018, respectively. The weighted average remaining term of the Company’s noncancelable operating leases is 3.1 years. Future minimum rental payments under the Company’s noncancelable operating leases at December 31, 2019 is as follows:

2020	\$	274,825
2021		288,226
2022		272,076
2023		53,902
Total		<u>889,029</u>
Present value adjustment		<u>(81,582)</u>
Lease liability at December 31, 2019	\$	<u>807,447</u>

Contingent consideration

We have recorded contingent consideration related to the acquisition of Ciclofilin on June 10, 2016 as well as executed several license agreements, as discussed in Note 7 and Note 12 to the consolidated financial statements, respectively. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) and we paid a related milestone payment of \$1,000,000 and issued 1,439 shares of our common stock with a fair value of \$55,398, representing 2.5% of our issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders. As of December 31, 2019, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability.

Employment agreements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Hepion Pharmaceuticals, Inc.
Edison, New Jersey

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Hepion Pharmaceuticals, Inc. (formerly known as ContraVir Pharmaceuticals, Inc.) and its subsidiaries (“the Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principles

As discussed in Note 4 to the consolidated financial statements, the Company changed its method of accounting for leases on January 1, 2019 due to the adoption of Accounting Standards Codification, Leases (ASC 842).

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered losses from operations and expects to continue to incur substantial losses in the future, which raise substantial doubt about its ability to continue as a going concern. Management’s plan in regard to these matters is also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2013

Woodbridge, NJ
May 14, 2020

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash	\$ 13,922,972	\$ 2,832,429
Prepaid expenses	465,693	135,591
Total current assets	14,388,665	2,968,020
Property and equipment, net	57,166	32,434
Right-of-use assets	797,913	—
In-process research and development	3,190,000	3,190,000
Goodwill	1,870,924	1,870,924
Other assets	127,939	127,794
Total assets	<u>\$ 20,432,607</u>	<u>\$ 8,189,172</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 491,557	\$ 748,428
Accrued expenses	493,636	661,421
Operating lease liabilities, current	266,696	—
Convertible debt	—	1,440,000
Total current liabilities	1,251,889	2,849,849
Contingent consideration	2,430,000	2,590,000
Deferred tax liability	18,752	360,700
Operating lease liabilities, non-current	540,751	—
Deferred rent liability	—	9,235
Derivative financial instruments, at estimated fair value—warrants	5,623	404,337
Total liabilities	4,247,015	6,214,121
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Series A convertible preferred stock, stated value \$10 per share, issued and outstanding 85,581 and 85,581 shares at December 31, 2019, and 2018, respectively	855,808	855,808
Series C convertible preferred stock, stated value \$1,000 per share, 1,827 and 1,974 shares issued and outstanding at December 31, 2019 and 2018, respectively	861,033	930,311
Common stock—\$0.0001 par value per share; 120,000,000 shares authorized, 3,760,255 and 247,013 shares issued and outstanding at December 31, 2019 and 2018, respectively	375	25
Additional paid in capital	97,651,006	76,652,839
Accumulated deficit	(83,185,630)	(76,463,932)
Total stockholders' equity	16,185,592	1,975,051
Total liabilities and stockholders' equity	<u>\$ 20,432,607</u>	<u>\$ 8,189,172</u>

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

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

	Year ended December 31, 2019	Year ended December 31, 2018
Revenues	\$ —	\$ —
Costs and expenses:		
Research and development	3,184,082	7,593,715
General and administrative	4,586,003	7,000,444
Total operating expenses	<u>7,770,085</u>	<u>14,594,159</u>
Loss from operations	(7,770,085)	(14,594,159)
Other income (expense):		
Change in fair value of debt	(179,652)	(108,942)
Interest expense	(554,998)	(339,158)
Change in fair value of derivative instruments—warrants and contingent consideration	558,715	5,056,964
Loss before income taxes	<u>(7,946,020)</u>	<u>(9,985,295)</u>
Income tax benefit	1,227,322	536,000
Net loss	<u>(6,718,698)</u>	<u>(9,449,295)</u>
Deemed dividend (see note 6)	(5,442,947)	(8,451,851)
Net loss attributable to common shareholders	<u>\$ (12,161,645)</u>	<u>\$ (17,901,146)</u>
<i>Weighted Average Common Shares Outstanding:</i>		
Basic and diluted	<u>2,043,244</u>	<u>183,879</u>
<i>Net loss per Common Share: (see note 12)</i>		
Basic and diluted	<u>\$ (5.95)</u>	<u>\$ (97.35)</u>

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 \$0.0001 par value		Preferred Stock, Series C \$0.0001 par value		Preferred Stock, Series D \$0.0001 par value		Preferred Stock, Series E \$0.0001 par value		Common Stock, \$0.0001 par value		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Par Value			
Balance December 31, 2018	85,581	\$ 855,808	1,974	\$ 930,311	—	\$ —	—	\$ —	247,013	\$ 25	\$ 76,652,839	\$ (76,463,932)	\$ 1,975,051
Issuance of common stock, private placement	—	—	—	—	—	—	—	—	47,429	5	486,608	—	486,613
Issuance of common stock, debt redemption	—	—	—	—	—	—	—	—	54,321	5	549,976	—	549,981
Issuance of common stock, net	—	—	—	—	—	—	—	—	1,031,071	103	7,683,391	—	7,683,494
Issuance of preferred stock, net	—	—	—	—	521	312,600	10,570	6,976,201	—	—	3,802,201	—	11,091,002
Conversion of preferred stock	—	—	(147)	(147,000)	(521)	(521,000)	(10,570)	(10,570,002)	1,825,044	182	11,237,820	—	—
Offering costs related to issuance of preferred stock	—	—	—	—	—	(29,526)	—	(472,311)	—	—	(536,787)	—	(1,038,624)
Placement agent warrants	—	—	—	—	—	(48,250)	—	(244,895)	—	—	293,145	—	—
Beneficial conversion feature of preferred stock	—	—	—	—	—	(186,692)	—	(581,350)	—	—	768,042	—	—
Accretion of beneficial conversion feature of preferred stock	—	—	—	—	—	186,692	—	581,350	—	—	(768,042)	—	—
Accretion of preferred stock discount upon conversion	—	—	—	77,722	—	286,176	—	4,311,007	—	—	(4,674,905)	—	—
Placement agent warrants	—	—	—	—	—	—	—	—	—	—	—	—	—
Exercise of warrants	—	—	—	—	—	—	—	—	555,377	55	2,090,542	—	2,090,597
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	66,176	—	66,176
Net loss	—	—	—	—	—	—	—	—	—	—	—	(6,718,698)	(6,718,698)
Balance December 31, 2019	<u>85,581</u>	<u>\$ 855,808</u>	<u>1,827</u>	<u>\$ 861,033</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>3,760,255</u>	<u>\$ 375</u>	<u>\$ 97,651,006</u>	<u>\$ (83,182,630)</u>	<u>\$ 16,185,592</u>

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 \$0.0001 par value		Preferred Stock, Series C \$0.0001 par value		Common Stock, \$0.0001 par value		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Par Value			
Balance December 31, 2017	104,013	\$ 1,040,128	—	\$ —	139,893	\$ 14	\$ 69,677,652	\$ (67,014,637)	\$ 3,703,157
Issuance of common stock, net	—	—	—	—	13,786	1	1,986,574	—	1,986,575
Issuance of Series C preferred	—	—	10,826	5,734,627	—	—	—	—	5,734,627
Offering costs related to issuance of Series C preferred	—	—	—	(411,259)	—	—	—	—	(411,259)
Placement agent warrants	—	—	—	(221,269)	—	—	221,269	—	—
Beneficial conversion feature of Series C preferred	—	—	—	(3,771,639)	—	—	3,771,639	—	—
Accretion of beneficial conversion feature of Series C preferred	—	—	—	3,771,639	—	—	(3,771,639)	—	—
Accretion of Series C preferred stock discount upon conversion	—	—	—	4,680,212	—	—	(4,680,212)	—	—
Conversion of Series A preferred	(18,432)	(184,320)	—	—	686	—	184,320	—	—
Conversion of Series C preferred	—	—	(8,852)	(8,852,000)	91,334	10	8,851,990	—	—
Exercise of warrants	—	—	—	—	1,314	—	176,736	—	176,736
Stock-based compensation expense	—	—	—	—	—	—	234,510	—	234,510
Net loss	—	—	—	—	—	—	—	(9,449,295)	(9,449,295)
Balance December 31, 2018	<u>85,581</u>	<u>\$ 855,808</u>	<u>1,974</u>	<u>\$ 930,311</u>	<u>247,013</u>	<u>\$ 25</u>	<u>\$ 76,652,839</u>	<u>\$ (76,463,932)</u>	<u>\$ 1,975,051</u>

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, 2019	Year ended December 31, 2018
Cash flows from operating activities:		
Net loss	\$ (6,718,698)	\$ (9,449,295)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	66,176	234,510
Change in fair value of derivative instrument—warrants	(398,714)	(5,322,362)
Change in the fair value of contingent consideration	(160,000)	265,398
Change in the fair value of debt	179,652	108,942
Amortization of debt discount recorded as interest expense	486,608	—
Non-cash interest for shares issued for debt redemption payments	49,732	—
Deferred taxes adjustment	(341,948)	(536,000)
Loss on the sale of assets	—	4,474
Depreciation and amortization expense	26,737	18,787
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	(424,357)	(897,695)
Deferred rent liability	—	9,235
Prepaid expenses and other assets	(330,247)	(82,021)
Net cash used in operating activities	<u>(7,565,059)</u>	<u>(15,646,027)</u>
Cash flows from investing activities:		
Proceeds from the sale of fixed assets	—	900
Purchase of property and equipment	(51,469)	—
Net cash provided by (used in) investing activities	<u>(51,469)</u>	<u>900</u>
Cash flows from financing activities:		
Proceeds from the issuance of common stock	7,683,554	1,635,140
Proceeds from issuance of Series C preferred stock, net	—	10,414,741
Proceeds from issuance of Series D preferred stock, net	403,120	—
Proceeds from issuance of Series E preferred stock, net	9,649,258	—
Proceeds from the exercise of warrants	2,090,542	142,600
Proceeds from debt financing	1,250,000	2,000,000
Repayment of debt financing	(1,250,000)	(668,942)
Payment of contingent consideration milestone	—	(1,000,000)
Repayment of convertible debt	(1,119,403)	—
Net cash provided by financing activities	<u>18,707,071</u>	<u>12,523,539</u>
Net increase (decrease) in cash	11,090,543	(3,121,588)
Cash at beginning of period	2,832,429	5,954,017
Cash at end of period	<u>\$ 13,922,972</u>	<u>\$ 2,832,429</u>
Supplementary disclosure of cash flow information:		
Cash paid for interest	\$ 26,756	\$ 131,058
Supplementary disclosure of non-cash financing activities:		
Stock issued to employees in lieu of cash payment for accrued bonus	\$ —	\$ 296,037
Issuance of common stock in conjunction with milestone payment	—	55,398
Derecognition of Series C warrants exercised	—	34,136
Conversion of Series A convertible preferred stock	—	184,320
Conversion of Series C convertible preferred stock (part of Series C deemed dividend)	147,000	4,680,212
Beneficial conversion factor of preferred stock accreted as deemed dividend	768,042	3,771,639
Conversion of Series D convertible preferred stock	521,000	—
Conversion of Series E convertible preferred stock	10,570,002	—
Accretion of Series C, D and E preferred stock discount upon conversion	4,674,905	—
Fair value of warrants issued in conjunction with common stock offering	—	5,091,373
Issuance of common stock for debt redemption	500,244	—
Adoption of lease accounting	773,330	—
Warrants issued to placement agent	293,145	221,269

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

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

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

CRV431

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

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

TXL

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

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

2. Basis of Presentation and Going Concern

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

Reverse Stock Split

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

Going Concern

As of December 31, 2019, Hepion had \$13.9 million in cash. Net cash used in operating activities was \$7.6 million for the year ended December 31, 2019. Net loss for the year ended December 31, 2019 was \$7.0 million. As of December 31, 2019, the Company had an accumulated deficit of \$83.2 million. As of December 31, 2019, Hepion had working capital of \$13.1 million, whereas on December 31, 2018 Hepion had working capital of \$0.1 million. The Company has not generated revenue to date and has incurred substantial losses and negative cash flows from operations since its inception. The Company has historically funded its operations through issuances of convertible debt, common stock and preferred stock. The Company expects to continue to incur losses for the next several years as it expands its research, development and clinical trials of CRV431. The Company is unable to predict the extent of any future losses or when the Company will become profitable, if at all.

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

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

At this time, there is significant uncertainty relating to the trajectory of the novel coronavirus outbreak and impact of related responses. The continued spread of the outbreak could materially harm our business, results of operations, and financial condition. Due to this uncertainty and plans outside of management's control, we may not be able to achieve and implement such plans within one year after the date that the financial statements are issued to address the substantial doubt that exists. See Note 15 for a detailed discussion regarding COVID-19.

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 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.

Cash

As of December 31, 2019 and 2018, the amount of cash was \$13.9 million and \$2.8 million, respectively, consisting of checking accounts held at U.S. and Canadian commercial banks. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced losses related to these balances.

Fair Value of Financial Instruments

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

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

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

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

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

Derivative Financial Instruments

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

The fair value of the warrants, issued in connection with the October 2015, April 2016, and April 2018 common stock offerings were deemed to be derivative instruments due to certain contingent put feature, was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the warrants issued, including a fixed term and exercise price.

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

The fair value of warrants was affected by changes in inputs to the Black-Scholes option pricing model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2019 and 2018, the fair value of all warrants was \$5,623 and \$0.4 million, respectively, which are classified as a long-term derivative liability on the Company's balance sheets.

Property, equipment and depreciation

As of December 31, 2019 and 2018, the Company had \$0.1 million and \$32,434, respectively, of property and equipment, consisting primarily of computer equipment, furniture and fixtures. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the depreciable assets are 3 to 5 years. Leasehold improvements are amortized using the straight-line method over their estimated useful lives, or the remaining term of the lease, whichever is shorter. Depreciation expense for the years ended December 31, 2019 and 2018 was \$26,737 and \$18,787, respectively. Expenditures for repairs and maintenance are charged to operations as incurred. The Company will periodically evaluate whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at December 31, 2019 and 2018.

Goodwill and In-Process Research & Development

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

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

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. There was no impairment of goodwill for the years ended December 31, 2019 and 2018.

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

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

There was no impairment of IPR&D for the years ended December 31, 2019 and 2018.

Income Taxes

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

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

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

Contingencies

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

Research and Development

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

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

Also as prescribed by ASC 730, non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. At December 31, 2019 and 2018, the Company had prepaid research and development costs of \$0.4 million and \$41,514, respectively.

Share-based payments

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

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

Foreign Exchange

The functional currency of Hepion and ContraVir Research Inc. is the U.S. dollar. The functional currency of ContaVir Research Corp. is the Canadian dollar. The Company’s reporting currency is the U.S. dollar. The assets and liabilities of Ciclofilin are translated into U.S. dollars using period-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a separate component of shareholders’ equity. The amount of currency translation adjustment was immaterial at December 31, 2019 and 2018.

Transactions in foreign currencies are remeasured into the functional currency of the relevant subsidiaries at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Resulting gains and losses are recorded in other foreign exchange (gain) loss within the consolidated statements of operations. The impact of foreign exchange gains (losses) was immaterial at December 31, 2019 and 2018.

Segment Information

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

Net loss per share

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

4. Recent Accounting Pronouncements

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

In August of 2018, the FASB issued ASU 2018-13 — Fair Value Measurement (Topic 820): Disclosure Framework —Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”), which amends disclosure requirements on fair value measurements in Topic 820. This amendment modifies the valuation process of fair value measurements by removing the disclosure requirements for the valuation processes for Level 3 fair value measurements, clarifying the timing of the measurement uncertainty disclosure, and including the changes in unrealized gains and losses for recurring Level 3 fair value measurements in other comprehensive income if held at the end of the reporting period. It also allows the disclosure of other quantitative information in lieu of the weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019 and should be applied prospectively for the most recent period presented in the initial fiscal year of adoption. The Company does not expect that the adoption of this guidance will have a material impact to the Company’s results of operations, financial position and cash flows.

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

Additionally, in July of 2018, the FASB issued ASU 2018-10 — Codification Improvements to Topic 842, Leases (“ASU 2018-10”), which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02 based on comments and questions raised by stakeholders during the assessment and implementation of ASU 2016-02. The Company has adopted this guidance in conjunction with the adoption of FASB issued ASU 2016-02, Leases (Topic 842) (“ASU 2016-02”). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at or entered after the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company’s primary lease arrangements at the date of adoption are associated with a lease for the Company’s corporate office. ASU 2016-02 became effective for the Company on January 1, 2019. The Company adopted ASU 2016-02 using a modified retrospective transition approach as of the effective date as permitted by the amendments in ASU 2018-11, which provides an alternative modified retrospective transition method (See Note 12). As a result, the Company was not required to adjust comparative period financial information for effects of the standard or make the new required lease disclosures for periods before the date of adoption (i.e. January 1, 2019). The Company has elected to adopt the package of transition practical expedients and, therefore, have not reassessed (1) whether existing or expired contracts contain a lease, (2) lease classification for existing or expired leases or (3) the accounting for initial direct costs that were previously capitalized. As of January 1, 2019, the Company recorded an operating lease liability of approximately \$0.8 million and operating right of use assets of approximately \$0.8 million.

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

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

In January of 2017, the FASB issued ASU No. 2017-04, Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment (“ASU 2017-04”), which amended the 2014 amendments to the FASB Accounting Standards Codification that allowed companies an alternative accounting treatment for subsequently measuring goodwill. This amendment is Phase 1 of a project by the FASB Board to simplify how an entity is required to test goodwill for impairment by eliminating step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit’s goodwill with the carrying amount of that goodwill. These amendments are to be applied on a prospective basis and are required to be adopted for annual and any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company does not expect that the adoption of this guidance will have a material impact to the Company’s results of operations, financial position and cash flows.

5. Debt

On March 13, 2019, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with an accredited investor (the “Investor”). Pursuant to the Securities Purchase Agreement, the Company issued to the Investor in a private placement (i) 47,429 shares of the Company’s common stock and (ii) an unsecured \$1.25 million aggregate principal amount debenture (the “Debenture”). The maturity date of the Debenture was June 30, 2019. Prior to the maturity date, no interest accrued on the Debenture. Upon an event of default, including upon the non-repayment of the principal amount at the maturity date, interest shall accrue on the Debenture at an interest rate equal to the lesser of 18% per annum or the maximum rate permitted by applicable law until such principal amount is paid in full. The Debenture ranks junior to the Company’s existing secured indebtedness. The relative fair value of Company shares of common stock issued was approximately \$0.5 million and was recorded as a debt discount, of which \$0.1 million was amortized as interest expense during the three months ended March 31, 2019. The Company repaid the outstanding debt balance in June 2019 and recorded the remaining unamortized debt discount of \$0.4 million as non-cash interest expense during the three months ended June 30, 2019.

On May 8, 2018, the Company entered into a securities purchase agreement (the “Securities Purchase Agreement”) with Iliad Research and Trading, L.P. (“IRT”), pursuant to which the Company issued to IRT a secured convertible promissory note (the “Note”) in the aggregate principal amount of \$3,325,000 for an aggregate purchase price of \$2,000,000 cash and \$1,000,000 aggregate principal amount of investor notes (the “Investor Notes”) payable to the Company in four tranches of \$250,000 upon request by the Company. Closing occurred on May 9, 2018. The Note carries an original issue discount of \$300,000, and the initial principal balance of \$2,225,000 also includes original issue discount of \$200,000 and \$25,000 to cover IRT’s transaction expenses. The Investor Notes have not been drawn as of September 30, 2019. The Note bears interest at the rate of 10% per annum and was paid in full on October 3, 2019. Beginning on November 8, 2018, IRT has the right to redeem all or any portion of the Note up to the Maximum Monthly Redemption Amount which is \$500,000. Payments of each redemption amount may be made in cash or shares of Company common stock at Company’s election (so long as the various conditions to paying stock set forth in the Note are satisfied) provided, however, that if the Company’s common stock is trading below \$112.00 per share (as adjusted for the reverse stock split), the redemption(s) must be in cash. Common stock issued upon redemption will be issued at a price equal to 80% of the lowest trade price of the common stock for the 20 consecutive trading days prior to the date of redemption, subject to adjustments; provided, however, that in no event will the redemption price be less than \$112.00. The Company has obtained a waiver to the redemption price to enable the Company to be able to redeem balances of the debt with the Company’s common stock. Because of this feature which allows the lender to redeem the entire outstanding balance at the Company’s option within twelve (12) months of initial issuance, the debt is classified as current. The Company also entered into a security agreement with IRT, pursuant to which IRT will receive a security interest in substantially all of the Company’s assets, except for intellectual property. The Company identified numerous embedded features to which bifurcation would be required. The Securities Purchase Agreement requires that the Company comply with certain non-financial covenants customary for financing of this nature which the Company complied with as of December 31, 2019.

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

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

During the years ended December 31, 2019, the Company made a cash redemption payment on the debt to IRT totaling \$1.1 million. The Company also made redemption payments on the debt to IRT utilizing the Company’s common stock totaling 54,321 shares with a redemption fair value of \$0.5 million. The remaining outstanding debt was paid in full in October 2019.

6. Stockholders’ Equity and Derivative Liability — Warrants

Preferred stock, Common Stock and Warrant Offering

During the period from August 5, 2016 to September 30, 2018, certain holders of the Company’s Series A Convertible Preferred Stock elected to convert approximately 1.2 million shares of Series A Convertible Preferred stock into approximately 3.0 million shares of the Company’s common stock.

Series E Convertible Preferred Stock Issuance

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

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

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

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

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

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

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

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

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

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

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

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series E, recognize any unamortized discount resulting from the initial allocation of proceeds issued to the common stock warrants. During the year ended December 31, 2019, the holders of Series E shares converted 10,570 shares of Series E into 1,761,667 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of \$4.3 million associated with the difference between the stated and carrying per share values of the Series E, including a \$0.7 million accretion related to issuance costs that had been allocated to the Series E which have been presented as a component of the net loss attributable to common stockholders in the Company's consolidated statement of operations.

Beneficial Conversion Feature-Series E Convertible Preferred Stock

Each share of Series E is convertible into shares of common stock, at any time at the option of the holder at a conversion price of \$6.00 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series E preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series E was \$0.6 million and the preferred stock was discounted by this amount. The beneficial conversion amount of \$0.6 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The \$0.6 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations for the year ended December 31, 2019.

Series D Convertible Preferred Stock Issuance

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

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

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

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

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

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

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

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

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

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

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

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

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

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series D, recognize any unamortized discount resulting from the initial allocation of proceeds issued to the common stock warrants. During the year ended December 31, 2019, the holders of Series D shares converted 521 shares of Series D into 62,064 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of \$0.3 million associated with the difference between the stated and carrying per share values of the Series D, including a \$0.1 million accretion related to issuance costs that had been allocated to the Series D which have been presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations.

Beneficial Conversion Feature-Series D Convertible Preferred Stock

Each share of Series D is convertible into shares of common stock, at any time at the option of the holder at a conversion price of \$8.40 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series D preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series D was \$0.1 million and the preferred stock was discounted by this amount. The beneficial conversion amount of \$0.1 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The \$0.1 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations for the year ended December 31, 2019.

Series C Convertible Preferred Stock Issuance

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

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

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

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

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

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

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

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

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

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

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

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

Beneficial Conversion Feature-Series C Convertible Preferred Stock

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

Controlled Equity Offering Sales Agreement

On March 9, 2015, the Company entered into a Controlled Equity Offering Sales Agreement (the "Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which the Company may offer and sell, from time to time, through Cantor shares of the Company's common stock, par value \$0.0001 per share (the "Shares"), up to an aggregate offering price of \$50.0 million. The Company intends to use the net proceeds from these sales to fund research and development activities and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated.

Under the Agreement, Cantor may sell the Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on the Nasdaq Capital Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell the Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions we may impose).

The Company is not obligated to make any sales of the Shares under the Agreement. The offering of Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the Shares subject to the Agreement or (2) the termination of the Agreement by Cantor or the Company. Hepion will pay Cantor a commission of up to 3.0% of the gross sales price per share sold and has agreed to provide Cantor with customary indemnification and contribution rights.

For the year ended December 31, 2018, we sold 10,947 shares of our common stock resulting in net proceeds of approximately \$1.6 million, under the Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent. We did not sell any shares of our common stock under this agreement during 2019.

Common Stock and Warrant Offering

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

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

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

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

	December 31, 2019	December 31, 2018
Price of Hepion common stock	\$ 5.36	\$ 19.74
Expected warrant term (years)	0.78 years	1.78 years
Risk-free interest rate	1.66%	2.48%
Expected volatility	72%	74%
Dividend yield	—	—

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

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

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

	December 31, 2019	December 31, 2018
Price of Hepion common stock	\$ 5.36	\$ 19.74
Expected warrant term (years)	1.26 years	2.26 years
Risk-free interest rate	1.66%	2.48%
Expected volatility	75%	74%
Dividend yield	—	—

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

If the Company consummates any merger, consolidation, sale or other reorganization event in which its common stock is converted into or exchanged for securities, cash or other property (“Fundamental transaction”), then the Company shall pay at the holder’s option, exercisable at any time commencing on the occurrence or the consummation of the fundamental transaction and continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such fundamental transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, the Company has determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in the Company’s statement of operations and comprehensive loss. Upon the issuance of these warrants, the fair value of approximately \$4.0 million was recorded as derivative financial instruments liability—warrants.

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

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

	December 31, 2019	December 31, 2018
Price of Hepion common stock	\$ 5.36	\$ 19.74
Expected warrant term (years)	2.31 years	3.31 years
Risk-free interest rate	1.66%	2.46%
Expected volatility	69%	74%
Dividend yield	—	—

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

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

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

	December 31, 2019	December 31, 2018
Price of Hepion common stock	\$ 5.36	\$ 19.74
Expected warrant term (years)	3.50 years	4.50 years
Risk-free interest rate	1.66%	2.51%
Expected volatility	65%	74%
Dividend yield	—	—

The following table sets forth the components of changes in the Hepion's derivative financial instruments liability balance for year ended December 31, 2019 and 2018:

Date	Description	Number of Warrants Outstanding	Derivative Instrument Liability
December 31, 2017	Balance of derivative financial instruments liability	20,384	\$ 669,462
	Issuance of warrants on July 3, 2018	88,928	5,091,373
	Change in fair value of warrant liability related to warrant exercise	(1,314)	(41,132)
	Derecognition of warrants		(34,136)
	Change in fair value of warrants for the year ended December 31, 2018	—	(5,281,230)
December 31, 2018	Balance of derivative financial instruments liability	107,998	404,337
	Change in fair value of warrants for the year ended December 31, 2019	—	(398,714)
December 31, 2019	Balance of derivative financial instruments liability	107,998	\$ 5,623

7. Fair Value Measurements

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

Description	Fair value	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2019:				
Convertible Debt	\$ —	\$ —	\$ —	\$ —
Contingent consideration	\$ 2,430,000	\$ —	\$ —	\$ 2,430,000
Derivative liabilities related to warrants	\$ 5,623	\$ —	\$ —	\$ 5,623
As of December 31, 2018:				
Convertible Debt	\$ 1,440,000	\$ —	\$ —	\$ 1,440,000
Contingent consideration	\$ 2,590,000	\$ —	\$ —	\$ 2,590,000
Derivative liabilities related to warrants	\$ 404,337	\$ —	\$ —	\$ 404,337

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities- warrants in the Company's statement of operations. See Note 6 for a rollforward of the derivative liability for the years ended December 31, 2019 and 2018. The financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

A lattice-based model was used to estimate the fair value of the Secured Convertible Note at December 31, 2018. The lattice model utilizes a "decision tree" whereby future movement in the company's common stock price is estimated based on a volatility factor. The Company classified the fair value of the Secured Convertible Note as a Level 3 measurement due to the lack of observable market data. The lattice model requires the development and use of assumptions including the Company's stock price volatility returns, an appropriate risk-free interest rate, default intensity rate and expected recovery rate given default. As of December 31, 2019, the convertible note was paid in full.

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

	Fair Value of Convertible Debt
Balance at May 8, 2018	\$ (2,000,000)
Change in fair value	(108,942)
Repayment of principal of debt financing	668,942
Balance at December 31, 2018	\$ (1,440,000)
Change in fair value	(179,652)
Repayment of principal of debt financing-stock redemption fair value	500,249
Repayment of principal of debt financing	1,119,403
Balance at December 31, 2019	\$ —

Contingent consideration was recorded for the acquisition of Ciclofilin on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of \$19.60. The Company completed the first segment of its Phase 1 clinical activities for CRV431 in October 2018 wherein the Company reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) and in the fourth quarter of 2018, the Company paid a related milestone payment of \$1,000,000 and issued 1,439 shares of the Company's common stock with a fair value of \$55,398, representing 2.5% of the Company's issued and outstanding common stock as of June, 2016, to the Ciclofilin shareholders. As of December 31, 2019, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability. The following table presents the change in fair value of the contingent consideration for the year ended December 31, 2019.

	Acquisition- related Contingent Consideration
Liabilities	
Balance at December 31, 2017	\$ 3,380,000
Settlement of first clinical milestone	(1,055,398)
Change in fair value recorded in earnings	265,398
Balance at December 31, 2018	2,590,000
Settlement of first clinical milestone	—
Change in fair value recorded in earnings	(160,000)
Balance at December 31, 2019	\$ 2,430,000

In connection with the June 2016 merger agreement with Ciclofilin Pharmaceuticals, Inc., we are obligated to pay Aurinia Pharmaceuticals, Inc. royalties at a low single-digit percentage related to sales of CRV 431 post approval by the FDA.

8. Indefinite-lived Intangible Assets and Goodwill

IPR&D

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

	Indefinite-lived Intangible Asset
CRV431 balance at December 31, 2017	\$ 3,190,000
Changes during the years ended December 31, 2018	—
CRV431 balance at December 31, 2018	3,190,000
Changes during the years ended December 31, 2019	—
CRV431 balance at December 31, 2019	\$ 3,190,000

No impairment losses were recorded on IPR&D during the years ended December 31, 2019 and 2018.

Goodwill

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

	Amount
Goodwill balance at December 31, 2017	\$ 1,870,924
Changes for the transition period ended December 31, 2018	—
Goodwill balance at December 31, 2018	1,870,924
Changes for the year ended December 31, 2019	—
Goodwill balance at December 31, 2019	\$ 1,870,924

9. Accrued Liabilities

The Company's accrued expenses consist of the following:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Payroll and related costs	\$ 346,244	\$ 280,235
Research and development	12,075	184,120
Professional fees	—	151,812
Legal fees	2,354	34,072
Other	132,963	11,182
Total accrued expenses	<u>\$ 493,636</u>	<u>\$ 661,421</u>

10. Accounting for Share-Based Payments

On June 3, 2013, Hepion adopted the 2013 Equity Incentive Plan (the "Plan"). Stock options granted under the Plan typically will vest after three years of continuous service from the grant date and will have a contractual term of ten years. Stockholder and Board approval was obtained on December 2, 2014 to increase the number of authorized shares to 11,607 and on December 14, 2016 Stockholder and Board approval was obtained to increase the number of authorized shares to 13,750. Stockholder and Board approval was obtained on February 21, 2018 to increase the number of authorized shares to 40,535. As of December 31, 2019, the Company had 0 shares of common stock available for grant under the Plan.

The Company classifies stock-based compensation expense in its 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. Hepion recorded the following stock-based compensation expense for the years ended:

	December 31, 2019	December 31, 2018
General and administrative	\$ 40,813	\$ 271,644
Research and development	25,363	(37,134)
Total stock-based compensation expense	<u>\$ 66,176</u>	<u>\$ 234,510</u>

A summary of stock option activity and of changes in stock options outstanding under the Plan is presented below:

	Number of Options	Exercise Price Per Share	Weighted Average Exercise Price Per Share	Intrinsic Value	Weighted Average Remaining Contractual Term
Balance outstanding, December 31, 2017	12,924	\$ 0.88 - \$30.64	\$ 11.84	\$ 5,958	7.00 years
Forfeited	(1,803)	\$ 2.96 - \$16.08	\$ 9.44		
Cancelled	(1,198)	\$ 4.64 - \$20.48	\$ 1.82		
Balance outstanding, December 31, 2018	9,923	\$ 0.88 - \$30.64	\$ 12.32	—	6.02 years
Granted	31,526	\$3.24	\$ —		
Forfeited	(24)	\$324.80	\$ 467.60		
Cancelled	(154)	\$324.80 - \$2,016.00	\$ 485.12		
Balance outstanding, December 31, 2019	<u>41,271</u>	\$ 3.24 - \$2,452.80	\$ 194.83	\$ 43,182	8.42 years
Vested awards and those expected to vest at December 31, 2019	39,733	\$ 3.24-\$2,452.80	\$ 202.74	\$ 71,655	8.42 years
Vested and exercisable at December 31, 2019	9,445	\$ 3.24-\$2,452.80	\$ 824.58	\$ 66,835	4.61 years

There were 31,526 and 0 options granted to employees during the years ended December 31, 2019 and 2018, respectively. The total fair value of the shares vested during the year ended December 31, 2019 was de minimis and the total fair value of shares vested during the year ended December 31, 2018 was \$1.1 million. Included within the above table are 2,410 non-employee options outstanding as of December 31, 2018, of which 266 are unvested as of December 31, 2018 and were subject to remeasurement. The remeasurement impact for the year ended December 31, 2018 was negative due to a decrease in the Company's stock price, which resulted in a decrease in the related expense recognized.

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

As of December 31, 2019, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was approximately \$0.1 million to be recognized over a weighted-average remaining vesting period of approximately 2.6 years.

There were no options granted during the year ended December 31, 2018. The following weighted-average assumptions were used in the Black-Scholes valuation model to estimate fair value of stock option awards granted to employees during the year ended December 31, 2019.

	Year Ended December 31, 2019
Stock price	\$ 3.24
Risk-free interest rate	1.85%
Dividend yield	—
Expected volatility	76.5%
Expected term (in years)	6.0 years

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

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

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

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

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

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

11. Income Taxes

The Company provides for income taxes under 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.

The Company's loss before income taxes was \$7.9 million and \$10.0 million for the years ended December 31, 2019 and 2018, respectively, and was generated entirely in the United States and Canada.

The income tax benefit for the years ended December 31, 2019 and 2018 was \$1.2 million and \$0.5 million, respectively. The income tax benefits resulted from the sale of state net operating losses totaling \$11.4 and \$0, for 2019 and 2018, respectively, and adjustments to the deferred tax liability resulting from the 2017 Tax Act. The 2017 Tax Act changed the Net Operating Loss carryforwards' period to now have an indefinite life and the Company recorded a \$0.5 million adjustment during the year ended December 31, 2018. The Company has sold a portion of its state NOLs and Research and Development credits in prior years under the State of New Jersey's Technology Business Tax Certificate Transfer Program and plans to sell additional NOLs and credits under the same program in the future.

Correction of Immaterial Errors – In connection with the preparation of the consolidated financial statements as of and for the year ended December 31, 2019, the Company determined that a revision was required to correct misstatements associated with the tax treatment of certain intercompany transactions associated with the transfer pricing arrangement in place with the Company's subsidiary in Canada. This resulted in the reduction of the Company's Canadian NOL and related Deferred tax asset valuation allowance of \$2.0 million. The Company recorded a corresponding increase to Federal net operating loss and Deferred tax asset valuation allowance of \$2.1 million. There was no impact to the Company's statement of operations and comprehensive loss as a result of these corrections. The correction had no impact on the previously reported amounts of consolidated cash flows from operating, investing or financing activities. The Company assessed the materiality of the misstatements both quantitatively and qualitatively and determined the correction of these errors to be immaterial to all prior consolidated financial statements taken as a whole and, therefore, amending previously filed reports to correct the errors was not required.

The following table presents the amounts as reported, net correction adjustments, and corrected amounts for items affected by the corrections for the year ended December 31, 2018:

	Year ended December 31, 2018		
	As reported December 31, 2018	Net adjustments	As corrected
Federal net operating loss ("NOL")	\$ 13,600,500	2,107,800	\$ 15,708,300
State NOL	2,116,300	-	2,116,300
Canadian NOL	1,978,500	(1,978,500)	-
Research and development credits	1,043,300	-	1,043,300
Lease Liability	-	-	-
Stock Compensation & Other	1,206,300	-	1,206,300
Deferred tax asset valuation allowance	(19,348,600)	(129,300)	(19,477,900)
Total Deferred Tax Asset	<u>\$ 596,300</u>	<u>-</u>	<u>\$ 596,300</u>

Additionally, the Company recorded immaterial corrections related to misstatements to the historical financial statements of the Company. During the fourth quarter in the year ended December 31, 2019, the Company recorded an out of period adjustment in the amount of \$126,300, which increased the income tax benefit for the year ended December 31, 2019. The corrections were made to a) accrue an uncertain tax position (included in accrued expenses on the consolidated balance sheet) and corresponding income tax expense related to tax, penalties and interest arising from a historical transfer of intellectual property to the Company from the Company's subsidiary in Canada during calendar year 2016; and b) to record the tax effected temporary foreign differences and other foreign tax credits related to activity of the Company's Canadian subsidiary resulting in an increase in deferred taxes and a corresponding increase to income tax benefit in the statement of operations and comprehensive loss. These corrections were determined to be immaterial individually and in the aggregate to the prior and current periods presented and were recorded as out of period adjustments in the fourth quarter of the year ended December 31, 2019.

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 the Company's deferred tax assets are comprised of the following:

	As of December 31, 2019	As of December 31, 2018
Federal net operating loss ("NOL")	\$ 16,650,007	\$ 15,708,300
State NOL	2,401,609	2,116,300
Research and development credits	1,493,666	1,043,300
Lease liability	242,234	—
Stock Compensation & Other	1,213,339	1,206,300
Deferred tax asset valuation allowance	(20,823,235)	(19,477,900)
Total Deferred Tax Asset	<u>1,177,620</u>	<u>596,300</u>
Deferred tax liability (In-Process R&D)	(957,000)	(957,000)
Right-of-use asset	(239,372)	—
Total Deferred Tax Liability	<u>(1,196,372)</u>	<u>(957,000)</u>
Net Deferred Tax Liability	<u>\$ (18,752)</u>	<u>\$ (360,700)</u>

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for its domestic deferred tax assets as of December 31, 2019 and 2018. The Company has recorded a net deferred tax liability of \$18,752 related to in-process research and development as a result of the acquisition of Ciclofilin and foreign deferred tax assets. It is the Company's position that the acquired in-process research and development is an indefinite-lived intangible asset and is not available as a source of income to support the realization of deferred tax assets.

The valuation allowance increased by \$1.4 million and \$3.4 million for the years ended December 31, 2019 and 2018, respectively, due primarily to the generation of net operating losses during the periods and also adjustments due to the December 22, 2017 enactment of the tax reform law.

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

	Year Ended December 31, 2019	Year Ended December 31, 2018
U.S. statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	11.6	7.3
Sale of New Jersey tax benefits	—	—
Research and development credits	4.0	(3.7)
Net operating loss	—	—
Warrant liability and contingent consideration	1.5	10.9
Foreign Tax Differential	(0.1)	1.7
Other	(4.7)	(1.6)
Valuation allowance	(17.9)	(30.3)
Effective tax rate	<u>15.4%</u>	<u>5.3%</u>

As of December 31, 2019 and 2018, the Company had U.S. federal and state net operating loss carryforwards of \$106.0 million and \$102.6 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2037. The Company also had federal and state research and development tax credit carry forwards of approximately \$1.2 million as of December 31, 2019, which will begin to expire in December 2027.

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 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 the Company can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on the value of the Company 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 ownership of the Company pursuant to Section 382.

The Company files income tax returns in the United States, Canada and various state jurisdictions. The Company's federal income tax returns for the years 2016 and forward and state income returns for the years 2015 and forward remain subject to examination by the Internal Revenue Service ("IRS") and state authorities.

As a result of the immaterial corrections recorded in the fourth quarter of the year ended December 31, 2019, the Company has an unrecognized tax benefit of \$224,000 and a corresponding accrual for penalties and interest in the amount of \$83,000, as a component of income tax expense, accrued through December 31, 2019. There are no amounts included in the unrecognized tax benefit at December 31, 2019 that will impact the effective rate if recognized. The Company expects that the entire amount of the unrecognized tax benefit to be reduced to \$0 in the next 12 months.

12. 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 ASC 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. In addition, the net loss attributable to common stockholders' is adjusted for the preferred stock deemed dividends related accretion of beneficial conversion feature and other discount on this instrument for the periods in which the preferred stock is outstanding.

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

	Year ended December 31, 2019	Year Ended December 31, 2018
Basic and diluted net (loss) income per common share		
Numerator:		
Net loss attributable to common stockholders — basic and diluted	\$ (12,161,645)	\$ (17,901,146)
Denominator:		
Weighted average common shares outstanding— basic and diluted	2,043,244	183,879
Net loss per share of common stock—basic and diluted	\$ (5.95)	\$ (97.35)

The following outstanding securities at December 31, 2019 and 2018 have been excluded from the computation of basic and diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year ended December 31, 2019	Year Ended December 31, 2018
Common shares issuable upon conversion of Series A preferred stock	85,581	3,184
Common shares issuable upon conversion of Series C preferred stock	1,827	18,194
Stock options	41,271	9,180
Warrants — liability classified	107,998	107,997
Warrants — equity classified	2,430,568	3,991
Total	2,667,245	142,546

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

13. Commitments and Contingencies

License Agreement with Chimerix, Inc.

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

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

Contractual Obligations

In August 2014, the Company entered into a lease for corporate office space in Edison, New Jersey. In December 2017, the Company entered an amendment to the lease for corporate office space in Edison, New Jersey expanding the office footprint and extending the lease for an approximate 5-year period. Rent expense for the years ended December 31, 2019 and 2018 was \$283,050 and \$289,504, respectively.

In May 2018, the Company entered into a lease for office equipment to be used at the Company's corporate office space in Edison, New Jersey. This term of this lease is 3 years and the Company has incurred expenses of approximately \$3,391 and \$1,978 relating to this lease for the years ended December 31, 2019 and 2018, respectively.

In October 2019, the Company entered into a lease for office and research laboratory space in Edmonton, Canada. The term of the lease is 3 years. Prior to signing this lease, the space was previously on a month to month basis.

Legal Proceedings

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

On October 30, 2019, Dark Arts Consulting, Inc. filed a complaint against us, in the Supreme Court of the State of New York, Nassau County, for breach of contract and related causes of action premised on allegations of non-payment of a technology services agreement. We had the action removed to the United States District Court, Eastern District of New York, on December 18, 2019. We deny the allegations in the complaint and on December 26, 2019 filed a pre-motion letter seeking leave to file a motion to dismiss the action. The Court referred the case to mediation on January 27, 2020. The Company reached a mutually agreeable settlement during the mediation meeting that occurred on March 11, 2020, which was not material to the Company's financial position.

Leases

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

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

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

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

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

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

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

The Company adopted ASC 842 in the first quarter of 2019 using an alternative modified retrospective approach, in which prior periods will not be restated. As a result of the adoption, as of January 1, 2019, the Company recognized an operating lease liability of \$773 thousand based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of \$764 thousand. As of December 31, 2019, the ROU assets are \$798 thousand and the lease liabilities are \$807 thousand, of which \$266 thousand is current and \$541 thousand are non-current. The discount rate used to account for the Company’s operating leases under ASC 842 is the Company’s estimated incremental borrowing rate of 6.5%.

Rent expense related to the Company’s operating leases was \$283 thousand and \$289 thousand for the years ended December 31, 2019 and 2018, respectively. The weighted average remaining term of the Company’s noncancelable operating leases is 3.2 years. Future minimum rental payments under the Company’s noncancelable operating leases at December 31, 2019 is as follows:

2020	\$ 274,825
2021	288,226
2022	272,076
2023	53,902
Total	889,029
Present value adjustment	(81,582)
Lease liability at December 31, 2019	\$ 807,447

Employment Agreements

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

14. Related Party Transactions

One of the Company’s Directors, Timothy Block, is President of the Baruch S. Blumberg Institute (“Blumberg Institute”). On May 29, 2015, the Company entered into a Sponsored Research Agreement (“Agreement”) with Blumberg Institute, pursuant to which the Company is sponsoring research by investigators affiliated with the Blumberg Institute with respect to TXL™. The Company did not incur any expenses related to the agreement in 2019 and incurred approximately \$50,000 for 2018.

15. Subsequent Events

Common Stock Offering

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

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

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

As of March 18, 2020, we sold 2,311,867 shares of our common stock resulting in net proceeds of \$6.8 million under the Sales Agreement.

Under the Sales Agreement, the Company may offer and sell an additional \$4.6 million under a prospectus supplement to the Form S-3 (File No. 333-229534) dated March 27, 2020 that was filed with the SEC pursuant to the Securities Act. As of April 30, 2020, we sold an additional 2,950,939 shares of our common stock resulting in net proceeds of \$4.5 million under the Sales Agreement. As of April 30, 2020, the Company sold a total of 5,262,806 shares and received total proceeds of \$11.3 million from the “at the market offerings”.

COVID-19 Pandemic

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

The full impact of the COVID-19 outbreak continues to evolve as of the date of this report. As such, it is uncertain as to the full magnitude that the pandemic will have on the Company’s financial condition, liquidity, and future results of operations. Management is actively monitoring the global situation and its impact on our financial condition, liquidity, operations, suppliers, industry, and workforce. Given the daily evolution of the COVID-19 outbreak and the global responses to curb its spread, the Company is not able to estimate the effects of the COVID-19 outbreak on its results of operations, financial condition, or liquidity for fiscal year 2020.

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

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change and the Company does not yet know the full extent of potential delays or impacts on the Company’s business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. Although the Company cannot estimate the length or gravity of the impact of the COVID-19 outbreak at this time, if the pandemic continues, it may have a material adverse effect on the Company’s results of future operations, financial position, liquidity, and capital resources, and those of the third parties on which the Company relies in fiscal year 2020.

The Company has applied for, and has received, funds under the Paycheck Protection Program after the period end in the amount of \$176,585. The application for these funds requires the Company to, in good faith, certify that the current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further requires the Company to take into account our current business activity and our ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The receipt of these funds, and the forgiveness of the loan attendant to these funds, is dependent on the Company having initially qualified for the loan and qualifying for the forgiveness of such loan based on our future adherence to the forgiveness criteria.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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, 2019, our Principal Executive Officer and Principal Financial Officer have 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 annual report on internal control over financial reporting. We are responsible for establishing and maintaining adequate internal control over our 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 and principal financial officers 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:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- (2) 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
- (3) 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, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations 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, 2019. 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, 2019, our principal executive officer and 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.

- (1) *Control environment* - We did not maintain an effective control environment. Our control environment was ineffective because we did not maintain a sufficient complement of personnel with an appropriate level of accounting knowledge, experience, and training in the application of Generally Accepted Accounting Principles (GAAP) commensurate with our financial reporting requirements and business environment.
- (2) *Period end financial close and reporting* - We did not maintain effective controls over the preparation and review of the interim and annual financial statements to ensure that we identified and accumulated all required supporting information to ensure the completeness and accuracy of the financial statements and that balances and disclosures reported in the financial statements, inclusive of tax and tax related balances, reconciled to the underlying supporting schedules and accounting records.

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 are in the process of taking steps to remediate the identified material weaknesses and continue to evaluate our internal controls over financial reporting, including the following:

- We assessed our companywide accounting resource requirements and as a result have hired, and are in the process of hiring additional experienced accounting personnel, and taken steps to improve the overall efficiency of our accounting and reporting processes. We will continue to regularly monitor our accounting resource sufficiency, our internal controls processes and procedures, and we may undertake additional measures as deemed necessary to fully remediate the control deficiencies.
- We are utilizing the services of external consultants for non-routine and/or technical accounting issues as they arise.

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

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 or qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

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, 2019 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 and principal financial officer concluded there were no such changes during the quarter ended December 31, 2019.

ITEM 9B. OTHER INFORMATION

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers, Directors and Key Employees

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each as of May 11, 2020.

Name	Age	Present Position with Hepion Pharmaceuticals, Inc.
Gary S. Jacob	72	Chairman of the Board of Directors
Dr. Robert T. Foster	61	Chief Executive Officer
John Cavan	61	Chief Financial Officer
John P. Brancaccio	71	Director
Timothy Block	65	Director
Arnold Lippa	73	Director
Thomas Adams	77	Director

Gary S. Jacob, Ph.D. has served as our Chairman of the Board of Directors since March 19, 2014, and earlier served as our Chief Executive Officer from May 15, 2013 until March 19, 2014. From November 2018 until March 2020, Dr. Jacob served as Chief Executive Officer of Immuron Limited, an Australian microbiome biopharmaceutical company. Previously, Dr. Jacob was the Chairman of the Board, President and Chief Executive Officer of Synergy Pharmaceuticals Inc., a biopharmaceutical company, where he held various positions from July 2008 to October 2018. On December 12, 2018, Synergy Pharmaceuticals Inc. filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code. Dr. Jacob served as Chief Executive Officer of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013 and a director from October 2004 until January 2013. Dr. Jacob currently serves as a director of Cardiff Oncology, Inc., a clinical-stage oncology therapeutics company. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England. Dr. Jacob's experience as a biotechnology company chief executive officer provides him with valuable management and leadership abilities which the Board believes qualifies him to be a director of our Company.

Dr. Robert T. Foster has served as Chief Executive Officer since October 3, 2018 and as our Chief Scientific Officer since June 10, 2016. Prior to Hepion, he was Chief Executive Officer and Founder of Ciclofilin Pharmaceuticals Inc. from January 2014 until it merged with us on June 10, 2016. Prior to Ciclofilin Pharmaceuticals, he founded Isotechnika Pharma Inc. in 1993, where he was Chairman and Chief Executive Officer for 21 years. Dr. Foster was founding Chief Executive Officer and later, Chief Scientific Officer of Aurinia Pharmaceuticals, Inc., after Isotechnika acquired Aurinia. Dr. Foster is currently a Board member of Transcriptome Sciences Inc. Dr. Foster's experience as an executive at a biotechnology company and his background as a scientist provides him with the leadership and management abilities which the Board believes qualifies him to be a director of our Company.

John Cavan has served as our Chief Financial Officer since April 1, 2016. From January 2016 to April 2016, Mr. Cavan served in the capacity of Interim CFO. Prior to joining Hepion, Mr. Cavan was a consultant with The Pine Hill Group from February 2012 to March 2016 where he was instrumental in completing multiple strategic and financial transactions, including initial public offerings, business combinations and strategic transactions. Prior to his role with the Pine Hill Group, from June 2006 until February 2012, he served as Chief Accounting Officer at Stemline Therapeutics, Inc. and as Vice President and Chief Accounting Officer at Aegerion Pharmaceuticals, Inc. where he was instrumental in the company's initial public offering, through which Aegerion achieved a \$2 billion market capitalization. He has also held financial positions within the healthcare industry at AlgoRx Pharmaceuticals, Inc. and Alpharma. Mr. Cavan served in a variety of financial and operational positions early in his career during tenures with large multinational public companies, including Sony, American Express, International Specialty Products (an Ashland Company) and Nestlé U.S.A. Mr. Cavan currently serves on the Board of Directors of Vantage Health Systems.

John P. Brancaccio, a retired CPA, has served as a director of our Company since May 15, 2013 and as a director of Synergy Pharmaceuticals, Inc. since July 2008. Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies from April 2004 until May 2017. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. Mr. Brancaccio is currently a director of Tamir Biotechnology, Inc. (formerly Alfacell Corporation) as well as a director of Cardiff Oncology, Inc. and Rasna Therapeutics, Inc., a biotechnology company. Mr. Brancaccio's chief financial officer experience provides him with valuable financial and accounting expertise which the Board believes qualifies him to serve as a director of our Company.

Dr. Timothy Block has served as a director of our Company since November 26, 2013. Dr. Block is Professor of Microbiology and Immunology, Drexel University College of Medicine and Director of its Drexel Institute for Biotechnology and Virology Research, and is also the Co-founder and President of the Hepatitis B Foundation (HBF) and its Baruch S. Blumberg Institute (formerly called the Institute for Hepatitis and Virus Research). Dr. Block is also President and CEO of the Pennsylvania Biotechnology Center. Dr. Block has been a member of medical school faculties as a professional researcher for more than 28 years, publishing more than 180 papers, 12 U.S. patents, and since 2006, has led or "co-led" more than \$50 million in research funding. Honors include an honorary Medical Doctorate (Bulgarian Academy of Medicine); the Lifetime Achievement Award from the Centrals Bucks Chamber of Commerce; named one of the regions 100 Most Outstanding People of the Century by the Daily Intelligencer; Distinguished Service Recognition from the National Cancer Institute's Early Detection Research Network; and a Special Citation from the U.S. House of Representatives in recognition of "outstanding achievements." Dr. Block has given frequent testimony to the U.S. Congress and State legislatures; has served on U.S. FDA and numerous NIH panels as well as commercial boards including the Bristol Myers Squibb Entecavir Advisory Board. In 2009, Dr. Block was named an elected Fellow of the American Association for the Advancement of Science (AAAS). Dr. Block's experience and expertise in the medical field with respect to Hepatitis B qualifies him to serve as a director of our Company.

Arnold Lippa, Ph.D. has served as a director of our company since December 3, 2015. Dr. Lippa has been Executive Chairman of the Board of RespireRx Pharmaceuticals Inc., since March 2013, and was appointed Chief Scientific Officer in August 2015. Previously, he served as Chief Executive Officer and President. He is also Chairman of the Board of Xintria Pharmaceutical Corporation, which he co-founded in 2006. Dr. Lippa is a Managing Member and founder of T Morgen Capital LLC, which is an investment and management company specializing in the creation and management of biomedical companies. Since 2005, T Morgen Capital has been a significant equity owner and a managing member of Aurora Capital LLC, a life science focused FINRA member firm, where Dr. Lippa represents T Morgen Capital as a Manager. In 2004, Dr. Lippa co-founded and currently is representing T Morgen Capital, a Managing Member, as a Manager of Atypical BioCapital Management LLC and Atypical BioVentures Fund LLC, a life science fund management company and fund, respectively, both of which are affiliates of Aurora Capital. Dr. Lippa was a founder of DOV Pharmaceutical, Inc., and served as Chairman of the Board and Chief Executive Officer from its inception in April 1995 until 2005. Prior to DOV, Dr. Lippa co-founded and co-managed a number of life sciences companies, including Praxis Pharmaceuticals, Inc., which he co-founded and took public in 1985, serving as President and Chief Operating Officer from 1984 until 1987. Dr. Lippa's experience as a biotechnology company executive and a financier qualifies him to be a director of our Company.

Thomas Adams, Ph.D. has served as a director of our Company since September 2016. Dr. Adams has been Chief Executive Officer of Cardiff Oncology, Inc., a clinical-stage oncology therapeutics company, since June 2018 and Chairman of the Board since April 2009. Dr. Adams has served as the Chairman of Clearbridge BioPhotonics, Inc., an imaging solutions company, since April 2013. From June 2005 through 2011, Dr. Adams served as a director of IRIS International, Inc., a diagnostics company, and has served as Chief Technology Officer of IRIS since April 2006. Dr. Adams was the Head of Iris Molecular Diagnostics from 2006 until November 2012 and has served as the President of Iris Personalized Medicine since 2011. In November 2012, IRIS was acquired by Danaher Corporation. Dr. Adams served as Chairman and Chief Executive Officer of Leucadia Technologies, a privately held medical-device company, from 1998 to April 2006, when Leucadia was acquired by IRIS. In 1989, Dr. Adams founded Genta, Inc., a publicly held biotechnology company in the field of antisense technology, and served as its Chief Executive Officer until 1997. Dr. Adams founded Gen-Probe, Inc. in 1984 and served as its Chief Executive Officer and Chairman until its acquisition by Chugai Biopharmaceuticals, Inc. in 1989. Dr. Adams has served as a director of Synergy Pharmaceuticals Inc., a biotechnology company, since July 2009. Dr. Adams holds a Ph.D. in Biochemistry from the University of California, at Riverside. The Board believes that Dr. Adams' executive leadership, particularly in the diagnostic field, and the extensive healthcare expertise he has developed qualifies Dr. Adams to serve as a director of our Company.

Directorships

Except as otherwise reported above, none of our directors held directorships in other reporting companies and registered investment companies at any time during the past five years.

Family Relationships

There are no family relationships among our directors and executive officers. There is no arrangement or understanding between or among our executive officers and directors pursuant to which any director or officer was or is to be selected as a director or officer.

Board Responsibilities and Structure

The Board oversees, counsels, and directs management in our long-term interest and our stockholders. The Board's responsibilities include establishing broad corporate policies and reviewing our overall performance. The Board is not, however, involved in the operating details on a day-to-day basis.

Board of Directors Meetings

During the year ended December 31, 2019, our Board met 6 times, including telephonic meetings, the Audit Committee met 4 times, the Compensation Committee met 1 time and the Corporate Governance/Nominating Committee met 1 time. All directors attended 100% of the aggregate number of meetings of the Board, all of the Audit Committee members attended 100% of the Audit Committee meetings, all of the Compensation Committee members attended 100% of the Compensation Committee meeting, and all of the Corporate Governance/Nominating Committee members attended 100% of the Corporate Governance/Nominating Committee meeting.

Information Regarding Board Committees

Our Board has established standing Audit, Compensation and Corporate Governance/Nominating Committees to devote attention to specific subjects and to assist it in the discharge of its responsibilities. All committees operate under a written charter adopted by our Board, each of which is available on our Internet website at www.HepionPharma.com under "Corporate Governance."

Audit Committee

The Audit Committee's responsibilities include: (i) reviewing the independence, qualifications, services, fees, and performance of the independent registered public accounting firm, (ii) appointing, replacing and discharging the independent registered public accounting firm, (iii) pre-approving the professional services provided by the independent registered public accounting firm, (iv) reviewing the scope of the annual audit and reports and recommendations submitted by the independent registered public accounting firm, and (v) reviewing our financial reporting and accounting policies, including any significant changes, with management and the independent registered public accounting firm. The Audit Committee also prepares the Audit Committee report that is required pursuant to the rules of the SEC.

The Audit Committee currently consists of John Brancaccio, chairman of the Audit Committee, Arnold Lippa and Thomas Adams. We believe that each of Mr. Brancaccio, Dr. Lippa and Dr. Adams is "independent" as that term is defined under applicable SEC and Nasdaq rules. Mr. Brancaccio is our audit committee financial expert. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Audit Committee. The charter is available on our website at www.HepionPharma.com.

Compensation Committee

The Compensation Committee has responsibility for assisting the board of directors in, among other things, (i) evaluating and making recommendations regarding the compensation of the executive officers and directors of our company, (ii) assuring that the executive officers are compensated effectively in a manner consistent with our stated compensation strategy, (iii) producing an annual report on executive compensation in accordance with the rules and regulations promulgated by the SEC, (iv) periodically evaluating the terms and administration of our incentive plans and benefit programs and (v) monitoring of compliance with the legal prohibition on loans to our directors and executive officers.

The Compensation Committee currently consists of Arnold Lippa, chairman of the Compensation Committee, John Brancaccio, and Thomas Adams. We believe that all of the members are "independent" under the current listing standards of Nasdaq. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Compensation Committee which is available on our website at www.HepionPharma.com.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee was, during the year ended December 31, 2019, an officer or employee of ours, was formerly an officer of ours or had any relationship requiring disclosure by us under Item 404 of Regulation S-K. No interlocking relationship as described in Item 407(e)(4) of Regulation S-K exists between any of our executive officers or Compensation Committee members, on the one hand, and the executive officers or compensation committee members of any other entity, on the other hand, nor has any such interlocking relationship existed in the past.

Corporate Governance/Nominating Committee

The Corporate Governance/Nominating Committee has responsibility for assisting the board of directors in, among other things, (i) effecting board organization, membership and function including identifying qualified board nominees, (ii) effecting the organization, membership and function of board committees including composition and recommendation of qualified candidates, (iii) establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive officers, (iv) development and evaluation of criteria for board membership such as overall qualifications, term limits, age limits and independence and (v) oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the board of directors based on the criteria, skills and qualifications that have been recognized by the Corporate Governance/Nominating Committee. While our nomination and corporate governance policy does not prescribe specific diversity standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, differences in viewpoints and skills, and personal qualities that will result in a well-rounded board of directors.

The Corporate Governance/Nominating Committee currently consists of Timothy Block, chairman of the Corporate Governance/Nominating Committee, Arnold Lippa, and John Brancaccio. We believe that all of the members are “independent” under the current listing standards of Nasdaq. The board of directors has adopted a written charter setting forth the authority and responsibilities of the Corporate Governance/Nominating Committee which is available on our website at www.HepionPharma.com.

Communications with our Board of Directors

Stockholders seeking to communicate with our Board should submit their written comments to our Chief Executive Officer, Dr. Robert Foster, at Hepion Pharmaceuticals, Inc., 399 Thornall Street, First Floor, Edison, NJ 08837. Dr. Foster will forward such communications to each member of our Board; provided that, if in the opinion of Dr. Foster it would be inappropriate to send a particular stockholder communication to a specific director, such communication will only be sent to the remaining directors (subject to the remaining directors concurring with such opinion).

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during the annual period ended December 31, 2019, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics to ensure that our business is conducted in a consistently legal and ethical manner. All of our employees, including our executive officers and directors, are required to comply with our Code of Business Conduct and Ethics.

The full text of the Code of Business Conduct and Ethics is posted on our website at <http://www.HepionPharma.com>. Any waiver of the Code of Business Conduct and Ethics for directors or executive officers must be approved by our Audit Committee. We will disclose future amendments to our Code of Business Conduct and Ethics, or waivers from our Code of Business Conduct and Ethics for our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, on our website within four business days following the date of the amendment or waiver. In addition, we will disclose any waiver from our Code of Business Conduct and Ethics for our other executive officers and our directors on our website. A copy of our Code of Business Conduct and Ethics will also be provided free of charge upon request to: Secretary, Hepion Pharmaceuticals Inc. 399 Thornall Street, First Floor, Edison, NJ 08837.

Item 11. Executive Compensation.

Summary Compensation Table

The following table contains compensation information for our Chief Executive Officer and certain other executives who were the most highly compensated executive officers for the years ended December 31, 2019 and 2018.

Name & Principal Position	Year	Salary	Bonus(1)	Stock In Lieu of Cash Bonus	Options granted(2)	Non-equity incentive plan compensation(1)(3)	Other	Total
Dr. Robert Foster.	December 2019	\$ 400,000	\$ —	\$ —	\$ 21,102	\$ 200,000	\$ —	\$ 621,102
Chief Executive Officer	December 2018	\$ 312,345	\$ —	\$ 62,244	\$ —	\$ —	\$ —	\$ 374,589
John Cavan.	December 2019	\$ 291,136	\$ —	\$ —	\$ 12,635	\$ 72,917	\$ —	\$ 376,688
Chief Financial Officer	December 2018	\$ 274,827	\$ —	\$ 64,007	\$ —	\$ —	\$ —	\$ 338,834

- (1) Bonus and non-equity incentive compensation amounts are for performance during the years ended December 31, 2019 and 2018, whether or not paid in the year the compensation was earned.
- (2) Our named executive officers will only realize compensation to the extent the fair market value of our common stock is greater than the exercise price of such stock options. The grant date fair value of option awards granted in 2019 is in accordance with ASC Topic 718, or ASC 718. For information regarding assumptions underlying the valuation of equity awards, see Note 10 of the Notes to Consolidated Financial Statements.
- (3) Represents cash incentive payments earned based upon the achievement of corporate objectives established by our Board of Directors for performance during the years ended December 31, 2019 and 2018.

Employment Agreements

On December 12, 2018, we entered into an Executive Agreement (the “Foster Agreement”) with Dr. Robert Foster, our Chief Executive Officer. The term of the Foster Agreement commenced on October 1, 2018 and will continue until October 1, 2021, following which time the Foster Agreement will be automatically renewed for successive one year periods at the end of each term, unless either party delivers written notice to the other party of their intent to not renew the Foster Agreement. Pursuant to the Foster Agreement, Dr. Foster’s current base compensation is \$400,000 per year. Dr. Foster is eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria.

If Dr. Foster’s employment is terminated by us for cause or as a result of Dr. Foster’s death or permanent disability, or if Dr. Foster terminates his the Foster Agreement voluntarily without Good Reason (as defined in the Foster Agreement), Dr. Foster will be entitled to receive a lump sum equal to (i) any portion of unpaid base compensation then due for periods prior to termination, (ii) any bonus earned but not yet paid, and (iii) all business expenses reasonably and necessarily incurred by Dr. Foster prior to the date of termination. If Dr. Foster’s employment is terminated by us without cause or by Dr. Foster for Good Reason, Dr. Foster will be entitled to receive the amounts due upon termination of his employment by us for cause or as a result of his death or permanent disability, or upon termination by Dr. Foster of his employment voluntarily without Good Reason, in addition to (provided that Dr. Foster executes a written release with respect to certain matters) a severance payment equal to his base compensation for 12 months from the date of termination and reimburse Dr. Foster’s payment of COBRA premiums for 12 months from the date of termination. In addition, if Dr. Foster’s employment is terminated: (a) by us without cause within 6 months prior to a change of control (as defined in the Foster Agreement) that was pending during such 6 month period, (b) by Mr. Foster for Good Reason within 12 months after a change of control, or (c) by us without cause at any time upon or within 12 months after a change of control, Dr. Foster would be entitled to receive the amounts due upon termination of his employment by us for cause or as a result of his death or permanent disability, or upon termination by Dr. Foster voluntarily without Good Reason, provided, if Dr. Foster executes a written release with respect to certain matters, he will be entitled to a severance payment equal to his base compensation for 12 months from the date of termination and reimbursement of his payment of COBRA premiums for 12 months from the date of termination. In addition, all of Dr. Foster’s unvested stock options and other equity awards would immediately vest and become fully exercisable (x) in the event a change of control transaction is pending, for a period of six months following the date of termination, and (y) in the event a change of control transaction is not then pending, for the period of time set forth in the applicable agreement evidencing the award.

Outstanding Equity Awards as of December 31, 2019

Name	Number of Securities Underlying Unexercised Options (#)		Option Exercise Price (\$)	Option Expiration Date(1), (2)
	Exercisable	Unexercisable		
Dr. Robert Foster	134	45	515.20	6/10/2026
Chief Executive Officer	9,700	—	3.24	7/24/2029
John Cavan	134	45	677.60	4/1/2026
Chief Financial Officer	34	—	616.00	8/26/2026
	18	9	324.80	7/20/2027
	5,820	—	3.24	7/24/2029

Director Compensation

During year ended December 31, 2019, our non-employee directors received the following compensation for their services on the Board and its committees:

Name	Cash Fees	Option Awards(1)	Total
Gary S. Jacob(2)	\$ 38,000	\$ —	\$ 38,000
John P. Brancaccio(3)	59,000	—	59,000
Arnold Lippa(4)	55,500	—	41,625
Timothy Block(5)	44,400	—	55,500
Thomas Adams(6)	50,500	—	50,500

As of December 31, 2019, we have recorded a liability of \$116,600 related to director fees, of which \$ 116,600 was paid in January 2020.

(1) 4,850 option awards were issued during the year ended December 31, 2019.

(2) As of December 31, 2019, Dr. Jacob held 2,782 option awards of which 2,782 are exercisable.

- (3) As of December 31, 2019, Mr. Brancaccio held 1,328 option awards of which 1,328 are exercisable.
(4) As of December 31, 2019, Dr. Lippa held 1,273 option awards of which 1,273 grants are exercisable.
(5) As of December 31, 2019, Dr. Block held 1,108 option awards of which 1,108 are exercisable.
(6) As of December 31, 2019, Dr. Adams held 1,050 option awards of which 1,050 are exercisable.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of May 11, 2020 by:

- our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of May 11, 2020, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 9,025,061 shares of common stock outstanding on May 11, 2020.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Hepion Pharmaceuticals, Inc., 399 Thornall Street, First Floor, Edison, New Jersey 08837.

Beneficial Owner	Number of Shares Beneficially Owned	Shares of common stock issuable upon exercise of stock options	Shares of common stock issuable upon exercise of warrants	Percentage of Common Stock Beneficially Owned
Directors and Executive Officers				
John Cavan	300	231	123	*
Dr. Robert Foster	259	179	—	*
Gary S. Jacob	59	62,782	123	*
John Brancaccio	4	61,328	25	*
Timothy Block	—	61,108	—	*
Arnold Lippa	—	61,273	123	*
Thomas Adams	—	61,050	—	*
All current executive officers and directors as a group (7 persons)	622	307,951	394	3.3%

*Represents beneficial ownership of less than 1%.

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

None

Item 14. Principal Accountant Fees and Services.

Independent Registered Public Accounting Firm's Fees

Audit Fees

The aggregate fees billed and unbilled for the years ended December 31, 2019 and 2018 for professional services rendered by our principal accountants for the audits of our annual financial statements on Form 10-K and Form 10-KT, the review of our financial statements included in our quarterly reports on Form 10-Q, services associated with other SEC filings, and consents were approximately \$415,660 and \$318,000, respectively.

Audit Committee's Pre-Approval Policies and Procedures

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our principal accountants on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our principal accountants.

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 50 of this report.

(a)(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
1.2	At Market Issuance Sales Agreement dated February 12, 2020 by and between Hepion Pharmaceuticals, Inc. and B. Riley FBR, Inc (filed as Exhibit 1.1 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on February 12, 2020 and incorporated herein by reference).
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 14, 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).
3.2	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).
4.1	Secured Convertible Promissory Note, dated May 8, 2018, by and between Hepion Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 4.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
4.2	Warrant Agency Agreement, dated as of July 2, 2018, by and between the Company and Philadelphia Stock Transfer, Inc. (filed as Exhibit 4.1 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).
4.3	Form of Unsecured Debenture issued to Investor dated March 14, 2019 (filed as Exhibit 10.2 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on March 19, 2019 and incorporated herein by reference).

4.4	Form of Warrant issued in April Offering (incorporated by reference to Exhibit 4.1 to Form S-1 filed on April 18, 2019).
4.5	Form of Warrant issued in June Offering (incorporated by reference to Exhibit 4.1 to Form S-1 filed on June 5, 2019).
4.6	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
10.1	2013 Equity Incentive Plan (filed as Exhibit 10.1 to the Company's Form S-8 filed with the Securities and Exchange Commission on May 4, 2015 and incorporated herein by reference).*
10.2	Executive Agreement, dated June 10, 2016, between Hepion Pharmaceuticals, Inc. and Dr. Robert Foster (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2016 and incorporated herein by reference).*
10.3	Securities Purchase Agreement, dated May 8, 2018, by and between Hepion Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 10.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
10.4	Security Agreement, dated May 8, 2018, by and between Hepion Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 10.2 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
10.5	Settlement Agreement and General Release between Hepion Pharmaceuticals, Inc. and Theresa Matkovits dated as of October 15, 2018 (filed as Exhibit 10.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on November 15, 2018 and incorporated herein by reference).
10.6	Separation Agreement and General Release between Hepion Pharmaceuticals, Inc. and James Sapirstein dated as of October 18, 2018 (filed as Exhibit 10.2 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on November 15, 2018 and incorporated herein by reference).
10.7	Form of Securities Purchase Agreement dated March 13, 2019 by and among the Company and the Investor (filed as Exhibit 10.1 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on March 19, 2019 and incorporated herein by reference).
10.8	Form of Securities Purchase Agreement in April Offering (incorporated by reference to exhibit 10.11 to Form S-1 filed on April 18, 2019).
10.9	Form of Securities Purchase Agreement in June Offering (incorporated by reference to Exhibit 10.12 to Form S-1 filed June 5, 2019).
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)
21.1	List of Subsidiaries
23.1	Consent of BDO USA, LLP, 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.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

† Confidential treatment is requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Exchange Act. In accordance with Rule 24b-2, these confidential portions have been omitted from this exhibit and filed separately with the Commission.

* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

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

Date: May 14, 2020

HEPION PHARMACEUTICALS, INC.

By: /s/ ROBERT FOSTER

Robert Foster
Chief Executive Officer
(Principal Executive Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, Dr. Robert Foster, and John Cavan, and each of them acting individually, as his attorney-in-fact, each 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ ROBERT FOSTER</u> Robert Foster	Chief Executive Officer (Principal Executive Officer)	May 14, 2020
<u>/s/ JOHN CAVAN</u> John Cavan	Chief Financial Officer (Principal Financial and Accounting Officer)	May 14, 2020
<u>/s/ GARY S. JACOB, PHD.</u> Gary S. Jacob, PhD.	Chairman, Board of Directors	May 14, 2020
<u>/s/ JOHN BRANCACCIO</u> John Brancaccio	Director	May 14, 2020
<u>/s/ ARNOLD LIPPA</u> Arnold Lippa	Director	May 14, 2020
<u>/s/ TIMOTHY BLOCK</u> Timothy Block	Director	May 14, 2020
<u>/s/ THOMAS ADAMS</u> Thomas Adams	Director	May 14, 2020

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of December 31, 2019, Hepion Pharmaceuticals, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, \$0.0001 par value per share ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Hepion" in this Exhibit 4.6 refer to Hepion Pharmaceuticals, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and bylaws, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.6 is a part.

Authorized Capitalization

Our authorized capital stock consists of 120,000,000 shares of Common Stock and 20,000,000 shares of preferred stock, \$0.0001 par value per share ("Preferred Stock") in one or more series. As of December 31, 2019, we had outstanding 3,760,255 shares of our Common Stock, 85,581 shares of our Series A Convertible Preferred Stock and 1,827 shares of our Series C Convertible Preferred Stock.

Transfer Agent and Registrar. The transfer agent for our Common Stock is Philadelphia Stock Transfer.

Listing. Our Common Stock is traded on the Nasdaq Capital Market under the symbol "HEPA."

Common Stock

Holders of our common stock are entitled to one vote per share. Our Certificate of Incorporation does not provide for cumulative voting. Holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our Board out of legally available funds. However, the current policy of our Board is to retain earnings, if any, for the operation and expansion of our company. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all of our assets which are legally available for distribution, after payment of or provision for all liabilities. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

LIST OF SUBSIDIARIES

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

Consent of Independent Registered Public Accounting Firm

Hepion Pharmaceuticals, Inc.
Edison, New Jersey 08837

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 No. 333-229534 and Form S-8 Nos. 333-203867, 333-215662 and 333-234728 of Hepion Pharmaceuticals, Inc. (formerly known as ContraVir Pharmaceuticals, Inc.) of our report dated May 14, 2020, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K. Our report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Woodbridge, New Jersey

May 14, 2020

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

I, Dr. Robert Foster, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hepion Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2020

/s/ ROBERT FOSTER

Dr. Robert Foster
Chief Executive Officer
(Principal Executive Officer)

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

I, John Cavan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hepion Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures, and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 14, 2020

/s/ John Cavan

John Cavan
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Annual Report of Hepion Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Dr. Robert Foster, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 14, 2020

/s/ ROBERT FOSTER

Dr. Robert Foster
Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Annual Report of Hepion Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Cavan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: May 14, 2020

/s/ JOHN CAVAN

John Cavan

Chief Financial Officer

(Principal Financial Officer)
