SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Hepion Pharmaceuticals, Inc.

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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, 2020
Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission File Number 001-36856

HEPION PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**46-2783806**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
399 Thornall Street, First Floor Edison, New Jersey	**08837**
(Address of Principal Executive Offices)	(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	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	HEPA	The Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

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, 2020 (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 $25.6 million based on the last reported sale price of the registrant's common stock on June 30, 2020.

The number of shares of the registrant's Common Stock outstanding as of March 24, 2021 was 76,225,245.

Documents Incorporated by Reference:

Parts of the registrant's Proxy Statement for the Registrant's 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K

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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 product candidates could increase our development costs;
- Our involvement in patent and other intellectual property litigation could be expensive and could divert management's attention;
- The possibility that there will be no market acceptance for our products; and
- Changes in third-party reimbursement policies could adversely affect potential future sales of any of our products that are approved for marketing.

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

Risk Factor Summary

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

Risks Related to Our Business

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

Our product candidate CRV431 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.

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.

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, 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.

We have limited experience in the development of small molecule product candidates and therefore may encounter difficulties developing our product candidate or managing our operations in the future.

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

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.

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

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

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

Our approach to the discovery and development of product candidates based on AI-POWR™ is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.

AI-POWR™ may fail to help us discover and/or develop additional potential product candidates.

Risks Relating to the Commercialization of our Product Candidates

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

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

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

Risks Related to Our Intellectual Property

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

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

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

Risks Related to Government Regulation

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

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.

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

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, 2020 and 2019, and if they continue to be ineffective could result in material misstatements in our financial statements.

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

We may be at risk of securities class action litigation.

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

PART I

ITEM 1. BUSINESS

Overview

We are a biopharmaceutical company headquartered in Edison, New Jersey, focused primarily on the development of drug therapy for treatment of chronic liver diseases. This therapeutic approach targets fibrosis and possibly 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 pan cyclophilin inhibitor that targets multiple pathologic pathways involved in the progression of liver disease. Preclinical studies with CRV431 in NASH models demonstrated consistent reductions in liver fibrosis and additional reductions in inflammation and cancerous tumors in some studies. CRV431 additionally showed *in vitro* antiviral activity towards hepatitis B, C, and D viruses which also trigger liver disease. Preclinical studies also have shown potentially therapeutic activities of CRV431 in experimental models of acute lung injury, platelet activation, and SARS-CoV-2 replication.

We have completed a Phase 1 program with CRV431 demonstrating safety, tolerability, and pharmacokinetics (PK). Our program consisted of three different clinical trials with CRV431, administered orally once daily, that included: 1) a Single Ascending Dose (SAD) study; 2) a Multiple Ascending Dose (MAD) study; and 3) a Drug-Drug Interaction (DDI) study. The SAD, MAD, and DDI studies were comprised of 32, 25, and 18 healthy subjects, respectively. Additionally, in the SAD study, 8 of the 32 subjects received placebo (24 received CRV431).

CRV431 appeared to be well-tolerated in the Phase 1 program, and there were no serious adverse effects (SAEs). The few adverse effects (AEs) observed were mild to moderate and mostly unrelated to study drug. The PK profile of each subject was characterized and CRV431 blood exposures were similar to those needed to elicit efficacy in the preclinical studies.

We are currently conducting a Phase 2a study in NASH patients with presumed fibrosis scores of F2 and F3, as characterized by the biomarkers indicative of advancing fibrosis. The first dosing cohort of 75 mg CRV431 once daily orally has been completed and the second dosing cohort of 225 mg CRV431 is underway.

NASH is a severe form of non-alcoholic fatty liver disease (NAFLD) characterized by inflammation and fibrosis (scarring) in the liver that can progress to cirrhosis, liver failure, and liver cancer. The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 25% of NAFLD patients, is growing and is driven primarily by the worldwide obesity epidemic. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, high blood sugar, elevated cholesterol and triglycerides, and systemic hypertension (a constellation commonly referred to as metabolic syndrome), and these further contribute to the risk of cardiovascular disease. The number of NASH cases in the US is projected to expand from 16.5 million in 2015 to 27 million in 2030, with similar prevalence growth expected in Europe. Diet and exercise are currently the standard of care for NAFLD and NASH, but adherence is poor, and there remains a high unmet need in the treatment of NASH.

NASH is the form of liver disease that is triggered by what has come to be known as the "Western diet", characterized especially by high-fat, high-sugar, and processed foods. Among the effects of a prolonged Western diet is fat accumulation in liver cells (steatosis) which is described as NAFLD and can predispose cells to injury. NAFLD may evolve into NASH when the fatty liver begins to progress through stages of cell injury, inflammation, fibrosis, and carcinogenesis. People who develop NASH 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 clinical 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, including the USA. NASH is the most common reason for individuals requiring a liver transplant in the USA. Considering the serious outcomes linked to advancing NASH, the economic and social burden of the disease is enormous. There are no simple blood tests to diagnose or track the progression of NASH, and 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, in part, 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 preventing or slowing liver injury and scarring as early and effectively as possible in order to decrease the progression of liver cancer.

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 results in the deaths of approximately 350,000 people per year. A similar number of people die each year from cirrhosis and other complications arising from HBV.

CRV431

We are developing CRV431 as our lead molecule. CRV431 is a compound that binds and inhibits the function of a specific class of isomerase enzymes called cyclophilins that mainly regulate protein folding. Many closely related isoforms of cyclophilins exist in humans. Cyclophilins A, B, and D are the best characterized cyclophilin isoforms. Inhibition of cyclophilins has been shown in the scientific literature to have therapeutic effects in a variety of experimental models, including liver disease models. In preclinical *in vitro* and/or *in vivo* experiments to date CRV431 decreased liver fibrosis, liver inflammation, liver tumors, and titers of HBV, HCV, HDV, and HIV-1. Importantly, reduction in liver fibrosis by CRV431 was observed *in vivo* in several experimental models and studies of NASH and liver fibrosis. Findings to date suggest that CRV431 might treat certain inciting agents of liver disease such as hepatitis viruses and also the ensuing disease processes resulting from those agents such as fibrosis.

Cyclophilins are pleiotropic enzymes that play a role in injury and steatosis through mechanisms including cell death occurring through mitochondrial 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.

To date, we have completed a number of separate preclinical animal efficacy studies of CRV431 to assess antifibrotic activity. These studies were conducted by independent laboratory collaborations at, for example, The Scripps Research Institute (San Diego, CA), SMC Corporation (Tokyo, Japan), and Physiogenex S.A.S. (France), Each of these studies demonstrated consistent and significant reductions in fibrosis in mice and rats. CRV431 was also tested in *ex vivo* Precision Cut Liver Slices and in Precision Cut Lung Slices obtained from human donors. Again, CRV431 demonstrated an antifibrotic effect in the human tissue that was consistent with the animal study findings. These studies provide support of advancing CRV431 into clinical trials for NASH, and potentially additional indications where fibrosis plays a role.

Many viruses have been shown to recruit cellular (“host”) cyclophilins into the life cycles of the viruses and therefore assist in viral replication and evasion of host immunity. These viruses include HBV, HCV, HDV, HIV-1 and several coronaviruses. CRV431 was found in *in vitro* experiments to decrease replication of HBV, HCV, HDV, HIV-1, and the SARS-CoV-2 coronavirus responsible for the COVID-19 pandemic. SARS-CoV-2 infection may, in some instances, be associated with acute lung injury and platelet-mediated thrombotic disorders. In experimental models, CRV431 decreased acute lung inflammation and platelet activation, and therefore CRV431 may have therapeutic benefits in COVID-19 patients.

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 approximately $346,000 to Aurinia Pharmaceuticals, Inc. ("Aurinia") and $654,000 to the former Ciclofilin shareholders along with the issuance of 1,439 shares of our common stock with a fair value of $55,398, representing 2.5% of our issued and outstanding common stock as of June, 2016, to the former Ciclofilin shareholders. Our CEO is a former Ciclofilin shareholder and received approximately $274,000 and 603 shares of common stock and Petrus Wijngaard, a director of our company, received $2,805 and 6 shares of common stock.

Additional milestone payments could potentially be payable to the former Ciclofilin shareholders pursuant to the Ciclofilin Merger Agreement as follows: (i) upon receipt of Phase II positive data from a proof of concept clinical trial of CRV431 in humans - 4,317 shares of common stock and $3,000,000, (ii) upon initiation of a Phase III trial of CRV431 - $5,000,000, and (iii) upon acceptance by the FDA of a new drug application for CRV431 - $8,000,000. In addition, on February 14, 2014, Ciclofilin had entered into a Purchase and Sale Agreement to acquire Aurinia’s entire interest in CRV431. This agreement contains future milestone payments payable by us based on clinical and marketing milestones of up to CAD $2.45 million. The milestone payments payable to the former Ciclofilin shareholders will be subject to offset by certain of the clinical and marketing milestone payments payable to Aurinia as follows: (a) the payments to the former Ciclofilin shareholders pursuant to (ii) above would be offset by payment to Aurinia of CAD $450,000, and (b) the payments to the former Ciclofilin shareholders pursuant to (iii) above would be subject to offset by payment to Aurinia of up to CAD $2,000,000. In addition to the above clinical and milestone payments, the Aurinia Agreement provides for the following additional contingent payment obligations: (x) a royalty of 2.5% on net sales of CRV431 which is uncapped, (y) a royalty of 5% on license revenue from CRV431 and (z) a payment equal to 30% of the proceeds from a Liquidity Event (as defined in the Purchase and Sale Agreement) with respect to Ciclofilin, of which approximately $150,000 plus interest is owing. The maximum obligation under both (y) and (z) is CAD $5,000,000.

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

On November 20, 2020, we submitted an IND to the FDA to support initiation of a CRV431 clinical development program in the United States for COVID-19. We received approval December 17, 2020, to conduct a COVID-19 clinical trial and are investigating potential sources of collaboration and/or funding for the trial.

Artificial Intelligence (AI)

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

AI-POWR™ is our acronym for **A**rtificial **I**ntelligence - **P**recision Medicine; **O**mics that include genomics, proteomics, metabolomics, transcriptomics, and lipidomics; **W**orld database access; and **R**esponse and clinical outcomes. AI-POWR™ allows for the selection of novel drug targets, biomarkers, and appropriate patient populations.

AI-POWR™ is used to identify responders from big data sources using our multi-omics approach, while modelling inputs and scenarios to increase response rates. The components of AI-POWR™ include access to publicly available databases, and in-house genomic and multi-omic big data, processed via machine learning algorithms. We believe AI outputs will allow for improved response outcomes through enhanced patient selection, biomarker selection and drug target selection. We believe AI outputs will help identify responders *a priori* and reduce the need for large sample sizes through study design enrichment.

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

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

Recent Developments

Effective February 16, 2021 we appointed Todd M. Hobbs, M.D. to the newly created position of Chief Medical Officer (“CMO”). In this role, Dr. Hobbs will help lead our engagement with the FDA, global and national thought leaders, key policymakers, and professional associations.

Dr. Hobbs joins from Novo Nordisk Inc., one of the world’s leading healthcare companies. His 16 years of progressive experience at Novo Nordisk includes positions ranging from field medical affairs leadership at the start of his corporate career through to his most recent role as North American Chief Medical Officer and Vice President. Prior to working at Novo Nordisk, Dr. Hobbs had established a clinical practice based in Louisville, Kentucky, focusing on the intensive management of patients with diabetes of all ages, and served as chairman of the medicine department for a large regional medical center in Kentucky.

Dr. Hobbs currently serves as a Member of the Board for the American Medical Group Association Foundation, the research foundation arm of the American Medical Group Association, in which he provides oversight for multiple clinical research initiatives. Dr. Hobbs earned his medical degree from the University of Louisville School of Medicine and has completed focused executive training at the University of Pennsylvania's Wharton School of Business.

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 candidates. 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 manufacture 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.

Human Capital

The human capital objectives we focus on in managing our business include attracting, developing, and retaining key personnel. Our employees are critical to the success of our organization and we are committed to supporting our employees' professional development. We believe our management team has the experience necessary to effectively implement our growth strategy and continue to drive shareholder value. We provide competitive compensation and benefits to attract and retain key personnel, while also providing a safe, inclusive and respectful workplace.

As of December 31, 2020, we had 13 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.

For the years ended December 31, 2020 and 2019, we had an accumulated deficit of $104.1 million, and $83.8 million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, 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. In November 2020 and February 2021, we raised net proceeds of approximately $31.6 million and $82.1 million, respectively, to fund our future operations. We currently anticipate that our cash and cash equivalents balances are sufficient to fund our anticipated operating cash requirements for more than one year from the date of issuance of the consolidated financial statements included in this Annual Report on Form 10-K. These consolidated financial statements have been prepared under the assumption that we will continue as a going concern. Our ability to raise additional funds is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying 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.

Our product candidate CRV431 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 candidates may have a material adverse effect on us. To date, we have not successfully developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully advance the development of our product candidates through preclinical studies and clinical trials, have these product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have these product candidates successfully commercialized by us or a strategic partner. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidates, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

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

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

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

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

Our product 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 an NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

If third party vendors upon whom we intend to rely on to conduct our preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product 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 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 these product candidates, 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 require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.

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

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

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

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

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

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

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidate will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if the FDA believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidate. If we adopt an alternative brand name, we 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 candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

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

We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. Any curtailment in the availability of 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 candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

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

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

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

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

We rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce bulk APIs, and product candidates for our clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time

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

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

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

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

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

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. 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 candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers 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 candidates according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidates. 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 candidates 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 candidates.

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

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

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

If in the future we decide to further expand our pipeline, we will be dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research

or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

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

The use of any of our 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 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 candidates 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 candidates. While we have not experienced delays to date, we may experience delays in the conduct of clinical testing of our product candidate. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. The 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. 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.

Our approach to the discovery and development of product candidates based on AI-POWR™ is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.

We intend to leverage AI-POWR™ to potentially identify novel indications for CRV431 and possibly identify new targets and new drug molecules to broaden our pipeline for patients whose diseases have not been adequately addressed to date by other approaches and to design and conduct efficient clinical trials with a higher likelihood of success. While we believe that applying AI-POWR™ to create medicines for defined patient populations may potentially enable drug research and clinical development that is more efficient than conventional drug research and development, our approach is both novel and unproven. Because our approach is both novel and unproven, the cost and time needed to develop our product candidates is difficult to predict, and our efforts may not result in the discovery and development of commercially viable medicines. We may also be incorrect about the effects of our product candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

AI-POWR™ may fail to help us discover and/or develop additional potential product candidates.

Any drug discovery that we are conducting using AI-POWR™ may not be successful in identifying compounds that have commercial value or therapeutic utility. AI-POWR™ may initially show promise in identifying potential product candidates, yet fail to yield viable product candidates for clinical development or commercialization for a number of reasons, including:

- research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- compounds found through AI-POWR™ may not demonstrate efficacy, safety or tolerability;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

Risks Relating to the Commercialization of our Product Candidates.

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

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 candidates, 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 candidates. 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 candidates 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 candidates, or otherwise fail to establish marketing and sales capabilities, we may not be able to successfully commercialize our products.

We currently have no infrastructure to support the commercialization of our product candidates, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if any of our product candidates 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 candidates 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 any of our product candidates 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 candidates 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 candidates.

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

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

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

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

Risks Related to Our Intellectual Property

If we are unable to adequately protect or expand our intellectual property related to our 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.

Risks Related to Government Regulation

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

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

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

Even if our product 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 candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of our product candidate and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

We intend to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product 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 13 employees as of December 31, 2020. To continue our clinical trials and commercialize our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. 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 candidates, which would impede sales.

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

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

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

Healthcare reform measures 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 inseverable 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, 2020 and 2019, 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, 2020 and 2019, our management has determined that we had material weaknesses in our control environment and in the period end financial close and reporting process. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could

be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly.

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

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

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results;
- catastrophic weather and/or global disease outbreaks, such as the 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 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 3,500 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

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

Holders of Record

As of March 24, 2021, there were 201 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, 2020.

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	2,460,677	$ 4.17	39,323

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 drug therapy for treatment of chronic liver diseases. 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 pathologic pathways involved in the progression of liver disease. Preclinical studies with CRV431 in NASH models demonstrated consistent reductions in liver fibrosis and additional reductions in inflammation and cancerous tumors in some studies. CRV431 additionally showed *in vitro* antiviral activity towards hepatitis B, C, and D viruses which also trigger liver disease. Preclinical studies also have shown potentially therapeutic activities of CRV431 in experimental models of acute lung injury, platelet activation, and SARS-CoV-2 coronavirus replication.

NASH is the form of liver disease that is triggered by what has come to be known as the "Western diet", characterized especially by high-fat, high-sugar, and processed foods. Among the effects of a prolonged Western diet is fat accumulation in liver cells (steatosis) which is described as NAFLD and can predispose cells to injury. NAFLD may evolve into NASH when the fatty liver begins to progress through stages of cell injury, inflammation, fibrosis, and carcinogenesis. People who develop NASH 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 clinical 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, including the USA. NASH is the leading reason for individuals requiring a liver transplant in the USA. Considering the serious outcomes linked to advancing NASH, the economic and social burden of the disease is enormous. There are no simple blood tests to diagnose or track the progression of NASH, and no drugs are approved to specifically treat the disease.

Artificial Intelligence (AI)

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

AI-POWR™ is our acronym for **A**rtificial **I**ntelligence - **P**recision Medicine; **O**mics that include genomics, proteomics, metabolomics, transcriptomics, and lipidomics; **W**orld database access; and **R**esponse and clinical outcomes. AI-POWR™ allows for the selection of novel drug targets, biomarkers, and appropriate patient populations. AI-POWR™ is used to identify responders from big data sources using our multi-omics approach, while modelling inputs and scenarios to increase response rates. The components of AI-POWR™ include access to publicly available databases, and in-house genomic and multi-omic big data, processed via machine learning algorithms. We believe AI outputs will allow for improved response outcomes through enhanced patient selection, biomarker selection and drug target selection. We believe AI outputs will help identify responders *a priori* and reduce the need for large sample sizes through study design enrichment.

We intend to use AI-POWR™ to help identify which NASH patients will best respond to CRV431. It is anticipated that applying this proprietary platform to our drug development program will ultimately save time, resources

and money. In so doing, we believe that AI-POWR™ is a risk-mitigation strategy that should reap benefits all the way through from clinical trials to commercialization.

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

Impact of COVID-19

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

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

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

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change and we do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. Although we cannot estimate the length or gravity of the impact of the COVID-19 outbreak nor estimate the potential impact to our fiscal year 2020 financial statements at this time, if the pandemic continues, it could have a material adverse effect on our results of future operations, financial position, liquidity, and capital resources, and those of the third parties on which we rely in fiscal year 2021.

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

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

issuance of the consolidated financial statements, we have not yet filed for loan forgiveness. The PPP Loan is reflected in the consolidated balance sheet as long-term debt based upon the terms and conditions of the Loan agreement.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2020, we have an accumulated deficit of approximately $104.1 million. From inception through December 31, 2020, 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 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 sold through B. Riley FBR 2,311,867 shares (the "Shares") of our common stock, par value $0.0001 per share (the "Common Stock"), for $6.8 million. The offer and sale of the Shares were 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"). Also, on March 27, 2020, we filed a prospectus supplement to the Form S-3 (File No. 333-229534) pursuant to which we sold an additional 2,950,939 shares of our common stock for $4.6 million. In total, we sold 5,262,806 shares of our common stock resulting in net proceeds of $11.2 million from the "at the market offerings".

On November 19, 2020, we terminated the Sales Agreement with B. Riley FBR, Inc. dated February 12, 2020, effective November 24, 2020.

On November 24, 2020, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity, a division of Fordham Financial Management, Inc., as the representative (the "Representative") of the underwriters listed therein (collectively, the "Underwriters"), with respect to an underwritten public offering (the "Offering") of 20,000,000 shares of our common stock, par value $0.0001 (the "Shares") at a public offering price of $1.50 per share and a 45-day option to purchase up to 3,000,000 additional shares of common stock to cover over-allotments. On November 25, 2020, the Representative exercised the over-allotment in full.

The Shares were offered by us pursuant to a registration statement on Form S-1 (No. 333- 249724) previously filed with the SEC and subsequently declared effective on November 24, 2020. The Offering closed on November 30, 2020 and we received net proceeds of $31.6 million.

On February 16, 2021, we entered into an underwriting agreement with the Representative with respect to an underwritten public offering of 44,200,000 shares of our common stock at a public offering price of $2.00 per share, in which we received net proceeds of approximately $82.1 million. The shares were offered by us pursuant to our effective shelf registration statement on Form S-3 (Registration No. 333-229534), which was declared effective on February 19, 2019, and the base prospectus included therein, as supplemented by the preliminary prospectus supplement, dated February 16, 2021 and final prospectus supplement, dated February 16, 2021.

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

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.

We believe that the assumptions and estimates associated with fair value of financial instruments, derivative financial instruments, income taxes, contingencies, research and development, goodwill and in-process research and development, and share-based payments have the greatest potential impact on our consolidated financial statements. We

evaluate these estimates on an ongoing basis. Actual results could differ from those estimates under different assumptions or conditions, and any differences could be material. For further information on all of our significant accounting policies, see Note 3 of the Notes to the Consolidated Financial Statements under Item 8 of this Annual Report on Form 10-K.

Fair Value of Financial Instruments

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

Contingent consideration was related to the acquisition of Ciclofilin and recorded on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and in 2016 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. In October 2020, the October 2015 warrants expired.

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 our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2020 and 2019, the fair value of such warrants was $11,673 and $5,623, respectively, which is classified as a long-term derivative liability in the consolidated 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 April 2019, we transferred New Jersey state net operating loss tax credits and received approximately $1.0 million in connection with the sale of the state net operating losses to a third party recorded as an income tax benefit in the consolidated statement of operations. We received approval for the sale of net operating losses through participation in the New Jersey Technology Business Tax Certificate Transfer (NOL) Program. We continue to maintain a full valuation allowance for our U.S net deferred tax assets. The current period income tax expense is related to our foreign operations.

Contingencies

In the normal course of business, we are subject to loss contingencies, such as legal proceedings and claims arising out of our business that cover a wide range of matters, including, among others, government investigations, shareholder lawsuits, product and environmental liability, and tax matters. In accordance with ASC Topic 450, Accounting for Contingencies, ("ASC 450"), we record accruals for such loss contingencies when it is probable that a liability will be incurred, and the amount of loss can be reasonably estimated. 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, 2020 and 2019, we had prepaid research and development costs of $1.8 million and $0.4 million, respectively.

Goodwill and In-Process Research & Development

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

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

The amendments also eliminate the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative

impairment test is necessary. We adopted ASU 2017-04 on January 1, 2020, and the adoption of this standard did not have a material effect on our consolidated financial statements.

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. As a result of the COVID-19 pandemic, we performed a qualitative assessment of goodwill and determined that it was not more likely than not that the fair value of our reporting was less than its carrying value. There was no impairment of goodwill for years ended December 31, 2020 and 2019.

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.

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, 2020.

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

On December 31, 2020, our status as an emerging growth company ended. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company on December 31, 2020, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes Oxley Act; (2) scaled executive compensation disclosures; and (3) the requirement to provide only two years of audited financial statements, instead of three years.

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

RESULTS OF OPERATIONS

Comparison of the Years ended December 31, 2020 and 2019:

	Year Ended December 31,		
	2020	2019	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	11,997,272	3,184,082	8,813,190
General and administrative	8,148,803	4,586,003	3,562,800
Loss from operations	(20,146,075)	(7,770,085)	(12,375,990)
Other income (expense):			
Change in fair value of debt	—	(179,652)	179,652
Interest expense	(31,229)	(554,998)	523,769
Change in fair value of derivative instruments (warrants) and contingent consideration	(146,050)	558,715	(704,765)
Loss before income taxes	(20,323,354)	(7,946,020)	(12,377,334)
Income tax (expense) benefit	(30,584)	908,682	(939,266)
Net loss	$ (20,353,938)	$ (7,037,338)	$ (13,316,600)

We had no revenues during the years ended December 31, 2020 and 2019, respectively, because we do not have any commercial biopharmaceutical products and we do not expect to have such products for several years, if at all.

Research and development expenses for the years ended December 31, 2020 and 2019 amounted to $12.0 million and $3.2 million, respectively. The $8.8 million increase was primarily due to an increase of $4.7 million for costs related to the production of our drug and various ongoing research studies, a $3.1 million increase in consulting and outside service costs related to various ongoing research studies, and a $0.6 million increase in stock-based compensation costs.

General and administrative expenses for the years ended December 31, 2020 and 2019 amounted to $8.1 million and $4.6 million, respectively. The increase of $3.5 million is primarily due to an increase of $1.8 million in stock-based compensation costs, a $0.3 million increase in insurance costs, and a $1.3 million increase in professional fees and consulting costs.

During the year ended December 31, 2020 and 2019, we recorded income tax expense of $30,584 and an income tax benefit of $0.9 million, respectively, resulting from an adjustment for deferred tax liability. Refer to Note 10 in the consolidated financial statements included in this Annual Report on Form 10-K.

Net loss for the year ended December 31, 2020 was $20.4 million, which was the result of the operating expenses discussed above and a loss of $0.1 million for the change in fair value of derivative instruments related to our warrants. Net loss for the year ended December 31, 2019 was $7.0 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.

Liquidity and Capital Resources

As of December 31, 2020, we had working capital of $38.0 million compared to working capital of $12.8 million as of December 31, 2019. The increase of $25.2 million in working capital is primarily related to an increase in cash and cash equivalents of $26.8 million from our equity offerings during 2020.

Cash Flows

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

	Year Ended December 31,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (16,165,202)	$ (7,565,059)
Investing activities	(85,789)	(51,469)
Financing activities	43,054,857	18,707,071
Net increase in cash	$ 26,803,866	$ 11,090,543

As of December 31, 2020, we had $40.7 million in cash. Net cash used in operating activities was $16.2 million for the year ended December 31, 2020 consisting primarily of our net loss of $20.4 million, adjusted for non-cash charges of $2.6 million primarily for stock-based compensation. Changes in working capital accounts had a positive impact of $1.6 million on cash.

Net cash used in operating activities was approximately $7.6 million for the year ended December 31, 2019 consisting of our net loss of $7.0 million, adjusted for non-cash charges primarily of $0.3 million. Changes in working capital accounts had a negative impact of $0.8 million on cash.

Net cash used in investing activities during the years ended December 31, 2020 and 2019 of was immaterial in both periods.

Net cash provided by financing activities was $43.1 million for the year ended December 31, 2020 due primarily to the issuance of common stock, net of issuance costs for our equity offerings $42.9 million.

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.

Common Stock Offerings during 2020

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 sold through B. Riley FBR 2,311,867 shares (the “Shares”) of our common stock, par value $0.0001 per share (the “Common Stock”), for $6.8 million. The offer and sale of the Shares were 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”). Also, on March 27, 2020, we filed a prospectus supplement to the Form S-3 (File No. 333-229534) pursuant to which we sold an additional 2,950,939 shares of our common stock for $4.6 million. In total, we sold 5,262,806 shares of our common stock resulting in net proceeds of $11.2 million from the “at the market offerings”.

On November 19, 2020, we terminated the Sales Agreement with B. Riley FBR, Inc. dated February 12, 2020, effective November 24, 2020.

On November 24, 2020, we entered into an underwriting agreement (the “Underwriting Agreement”) with ThinkEquity, a division of Fordham Financial Management, Inc., as the representative (the “Representative”) of the underwriters listed therein (collectively, the “Underwriters”), with respect to an underwritten public offering (the “Offering”) of 20,000,000 shares of our common stock, par value $0.0001 (the “Shares”) at a public offering price of $1.50 per share and a 45-day option to purchase up to 3,000,000 additional shares of common stock to cover over-allotments. On November 25, 2020, the Representative exercised the over-allotment in full.

The Shares were offered by us pursuant to a registration statement on Form S-1 (No. 333- 249724) previously filed with the SEC and subsequently declared effective on November 24, 2020. The Offering closed on November 30, 2020 and we received net proceeds of $31.6 million.

Common Stock Offerings during 2021

On February 16, 2021, we entered into an underwriting agreement with the Representative with respect to an underwritten public offering of 44,200,000 shares of our common stock at a public offering price of $2.00 per share, in which we received net proceeds of approximately $82.1 million. The shares were offered by us pursuant to our effective shelf registration statement on Form S-3 (Registration No. 333-229534), which was declared effective on February 19, 2019, and the base prospectus included therein, as supplemented by the preliminary prospectus supplement, dated February 16, 2021 and final prospectus supplement, dated February 16, 2021.

Operating and Capital Expenditure Requirements

As of December 31, 2020, we had an accumulated deficit of $104.1 million and expect to incur a significant increase in operating losses for the next several years as we expand our research, development and clinical trials of CRV431. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We will be required to raise additional capital in a future year to continue the development and commercialization of current product candidates and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. Recently worldwide economic conditions and the international equity and credit markets have 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.

Contractual Obligations and Commitments

We have a long-term contractual cash obligation as of December 31, 2020, comprised of operating lease obligations. The following table summarizes this obligation:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**4-5 Years**	**After 5 Years**
Lease obligations	$ 613,764	$ 287,977	$ 325,787	$ —	$ —
Total contractual obligations	$ 613,764	$ 287,977	$ 325,787	$ —	$ —

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 6 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.

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.

Rent expense related to our operating leases was $0.3 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively. The weighted average remaining term of our noncancelable operating leases is 2.1 years.

Future minimum rental payments under our noncancelable operating leases at December 31, 2020 is as follows:

2021	$	287,977
2022		271,885
2023		53,902
2024 and thereafter		—
Total		613,764
Present value adjustment		(38,183)
Lease liability at December 31, 2020	$	575,581

Contingent Consideration

Contingent consideration was recorded for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and our stock, upon the achievement of certain milestones and in 2016 was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of $19.60. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin and in the fourth quarter of 2018, we paid a related milestone payment of $1,000,000 and issued 1,439 shares of our common stock with a fair value of $55,398, representing 2.5% of our issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders. As of December 31, 2020, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability.

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. and its subsidiaries ("the Company") as of December 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matter

As described in Notes 1 and 6 to the consolidated financial statements, the Company has a contingent consideration liability of $2,570,000 recorded as of December 31, 2020. The contingent consideration was recorded by the Company in connection with the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and the Company's stock, to the Ciclofilin shareholders and Aurinia Pharmaceuticals Inc. upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing, significant unobservable inputs, which include 1) the discount rate, 2) the probability of success of milestone achievement, and 3) the projected milestone achievement dates.

Valuation of Contingent Consideration Liability

We identified the contingent consideration liability as critical audit matter. The principal considerations for our determination that performing procedures relating to the fair value of contingent consideration liabilities is a critical audit matter are the significant judgment by management when measuring the fair value of the contingent consideration liability, including a high degree of estimation uncertainty in evaluating the discount rate, the probability of success of milestone achievement and the projected milestone achievement dates. Auditing these elements involved significant and subjective auditor judgment in performing procedures to evaluate the fair value of the contingent consideration liability.

The primary procedures we performed to address this critical audit matter included:

- Testing management's process for estimating the fair value of contingent consideration liabilities, including corroborating with research and development personnel with regard to the current status of the clinical development of the Company's product candidate used to support the projected milestone achievement dates.
- Testing management's probability-weighted discounted cash flow model, evaluating the appropriateness of the valuation method used, verifying the inputs to the discounted cash flow model to underlying source data and recalculating the results.
- Comparing inputs and assumptions used by management to determine the discount rate and the probability of success of milestone achievement to external market and industry data.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2013

Woodbridge, NJ
March 31, 2021

HEPION PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 40,726,838	$ 13,922,972
Prepaid expenses	1,907,461	465,693
Total current assets	42,634,299	14,388,665
Property and equipment, net	108,440	57,166
Right-of-use assets	556,492	797,913
In-process research and development	3,190,000	3,190,000
Goodwill	1,870,924	1,870,924
Other assets	285,098	306,880
Total assets	$ 48,645,253	$ 20,611,548
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,722,429	$ 491,557
Accrued expenses	659,572	851,202
Operating lease liabilities, current	279,826	266,696
Total current liabilities	4,661,827	1,609,455
Contingent consideration	2,570,000	2,430,000
Long-term debt	176,585	—
Deferred tax liability	409,022	409,022
Operating lease liabilities, non-current	295,755	540,751
Derivative financial instruments, at estimated fair value—warrants	11,673	5,623
Total liabilities	8,124,862	4,994,851
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Series A convertible preferred stock, stated value $10 per share, 85,581 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively.	855,808	855,808
Series C convertible preferred stock, stated value $1,000 per share, 1,817 and 1,827 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively.	856,320	861,033
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 32,025,153 and 3,760,255 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively.	3,203	375
Additional paid in capital	142,910,523	97,651,006
Accumulated deficit	(104,105,463)	(83,751,525)
Total stockholders' equity	40,520,391	15,616,697
Total liabilities and stockholders' equity	$ 48,645,253	$ 20,611,548

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,	
	2020	2019
Revenues	$ —	$ —
Costs and expenses:		
Research and development	11,997,272	3,184,082
General and administrative	8,148,803	4,586,003
Total operating expenses	20,146,075	7,770,085
Loss from operations	(20,146,075)	(7,770,085)
Other income (expense):		
Change in fair value of debt	—	(179,652)
Interest expense	(31,229)	(554,998)
Change in fair value of derivative instruments (warrants) and contingent consideration	(146,050)	558,715
Loss before income taxes	(20,323,354)	(7,946,020)
Income tax benefit (expense)	(30,584)	908,682
Net loss	(20,353,938)	(7,037,338)
Deemed dividend (see Note 5)	(5,287)	(5,442,947)
Net loss attributable to common shareholders	$ (20,359,225)	$ (12,480,285)
Weighted average common shares outstanding:		
Basic and diluted	9,677,832	2,043,244
Net loss per common share: (see Note 11)		
Basic and diluted	$ (2.10)	$ (6.11)

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

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

	Preferred Stock Series A		Preferred Stock Series C		Preferred Stock, Series D $0.0001 par value		Preferred Stock, Series E $0.0001 par value		Common Stock		Additional Paid in	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2018	85,581	$ 855,808	1,974	$ 930,311	—	$ —	—	$ —	247,013	$ 25	$ 76,652,839	$ (76,714,187)	$ 1,724,796
Net loss	—	—	—	—	—	—	—	—	—	—	—	(7,037,338)	(7,037,338
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	66,176	—	66,176
Issuance of preferred stock	—	—	—	—	521	312,600	10,570	6,976,201	—	—	3,802,201	—	11,091,002
Conversion of preferred stock to common	—	—	(147)	(147,000)	(521)	(521,000)	(10,570)	(10,570,002)	1,825,044	182	11,237,820	—	—
Offering costs	—	—	—	—	—	(29,526)	—	(472,311)	—	—	(536,787)	—	(1,038,624
Placement agent warrants	—	—	—	—	—	(48,250)	—	(244,895)	—	—	293,145	—	—
Beneficial conversion feature	—	—	—	—	—	(186,692)	—	(581,350)	—	—	768,042	—	—
Accretion of beneficial conversion feature	—	—	—	—	—	186,692	—	581,350	—	—	(768,042)	—	—
Accretion of discount	—	—	—	77,722	—	286,176	—	4,311,007	—	—	(4,674,905)	—	—
Issuance of common stock, net	—	—	—	—	—	—	—	—	1,031,071	103	7,683,391	—	7,683,494
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
Warrant exercises	—	—	—	—	—	—	—	—	555,377	55	2,090,542	—	2,090,597
Balance at December 31, 2019	85,581	855,808	1,827	861,033	—	—	—	—	3,760,255	375	97,651,006	(83,751,525)	15,616,697
Net loss	—	—	—	—	—	—	—	—	—	—	—	(20,353,938)	(20,353,938
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,379,360	—	2,379,360
Conversion of preferred stock to common	—	—	(10)	(10,000)	—	—	—	—	92	—	10,000	—	—
Accretion of discount	—	—	—	5,287	—	—	—	—	—	—	(5,287)	—	—
Issuance of common stock, net	—	—	—	—	—	—	—	—	28,262,806	2,828	42,863,444	—	42,866,272
Warrant exercises	—	—	—	—	—	—	—	—	2,000	—	12,000	—	12,000
Balance at December 31, 2020	85,581	$ 855,808	1,817	$ 856,320	—	$ —	—	$ —	32,025,153	$ 3,203	$ 142,910,523	$ (104,105,463)	$ 40,520,391

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,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (20,353,938)	$ (7,037,338)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,379,360	66,176
Depreciation and amortization	34,515	26,737
Change in fair value of derivative instrument-warrants	6,050	(398,714)
Change in fair value of contingent consideration	140,000	(160,000)
Change in fair value of debt	—	179,652
Amortization of debt discount recorded as interest expense	—	486,608
Non-cash interest for shares issued for debt redemption payments	—	49,732
Change in net deferred tax liability	—	48,322
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	3,039,242	(317,046)
Prepaid expenses and other assets	(1,410,431)	(509,188)
Net cash used in operating activities	(16,165,202)	(7,565,059)
Cash flows from investing activities:		
Purchase of property and equipment	(87,983)	(51,469)
Proceeds from disposal of property and equipment	2,194	—
Net cash used in investing activities	(85,789)	(51,469)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	42,866,272	7,683,554
Proceeds from the issuance of Series D and warrants, net of issuance costs	—	403,120
Proceeds from the issuance of Series E and warrants, net of issuance costs	—	9,649,258
Proceeds from the exercise of warrants	12,000	2,090,542
Proceeds from debt financing	176,585	1,250,000
Repayment of debt financing	—	(1,250,000)
Repayment of convertible debt	—	(1,119,403)
Net cash provided by financing activities	43,054,857	18,707,071
Net increase in cash	26,803,866	11,090,543
Cash at beginning of period	13,922,972	2,832,429
Cash at end of period	$ 40,726,838	$ 13,922,972
Supplementary disclosure of cash flow information:		
Cash paid for interest	$ —	$ 26,756
Supplementary disclosure of non-cash financing activities:		
Conversion of Series C convertible preferred stock (part of Series C deemed dividend)	$ 10,000	$ 147,000
Conversion of Series D convertible preferred stock	—	521,000
Conversion of Series E convertible preferred stock	—	10,570,002
Accretion of Series C preferred stock discount upon conversion	5,287	4,674,905
Beneficial conversion factor of preferred stock accreted as deemed dividend	—	768,042
Issuance of common stock for debt redemption	—	500,244
Adoption of lease accounting	—	773,330
Fair value of underwriter warrants issued in conjunction with common stock offering	1,278,432	—
Warrants issued to placement agent	—	293,145

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

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1. Business Overview

Hepion Pharmaceuticals, Inc. (we, our, or us) is a biopharmaceutical company headquartered in Edison, New Jersey, focused on the development of drug therapy for treatment of chronic liver diseases. This therapeutic approach targets fibrosis 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 pathologic pathways involved in the progression of liver disease. Preclinical studies with CRV431 in NASH models demonstrated consistent reductions in liver fibrosis and additional reductions in inflammation and cancerous tumors in some studies. CRV431 additionally showed *in vitro* antiviral activity towards hepatitis B, C, and D viruses which also trigger liver disease. Preclinical studies also have shown potentially therapeutic activities of CRV431 in experimental models of acute lung injury, platelet activation, and SARS-CoV-2 coronavirus replication.

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 compound that binds and inhibits the function of a specific class of isomerase enzymes called cyclophilins that regulate protein folding. Many closely related isoforms of cyclophilins exist in humans. Cyclophilins A, B, and D are the best characterized cyclophilin isoforms. Inhibition of cyclophilins has been shown in the scientific literature to have therapeutic effects in a variety of experimental models, including liver disease models. In preclinical *in vitro* and/or *in vivo* experiments to date CRV431 decreased liver fibrosis, liver inflammation, liver tumors, and titers of HBV, HCV, HDV, and HIV-1. Importantly, reduction in liver fibrosis by CRV431 was observed *in vivo* in several experimental models and studies of NASH and liver fibrosis. Findings to date suggest that CRV431 might treat certain inciting agents of liver disease such as hepatitis viruses and also the ensuing disease processes resulting from those agents such as fibrosis.

On May 10, 2018, we submitted an Investigational New Drug Application (“IND”) to the U.S. Food and Drug Administration (“FDA”) to support initiation of our CRV431 HBV clinical development program in the United States and received approval in June 2018. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. (“Ciclofilin”) and we paid a related milestone payment of approximately $346,000 to Aurinia Pharmaceuticals, Inc. ("Aurinia") and $654,000 to the former Ciclofilin shareholders along with the issuance of 1,439 shares of our common stock with a fair value of $55,398, representing 2.5% of our issued and outstanding common stock as of June, 2016, to the former Ciclofilin shareholders. Our CEO is a former Ciclofilin shareholder and received approximately $274,000 and 603 shares of common stock and Petrus Wijngaard, a director of our company, received $2,805 and 6 shares of common stock.

Additional milestone payments could potentially be payable to the former Ciclofilin shareholders pursuant to the Ciclofilin Merger Agreement as follows: (i) upon receipt of Phase II positive data from a proof of concept clinical trial of CRV431 in humans - 4,317 shares of common stock and $3,000,000, (ii) upon initiation of a Phase III trial of CRV431 - $5,000,000, and (iii) upon acceptance by the FDA of a new drug application for CRV431 - $8,000,000. In addition, on February 14, 2014, Ciclofilin had entered into a Purchase and Sale Agreement to acquire Aurinia’s entire interest in CRV431. This agreement contains future milestone payments payable by us based on clinical and marketing milestones of up to CAD $2.45 million. The milestone payments payable to the former Ciclofilin shareholders will be subject to offset by certain of the clinical and marketing milestone payments payable to Aurinia as follows: (a) the payments to the former Ciclofilin shareholders pursuant to (ii) above would be offset by payment to Aurinia of CAD $450,000, and (b) the payments to the former Ciclofilin shareholders pursuant to (iii) above would be subject to offset by payment to Aurinia of up to CAD $2,000,000. In addition to the above clinical and milestone payments, the Aurinia Agreement provides for the following additional contingent payment obligations: (x) a royalty of 2.5% on net sales of CRV431 which is uncapped, (y) a royalty of 5% on license revenue from CRV431 and (z) a payment equal to 30% of the proceeds from a Liquidity Event (as defined in the Purchase and Sale Agreement) with respect to Ciclofilin, of which approximately $150,000 plus interest will be paid to Aurinia upon the closing of this offering. The maximum obligation under both (y) and (z) is CAD $5,000,000.

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

On November 20, 2020, we submitted an IND to the FDA to support initiation of a CRV431 clinical development program in the United States for COVID-19. We received approval December 17, 2020, to conduct a COVID-19 clinical trial and are investigating potential sources of collaboration and/or funding for the trial.

2. Basis of Presentation

Basis of presentation

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

Principles of Consolidation

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

Correction of Immaterial Errors

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

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

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

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

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

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

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

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

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

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

We had an unrecognized tax position of $283,600, a corresponding accrual for penalties and interest in the amount of $148,400, as a component of income tax expense, accrued through December 31, 2019 and an unrecognized tax position of $185,400 and a corresponding accrual for penalties and interest of $64,800, respectively, as of December 31, 2018. There are no amounts included in the unrecognized tax benefit at December 31, 2019 that will impact the effective rate if recognized. We expect that the entire amount of the unrecognized tax benefit to be reduced to $0 in the next 12 months.

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Liquidity

For the years ended December 31, 2020 and 2019, we had an accumulated deficit of $104.1 million, and $83.8 million, respectively. For the years ended December 31, 2020, cash used in operating activities was $16.2 million and we had a net loss of $20.4 million. We have not generated revenue to date and have incurred substantial losses and negative cash flows from operations since our inception. We have historically funded our operations through issuances of convertible debt, common stock and preferred stock. We expect to continue to incur losses for the next several years as we expand our research, development and clinical trials of CRV431. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

During the year ended December 31, 2020, we raised net proceeds of $42.9 million in order to fund future operations (see Note5). As of December 31, 2020, our cash balance was $40.7 million. Subsequent to the year ended December 31, 2020, we raised an additional net proceeds of approximately $82.1 million (see Note 13). We expect to continue to use the proceeds from previous financing transactions primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding our operations. We currently anticipate that our cash and cash equivalents balances are sufficient to fund our anticipated operating cash requirements for more than one year from the date of issuance of consolidated financial statements. These consolidated financial statements have been prepared under the assumption that we will continue as a going concern.

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

COVID-19 Pandemic

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

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

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

The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change and we do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. Although we cannot estimate the length or gravity of the impact of the COVID-19 outbreak nor estimate the potential impact to our fiscal year 2020 financial statements at this time, if the

pandemic continues, it could have a material adverse effect on our results of future operations, financial position, liquidity, and capital resources, and those of the third parties on which we rely in fiscal year 2021.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), as amended on June 5, 2020 by the Paycheck Protection Program ("PPP"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property. On April 13, 2020, we were granted a loan (the "Loan") from JPMorgan Chase Bank, N.A. in the aggregate amount of $176,585, pursuant to the PPP under Division A, Title I of the CARES Act. The Loan also provides for customary events of default, including, among others, events of default relating to failure to make payments, bankruptcy, breaches of representations, and material adverse effects. Additionally, the Loan is subject to the terms and conditions applicable to loans administered by the SBA under the CARES Act. We may also be subject to CARES Act-specific lookbacks and audits that may be conducted by other federal agencies, including several oversight bodies created under the CARES Act. These bodies have the ability to coordinate investigations and audits and refer matters to the Department of Justice for civil or criminal enforcement and other actions.

The Loan, which was in the form of a Note dated April 13, 2020 issued by us, matures on April 13, 2022 and bears interest at a rate of 0.98% per annum. The Note may be prepaid by us at any time prior to maturity with no prepayment penalties. Funds from the Loan may only be used for payroll costs, rent and utilities. We used the entire Loan amount for qualifying expenses. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. We believe that we have properly satisfied all eligibility requirements for the PPP loan and we intend to comply with the loan forgiveness provisions in the legislation; however, there can be no assurance that we will obtain full forgiveness of the loan based on the legislation. We are currently in the process of filing for loan forgiveness. As of the date of the issuance of the consolidated financial statements, we have not yet filed for loan forgiveness. The PPP Loan is reflected in the consolidated balance sheet as long-term debt based upon the terms and conditions of the Loan agreement.

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of 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, 2020 and 2019, the amount of cash was $40.7 million and $13.9 million, respectively, consisting of checking accounts held at U.S. and Canadian commercial banks. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have never experienced losses related to these balances.

Fair Value of Financial Instruments

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

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

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that we can access.

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

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

Financial instruments consist of cash and accounts payable, long-term debt, derivative instruments (warrants) and contingent consideration. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature, except for derivative instruments (warrants) and contingent consideration, which were recorded at fair value at the end of each reporting period. See Note 5 for additional information of the fair value of the derivative liabilities. We recorded contingent consideration from the 2016 acquisition of Ciclofilin, which is required to be carried at fair value. See Note 6 for additional information on the fair value of the contingent consideration.

Derivative Financial Instruments

We have issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments based on certain contingent put features, was recorded as a derivative liability under the provisions of ASC Topic 815 Derivatives and Hedging ("ASC 815") upon issuance. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in the fair value of derivative liabilities are recorded in the statements of operations under the caption "Change in fair value of derivative financial instruments—warrants." See Note 5 for additional information.

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

The warrants, issued in connection with the July 2018 Rights Offering (See Note 5) are deemed to be derivative instruments since if we do not maintain an effective registration statement, we are obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside our control. Therefore, the fair value of the warrants was determined using the Black-Scholes option pricing model, deemed to be an appropriate model due to the terms of the warrants issued, including a fixed term and exercise price.

The fair value of warrants was affected by changes in inputs to the Black-Scholes option pricing model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2020 and 2019, the fair value of all warrants was $11,673 and $5,623, respectively, which are classified as a long-term derivative liability in our consolidated balance sheets.

Property, equipment and depreciation

As of December 31, 2020 and 2019, we had $0.1 million and $0.1 million, respectively, of property and equipment, consisting primarily of computer equipment, research equipment and furniture and fixtures. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the depreciable assets are 3 to 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 years ended December 31, 2020 and 2019 was $34,515 and $26,737, respectively. Expenditures for repairs and maintenance are charged to operations as incurred. We will periodically evaluate whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at December 31, 2020 and 2019.

Goodwill and In-Process Research & Development

In accordance with ASC Topic 350, *Intangibles — Goodwill and Other* ("ASC Topic 350"), goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for

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

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

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

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. We performed a qualitative assessment of goodwill and determined that it was not more likely than not that the fair value of our reporting was less than its carrying value. There was no impairment of goodwill for the years ended December 31, 2020 and 2019.

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.

We performed a qualitative assessment of IPR&D and determined that it was not more likely than not that the asset was impaired. There was no impairment of IPR&D for the years ended December 31, 2020 and 2019.

Income Taxes

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

In April 2019, we transferred New Jersey state net operating loss tax credits and received approximately $1.0 million in connection with the sale of the state net operating losses to a third party recorded as an income tax benefit in the consolidated statement of operations. We received approval for the sale of net operating losses through participation in the New Jersey Technology Business Tax Certificate Transfer (NOL) Program. We continue to maintain a full valuation allowance for our U.S net deferred tax assets. The current period income tax expense is related to our foreign operations.

Contingencies

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

Research and Development

Research and development costs, which include expenditures in connection with an in-house research and development laboratory, salaries and staff costs, application and filing for regulatory approval of proposed products, purchased in-process research and development, license costs, regulatory and scientific consulting fees, as well as contract research, insurance and FDA consultants, are accounted for in accordance with ASC Topic 730, *Research and 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, 2020 and 2019, we had prepaid research and development costs of $1.8 million and $0.4 million, respectively.

Share-based payments

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

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

Foreign Exchange

The functional currency of Hepion Pharmaceuticals, Inc. and ContraVir Research Inc. is the U.S. dollar. The functional currency of Hepion Research Corp. is the Canadian dollar. Our reporting currency is the U.S. dollar. The assets and liabilities of Hepion Research Corp. are translated into U.S. dollars using period-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a separate component of shareholders' equity. The amount of currency translation adjustment was immaterial at December 31, 2020 and 2019.

Transactions in foreign currencies are remeasured into the functional currency of the relevant subsidiaries at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Resulting gains and losses are recorded in other foreign exchange (gain) loss within the consolidated statements of operations. The impact of foreign exchange gains (losses) was immaterial at December 31, 2020 and 2019.

Segment Information

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

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 August 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. The standard eliminates the liability and equity separation model for convertible instruments with a cash conversion feature. As a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. Additionally, the embedded conversion feature will no longer be amortized into income as interest expense over the instrument's life. Instead, entities will account for a convertible debt instrument wholly as debt unless (1) a convertible instrument contains features that require bifurcation as a derivative under ASC Topic 815, Derivatives and Hedging, or (2) a convertible debt instrument was issued at a substantial premium. Additionally, the standard requires applying the if-converted method to calculate convertible instruments' impact on diluted earnings per share ("EPS"). The standard is effective for fiscal years beginning after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020. It can be adopted on either a full retrospective or modified retrospective basis. We are currently evaluating the effect this ASU will have on our consolidated financial statements and related disclosures. We expect to elect to early adopt the new standard in the first quarter of 2021.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). We adopted this standard on January 1, 2020 and the impact that this guidance had on our consolidated financial statements was immaterial.

In August of 2018, the FASB issued ASU 2018-13 — Fair Value Measurement (Topic 820): *Disclosure Framework— Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which amends disclosure requirements on fair value measurements in Topic 820. This amendment modifies the valuation process of fair value measurements by removing the disclosure requirements for the valuation processes for Level 3 fair value measurements, clarifying the timing of the measurement uncertainty disclosure, and including the changes in unrealized gains and losses for recurring Level 3 fair value measurements in other comprehensive income if held at the end of the reporting period. It also allows the disclosure of other quantitative information in lieu of the weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019 and should be applied prospectively for the most recent period presented in the initial fiscal year of adoption. We adopted this standard on January 1, 2020 and the impact that this guidance had on our consolidated financial statements was immaterial.

5. Stockholders' Equity and Derivative Liability — Warrants

Series A Convertible Preferred Stock

On October 14, 2014, our Board of Directors authorized the sale and issuance of up to 1,250,000 shares of Series A Convertible Preferred Stock (the "Series A"). All shares of the Series A were issued between October 2014 and February 2015. Each share of the Series A is convertible at the option of the holder into the number of shares of common stock determined by dividing the stated value of such share by the conversion price that is subject to adjustment. As of December 31, 2020, there were 85,581 shares outstanding. During the year ended December 31, 2020, no shares of the Series A were converted.

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Series C Convertible Preferred Stock Issuance

On July 3, 2018, we completed a rights offering pursuant to our effective registration statement on Form S-1. We offered for sale units in the rights offering and each unit sold in connection with the rights offering consisted of 1 share of our Series C Convertible Preferred Stock, or Series C, and common stock warrants (the "Rights Offering"). Upon completion of the offering, pursuant to the rights offering, we sold an aggregate of 10,826 units at an offering price of $1,000 per unit comprised of 10,826 shares of Series C and 88,928 common stock warrants. As of September 30, 2020, there were 1,817 shares outstanding. During the year ended December 31, 2020, 10 shares of the Series C were converted into 92 shares of our common stock.

Common Stock and Warrant Offering

On October 7, 2015, we entered into an underwriting agreement related to the public offering and sale of 8,929 shares of common stock and warrants to purchase up to 5,357 shares of common stock, at a fixed combined price to the public of $1,680 under our prior shelf registration statement on Form S-3. The shares of common stock and warrants were issued separately on October 13, 2015. The warrants were immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of $2,380.00 per share. In October 2020, the October 2015 warrants expired.

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

If we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property ("Fundamental Transaction"), then we shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the Fundamental Transaction and continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such Fundamental Transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, we have determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in our consolidated statement of operations. Upon the issuance of these warrants, the fair value of approximately $1.5 million was recorded as derivative financial instruments liability-warrants. "Refer to Note 6".

The fair value of these liability classified warrants was estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement. The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of December 31, 2020 and 2019:

	December 31,	
	2020	2019
Price of Hepion common stock	$ 2.19	$ 5.36
Expected warrant term (years)	0.25 years	1.26 years
Risk-free interest rate	0.27 %	1.66 %
Expected volatility	124 %	75 %
Dividend yield	—	—

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

If we consummate any merger, consolidation, sale or other reorganization event in which our common stock is converted into or exchanged for securities, cash or other property ("Fundamental Transaction"), then we shall pay at the holder's option, exercisable at any time commencing on the occurrence or the consummation of the Fundamental Transaction and continuing for 90 days, an amount of cash equal to the value of the remaining unexercised portion of the warrant as determined in accordance with the Black-Scholes option pricing model on the date of such Fundamental Transaction. As a result of these terms, in accordance with the guidance contained in ASC Topic 815-40, we have determined that the warrants issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis in our consolidated statement of operations and comprehensive loss. Upon the issuance of these warrants, the fair value of approximately $4.0 million was recorded as derivative financial instruments liability-warrants. "Refer to Note 6".

The fair value of these liability classified warrants were estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of December 31, 2020 and 2019:

	December 31,	
	2020	2019
Price of Hepion common stock	$ 2.19	$ 5.36
Expected warrant term (years)	1.31 years	2.31 years
Risk-free interest rate	0.27 %	1.66 %
Expected volatility	115 %	69 %
Dividend yield	—	—

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

The fair value of these liability classified warrants were estimated using the Black-Scholes option pricing model. Other than for the fair value of common stock, we developed our own assumptions for use in the Black-Scholes option pricing model that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of our common stock, our stock price volatility (stock price volatility of comparable companies prior to 2020), the contractual term of the warrants, risk free interest rates and dividend yields. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The following assumptions were used to measure the warrants at issuance and to remeasure the liability as of December 31, 2020 and 2019:

	December 31,	
	2020	2019
Price of Hepion common stock	$ 2.19	$ 5.36
Expected warrant term (years)	2.50 years	3.50 years
Risk-free interest rate	0.27 %	1.66 %
Expected volatility	118 %	65 %
Dividend yield	—	—

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The following table sets forth the components of changes in our derivative financial instruments liability balance for the years ended December 31, 2020 and 2019:

Date	Description	Number of Warrants Outstanding	Derivative Instrument Liability
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
	Expiration of warrants	(5,356)	—
	Change in fair value of warrants for the year ended December 31, 2020	—	6,050
December 31, 2020	Balance of derivative financial instruments liability	102,642	$ 11,673

Common Stock Offerings

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 sold through B. Riley FBR 2,311,867 shares (the "Shares") of our common stock, par value $0.0001 per share (the "Common Stock"), for $6.8 million. The offer and sale of the Shares were 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"). Also, on March 27, 2020, we filed a prospectus supplement to the Form S-3 (File No. 333-229534) pursuant to which we sold an additional 2,950,939 shares of our common stock for $4.6 million. In total, we sold 5,262,806 shares of our common stock resulting in net proceeds of $11.2 million from the "at the market offerings".

On November 19, 2020, we terminated the Sales Agreement with B. Riley FBR, Inc. dated February 12, 2020, effective November 24, 2020.

On November 24, 2020, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity, a division of Fordham Financial Management, Inc., as the representative (the "Representative") of the underwriters listed therein (collectively, the "Underwriters"), with respect to an underwritten public offering (the "Offering") of 20,000,000 shares of our common stock, par value $0.0001 (the "Shares") at a public offering price of $1.50 per share and a 45-day option to purchase up to 3,000,000 additional shares of common stock to cover over-allotments. On November 25, 2020, the Representative exercised the over-allotment in full. Upon closing of the offering, we issued to the Representative as compensation warrants to purchase 690,000 shares of common stock, or the Representative's Warrants. The Representative's Warrants will be exercisable at $1.875 per share. The Representative's Warrants are exercisable at any time and from time to time, in whole or in part, during the four and one half year period commencing 180 days from November 30, 2020. We determined that the Representative Warrants should be recorded in the consolidated financial statements as equity classified.

The Shares were offered by us pursuant to a registration statement on Form S-1 (No. 333- 249724) previously filed with the SEC and subsequently declared effective on November 24, 2020. The Offering closed on November 30, 2020 and we received net proceeds of $31.6 million.

6. Fair Value Measurements

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

Description	Fair Value Measurements at Reporting Date Using Total	(Level 1)	(Level 2)	(Level 3)
As of December 31, 2020:				
Contingent consideration	$ 2,570,000	$ —	$ —	$ 2,570,000
Derivative liabilities related to warrants	$ 11,673	$ —	$ —	$ 11,673
As of December 31, 2019:				
Contingent consideration	$ 2,430,000	$ —	$ —	$ 2,430,000
Derivative liabilities related to warrants	$ 5,623	$ —	$ —	$ 5,623

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities-warrants in our consolidated statement of operations. See Note 5 for a rollforward of the derivative liability for the years ended December 31, 2020 and 2019. The financial instrument's level within the fair value hierarchy is

based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, we review the assets and liabilities that are subject to ASC 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

Contingent consideration was recorded for the acquisition of Ciclofilin Pharmaceuticals, Inc. (Ciclofilin) on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and our stock, upon the achievement of certain milestones and in 2016 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.

At December 31, 2020, the assumptions we used to calculate the fair value were as follows:

	Assumptions	
	2020	2019
Discount rate	8.0%	8.0%
Stock price	$2.19	$5.36
Projected milestone achievement dates	Jun 2021–Jan 2025	Nov 2020–Jan 2025
Probability of success of milestone achievements	13% – 40%	13% – 40%

We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin and in the fourth quarter of 2018, we paid a related milestone payment of $1,000,000 and issued 1,439 shares of our common stock with a fair value of $55,398, representing 2.5% of our issued and outstanding common stock as of June 2016, to the Ciclofilin shareholders. As of December 31, 2020, due to the uncertainty in the timing of the clinical development of the associated product candidate, the entire balance is classified as a non-current liability.

The following table presents the change in fair value of the contingent consideration for the years ended December 31, 2020 and 2019.

	Acquisition-related Contingent Consideration
Liabilities:	
Balance at December 31, 2018	$ 2,590,000
Change in fair value recorded in earnings	(160,000)
Balance at December 31, 2019	2,430,000
Change in fair value recorded in earnings	140,000
Balance at December 31, 2020	$ 2,570,000

7. Indefinite-lived Intangible Assets and Goodwill

IPR&D

Our IPR&D asset consisted of the following at:

	Indefinite-lived Intangible Asset
CRV431 balance at December 31, 2018	$ 3,190,000
Change in fair value during the year ended December 31, 2019	—
CRV431 balance at December 31, 2019	$ 3,190,000
Change during the year ended December 31, 2020	—
CRV431 balance at December 31, 2020	$ 3,190,000

No impairment losses were recorded on IPR&D during the years ended December 31, 2020 and 2019.

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Goodwill

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

	Amount
Goodwill balance at December 31, 2018	$ 1,870,924
Changes during the year ended December 31, 2019	—
Goodwill balance at December 31, 2019	$ 1,870,924
Changes during the year ended December 31, 2020	—
Goodwill balance at December 31, 2020	$ 1,870,924

No impairment losses were recorded to goodwill during years ended December 31, 2020 and 2019.

8. Accrued Liabilities

Accrued expenses consist of the following:

	December 31,	
	2020	2019
Payroll and related costs	$ 150,702	$ 346,244
Research and development	438,856	12,075
Legal fees	—	2,354
Accrued taxes	37,160	431,923
Other	32,854	58,606
Total accrued expenses	$ 659,572	$ 851,202

9. Accounting for Share-Based Payments

On June 3, 2013, we adopted the 2013 Equity Incentive Plan (the "Plan"). Stock options granted under the Plan typically will vest after three years of continuous service from the grant date and will have a contractual term of ten years. At our annual meeting of stockholders on July 30, 2020, we received shareholder approval to increase the number of shares issuable under the Plan to 2,500,000. As of December 31, 2020, we had 39,323 shares of common stock available for grant under the Plan.

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

	Year Ended December 31,	
	2020	2019
General and administrative	$ 1,798,288	$ 40,813
Research and development	581,072	25,363
Total stock-based compensation expense	$ 2,379,360	$ 66,176

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, 2019	41,271	$ 3.24 - $ 2,452.80	$ 194.83	$ 43,182	8.42 years
Granted	2,423,500	$ 1.63 - $ 3.72	$ 2.50	$ 765,890	
Forfeited	—	$ — - $ —	$ —	$ —	
Cancelled	(4,094)	$ — - $ —	$ 1,081.02	$ —	
Balance outstanding, December 31, 2020	2,460,677	$ 1.63 - $ 2,452.80	$ 4.17	$ 990,930	9.40 years
Vested awards and those expected to vest as of December 31, 2020	2,381,240	$ 3.24 - $ 2,452.80	$ 4.23	$ 960,978	9.40 years
Vested and exercisable at December 31, 2020	38,140	$ 3.24 - $ 2,452.80	$ 109.63	$ 8,063	8.39 years

There were 31,526 granted to employees during 2019. The total fair value of awards vested during the year ended December 31, 2020 was $0.1 million and was de minimis for the year ended December 31, 2019.

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

As of December 31, 2020, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was approximately $6.1 million to be recognized over a weighted-average remaining vesting period of approximately 2.2 years.

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 years ended December 31, 2020.

	Year Ended December 31,	
	2020	2019
Stock price	$ 2.50	$ 3.24
Risk-free interest rate	0.34 %	1.85 %
Dividend yield	—	—
Expected volatility	126.3 %	76.5 %
Expected term (in years)	6.0	6.0

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

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

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

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

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

Forfeitures—ASC 718 allows for the election of forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. On April 1, 2016, we determined that we had sufficient history of issuing stock options and decreased our estimated forfeiture rate from 10%, which was based on the historical experience of our former parent, to 3%, which is our actual historical forfeiture rate. The forfeiture rate was 10% through the end of the 3rd fiscal quarter ended March 31, 2016 and was the adjusted to 3% through the end of the fiscal year June 30, 2016 based on the aforementioned historical analysis. The forfeiture rate was 3% for the years ended December 31, 2020 and 2019. We will continue to analyze the forfeiture rate on at least an annual basis or when there are any identified triggers that would justify immediate review.

10. Income Taxes

We provide 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.

Our loss before income taxes was $20.3 million and $7.9 million for the years ended December 31, 2020 and 2019, respectively, and was generated entirely in the United States and Canada.

The income tax expense for the year ended December 31, 2020 was $30,584 and income tax benefit for the year ended December 31, 2019 was $0.9 million. For 2020, taxes paid are related to our Canadian entity. For 2019, the income tax benefit resulted from the sale of state net operating losses totaling $11.4 million.

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

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

	As of December 31,	
	2020	2019
Federal net operating loss ("NOL")	$ 19,665,840	$ 16,812,626
State NOL	4,497,069	2,439,015
Research and development credits	2,099,921	1,350,305
Lease liability	172,674	242,234
Stock compensation & other	1,108,314	889,167
Deferred tax asset valuation allowance	(26,812,522)	(20,945,997)
Total deferred tax asset	731,296	787,350
Deferred tax liability (In-Process R&D)	(957,000)	(957,000)
Right-of-use asset	(183,318)	(239,372)
Total deferred tax liability	(1,140,318)	(1,196,372)
Net deferred tax liability	$ (409,022)	$ (409,022)

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. Based on our history of operating losses since inception, we have concluded that it is more likely than not that the benefit of our deferred tax assets will not be realized. Accordingly, we have provided a full valuation allowance for deferred tax assets as of December 31, 2020 and 2019, including those related to Canada. The valuation allowance for deferred tax assets related to Canada as of December 31, 2019 were recorded during 2020, as described in Note 2. We have recorded a net deferred tax liability of $409,022 related to in-process research and development as a result of the acquisition of Ciclofilin. It is our 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/(decreased) by $5.9 million and $1.4 million for the years ended December 31, 2020 and 2019, respectively, due primarily to the generation of net operating losses during these periods.

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,	
	2020	2019
U.S. statutory income tax rate	21.0 %	21.0 %
State income taxes, net of federal benefit	8.6	11.6
Research and development credits	2.1	4.0
Warrant liability and contingent consideration	(0.2)	1.5
Foreign tax differential	—	(0.1)
Other	(1.7)	(4.7)
Valuation allowance	(29.9)	(21.9)
Effective tax rate	(0.1)%	11.4 %

As of December 31, 2020 and 2019, we had U.S. federal and state net operating loss carryforwards of $148.1 million and $107.3 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2022. We also had federal and state research and development tax credit carryforwards of approximately $1.7 million as of December 31, 2020, which will begin to expire in December 2023.

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 we

can utilize annually to offset future taxable income or tax liabilities. The amount of the annual limitation, if any, will be determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The utilization of these NOLs is subject to limitations based on past and future changes in our ownership pursuant to Section 382. We have completed several financings since our inception which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code or could result in a change in control in the future. We have not conducted an assessment to determine whether there may have been a Section 382 or 383 ownership change.

We file income tax returns in the United States, Canada and various state jurisdictions. Our 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. Our tax returns in Canada are also subject to examination.

We had an unrecognized tax position of $283,600, a corresponding accrual for penalties and interest in the amount of $148,400, as a component of income tax expense, accrued through December 31, 2019. There are no amounts included in the unrecognized tax benefit at December 31, 2019 that will impact the effective rate if recognized. During the year ended December 31, 2020, the unrecognized tax position along with the corresponding interest and penalties were paid and the accrual has been reduced to $0 at December 31, 2020 and we no longer have an unrecognized tax position.

11. 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,	
Basic and diluted net (loss) income per common share	**2020**	**2019**
Numerator:		
Net loss	$ (20,353,938)	$ (7,037,338)
Preferred stock deemed dividend	(5,287)	(5,442,947)
Net loss attributable to common stockholders	$ (20,359,225)	$ (12,480,285)
Denominator:		
Weighted average common shares outstanding	9,677,832	2,043,244
Net loss per share of common stock—basic and diluted	$ (2.10)	$ (6.11)

The following outstanding securities at December 31, 2020 and 2019 have been excluded from the computation of basic and diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year Ended December 31,	
	2020	**2019**
Common shares issuable upon conversion of Series A preferred stock	3,184	85,581
Common shares issuable upon conversion of Series C preferred stock	16,747	1,827
Stock options	2,460,677	41,271
Warrants – liability classified	102,642	107,998
Warrants – equity classified	3,118,568	2,430,568
Total	5,701,818	2,667,245

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 our common stock for the period they were outstanding.

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12. Commitments and Contingencies

Contractual Obligations

In August 2014, we entered into a lease for corporate office space in Edison, New Jersey. In December 2017, we entered an amendment to the lease for corporate office space in Edison, New Jersey expanding the office footprint and extending the lease for an approximate 5-year period. In May 2018, we entered into a 3-year lease for office equipment to be used at our corporate office space in Edison, New Jersey. In October 2019, we entered into a 3-year lease for office and research laboratory space in Edmonton, Canada. Prior to signing this lease, the space was previously on a month-to-month basis.

Legal Proceedings

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

Leases

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

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

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

We adopted ASC 842 in the first quarter of 2019 using an alternative modified retrospective approach, in which prior periods will not be restated. As a result of the adoption, as of January 1, 2019, we recognized an operating lease liability of $0.8 million based on the present value of the minimum rental payments of the leases and a corresponding ROU asset of $0.8 million. As of December 31, 2020, the ROU assets were $0.6 million, the current lease liabilities were $0.3 million, and the non-current lease liabilities were $0.3 million. The discount rate used to account for our operating leases under ASC 842 is our estimated incremental borrowing rate of 6.5%.

Rent expense for the years ended December 31, 2020 and 2019 was $0.3 million and $0.3, respectively. The weighted average remaining term of our noncancelable operating leases is 2.13 years. Future minimum rental payments under our noncancelable operating leases at December 31, 2020 is as follows:

2021	$	287,977
2022		271,885
2023		53,902
2024 and thereafter		—
Total		613,764
Present value adjustment		(38,183)
Lease liability at December 31, 2020	$	575,581

Employment Agreements

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

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13. Subsequent Events

On February 16, 2021, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity, a division of Fordham Financial Management, Inc., as the representative (the "Representative") of the underwriters listed therein (collectively, the "Underwriters"), with respect to an underwritten public offering (the "Offering") of 44,200,000 shares of our common stock, par value $0.0001 (the "Shares"), at a public offering price of $2.00 per share, which resulted in net proceeds to us of approximately $82.1 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this Offering to fund our research and development activities and general corporate purposes, including working capital, operating expenses and capital expenditures.The Offering closed on February 18, 2021, subject to customary closing conditions.

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, 2020, 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, 2020. 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, 2020. 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, 2020, 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:

Control environment:

- We are utilizing the services of external consultants to review our internal controls environment and make recommendations to remediate the material weaknesses in our financial reporting.

Period end financial close and reporting:

- We assessed our companywide accounting resource requirements and as a result have hired a Director of Financial Reporting with the appropriate technical accounting and financial reporting experience and are in the process of hiring additional experienced accounting personnel in order to improve the overall efficiency of our accounting and reporting processes.
- We have implemented several software solutions including software for the reporting of stock-based compensation and software related to public company reporting in order to improve our financial reporting process.
- We are utilizing the services of external consultants for non-routine and\or technical accounting issues as they arise.
- We are utilizing the services of external tax consultants to improve our income taxes reporting process for deferred tax assets, deferred tax liabilities and income taxes payable and the related income tax expense.
- We have engaged a third party consultant to assist us in reviewing our business process internal controls and improving our internal control documentation.

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

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

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2020 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, 2020.

ITEM 9B. OTHER INFORMATION

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding our directors, executive officers and corporate governance will be included in our 2021 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2021 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding security ownership of certain beneficial owners and management will be included in our 2021 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2021 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accounting fees and services will be included in our 2021 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Hepion Pharmaceuticals, Inc. appearing on page 57 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	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).
4.2	Form of Warrant issued in April Offering (incorporated by reference to Exhibit 4.1 to Form S-1 filed on April 18, 2019).
4.3	Form of Warrant issued in June Offering (incorporated by reference to Exhibit 4.1 to Form S-1 filed on June 5, 2019).

4.4	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as Exhibit 4.6 to Form 10-K filed with the Securities and Exchange Commission on May 14, 2020 and incorporated herein by reference).
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	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).
10.4	Form of Securities Purchase Agreement in April Offering (incorporated by reference to exhibit 10.11 to Form S-1 filed on April 18, 2019).
10.5	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

* 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: March 31, 2021

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.

Signature	Title	Date
/s/ ROBERT FOSTER Robert Foster	Chief Executive Officer (Principal Executive Officer)	March 31, 2021
/s/ JOHN CAVAN John Cavan	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2021
/s/ GARY S. JACOB, PHD. Gary S. Jacob, PhD.	Chairman, Board of Directors	March 31, 2021
/s/ JOHN BRANCACCIO John Brancaccio	Director	March 31, 2021
/s/ ARNOLD LIPPA Arnold Lippa	Director	March 31, 2021
/s/ TIMOTHY BLOCK Timothy Block	Director	March 31, 2021
/s/ THOMAS ADAMS Thomas Adams	Director	March 31, 2021
/s/ PETRUS WIJNGAARD Petrus Wijngaard	Director	March 31, 2021

Exhibit 21.1

LIST OF SUBSIDIARIES

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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. 333-252188, 333-203867, 333-215662 and 333-234728) of Hepion Pharmaceuticals, Inc. of our report dated March 31, 2021, relating to the consolidated financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, LLP
Woodbridge, New Jersey

March 31, 2021

Exhibit 31.1

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: March 31, 2021

/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: March 31, 2021

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

Exhibit 32.1

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, 2020, 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: March 31, 2021

/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, 2020, 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: March 31, 2021

/s/ JOHN CAVAN
John Cavan
Chief Financial Officer
(Principal Financial Officer)