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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, 2018

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

CONTRAVIR 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	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	The Nasdaq Capital Market

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

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

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

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

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

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

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

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

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

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

As of June 30, 2018 (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 $13.9 million based on the last reported sale price of the registrant's common stock on June 30, 2018.

The number of shares of the registrant's Common Stock outstanding as of March 12, 2019 was 17,179,331.

Documents Incorporated by Reference:

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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;
- 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.

PART I

ITEM 1. BUSINESS

Transition Period

On December 14, 2017, the Company's Board of Directors approved a change in our fiscal year end from June 30 to December 31, effective December 31, 2017. The transition period included in this Form 10-K and previously included in Form 10-KT is for the six months ended December 31, 2017 (which we sometimes refer to in the Transition Report as the "transition period"). In this Annual Report, our fiscal years are identified according to the calendar year in which they historically ended (e.g., the fiscal years ended June 30, 2017 is referred to as "fiscal 2017" and June 30, 2016 is referred to as "fiscal 2016" as if we had not changed our fiscal year to a calendar year on December 14, 2017 (effective December 31, 2017)).

Overview

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

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

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

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

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

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

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

Our second compound, Tenofovir exalidex ("TXL™"), is more advanced clinically with a completed phase 2 study. TXL is a nucleotide pro-drug of tenofovir that inhibits hepatitis B viral replication, and targets the liver, the reservoir for the hepatitis B virus. As our focus is on development of CRV431 in liver disease, we anticipate that we will out-license, partner, or divest ourselves of TXL.

CRV431

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

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

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

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

On May 10, 2018, we submitted an Investigational New Drug Application ("IND") to the U.S. Food and Drug Administration ("FDA") to support initiation of our CRV431 HBV clinical development program in the United States and received approval in June 2018. We completed the first segment of our Phase 1 clinical activities for CRV431 in October 2018 wherein we reached a major clinical milestone of positive data from a Phase I trial of CRV431 in humans. This achievement triggered the first milestone payment, as stated in the Merger Agreement for the acquisition of Ciclofilin Pharmaceuticals, Inc. ("Ciclofilin") and we paid a related milestone payment of $1,000,000 and issued 100,737 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.

TXL

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

We in-licensed TXL from Chimerix in exchange for an upfront payment of 120,000 shares of our preferred stock, valued at $1.2 million at the (time of the deal). Our intellectual property provides protection to at least 2031.

We completed a Phase 1b safety and pharmacokinetic study in 2016. Data from the Phase 1b study demonstrate that TXL was safe and well tolerated by healthy volunteers in all dosing groups. We also completed a Phase 2a multiple ascending dose proof of concept clinical trial. The study enrolled 62 treatment-naïve patients with chronic HBV infection and compared TXL to the standard dose of TDF. Data from the Phase 2a study demonstrated that TXL was safe and well tolerated by patients with chronic HBV infection in all dosing groups.

The data in the Phase 2a study demonstrated that doses of TXL from 50-mg to 100-mg resulted in comparable mean HBV viral load reductions to the 300-mg dose of TDF after 28 days of treatment. The data also demonstrated that TXL, at all doses tested, resulted in substantially lower systemic circulating levels of tenofovir in the blood compared to levels observed after dosing with TDF. These results demonstrate the potential for TXL to reduce the risk of bone and kidney-related toxicities associated with TDF.

We submitted an IND to the FDA to support initiation of our HBV clinical development program in the United States and received a notice of approval in September 2017.We conducted a safety study in patients with severe renal impairment during the fourth quarter of 2017. The study comprised 16 subjects including 8 healthy subjects with normal kidney functions and 8 subjects with severely impaired kidney function. Results from the study confirmed that TXL was safe and well tolerated in both patient groups. Importantly, the data showed that the blood concentrations of tenofovir in severely renally-impaired subjects receiving 50 mg of TXL were similar to the TFV exposure levels observed after dosing of TDF 300 mg. These findings indicate that dosing strength adjustments of TXL is not warranted in patients with compromised renal function. Data from the study provided further support on the strong safety profile of TXL in patients with comorbidities. Additionally, we received approval for our Clinical Trial Application ("CTA") in the United Kingdom.

On January 8, 2018, we met with the FDA's Division of Antiviral Products at the Center for Drug Evaluation and Research, to review and discuss the data generated for TXL to date, as well as the data package that would be required for the filing of an NDA and successful registration of TXL in the U.S. leveraging the 505(b)(2) regulatory pathway. The 505(b)(2) regulatory pathway allows us to rely upon FDA's previous findings of safety and efficacy of an approved and marketed product to supplement its own safety and efficacy data, and may be considered in the review by the FDA of a future New Drug Application (NDA). On February 12, 2018, we received agreement from the FDA allowing us to utilize the 505(b)(2) regulatory pathway to streamline the development and registration of TXL. On February 22, 2018, the FDA granted Orphan Drug Designation to TXL for the treatment of chronic hepatitis B infection in a pediatric patient population (up to 11 years of age).

We have made the decision to out-license/partner TXL, as TXL is in late-stage clinical trials which would consume many important company resources. Importantly, we are aligning our programs to address the broader needs of treating liver diseases including NASH, fibrosis, and HCC while also addressing an important risk factor for the development of such diseases (i.e., HBV infection). For this reason, we plan to focus resources and development programs on further advancing CRV431 while seeking partnership opportunities for TXL.

License Agreement

Under the terms of the License Agreement, we licensed TXL™ from Chimerix in exchange for an upfront payment consisting of 120,000 shares of our Series B Convertible Preferred Stock with a stated value of $1.2 million. In addition, Chimerix is eligible to receive up to approximately $20 million in clinical, regulatory and initial commercial milestones in the United States and Europe, as well as royalties and additional milestones based on commercial sales in those territories. Either party may terminate the License Agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy or insolvency of the other party. We may also terminate the License Agreement without cause on a country by country basis upon sixty (60) days prior written notice to Chimerix.

On September 30, 2016 Chimerix converted all shares of Series B Preferred Stock into approximately 134,000 shares of our common stock.

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 of its outstanding equity interests. Ciclofilin's lead asset, CPI-431-32 which we renamed CRV431.strengthens ContraVir's liver disease portfolio and is currently in preclinical development for the treatment of liver fibrosis and also 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.

The TXL™ assets acquired by us from Chimerix are licensed pursuant to the terms of the December 18, 2014 Agreement ("Agreement"). Per the Agreement, we received from Chimerix a license to develop, make, have made, use, sell, offer for sale, export and import TXL™. Per the Agreement, we acquired patented rights owned by Chimerix, including rights licensed to Chimerix by Regents of the University of California pursuant to the terms of an agreement, dated May 12, 2002, by and between Chimerix and the

Regents of the University of California ("UC Agreement"), as amended on September 11, 2002, December 17, 2010, September 14, 2011, and July 19, 2012.

As of the date of this report, we currently license directly from Chimerix two issued United States patents related to TXL™. One of these patents covers a composition of matter of a stable crystalline salt of TXL™ and was issued on April 14, 2015 and will expire in 2031. The other United States patent covers methods of use of TXL™ and was issued on March 31, 2015 and will expire in 2030. In addition, we currently directly license from Chimerix one granted Australian patent which covers the composition of matter of a stable crystalline salt of TXL™ which will expire in 2031. We also directly license ten foreign granted patents (Australia, China, Europe, Japan, Mexico, and South Africa) which cover methods of use of TXL™ and expire between 2028 and 2030. We directly license five pending foreign patent applications and one pending US patent application which cover the composition of matter of a stable crystalline salt of TXL™. We also directly license from Chimerix 21 additional pending foreign patent applications and 4 pending US patent applications which cover methods of use of TXL™. The US patent applications, if allowed, will expire in 2030, 2031 and 2033, non-inclusive of any time awarded by the United States Patent Office for Patent Term Adjustment. The foreign patent applications, if allowed, will expire between 2028 and 2033.

As of the date of this report, we currently license from Chimerix, pursuant to the terms of the UC Agreement, five issued United States patents and one allowed patent application related to TXL™. Four of the issued patents cover a composition of matter of TXL™ and were issued between 2004 and 2012 and will expire between 2020 and 2021. The allowed patent application also covers compositions of matter and will likely expire in 2020, non-inclusive of any time awarded by the United States Patent Office for Patent Term Adjustment.

The other United States patent covers methods of use of TXL™ and was issued on September 7, 2010 and will expire in 2020.

In addition, we currently license from Chimerix, via the UC Agreement, 36 granted foreign patents covering the composition of matter of TXL™ in Australia, Canada, Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal, Sweden, and Turkey, Hong Kong, India, Japan, Mexico, China, Russia, and South Africa. We also license two additional pending patent applications covering the composition of matter in Japan and India. All foreign patents and pending patent applications will expire in 2020.

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. At this time, 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 time lines.

We intend to use contract manufacturers to produce clinical trial material for use in the clinical trials of TXL™ and 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 a 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 a 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 II 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 a 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-Phase2 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 a 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, a 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 a 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 a 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 a 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.

A 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 of 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 a NDA or BLA once it is submitted, and the actual time required for any product candidate to be approved may vary substantially, depending upon the nature, complexity and novelty of the product candidate.

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

Post-Approval Regulations

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

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

The labeling, advertising, promotion, marketing and distribution of an approved drug or biologic product must also comply with FDA and Federal Trade Commission ("FTC") requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result

in penalties, including the issuance of a Warning Letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

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

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

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

Foreign Regulatory Approval

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

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

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

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

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

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

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

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

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

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

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

Employees

As of December 31, 2018, we had fourteen 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.contravir.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 and our independent registered public accounting firm's report, contained herein, includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern, indicating the possibility that we may not be able to operate in the future.

As of the year ended December 31, 2018, the transition period ended December 31, 2017 and the fiscal year ended June 30, 2017, we had an accumulated deficit of $76.5 million, $67.0 million, and $59.5 million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, continue our clinical trials, acquire or license technologies, advance other product candidates into clinical development, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. Primarily as a result of our losses incurred to date, our expected continued future losses, and limited cash balances, management concluded that there is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has also included in its report an explanatory paragraph regarding this uncertainty. Our ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

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

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

Our product candidate CVRV431 is in the early stages of development and its commercial viability remains subject to the successful outcome of current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidate, our business will be materially harmed.

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

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

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

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidates to obtain regulatory approval to further advance clinical development or to market them. Even if our product candidates demonstrate biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. In preclinical studies and clinical trials we have conducted to date, our product candidates have 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 candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

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

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidates, 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 candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

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

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

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

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

If approved and commercialized, TXL™ intends to compete with at least five currently approved prescription therapies for the treatment of HBV: Viread, Vemlidy, Baraclude, Tyzeka, Hespera, and Epivir. To our knowledge, other potential competitors are in 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 TXL™.

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 candidates.

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

The product candidates that we, or our collaborators, 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 candidates are also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidates' safety and efficacy before they can be approved for the targeted indications. Our product candidates have not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates 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 candidates, 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 candidates 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 candidates through clinical development, and ultimately commercialize them, may:

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

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

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

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

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

Our product candidates, CRV431 and TXL™, are chemical compounds, 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 a number of 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 candidates, 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 candidates.

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

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

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidate will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if the FDA believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidates 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 candidates.

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

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

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates 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 candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates 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 candidates, 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 candidates or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates 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 candidates 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 candidates, 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 candidates 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 candidates.

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

candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, 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 candidates, 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 candidates 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 candidates, 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 candidates, and we cannot predict success in these jurisdictions.

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

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

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

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

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

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

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

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

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

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

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate

our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates 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 candidates currently under development. Any approvals we may obtain may not cover all of 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 candidates for the claimed intended uses. Following any regulatory approval of our product candidates, 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 candidates in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, 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, TXL™ intends to compete with at least 5 currently approved prescription therapies for the treatment of HBV, Viread, Baraclude, Tyzeka, Hespera, and Epivir. To our knowledge, other potential competitors are in 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 TXL™.

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 candidates.

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 candidates 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 candidates, 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 candidates in international markets.

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

If the manufacturers upon whom we 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 for the production of 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 increase successfully 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 increase successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product 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 for the production of 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 a number of 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, TXL™ 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 of 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.

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 a number of 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.

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.

If we materially breach or default under the Chimerix Agreement, they will have the right to terminate the agreement and we could lose critical license rights, which would materially harm our business.

We do not currently own any patents, trademarks, or copyrights; however, our business is substantially dependent upon certain intellectual property rights that we license from Chimerix. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under the Agreement. The Agreement provides the right to terminate if the Agreement for an uncured breach by us, or if we are insolvent or the subject of a bankruptcy proceeding, or potentially other reasons. We expect that other technology in-licenses that we may enter into in the future will contain similar provisions and impose similar obligations on us. If we fail to comply with any such obligations such licensor will likely terminate their out-licenses to us, in which case we would not be able to market products covered by these licenses, including our TXL™ asset. The loss of any other licenses that we enter into in the future, would have a material adverse effect on our business. In addition, our failure to comply with obligations under our material in-licenses may cause us to become subject to litigation or other potential disputes under any such license agreements.

In addition, the Chimerix Agreement requires us to make certain payments, including license fees, milestone payments royalties, and other such terms typically required under licensing agreements and these types of technology in-licenses generally could make it difficult for us to find corporate partners and less profitable for us to develop product candidates utilizing these existing product candidates and technologies.

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 particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

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

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

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

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

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

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

- issue warning letters;
- impose civil or criminal penalties;

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

Even if our product 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 candidates in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of 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 candidates 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 14 employees as of December 31, 2018. 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 a number of 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 a number of 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 2017 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". 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.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

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, 2018, December 31, 2017, and June 30, 2017 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 assessments of the effectiveness of our internal control over financial reporting. As of December 31, 2018, December 31, 2017, and June 30, 2017, our management has determined that we had material weaknesses in our control environment and in the period end financial close and reporting process. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly.

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

On August 29, 2018, we received a written notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") that we were not in compliance with Nasdaq Listing Rule 5550(a)(2),(the "Rule") as the minimum bid price of our common stock had been below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had until February 25, 2019, to regain compliance with the minimum bid price requirement. On February 27, 2019, we received a letter from Nasdaq indicating that, based upon our continued non-compliance with the minimum bid price requirement as well as the fact that we have not yet held an annual meeting of shareholders within twelve months of the end of our fiscal year end, our common stock would be subject to delisting unless we timely request a hearing before a Nasdaq Hearings Panel (the "Panel"). We requested a hearing before the Panel, which request will stay any further action by Nasdaq at least pending a decision following the hearing and the expiration of any additional extension that may be granted by the Panel and were granted a meeting, scheduled to occur on April 11, 2019. We are considering all of our options to regain compliance; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the continued listing criteria within the period of time that the Panel may grant it to do so.

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

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

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

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;

- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results; 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.

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

On December 22, 2017, the "Tax Cuts and Jobs Act" (TCJA) was signed in to 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, 2018, 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 ContraVir Certificate of Incorporation, By-laws and the DCGL."

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity

securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could remain an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in February 2014, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior December 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of CRV431 and TXL™. 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 approximate 2,200 square feet of leased office and laboratory space located at 2011-94 Street, NW, Suite 102, Edmonton, AB, CANADA, T6N 1H1

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any legal proceedings, however, 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 has been traded on The Nasdaq Capital Market under the symbol "CTRV" since February 27, 2015

Holders of Record

As of December 31, 2018, there were approximately 207 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, 2018.

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	642,596	$ 12.32	694,904

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.

Historically, our fiscal years ended on June 30. On December 14, 2017, our Board of Directors approved a change in our fiscal year from June 30 to December 31, effective December 31, 2017. In this Annual Report, our fiscal years are identified according to the calendar year in which they are historically ended (e.g. the fiscal year ended June 30, 2017 is referred to as "fiscal 2017," and June 30, 2016 is referred to as "fiscal 2016," as if we had not changed our fiscal year to a calendar year on December 14, 2017 (effective December 31, 2017)). The transition period is for the six months ending December 31, 2017.

Business Overview

We are a biopharmaceutical company headquartered in Edison, New Jersey, focused on the development of targeted pharmaceutical therapies for liver disease. Liver disease may arise from chronic alcohol use, chronic hepatitis B, C and D virus (HBV, HCV, HDV), and non-alcoholic steatohepatitis (NASH). Fat accumulation in the liver (steatosis), inflammation, ballooning

degeneration, and fibrosis are some of the changes observed with liver disease. In some instances, disease may progress to cirrhosis and hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

Up to 25% of people with chronic hepatitis B virus (HBV) infection die prematurely from liver failure, cirrhosis, or liver cancer. Further, HBV-related end-stage liver disease or HCC account for almost 1 million deaths per year and approximately 5-10% of liver transplant cases. The cumulative sales in the US, EU Five, and Japan is expected to exceed $200 billion over the next 20 years. HCC is the fifth most common cancer in men and the seventh most common cancer in women. The five-year survival of HCC patients is only about 10%.

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

Our second compound, 'TXL', is more advanced clinically (completed phase 2). TXL is a nucleotide pro-drug of tenofovir that inhibits hepatitis B viral replication, and targets the liver, the reservoir for the hepatitis B virus. CRV431 and TXL have differing modes of action and, therefore, may complement one another in the treatment of HBV. Both compounds address a significant risk factor for the development of liver disease, HBV, whereas CRV431 additionally targets advancing stages of liver disease (e.g., fibrosis/HCC).

CRV431

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

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

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

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

On May 10, 2018, we submitted an Investigational New Drug Application ("IND") to the U.S. Food and Drug Administration ("FDA") 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 in which 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) in June 2016 wherein we paid a related milestone payment of $1,000,000 and issued 100,737 shares of our common stock, representing 2.5% of our issued and outstanding common stock as of June, 2016 to the Ciclofilin shareholders.

TXL

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

We licensed TXL from Chimerix in exchange for an upfront payment of 120,000 shares of our preferred stock, valued at $1.2 million at the (time of the deal). Our intellectual property provides protection to at least 2031.

We completed a Phase 1b safety and pharmacokinetic study in 2016. Data from the Phase 1b study demonstrate that TXL was safe and well tolerated by healthy volunteers in all dosing groups. We also completed a Phase 2a multiple ascending dose proof of concept clinical trial. The study enrolled 62 treatment-naïve patients with chronic HBV infection and compared TXL to the standard dose of TDF. Data from the Phase 2a study demonstrated that TXL was safe and well tolerated by patients with chronic HBV infection in all dosing groups. The data in the Phase 2a study demonstrated that doses of TXL from 50-mg to 100-mg resulted in comparable mean HBV viral load reductions to the 300-mg dose of TDF after 28 days of treatment. The data demonstrated that TXL at all doses tested, resulted in substantially lower systemic circulating levels of tenofovir in the blood compared to levels observed after dosing with TDF. These results demonstrate the potential for TXL to reduce the risk of bone and kidney-related toxicities associated with TDF.

We submitted an IND to the FDA to support initiation of our HBV clinical development program in the United States and received a notice of approval in September 2017.

We conducted a safety study in patients with severe renal impairment during the fourth quarter of 2017. The study comprised 16 subjects including 8 healthy subjects with normal kidney functions and 8 subjects with severely impaired kidney function. Results from the study confirmed that TXL was safe and well tolerated in both patient groups. Importantly, the data showed that the blood concentrations of tenofovir (TFV) in severely renally-impaired subjects receiving 50 mg of TXL were similar to the TFV exposure levels observed after dosing of TDF 300 mg. These findings indicate that dosing strength adjustments of TXL is not warranted in patients with compromised renal function. Data from the study provided further support on the strong safety profile of TXL in patients with comorbidities. Additionally, we received approval for our Clinical Trial Application ("CTA") in the United Kingdom.

On January 8, 2018, we met with the FDA's Division of Antiviral Products at the Center for Drug Evaluation and Research, to review and discuss the data generated for TXL to date, as well as the data package that would be required for the filing of an NDA and successful registration of TXL in the U.S. leveraging the 505(b)(2) regulatory pathway. The 505(b)(2) regulatory pathway allows us to rely upon FDA's previous findings of safety and efficacy of an approved and marketed product to supplement its own safety and efficacy data, and may be considered in the review by the FDA of a future New Drug Application ("NDA"). On February 12, 2018, we received agreement from the FDA allowing us to utilize the 505(b)(2) regulatory pathway to streamline the development and registration of TXL B. On February 22, 2018, the FDA granted Orphan Drug Designation to TXL for the treatment of chronic hepatitis B infection in a pediatric patient population (up to 11 years of age).

We have made the decision to out-license/partner TXL, as TXL is in late-stage clinical trials which would consume many important company resources. Importantly, we are aligning our programs to address the broader needs of treating liver diseases including NASH, fibrosis, and HCC while also addressing an important risk factor for the development of such diseases (i.e., HBV infection). For this reason, we plan to focus resources and development programs on further advancing CRV431 while seeking partnership opportunities for TXL.

FINANCIAL OPERATIONS OVERVIEW

From inception through December 31, 2018, we have an accumulated deficit of approximately $76.5 million. From inception through December 31, 2018, 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 October 7, 2015, we entered into an underwriting agreement related to the public offering and sale of 625,000 shares of common stock and warrants to purchase up to 375,000 shares of common stock, at a fixed combined price to the public of $24.00 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 are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of $34.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued

in the offering contemplated by the Underwriting Agreement. We also granted the Underwriters a 45-day option to purchase up to an additional 93,750 additional shares of common stock and additional warrants to purchase up to 56,250 shares of common stock at $24.00, which was not exercised. The gross proceeds to us were $15.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately $1.5 million. If the warrants were exercised in full, ContraVir would receive additional proceeds of approximately $12.8 million.

On July 3, 2018, we completed a rights offering pursuant to its effective registration statement on Form S-1. We offered units in the rights offering and each unit sold in connection with the rights offering consists of 1 share of our Series C Convertible Preferred Stock, or Series C, and 575 common stock warrants. Upon completion of the offering, pursuant to this 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 6,224,950 common stock warrants. We received net proceeds of $9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and offering expenses, totaling approximately $0.9 million, and excluding any proceeds received upon exercise of any warrants. The common stock warrants are exercisable at $1.55 per share and subject to adjustments upon the occurrence of certain dilutive events. The warrants expire on the fifth anniversary from their original issuance date. We may redeem the warrants for $0.01 per warrant if our common stock closes above $6.20 per share for ten consecutive trading days, provided that we may not do so prior to the first anniversary of the closing of the unit offering. The warrants are being sold under a written public offering. If a warrant is exercised during a period where a registration statement is not declared effective, we cannot assert that settlement in unregistered shares is permitted. As a result, the warrants are liability classified and carried at their estimated fair value at each reporting until they exercised, terminated or otherwise settled.

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

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

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

Going Concern

As of the year ended December 31, 2018, we had $2.8 million in cash. Net cash used in operating activities was $15.6 million for the year ended December 31, 2018. Net loss for the year ended December 31, 2018 was $9.4 million. As of December 31, 2018 we had an accumulated deficit of $76.5 million. As of December 31, 2018, we had working capital of $0.1 million, whereas on December 31, 2017 and June 30, 2017 we had working capital of $3.5 million and $10.2 million, respectively. We expect to incur losses for the next several years as we expand our research, development and clinical trials of TXL™ and CRV143. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

We will be required to raise additional capital within the next year to continue the development and commercialization of current product 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 product candidates; (ii) seek collaborators for product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than

might otherwise be available; or (iii) relinquish or otherwise dispose of rights to technologies, product candidate or products that we would otherwise seek to develop or commercialize ourselves on unfavorable terms.

Fair Value of Financial Instruments

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

A lattice-based model is used to estimate the fair value of the Secured Convertible Note. The lattice model utilizes a "decision tree" whereby future movement in our common stock price is estimated based on a volatility factor. We classified the fair value of the Secured Convertible Note as a Level 3 measurement due to the lack of observable market data. The lattice model requires the development and use of assumptions including our stock price volatility returns, an appropriate risk- free interest rate, default intensity rate and expected recovery rate given default. The estimated fair value of the Secured Convertible Note as of December 31, 2018 was $1.44 million and was based on the following inputs: stock volatility of 80.0 percent, risk- free rate of 2.61 percent related to assumed term of 0.85 years, default Intensity of 23.7 percent and a recovery rate of 30.0 percent.

Contingent consideration was related to the acquisition of Ciclofilin and recorded on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of $0.28. 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 100,737 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.

Warrants

We have issued common stock warrants in connection with the execution of certain equity financings. The fair value of certain warrants, deemed to be derivative instruments, were recorded as derivative liabilities under the provisions of Financial Accounting Standards Board ("FASB") Accounting Standard Codification ("ASC") Topic 815 Derivatives and Hedging ("ASC 815") upon issuance. Subsequently the liability was adjusted to fair value as of each reporting period and the changes in fair value of derivative liabilities were recorded in the statements of operations under the caption "Change in fair value of derivative liabilities."

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

The warrants, issued in connection with the July 2018 Rights Offering are deemed to be derivative instruments since if we do not maintain an effective registration statement, we are obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside of our control. Therefore the fair value of the warrants were 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 is affected by changes in inputs to the 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, 2018, December 31, 2017, and June 30, 2017, the fair value of such warrants was $0.4 million, $0.7 million, and $1.7 million, respectively, which we classified as a long term derivative liability on our 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 carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which we expect to recover or settle those temporary differences. The effect of a change in tax rates on deferred tax assets and liabilities is recorded 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 conjunction with the acquisition of Ciclofilin in June 2016, a deferred tax liability of $1.3 million was recorded reflecting the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset the deferred tax assets when analyzing our valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of the related IPR&D. The deferred tax liability has been adjusted to $0.9 million during the transition period ended December 31, 2017 based on changes in the tax rate due to the enactment of tax reform law on December 22, 2017. In conjunction with the enactment of tax reform law in December 2017, we also performed an evaluation with regard to Deferred Tax Assets generated by temporary differences, which would reverse and turn into indefinite lived NOL carryforwards, and also if Deferred Tax Liabilities associated with IPR&D could offset indefinite lived DTAs. As of December 31, 2017 there was a gross value of DTAs of $3.2 million, therefore based on a 21% effective tax rate and subject to an 80% cap an NOL of approximately $536,000 should have been recorded as of December 31, 2017. This adjustment was made in the three months ended March 31, 2018.

Contingencies

In the normal course of business, we are subject to loss contingencies, such as legal proceedings and claims arising out of its 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 FASB 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, 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 the year ended December 31, 2018, the transition period ended December 31, 2017 and the year ended June 30, 2017 we had prepaid research and development costs of $41,514, $32,903, and $75,484, 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 & development, or IPR&D, are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually, in our fourth quarter, and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired. Pursuant to ASU No. 2011-08, *Intangibles — Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, and ASU No. 2012-02, *Intangibles — Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, we have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that the goodwill or the acquired IPR&D is impaired. If we choose to first assess qualitative factors and determines that it is not more likely than not goodwill or acquired IPR&D is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others. Our CRV431 intangible asset and goodwill are assessed for impairment annually on December 31st of our fiscal year or more frequently if impairment indicators exist. We performed a quantitative impairment test of the CRV431 intangible asset and a qualitative impairment test of goodwill. As of December 31, 2018, we determined there was no impairment to our CRV431 intangible asset and goodwill.

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

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. There was no impairment of goodwill for the year ended December 31, 2018, the transition period ended December 31, 2017, or the fiscal year ended June 30, 2017.

IPR&D acquired in a business combination is capitalized as indefinite-lived assets on our consolidated balance sheets at its 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 its revised fair value with the related impairment charge recognized in the period in which the impairment occurs. If the carrying value of the asset becomes impaired as the result of unfavorable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercializing our programs, we could incur significant charges in the period in which the impairment occurs.

There was no impairment of IPR&D for the year ended December 31, 2018, the transition period ended December 31, 2017 or the fiscal year ended June 30, 2017. The discount rates applied to the estimated cash flows for our December 31, 2018 IPR&D impairment test was 35%, depending on the overall risk associated with the particular asset and other market factors. We believe the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Our assumed discount rate used in the impairment assessment would have to change by more than 800 basis points for there to be a material change in our analysis.

Share-based payments

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

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

We account for stock options issued to non-employees in accordance with ASC Topic 505-50 "Equity-Based Payment to Non-Employees" and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

ASC 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. Due to our accumulated deficit position, no excess tax benefits have been recognized. In March 2016, the FASB issued Accounting Standards Updates ("ASU") No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09") (see Note 4 to our audited financial statements appearing elsewhere in this Annual Report) which states that excess tax benefits should be classified along with other income tax cash flows as an operating activity. This guidance is effective for us for annual reporting periods beginning after December 15, 2017, with early adoption permitted. Due to our accumulated deficit position, no excess tax benefits have been recognized.

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. Due to the net losses incurred to date and because the exercise price of all liability classified warrants exceeds our average stock market price for the period they were outstanding, all stock equivalents have been anti-dilutive, thus, basic and dilutive net loss per share are the same.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of December 31, 2018.

RECENT ACCOUNTING PRONOUNCEMENTS

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 are currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In July of 2018, the FASB issued ASU 2018-11 — *Leases (Topic 842) Targeted Improvements ("ASU 2018-11")*, which addresses stakeholders' inquiries that are applicable to us regarding reporting requirements for initial adoption of ASU 2016-02. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard in ASU 2016-02, allowing an entity to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments in ASU 2018-11follow the same effective dates as ASU 2016-02 for us. We are currently evaluating the impact that this guidance will have in conjunction with the guidance in ASU 2016-02 (as described below).

In July of 2018, the FASB issued ASU 2018-10 — *Codification Improvements to Topic 842, Leases ("ASU 2018-10")*, which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02 based on comments and questions raised by stakeholders during the assessment and implementation of ASU 2016-02. The amendments in ASU 2018-10 follow the same effective dates as ASU 2016-02. We are currently evaluating the impact that this guidance will have in conjunction with the guidance in ASU 2016-02 (as described below).

In June of 2018, the FASB issued ASU 2018-07 — *Compensation — Stock Compensation (Topic 718) ("ASU 2018-07")*, which expands the scope of Topic 718 to include share-based payment transaction for acquiring goods and services from nonemployees. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. We are currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In March of 2018, the FASB issued ASU 2018-05 — *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 ("ASU 2018-05")*, which amends the FASB Accounting Standards Codification and XBRL Taxonomy based on the Tax Cuts and Jobs Act (the "Act") that was signed into law on December 22, 2017 and Staff Accounting Bulletin No. 118 ("SAB 118") that was released by the Securities and Exchange Commission. The Act changes numerous provisions that impact U.S. corporate tax rates, business-related exclusions, and deductions and credits and may additionally have international tax consequences for many companies that operate internationally. We have evaluated the impact of the Act as well as the guidance of SAB 118 and incorporated the changes into the determination of a reasonable estimate of our deferred tax liability and appropriate disclosures in the notes to our consolidated financial statements (see Note 11 to our audited financial statements appearing elsewhere in this Annual Report).

In May of 2017, the FASB issued ASU No. 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09")*, which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This guidance is to be applied for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted and should be applied prospectively to an award modified on or after the adoption date. We have adopted ASU 2017-09. The adoption of this guidance did not have a material impact on our financial statements.

In January of 2017, the FASB issue ASU No. 2017-04, *Intangibles — Goodwill and Other (Topic 350) ("ASU 2017-04")*, which amended the 2014 amendments to the FASB Accounting Standards Codification that allowed companies an alternative accounting treatment for subsequently measuring goodwill. This amendment is Phase 1 of a project by the FASB Board to simplify how an entity is required to test goodwill for impairment by eliminating step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. These amendments are to be applied on a prospective basis and are required to be adopted for annual and any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. We are currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In August 2016, the FASB issued ASU No. 2016-15*, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which amended the existing accounting standards for the statement of cash flows. The amendments provide guidance on eight classification issues related to the statement of cash flows. We are required to adopt the guidance in the first quarter of fiscal 2019 and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the amendments may be applied prospectively as of the earliest date practicable. We are currently evaluating the timing and the impact of these amendments on our statement of cash flows.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The new standard identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for us for annual reporting periods beginning after December 15, 2017, with early adoption permitted. We have adopted ASU 2016-09. The adoption of this guidance did not have a material impact on our financial statements.

In February 2016, the FASB issued ASU No. 2016-02*, Leases (Topic 842)* ("ASU 2016-02"). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. Our primary lease arrangement is associated with a lease for its corporate office space. We are is still evaluating the impact of the adoption of this standard; however, based on the size of our future operating lease commitments as of December 31, 2018 (discussed in Note 13 to our audited financial statements appearing elsewhere in this Annual Report), we expect to record a ROU asset and a lease liability on the balance sheet upon adoption and we expect that adoption of the new lease accounting standard will have a material impact on our balance sheet on the date of adoption.

JOBS Act

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

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

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

We may take advantage of these provisions up to the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the distribution; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

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

RESULTS OF OPERATIONS

Comparison of the Years ended December 31, 2018 and 2017:

	Years ended		
	December 31, 2018	(Unaudited) December 31, 2017	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	7,593,715	13,368,165	(5,774,450)
General and administrative	7,000,444	7,277,951	(277,507)
Loss from operations	(14,594,159)	(20,646,116)	(6,051,957)
Other income (expense):			
Change in fair value of debt	(108,942)	—	(108,942)
Interest on debt	(339,158)	—	(339,158)
Change in fair value of derivatives instruments – warrants and contingent consideration	5,056,964	5,618,598	(561,634)
Loss before income taxes	(9,985,295)	(15,027,518)	5,042,223
Income tax benefit	536,000	1,947,760	(1,411,760)
Net loss	$ (9,449,295)	$ (13,079,758)	$ 3,630,463

The unaudited information for the year ended December 31, 2017 in the above schedule has been derived by calculating the six months ended June 30, 2017 derived from audited consolidated financial statements and unaudited condensed consolidated financial statements of ContraVir Pharmaceuticals, Inc. previously filed on Form 10-K and Form 10-Q with the U.S. Securities and Exchange Commission and adding financial information to the audited consolidated financial statements previously filed on From 10-KT for the transition period ended December 31, 2017.

We had no revenues during the years ended December 31, 2018 and 2017, 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, 2018 and 2017 amounted to $7.6 million and $13.4 million, respectively. The $5.8 million decrease is mainly due to a $3.0 million decrease in clinical development costs associated with our Valnivudine clinical trials, a $1.0 million decrease in purchases of lab supplies, a $1.0 decrease in clinical trial costs related to TXL, a $0.7 million decrease in outside services, a $0.5 million decrease in stock based compensation, a $0.5 million decrease in payroll and related costs and $0.3 million lower costs for manufacturing partially offset by a $1.2 million increase in clinical trial costs related to CRV 431.

General and administrative expenses for the years ended December 31, 2018 and 2017 amounted to $7.0 million and $7.3 million, respectively. The $0.3 million decrease is mainly due to a $0.8 million decrease in stock compensation expense primarily due to forfeiture of options associated with the departure of our Chief Executive Officer and Chief Operating Officer and a $0.3 million decrease in professional fees partially offset by a $0.7 million increase in payroll and related costs primarily associated with severance.

During the year ended December 31, 2018, we recorded an income tax benefit of $0.5 million resulting from an adjustment for deferred tax liability. During the year ended December 31, 2017, we received an income tax benefit of $1.9 million, $1.6 million resulting from the sale of our net operating losses to a third party and $0.4 million from an adjustment for deferred tax liability due to the change in tax rate based on the Tax Cuts and Jobs Act of 2017.

Net loss for the years ended December 31, 2018 and 2017 was $9.4 million and $13.0 million, respectively, which was the result of the operating expenses discussed above, offset by other income resulting from the change in fair value of derivative instruments-warrants of $5.1 million and $5.6 million for the years ended December 31, 2018 and 2017, and a $0.3 million accrued interest on debt expense for the year ended December 31, 2018.

Comparison of the transition period ended December 31, 2017 and 2016:

	Transition period ended		
	December 31, 2017	(Unaudited) December 31, 2016	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	7,163,530	7,447,352	(283,822)
General and administrative	3,358,091	3,452,025	(93,934)
Loss from operations	(10,521,621)	(10,899,377)	(377,756)
Other income (expense):			
Change in fair value of warrant liability and contingent consideration	1,062,769	(331,010)	1,393,779
Loss before income taxes	(9,458,852)	(11,230,387)	1,771,535
Income tax benefit	1,947,760	1,908,003	39,757
Net loss	$ (7,511,092)	$ (9,322,384)	$ 1,811,292

The unaudited information for the six months ended December 31, 2016 in the above schedule has been obtained from the unaudited condensed consolidated financial statements of ContraVir Pharmaceuticals, Inc. on Form 10-Q with the U.S. Securities and Exchange Commission previously filed on February 14, 2017.

We had no revenues during the transition period ended December 31, 2017 or 2016 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 transition period ended December 31, 2017 and 2016 amounted to $7.2 million and $7.4 million, respectively. The $0.3 million decrease is mainly due to a $1.1 million decrease in TXL™ clinical trial costs associated with our Phase 2 trials conducted in 2016 and a $0.8 million decrease in costs associated with Valnivudine associated with the discontinuance of the clinical program offset by a $1.6 million increase in preclinical costs associated with CRV431.

General and administrative expenses for the transition period ended December 31, 2017 and 2016 amounted to $3.4 million and $3.5 million, respectively. The decrease of $0.1 million is primarily due to $0.2 million of lower stock based compensation offset by an increase of $0.1 of professional fees.

Net loss for the transition period ended December 31, 2017 and 2016 was approximately $7.5 million and $9.3 million, respectively, which was a result of the operating expenses discussed above, offset by other income resulting from the change in fair value of derivative instruments-warrants of approximately $1.1 million for the transition period ended December 31, 2017, in addition to a $0.4 million adjustment to our deferred tax liability resulting from the recently enacted tax reform and a $1.6 million income tax benefit resulting from the sale of our state net operating losses to a third party.

Comparison of Years Ended June 30, 2017 and 2016:

	Year ended		
	June 30, 2017	June 30, 2016	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	13,651,987	15,019,276	(1,367,289)
General and administrative	7,371,885	5,786,209	1,585,676
Loss from operations	(21,023,872)	(20,805,485)	(218,387)
Other income/(expense):			
Change in fair value of warrant liability and contingent consideration	4,224,819	3,806,847	417,972
Loss before income taxes	(16,799,053)	(16,998,638)	199,585
Income tax benefit	1,908,003	—	1,908,003
Net loss	$ (14,891,050)	$ (16,998,638)	$ 2,107,588

We had no revenues during the years ended June 30, 2017 and 2016, 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 June 30, 2017 and 2016 amounted to $13.7 million and $15.0 million, respectively. The decrease of $1.4 million is primarily due to a $3.6 million decrease in Valnivudine clinical trial expenses partially offset by a $1.3 million increase in payroll related costs due to an increase in research and development staffing, a $0.6 million increase in TXL™ development costs related to our Phase 1b and Phase 2a clinical trials and a $0.4 million increase in stock based compensation.

General and administrative expenses for the years ended June 30, 2017 and 2016 amounted to $7.4 million and $5.8 million, respectively. The increase of $1.6 million is primarily due to an increase of $0.4 million in payroll related costs due to an increase in finance and administrative staffing, an increase of $0.3 million related in general operating costs resulting from the acquisition we completed in June 2016, an increase of $0.5 million in stock-based compensation expense and $0.1 million for legal, investor relations and professional fees.

In the years ended June 30, 2017 and 2016, we had income of $4.2 million and $3.8 million, respectively, related to a change in the fair value of our warrant liabilities. This change in fair value of the derivative liabilities is primarily due to a decrease in our stock price, which is one of the inputs used in the Black-Scholes option pricing model used to revalue the liability-classified warrants each reporting period.

During the year ended June 30, 2017, we received an income tax benefit of $1.9 million resulting from the sale of our net operating losses to a third party.

Net loss for the years ended June 30, 2017 and 2016 was $14.9 million and $17.0 million, respectively, which was a result of the operating expenses and change in fair value of our warrant liability discussed above.

Liquidity and Capital Resources

The following table summarizes our cash flows for the year ended December 31, 2018, the transition period ended December 31, 2017, and the year ended June 30, 2017:

	Year ended December 31, 2018	For the transition period ended December 31, 2017	Year ended June 30, 2017
Net cash (used in) provided by:			
Operating activities	$ (15,646,027)	$ (8,209,286)	$ (19,172,110)
Investing activities	900	—	(14,709)
Financing activities	12,523,539	1,180,555	24,765,627
Net decrease in cash	$ (3,121,588)	$ (7,028,731)	$ 5,578,808

As of December 31, 2018, we had $2.8 million in cash, as compared to $6.0 and $13.0 million as of December 31, 2017 and June 30, 2017, respectively. Net cash used in operating activities for the year ended 2018, the transition period ended December 31, 2017 and the year ended June 30, 2017 was $15.6 million, $8.2 million and $19.2 million, respectively, and relates primarily to net cash used to fund our clinical research and development activities and our general and administrative operations. As of December 31, 2018 we had working capital of $0.1 million, as compared to $3.5 million, and $10.2 as of December 31, 2017 and June 30, 2017, respectively.

Net cash provided by financing activities for the year ended December 31, 2018 primarily consisted of net proceeds of $9.9 million from the Rights Offering, described further below, $2.0 million of proceeds from the debt financing, $1.6 million from the issuance of common stock, and $0.1 million of proceeds from the exercise of warrants partially offset by $1.0 million of Contingent Consideration milestone payments and $0.7 million of debt financing repayments. Net cash provided by financing activities for the transition period ended December 31, 2017 primarily consisted of net proceeds of $1.2 million from an equity offering and the Controlled Equity Offering. Net cash provided by financing activities for the year ended June 30, 2017 primarily consisted of net proceeds of $24.8 million from an equity offering and the Controlled Equity Offering.

On July 3, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in May 2018 (the "Rights Offering"). Pursuant to the Rights Offering, we sold an aggregate of 10,826 units consisting of an aggregate 10,826 shares of Series C Preferred Stock and 6,224,950 warrants, with each warrant exercisable for one share of common stock at an exercise price of $1.55 per share, resulting in net proceeds to us of approximately $9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

The gross proceeds of the offering were first allocated to the warrants based on the fair value of the warrants at that time, with the residual proceeds allocated to the Series C. All offering costs were allocated between the Series C and the warrants. In addition, pursuant to a private offering, the placement agent received, as compensation for the transaction, equity warrants to purchase 279,381 shares of our common stock priced at $1.71 per share. The fair value of the placement agent equity classified warrants was $0.2 million at the time of issuance and $0.1 million was allocated to the Series C and $0.1 million was allocated to the liability classified common stock warrants. All costs allocated to the liability classified warrants were expensed immediately and as a component of general and administrative expenses within our consolidated statement of operations.

Each share of Series C Preferred Stock ("Series C") will be convertible, at our option at any time on or after the first anniversary of the closing of the Rights Offering (as defined below) or at the option of the holder at any time, into the number of shares of our common stock, par value $0.0001 per share (the "Common Stock") determined by dividing the $1,000 stated value per share of the Series C by a conversion price of $1.55 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series C Preferred Stock will not have the right to convert any portion of the Series C to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of the holder's shares of Series C. The holder, upon notice to us, may increase or decrease the beneficial ownership limitation applicable to its shares of Series C, provided that in no event shall the limitation exceed 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon conversion of the holder's shares of Series C.

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

Holders of Series C shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the Common Stock when, as and if such dividends are paid on shares of Common Stock. Except as otherwise provided in the Certificate of Designation or as otherwise required by law, the Series C has no voting rights. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series C will be entitled to receive out of the assets, whether capital or surplus, of the same amount that a holder of Common Stock would receive if the Series C were fully converted (disregarding for such purpose any conversion limitations thereunder) to Common Stock, which amounts shall be paid pari passu with all holders of Common Stock. We are not obligated to redeem or repurchase any shares of Series C. Shares of Series C are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

There are no stated dividends or redemption features associated with the Series C. The Series C have no voting rights. Each share of the Series C 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. The Series C conversion price is currently $1.55. The preferred stock is automatically convertible into common stock in the event of a fundamental transaction to us. Based on these facts, the Series C is classified as permanent equity.

Beneficial Conversion Feature- Series C Preferred Stock

Each share of Series C is convertible into shares of common stock, at any time at the option of the holder at a conversion price of $1.55 per share. Based on the guidance in ASC 470-20-20, we have determined that a beneficial conversion feature exists, as the effective conversion price for the Series C preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series C was $3.8 million and the preferred stock was discounted by this amount. The beneficial conversion amount of $3.8 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. Based on the additional conversions of Series C preferred stock in the fourth quarter of 2018, the beneficial conversion feature accreted back to the preferred stock as a dividend charged to additional paid in capital is $3.8 million as of December 31, 2018.

On May 8, 2018, we entered into a securities purchase agreement (the "Securities Purchase Agreement") with Iliad Research and Trading, L.P. ("IRT"), pursuant to which we issued to IRT a secured convertible promissory note (the "Note") in the aggregate principal amount of $3,325,000 for an aggregate purchase price of $2,000,000 cash and $1,000,000 aggregate principal amount of investor notes (the "Investor Notes") payable to us in four tranches of $250,000 upon request by us. Closing occurred on May 9, 2018. The Note carries an original issue discount of $300,000, and the initial principal balance of $2,225,000 also includes original issue

discount of $200,000 and $25,000 to cover IRT's transaction expenses. The Investor Notes have not been drawn as of December 31, 2018. We plan to use the proceeds for the continued development of our TXL and CRV431 compounds for the treatment of Hepatitis B Virus and general corporate purposes. The Note bears interest at the rate of 10% per annum and matures on November 8, 2019. Beginning on November 8, 2018, IRT has the right to redeem all or any portion of the Note up to the Maximum Monthly Redemption Amount which is $500,000. Payments of each redemption amount may be made in cash or shares of our common stock at our election (so long as the various conditions to paying stock set forth in the Note are satisfied) provided, however, that if our common stock is trading below $1.60 per share (as adjusted for the reverse stock split), the redemption(s) must be in cash. Common stock issued upon redemption will be issued at a price equal to 80% of the lowest trade price of the common stock for the 20 consecutive trading days prior to the date of redemption, subject to adjustments; provided, however, that in no event will the redemption price be less than $1.60. Because of this feature which allows the lender to redeem the entire outstanding balance at its option within twelve (12) months of initial issuance, the debt is classified as current. We also entered into a security agreement with IRT, pursuant to which IRT will receive a security interest in substantially all of our assets, except for intellectual property. We identified numerous embedded features to which bifurcation would be required. The Securities Purchase Agreement requires that we comply with certain non-financial covenants customary for financing of this nature which we were in compliance with as of December 31, 2018. During November and December of 2018, we received redemption requests totaling $0.8 million from IRT, approximately $0.1 million of which was attributed to interest.

We are eligible to elect the fair value option under ASC 815 and bypass analysis of potential embedded derivatives and further analysis of bifurcation of any such and have elected such option. Therefore, the debt will be recorded at its fair value upon issuance and subsequently re-measured at each reporting period until maturity. Additionally, all issuance costs incurred in connection with a debt instrument that is measured at fair value pursuant to the election of the fair value option are expensed during the period the debt is acquired. We incurred $200,000 of debt issuance costs, which were expensed as incurred due to the election of the fair value option and were included in interest expense in the accompanying consolidated statement of operation for the quarter ended June 30, 2018. The Note carries total debt discount of $225,000 (comprising of original issue discount of $200,000 and $25,000 payment to IRT for transaction expenses) which was not recorded due to the election of the fair value option.

On April 25, 2017 we closed on a public offering of 1,500,000 shares of our common stock and warrants to purchase up to 750,000 shares of common stock, at a fixed combined price to the public of $8.00 under a shelf registration statement on Form S-3, which expired on March 16, 2018. The warrants are exercisable for a period of 5 years from the date of issuance at an exercise price of $10.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering. The gross proceeds to us were $12.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately $0.9 million.

On March 9, 2015, we entered into a Controlled Equity Offering Sales Agreement (the "Agreement"), with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock, par value $0.0001 per share (the "Shares"), up to an aggregate offering price of $50.0 million. We intend to use the net proceeds from these sales to fund our research and development activities, and for working capital and other general corporate purposes, and possible acquisitions of other companies, products or technologies, though no such acquisitions are currently contemplated. Under the Agreement, Cantor may sell the Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on The Nasdaq Capital Market, on any other existing trading market for the Shares or to or through a market maker. In addition, under the Agreement, Cantor may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, Cantor will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell the Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose).

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

For the year ended December 31, 2018 and the transition period December 31, 2017, we sold approximately 766,288 and 280,100 shares of our common stock resulting in net proceeds of approximately $1.6 million and $1.2 million, respectively, under the Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent.

Operating and Capital Expenditure Requirements

As of December 31, 2018, we had an accumulated deficit of $76.5 million, and expect to incur significant and increasing operating losses for the next several years as we expand our research, development and clinical trials of TXL™ and CRV431. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

The audited financial statements as of December 31, 2018 have been prepared under the assumption that we will continue as a going concern within one year after the financial statements are issued. Due to our recurring and expected continuing losses from operations, we have concluded there is substantial doubt in our ability to continue as a going concern without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We will be required to raise additional capital within the next year to continue the development and commercialization of 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 no material long-term contractual cash obligations as of December 31, 2018, other than our debt (see Note 5) and an operating lease for our office space. 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**
Operating lease	$ 872,723	$ 202,734	$ 616,087	$ 53,902	$ —
Convertible debt (remaining principal)	1,556,000	1,556,000	—	—	—
Total contractual obligations	$ 2,428,723	$ 1,758,734	$ 616,087	$ 53,902	$ —

We have recorded contingent consideration for the acquisition of Ciclofilin on June 10, 2016 as well as executed several license agreements, as discussed in Note 7 and Note 13 to the consolidated financial statements, respectively. Other than the payments noted in the table above, 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of ContraVir Pharmaceuticals, Inc. and its subsidiaries ("the Company") as of December 31, 2018 and December 31, 2017, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for year ended December 31, 2018, the six month transition period ended December 31, 2017, the year ended June 30, 2017, 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, 2018, December 31, 2017, and June 30, 2017, and the results of their operations and cash flows for the year ended December 31, 2018, the six month transition period ended December 31, 2017 and the year ended June 30, 2017, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

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

Basis for Opinion

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

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

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2013

Woodbridge, New Jersey

March 13, 2019

CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current Assets:		
Cash	$ 2,832,429	$ 5,954,017
Prepaid expenses	135,591	108,075
Total Current Assets	2,968,020	6,062,092
Property and equipment, net	32,434	56,595
In-process research and development	3,190,000	3,190,000
Goodwill	1,870,924	1,870,924
Other assets	127,794	73,289
Total Assets	$ 8,189,172	$ 11,252,900
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 748,428	$ 1,556,883
Accrued expenses	661,421	1,046,698
Convertible debt	1,440,000	—
Total Current Liabilities	2,849,849	2,603,581
Contingent consideration	2,590,000	3,380,000
Deferred tax liability	360,700	896,700
Deferred rent liability	9,235	—
Derivative financial instruments, at estimated fair value—warrants	404,337	669,462
Total Liabilities	6,214,121	7,549,743
Commitments and contingencies (Note 13)		
Stockholders' Equity:		
Convertible preferred stock, par value $0.0001 per share. Authorized 20,000,000 shares	—	—
Series A convertible preferred stock, stated value $10 per share, issued and outstanding 85,581 and 104,013 shares at December 31, 2018, and December 31, 2017, respectively	855,808	1,040,128
Series C convertible preferred stock, stated value $1,000 per share, 1,974 and 0 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	930,311	—
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 16,608,512 and 9,792,497 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1,661	979
Additional paid in capital	76,651,203	69,676,687
Accumulated deficit	(76,463,932)	(67,014,637)
Total Stockholders' Equity	1,975,051	3,703,157
Total Liabilities and Stockholders' Equity	$ 8,189,172	$ 11,252,900

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

CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31, 2018	For the transition period ended December 31, 2017	Year ended June 30, 2017
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	7,593,715	7,163,530	13,651,987
General and administrative	7,000,444	3,358,091	7,371,885
Total Operating Expenses	14,594,159	10,521,621	21,023,872
Loss From Operations	(14,594,159)	(10,521,621)	(21,023,872)
Other Income (Expense):			
Change in fair value of debt	(108,942)	—	—
Interest on debt	(339,158)	—	—
Change in fair value of derivative instruments—warrants and contingent consideration	5,056,964	1,062,769	4,224,819
Loss before income taxes	(9,985,295)	(9,458,852)	(16,799,053)
Income tax benefit	536,000	1,947,760	1,908,003
Net loss	(9,449,295)	(7,511,092)	(14,891,050)
Series C deemed dividend (see note 6)	(8,451,851)	—	—
Net loss Attributable to Common Shareholders	$ (17,901,146)	$ (7,511,092)	$ (14,891,050)
Weighted Average Common Shares Outstanding			
Basic	12,871,530	9,678,329	7,286,304
Diluted	12,871,530	9,678,329	7,292,327
Net loss per Common Share (see note 12)			
Basic	$ (1.39)	$ (0.78)	$ (2.04)
Diluted	$ (1.39)	$ (0.78)	$ (2.41)

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

CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

For the year ended December 31, 2018, the transition period ended December 31, 2017 and the fiscal year ended June 30, 2017

	Preferred Stock, Series A $0.0001 par value		Preferred Stock, Series B $0.0001 par value		Preferred Stock, Series C $0.0001 par value		Common Stock, $0.0001 par value		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Par Value			
Balance June 30, 2016	1,250,000	$ 12,500,000	120,000	$ 1,200,000	—	$ —	4,028,905	$ 403	$ 32,229,672	$ (44,612,495)	$ 1,317,580
Issuance of common stock, net	—	—	—	—	—	—	2,305,235	231	24,659,528	—	24,659,759
Conversion of preferred stock	(1,145,987)	(11,459,872)	(120,000)	(1,200,000)	—	—	3,118,271	311	12,659,561	—	—
Fair value of warrants issued in connection with equity offering	—	—	—	—	—	—	—	—	(3,976,501)	—	(3,976,501)
Exercise of warrants	—	—	—	—	—	—	6,250	1	160,416	—	160,417
Stock option exercise	—	—	—	—	—	—	4,758	0	31,277	—	31,277
Stock-based compensation expense	—	—	—	—	—	—	—	0	1,756,385	—	1,756,385
Net loss	—	—	—	—	—	—	—	—	—	(14,891,050)	(14,891,050)
Balance June 30, 2017	104,013	$ 1,040,128	—	$ —	—	$ —	9,463,419	$ 946	$ 67,520,338	$ (59,503,545)	$ 9,057,867
Issuance of common stock, net	—	—	—	—	—	—	329,078	33	1,410,608	—	1,410,641
Stock-based compensation expense	—	—	—	—	—	—	—	—	745,741	—	745,741
Net loss	—	—	—	—	—	—	—	—	—	(7,511,092)	(7,511,092)
Balance December 31, 2017	104,013	$ 1,040,128	—	$ —	—	$ —	9,792,497	$ 979	$ 69,676,687	$ (67,014,637)	$ 3,703,157
Issuance of common stock, net	—	—	—	—	—		965,052	97	1,986,478	—	1,986,575
Issuance of Series C Preferred	—	—	—	—	10,826	5,734,627	—	—	—	—	5,734,627
Offering costs related to Issuance of Series C Preferred	—	—	—	—	—	(411,259)	—	—	—	—	(411,259)
Placement agent warrants	—	—	—	—	—	(221,269)	—	—	221,269	—	—
Beneficial conversion feature of Series C Preferred	—	—	—	—	—	(3,771,639)	—	—	3,771,639	—	—
Accretion of beneficial conversion feature of Series C Preferred	—	—	—	—	—	3,771,639	—	—	(3,771,639)	—	—
Accretion of Series C Preferred stock discount upon conversion	—	—	—	—	—	4,680,212	—	—	(4,680,212)	—	—
Conversion of Series A Preferred	(18,432)	(184,320)	—	—	—	—	48,000	5	184,315	—	—
Conversion of Series C Preferred	—	—	—	—	(8,852)	(8,852,000)	5,710,963	571	8,851,429	—	—
Exercise of warrants	—	—	—	—	—	—	92,000	9	176,727	—	176,736
Stock-based compensation expense	—	—	—	—	—	—	—	—	234,510	—	234,510
Net loss	—	—	—	—	—	—	—	—	—	(9,449,295)	(9,449,295)
Balance December 31, 2018	85,581	$ 855,808	—	$ —	1,974	$ 930,311	16,608,512	$ 1,661	$ 76,651,203	$ (76,463,932)	$ 1,975,051

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

CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year ended December 31, 2018	For the transition period ended December 31, 2017	Year ended June 30, 2017
Cash Flows From Operating Activities:			
Net loss	$ (9,449,295)	$ (7,511,092)	$ (14,891,050)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	234,510	745,741	1,700,225
Stock issued for services			56,160
Change in fair value of derivative instrument—warrants	(5,322,362)	(1,062,769)	(4,224,819)
Change in the fair value of contingent consideration	265,398	—	—
Change in the fair value of debt	108,942	—	—
Deferred tax liability adjustment	(536,000)	(372,920)	—
Loss on the sale of assets	4,474	—	—
Depreciation and amortization expense	18,787	10,969	27,993
Changes in operating assets and liabilities:			
Accounts payable and accrued expenses	(897,695)	(111,207)	(2,128,263)
Deferred rent liability	9,235	—	—
Prepaid expenses and other assets	(82,021)	91,992	287,644
Net Cash Used In Operating Activities	(15,646,027)	(8,209,286)	(19,172,110)
Cash Flows From Investing Activities:			
Proceeds from the sale of fixed assets	900	—	—
Purchase of property and equipment	—	—	(14,709)
Net Cash Provided By (Used In) Investing Activities	900	—	(14,709)
Cash Flows From Financing Activities:			
Proceeds from the issuance of common stock	1,635,140	1,180,555	24,659,760
Proceeds from issuance of Series C Preferred stock, net	10,414,741	—	—
Proceeds from the exercise of warrants	142,600	—	85,000
Proceeds from stock options exercised	—	—	31,277
Proceeds from debt financing	2,000,000	—	—
Repayment of debt financing	(668,942)	—	—
Payment of contingent consideration milestone	(1,000,000)	—	—
Change in current portion of capital lease	—	—	(10,410)
Net cash provided by financing activities	12,523,539	1,180,555	24,765,627
Net (decrease) increase in cash	(3,121,588)	(7,028,731)	5,578,808
Cash at beginning of period	5,954,017	12,982,748	7,403,940
Cash at end of period	$ 2,832,429	$ 5,954,017	$ 12,982,748
Supplementary Disclosure Of Cash Flow Information:			
Cash paid for Interest	$ 131,058	$ —	$ —
Supplementary Disclosure Of Non-Cash Financing Activities:			
Stock issued to employees in lieu of cash payment for accrued bonus	$ 296,037	$ 230,086	$ —
Issuance of common stock in conjunction with milestone payment	$ 55,398	$ —	$ —
Derecognition of Series C warrants exercised	$ 34,136	$ —	$ 75,417
Conversion of Series A convertible preferred stock	$ 184,320	$ —	$ —
Conversion of Series C convertible preferred stock (part of Series C deemed dividend)	$ 4,680,212	$ —	$ —
Beneficial Conversion Factor accreted as Series C deemed dividend	$ 3,771,639	$ —	$ —
Fair value of warrants issued in conjunction with common stock offering	$ 5,091,373	$ —	$ 3,976,501
Warrants issued to Placement Agent	$ 221,269	$ —	$ —

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

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

1. Business Overview

ContraVir Pharmaceuticals Inc. ("ContraVir" or the "Company") is a biopharmaceutical company focused on the development of targeted pharmaceutical therapies for liver disease. Liver disease may arise from chronic alcohol use, chronic hepatitis B, C and D virus (HBV, HCV, HDV), and non-alcoholic steatohepatitis (NASH). Fat accumulation in the liver (steatosis), inflammation, ballooning degeneration, and fibrosis are some of the changes observed with liver disease. In some instances, disease may progress to cirrhosis and hepatocellular carcinoma (HCC), the most common type of primary liver cancer.

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

The Company's second compound, 'TXL', is more advanced clinically (completed phase 2). TXL is a nucleotide pro-drug of tenofovir that inhibits hepatitis B viral replication, and targets the liver, the reservoir for the hepatitis B virus. CRV431 and TXL have differing modes of action and, therefore, may complement one another in the treatment of HBV. Both compounds address a significant risk factor for the development of liver disease, HBV, whereas CRV431 additionally targets advancing stages of liver disease (e.g., fibrosis/HCC).

On June 10, 2016, the Company, through a wholly-owned subsidiary now known as ContraVir Research Inc., acquired Ciclofilin Pharmaceuticals, Inc. a biopharmaceutical company incorporated on January 13, 2014 in California and reincorporated in Delaware on October 15, 2014. Ciclofilin Pharmaceuticals, Inc. had one wholly-owned subsidiary, Ciclofilin Pharmaceuticals Corp., incorporated in Canada on January 24, 2014. Together, Ciclofilin Pharmaceuticals, Inc. and Ciclofilin Pharmaceuticals Corp ("Ciclofilin") are a wholly-owned subsidiary known as ContraVir Research Inc. that specializes in the development of cyclophilin inhibitors, an emerging class of drugs for infectious, inflammatory, and degenerative diseases. Ciclofilin's lead drug candidate, CRV431, is a potent cyclophilin inhibitor that blocks multiple HBV activities including entry into cells and replication, and is currently in pre-clinical development.

2. Basis of Presentation and Going Concern

Basis of presentation

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

Principles of Consolidation

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

Going Concern

As of December 31, 2018, ContraVir had $2.8 million in cash. Net cash used in operating activities was $15.6 million for the year ended December 31, 2018. Net loss for the year ended December 31, 2018 was $9.4 million. As of December 31, 2018 the Company had an accumulated deficit of $76.5 million. As of December 31, 2018, ContraVir had working capital of $0.1 million, whereas on December 31, 2017 ContraVir had working capital of $3.5 million. The Company has not generated revenue to date and has incurred substantial losses and negative cash flows from operations since its inception. The Company has historically funded its operations through issuances of convertible debt, common stock and preferred stock. The Company expects to continue to incur losses for the next several years as it expands its research, development and clinical trials of TXL™ and CRV431. The Company is unable to predict the extent of any future losses or when the Company will become profitable, if at all.

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

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

3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of 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, 2018 and December 31, 2017, the amount of cash was approximately $2.8 million and $6.0 million, respectively, consisting of checking accounts held at U.S. and Canadian commercial banks. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. The Company has never experienced losses related to these balances.

Fair Value of Financial Instruments

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

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

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

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining

fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments consist of cash, accounts payable 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 derivative instruments, which were marked to market at the end of each reporting period. See Note 6 for additional information of the fair value of the derivative liabilities. The Company recorded contingent consideration in its acquisition of Ciclofilin, which is required to be carried at fair value. See Note 7 for additional information on the fair value of the contingent consideration.

Derivative Financial Instruments

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

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

The warrants, issued in connection with the July 2018 Rights Offering are deemed to be derivative instruments since if the Company does not maintain an effective registration statement, the Company is obligated to deliver registered shares upon exercise and settlement of the warrant because there are further registration and prospectus delivery requirements that are outside of the control of the Company. Therefore the fair value of the warrants were 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 were affected by changes in inputs to the Black-Scholes option pricing model including the Company's stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. This model uses Level 3 inputs, including stock price volatility, in the fair value hierarchy established by ASC 820 Fair Value Measurement. At December 31, 2018 and December 31, 2017, the fair value of all warrants was $0.4 million and $0.7 million, respectively, which are classified as a long term derivative liability on the Company's balance sheets.

Property, equipment and depreciation

As of December 31, 2018 and December 31, 2017, the Company had $32,434 and $56,595, respectively, of property and equipment, consisting primarily of computer equipment, furniture and fixtures. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the depreciable assets are 2 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 year ended December 31, 2018, the transition period ended December 31, 2017, and June 30, 2017 was $18,787, $10,969, and $27,993, respectively. Expenditures for repairs and maintenance are charged to operations as incurred. The Company will periodically evaluate whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable. There were no adjustments to the carrying value of property and equipment at December 31, 2018 and December 31, 2017.

Lease Accounting

The Company accounts for operating lease transactions by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date it gains possession of leased property. Capital lease transactions are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in property and equipment, net, in the Consolidated Balance Sheets and depreciated over their estimated useful lives.

Goodwill and In-Process Research & Development

In accordance with ASC Topic 350, *Intangibles — Goodwill and Other* ("ASC Topic 350"), goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually, in the Company's fourth quarter, and between annual tests if the Company becomes aware of an event or a change in circumstances that would indicate the carrying value may be impaired. Pursuant to ASU No. 2011-08, *Intangibles — Goodwill and Other (Topic 350): Testing Goodwill for Impairment*, and ASU No. 2012-02, *Intangibles — Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*, the Company has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads the Company to determine that it is more likely than not (that is, a likelihood of more than 50%) that the goodwill or the acquired IPR&D is impaired. If the Company chooses to first assess qualitative factors and determines that it is not more likely than not goodwill or acquired IPR&D is impaired, the Company is not required to take further action to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which the Company may choose to do in some periods but not in others. The Company's CRV431 intangible asset and goodwill are assessed for impairment annually on December 31st of the Company's fiscal year or more frequently if impairment indicators exist. The Company performed a quantitative impairment test of the CRV431 intangible asset and a qualitative impairment test of goodwill. As of December 31, 2018, the Company determined there was no impairment to the Company's CRV431 intangible asset and goodwill.

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

Goodwill relates to amounts that arose in connection with the acquisition of Ciclofilin. Goodwill represents the excess of the purchase price over the fair value of the net assets acquired when accounted for using the acquisition method of accounting for business combinations. There was no impairment of goodwill for the year ended December 31, 2018, the transition period ended December 31, 2017, or the fiscal year ended June 30, 2017.

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

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

There was no impairment of IPR&D for the year ended December 31, 2018, the transition period ended December 31, 2017 or the fiscal year ended June 30, 2017.

The discount rates applied to the estimated cash flows for the Company's December 31, 2018 IPR&D impairment test was 35%, depending on the overall risk associated with the particular asset and other market factors. The Company believes the discount rates and other inputs and assumptions are consistent with those that a market participant would use. Our assumed discount rate used in the impairment assessment would have to change by more than 800 basis points for there to be a material change in our analysis.

Income Taxes

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

In conjunction with the acquisition of Ciclofilin in June 2016, a deferred tax liability of $1.3 million was recorded reflecting the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset the deferred tax assets when analyzing the Company's valuation allowance as the acquired IPR&D is considered to have an indefinite life

until the Company completes or abandons development of the related IPR&D. The re-measurement of the deferred tax balances to the new corporate rate was completed as of December 31, 2017 and resulted in an adjustment of approximately $900,000 recorded as a reduction in the deferred tax liability offset by a credit to Income Tax benefit at that time. The 2017 Tax Act also changed the Net Operating Loss carryforwards' period to now have an indefinite life. The Company performed an evaluation with regard to the impact of Deferred Tax Assets ("DTA") that were generated by Temporary Differences (such as Stock Compensation, Accrued Vacation, depreciation, etc.) which would reverse and turn into indefinite lived NOL carryforwards and whether the Deferred Tax Liability associated with In-Process R&D could be used to offset indefinite lived DTAs. In March 2018, the Company recorded an adjustment to the valuation allowance in the approximate amount of $536,000 This adjustment reflects the adjustment allowed by the Tax Cuts and Jobs Act of 2017 to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets in conjunction with the evaluation of the amount of valuation allowance needed..

Contingencies

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

Research and Development

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

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

Also as prescribed by ASC 730, non-refundable advance payments for goods or services that will be used or rendered for future research and development activities should be deferred and capitalized. As the related goods are delivered or the services are performed, or when the goods or services are no longer expected to be provided, the deferred amounts would be recognized as an expense. At December 31, 2018 and December 31, 2017, the Company had prepaid research and development costs of $41,514 and $32,903, respectively.

Share-based payments

ASC Topic 718 "Compensation—Stock Compensation" ("ASC 718") requires companies to measure the cost of 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, the Company issues stock options with only service-based vesting conditions and records the expense for these 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 Company has a limited trading history in its common stock and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's 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 the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The Company accounts for stock options issued to non-employees in accordance with ASC Topic 505-50 "Equity-Based Payment to Non-Employees" and accordingly the value of the stock compensation to non-employees is based upon the measurement date as determined at either a) the date at which a performance commitment is reached, or b) at the date at which the necessary performance to earn the equity instruments is complete. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

ASC 718 requires that cash flows resulting from tax deductions in excess of the cumulative compensation cost recognized for options exercised (excess tax benefits) be classified as cash inflows from financing activities and cash outflows from operating activities. In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09") (see Note 4) which states that excess tax benefits should be classified along with other income tax cash flows as an operating activity. This guidance is effective for the Company for annual reporting periods beginning after December 15, 2017, with early adoption permitted. Due to the Company's accumulated deficit position, no excess tax benefits have been recognized.

Foreign Exchange

The functional currency of ContraVir and ContraVir Research Inc. is the U.S. dollar. The functional currency of ContraVir Research Corp. is the Canadian dollar. The Company's reporting currency is the U.S. dollar. The assets and liabilities of Ciclofilin are translated into U.S. dollars using period-end exchange rates; income and expenses are translated using the average exchange rates for the reporting period. Unrealized foreign currency translation adjustments are deferred in accumulated other comprehensive loss, a separate component of shareholders' equity. The amount of currency translation adjustment was immaterial at December 31, 2018, December 31, 2017, and June 30, 2017.

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, 2018, December 31, 2017, and June 30, 2017.

Segment Information

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

Net loss per share

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

Reclassifications

Certain prior period balances have been reclassified to conform with the current year presentation. Such reclassification had no impact on the Company's financial position, results of operations or cash flows in those years.

Immaterial Correction of Misstatements

Subsequent to the issuance of the unaudited condensed consolidated financial statements as of and for the three and nine months ended September 30, 2018 filed on Form 10-Q, the Company determined that a reclassification was required to correct the disclosure of the components of total stockholders' equity, namely to increase the amount of Series C convertible preferred stock and to decrease the amount of additional paid-in capital in the approximate amount of $835,000. The reclassification had no effect on total stockholders' equity; net loss, cash flows or the Company's financial position as previously reported. The Company also determined that a revision was required to adjust an over accretion upon conversion of the Series C preferred stock to common stock resulting in an adjustment to decrease the previously reported Deemed Dividend and to decrease the amount of Net loss Attributable to Common Shareholders in the approximate amount of $500,000. This adjustment had no impact to net loss or cash flows of the Company or the Company's financial position as previously reported and was determined to be immaterial and was corrected as an out of period adjustment in the year ended December 31, 2018.

In connection with the preparation of the unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2018 the Company identified a $0.5 million reduction to the Company's deferred tax liabilities that should have been recorded to the valuation allowance to reflect the adjustment allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets in conjunction with the evaluation of the amount of valuation allowance needed. This adjustment was determined to be immaterial and was corrected as an out of period adjustment recorded in the quarter ended March 31, 2018.

4. Recent Accounting Pronouncements

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

In July of 2018, the FASB issued ASU 2018-11 — *Leases (Topic 842) Targeted Improvements ("ASU 2018-11")*, which addresses stakeholder's inquiries that are applicable to the Company regarding reporting requirements for initial adoption of ASU 2016-02. ASU 2018-11 provides entities with an additional (and optional) transition method to adopt the new leases standard in ASU 2016-02, allowing an entity to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments in ASU 2018-11 follow the same effective dates as ASU 2016-02 for the Company. The Company is currently evaluating the impact that this guidance will have in conjunction with the guidance in ASU 2016-02 (see below).

In July of 2018, the FASB issued ASU 2018-10 — *Codification Improvements to Topic 842, Leases ("ASU 2018-10")*, which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02 based on comments and questions raised by stakeholders during the assessment and implementation of ASU 2016-02. The amendments in ASU 2018-10 follow the same effective dates as ASU 2016-02. (see below).

In June of 2018, the FASB issued ASU 2018-07 — *Compensation — Stock Compensation (Topic 718) ("ASU 2018-07")*, which expands the scope of Topic 718 to include share-based payment transaction for acquiring goods and services from nonemployees. The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company is currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In March of 2018, the FASB issued ASU 2018-05 — *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 ("ASU 2018-05")*, which amends the FASB Accounting Standards Codification and XBRL Taxonomy based on the Tax Cuts and Jobs Act (the "Act") that was signed into law on December 22, 2017 and Staff Accounting Bulletin No. 118 ("SAB 118") that was released by the Securities and Exchange Commission. The Act changes numerous provisions that impact U.S. corporate tax rates, business-related exclusions, and deductions and credits and may additionally have international tax consequences for many companies that operate internationally. The Company has evaluated the impact of the Act as well as the guidance of SAB 118 and incorporated the changes into the final adjustment of its deferred tax liability and appropriate disclosures in the notes to our consolidated financial statements (See Note 11).

In May of 2017, the FASB issued ASU No. 2017-09, *Compensation — Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09")*, which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. This guidance is to be applied for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted and should be applied prospectively to an award modified on or after the adoption date. The Company has adopted ASU 2017-09. The adoption of this guidance did not have a material impact on the Company's financial statements.

In January of 2017, the FASB issue ASU No. 2017-04, Intangibles — Goodwill and Other (Topic 350) ("ASU 2017-04"), which amended the 2014 amendments to the FASB Accounting Standards Codification that allowed companies an alternative accounting treatment for subsequently measuring goodwill. This amendment is Phase 1 of a project by the FASB Board to simplify how an entity is required to test goodwill for impairment by eliminating step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. These amendments are to be applied on a prospective basis and are required to be adopted for annual and any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

In August 2016, the FASB issued ASU No. 2016-15*, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), which amended the existing accounting standards for the statement of cash flows. The amendments provide guidance on eight classification issues related to the statement of cash flows. The Company is required to adopt the guidance in the first quarter of fiscal 2019 and early adoption is permitted. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the amendments may be applied prospectively as of the earliest date practicable. The Company is currently evaluating the timing and the impact of these amendments on its statement of cash flows.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). The new standard identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for the Company for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has adopted ASU 2016-09. The adoption of this guidance did not have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02*, Leases (Topic 842)* ("ASU 2016-02"). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is

required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company's primary lease arrangement is associated with a lease for its corporate office space. The Company is still evaluating the impact of the adoption of this standard; however, based on the size of the Company's future operating lease commitments as of December 31, 2018 (discussed in Note 13), the Company expects to record a ROU asset and a lease liability on the balance sheet upon adoption and the Company expects that adoption of the new lease accounting standard will have a material impact on our balance sheet on the date of adoption.

5. Debt

On May 8, 2018, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with Iliad Research and Trading, L.P. ("IRT"), pursuant to which the Company issued to IRT a secured convertible promissory note (the "Note") in the aggregate principal amount of $3,325,000 for an aggregate purchase price of $2,000,000 cash and $1,000,000 aggregate principal amount of investor notes (the "Investor Notes") payable to the Company in four tranches of $250,000 upon request by the Company. Closing occurred on May 9, 2018. The Note carries an original issue discount of $300,000, and the initial principal balance of $2,225,000 also includes original issue discount of $200,000 and $25,000 to cover IRT's transaction expenses. The Investor Notes have not been drawn as of December 31, 2018. The Note bears interest at the rate of 10% per annum and matures on November 8, 2019. Beginning on November 8, 2018, IRT has the right to redeem all or any portion of the Note up to the Maximum Monthly Redemption Amount which is $500,000. Payments of each redemption amount may be made in cash or shares of Company common stock at Company's election (so long as the various conditions to paying stock set forth in the Note are satisfied) provided, however, that if the Company's common stock is trading below $1.60 per share (as adjusted for the reverse stock split), the redemption(s) must be in cash. Common stock issued upon redemption will be issued at a price equal to 80% of the lowest trade price of the common stock for the 20 consecutive trading days prior to the date of redemption, subject to adjustments; provided, however, that in no event will the redemption price be less than $1.60. Because of this feature which allows the lender to redeem the entire outstanding balance at its option within twelve (12) months of initial issuance, the debt is classified as current. The Company also entered into a security agreement with IRT, pursuant to which IRT will receive a security interest in substantially all of the Company's assets, except for intellectual property. The Company identified numerous embedded features to which bifurcation would be required. The Securities Purchase Agreement requires that the Company comply with certain non-financial covenants customary for financing of this nature which the Company complied with as of December 31, 2018.

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

The Company incurred $200,000 of debt issuance costs, which were expensed as incurred due to the election of the fair value option and were included in interest expense in the accompanying consolidated statement of operation for the year ended December 31, 2018.

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

During November and December of 2018, the Company made cash redemption payments totaling $800,000 against the Note, $131,058 of which was applied towards interest resulting in a $1.6 million balance of remaining principal as of December 31, 2018.

6. Stockholders' Equity and Derivative Liability — Warrants

Preferred stock, Common Stock and Warrant Offering

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

Series C Preferred Stock Issuance

On July 3, 2018, the Company completed its rights offering pursuant to its effective registration statement on Form S-1. The Company offered for sale units in the rights offering and each unit sold in connection with the rights offering consists of 1 share of the Company's Series C Convertible Preferred Stock, or Series C, and 575 common stock warrants (the "Rights Offering"). Upon completion of the offering, pursuant to this rights offering, the Company sold an aggregate of 10,826 units at an offering price of $1,000 per unit comprised of 10,826 shares of Series C and 6,224,950 common stock warrants. The Company received net proceeds of $9.9 million, after deducting expenses relating to the Rights Offering, including dealer-manager fees and offering expenses, totaling approximately $0.9 million, and excluding any proceeds received upon exercise of any warrants.

The common stock warrants are exercisable at $1.55 per share and subject to adjustments upon the occurrence of certain dilutive events. The warrants expire on the fifth anniversary from their original issuance date. The Company may redeem the warrants for $0.01 per warrant if the Company's common stock closes above $6.20 per share for ten consecutive trading days, provided that the Company may not do so prior to the first anniversary of the closing of the unit offering. The warrants are being sold under a written

public offering. If a warrant is exercised during a period where a registration statement is not declared effective, the Company cannot assert that settlement in unregistered shares is permitted. As a result, the warrants are liability classified and carried at their estimated fair value at each reporting until they are exercised, terminated or otherwise settled.

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

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

Dividends

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

Voting

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

Liquidation

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

Conversion

Each share of Series C is convertible into common stock at any time at the option of the holder thereof at the conversion price then in effect. The conversion price for the Series C is determined by dividing the stated value of $1,000 per share by $1.55 per share (subject to adjustments upon the occurrence of certain dilutive events).

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

The gross proceeds of the offering were first allocated to the warrants based on the fair value of the warrants at that time, with the residual proceeds allocated to the Series C. All offering costs were allocated between the Series C and the warrants. In addition, the placement agent received, as compensation for the transaction, unregistered equity warrants to purchase 279,381 shares of the Company's common stock priced at $1.71 per share. The fair value of the placement agent equity classified warrants was $0.2 million at the time of issuance and $0.1 million was allocated to the Series C and $0.1 million was allocated to the liability classified common stock warrants. All costs allocated to the liability classified warrants were expensed immediately and as a component of general and administrative expenses within the Company's consolidated statement of operations.

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

As a result of the Company's issuance of convertible preferred shares that included a beneficial conversion feature, the Company may, upon conversion of the Series C, recognize any unamortized discount resulting from the initial allocation of proceeds issued to the liability classified warrants. During the year ended December 31, 2018, the holders of Series C shares converted 8,852 shares of Series C into 5,710,963 shares of common stock. As a result of the conversion, the Company recognized a deemed dividend charged to additional paid in capital of $4.7 million associated with the difference between the stated and carrying per share values of the Series C, including a $0.5 million accretion related to issuance costs that had been allocated to the Series C which have been presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations.

Beneficial Conversion Feature-Series C Preferred Stock

Each share of Series C is convertible into shares of common stock, at any time at the option of the holder at a conversion price of $1.55 per share. Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series C preferred shares at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series C was $3.8 million and the preferred stock was discounted by this amount. The beneficial conversion amount of $3.8 million was then accreted back to the preferred stock as a dividend charged to additional paid in capital as the preferred stock was 100% convertible immediately. The $3.8 million accretion was recorded as a dividend reflected in additional paid in capital and also presented as a component of net loss attributable to common stockholders in the Company's consolidated statement of operations.

Controlled Equity Offering Sales Agreement

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

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

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

During the year ended December 31, 2018 and the transition period ended December 31, 2017, the Company sold approximately 766,300 and 280,100 shares of the Company's common stock resulting in proceeds, net of issuance costs, of approximately $1.6 million and $1.2 million under the Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., as sales agent.

Common Stock and Warrant Offering

On October 7, 2015, the Company entered into an underwriting agreement related to the public offering and sale of 625,000 shares of common stock and warrants to purchase up to 375,000 shares of common stock, at a fixed combined price to the public of $24.00 under the Company's prior shelf registration statement on Form S-3. The shares of common stock and warrants were issued separately on October 13, 2015. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of $34.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering contemplated by the Underwriting Agreement.

The Company also granted the Underwriters a 45-day option to purchase up to an additional 93,750 additional shares of common stock and additional warrants to purchase up to 56,250 shares of common stock at $24.00, which was not exercised. The gross proceeds to the Company were $15 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately $1.5 million. If the warrants were exercised in full, ContraVir would receive additional proceeds of approximately $12.8 million.

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

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

The following assumptions were used to remeasure the warrants liability as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Price of ContraVir common stock	$ 0.28	$ 2.88
Expected warrant term (years)	1.78 years	2.78 years
Risk-free interest rate	2.48%	2.09%
Expected volatility	74%	67%
Dividend yield	—	—

On April 4, 2016, the Company closed on a public offering of 616,197 shares of its common stock and warrants to purchase up to 308,098 shares of common stock, at a fixed combined price to the public of $11.36 under the Company's prior shelf registration statement on Form S-3. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of $13.60 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering contemplated by the Underwriting Agreement. The gross proceeds to the Company were $7.0 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately $0.7 million. If the warrants were exercised in full, ContraVir would receive additional proceeds of approximately $4.2 million.

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

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

The following assumptions were used to remeasure the warrants liability as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Price of ContraVir common stock	$ 0.28	$ 2.88
Expected warrant term (years)	2.26 years	3.00 years
Risk-free interest rate	2.48%	2.09%
Expected volatility	74%	67%
Dividend yield	—	—

On April 25, 2017, the Company closed on a public offering of 1,500,000 shares of its common stock and warrants to purchase up to 750,000 shares of common stock, at a fixed combined price to the public of $8.00 under the Company's prior shelf registration statement on Form S-3. The warrants are immediately exercisable and will be exercisable for a period of five years from the date of issuance at an exercise price of $10.00 per share. There is not, nor is there expected to be, any trading market for the warrants issued in the offering contemplated by the Underwriting Agreement. The gross proceeds to the Company were $12.0 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately $0.5 million. If the warrants were exercised in full, ContraVir would receive additional proceeds of approximately $7.5 million.

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

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

The following assumptions were used to remeasure the warrants liability as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Price of ContraVir common stock	$ 0.28	$ 2.88
Expected warrant term (years)	3.31 years	4.00 years
Risk-free interest rate	2.46%	2.09%
Expected volatility	74%	68%
Dividend yield	—	—

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

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

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

	December 31, 2018	July 3, 2018
Price of ContraVir common stock	$ 0.28	$ 1.36
Expected warrant term (years)	4.50 years	5.00 years
Risk-free interest rate	2.51%	2.72%
Expected volatility	74%	75%
Dividend yield	—	—

The following table sets forth the components of changes in the ContraVir's derivative financial instruments liability balance for the periods indicated:

Date	Description	Number of Warrants Outstanding	Derivative Instrument Liability
6/30/2017	Balance of derivative financial instruments liability	1,426,848	$ 1,702,231
	Change in fair value of warrants for the transition period ended December 31, 2017	—	(1,032,769)
12/31/2017	Balance of derivative financial instruments liability	1,426,848	669,462
	Issuance of warrants on July 3, 2018	6,224,950	5,091,373
	Change in fair value of warrant liability related to warrant exercise	(92,000)	(41,132)
	Derecognition of warrants		(34,136)
	Change in fair value of warrants for the year ended December 31, 2018		(5,281,230)
12/31/2018	Balance of derivative financial instruments liability	7,559,798	$ 404,337

7. Fair Value Measurements

The following table presents the Company's liabilities that are measured and recognized at fair value on a recurring basis classified under the appropriate level of the fair value hierarchy as of the year ended December 31, 2018 and the transition period ended December 31, 2017.

Description	Fair value	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2018				
Convertible Debt	$ (1,440,000)	$ —	$ —	$ (1,440,000)
Contingent consideration	$ (2,590,000)	$ —	$ —	$ (2,590,000)
Derivative liabilities related to warrants	$ (404,337)	$ —	$ —	$ (404,337)
As of December 31, 2017				
Contingent consideration	$ (3,380,000)	$ —	$ —	$ (3,380,000)
Derivative liabilities related to warrants	$ (669,462)	$ —	$ —	$ (669,462)

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities- warrants in the Company's statement of operations. See Note 6 for a rollfoward of the derivative liability for the year ended December 31, 2018 and the transition period ended December 31, 2017. The financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC 815-40. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs or instruments which trade infrequently and therefore have little or no price transparency are classified as Level 3.

A lattice-based model is used to estimate the fair value of the Secured Convertible Note. The lattice model utilizes a "decision tree" whereby future movement in the company's common stock price is estimated based on a volatility factor. The Company classified the fair value of the Secured Convertible Note as a Level 3 measurement due to the lack of observable market data. The lattice model requires the development and use of assumptions including the Company's stock price volatility returns, an appropriate risk-free interest rate, default intensity rate and expected recovery rate given default. The estimated fair value of the Secured Convertible Note as of December 31, 2018 was $1.44 million and was based on the following inputs: stock volatility of 80.0 percent, risk- free rate of 2.61 percent related to assumed term of 0.85 years, default Intensity of 23.7 percent and a recovery rate of 30.0 percent.

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

	Fair Value of Convertible Debt
Balance at May 8, 2018	$ (2,000,000)
Change in fair value	(108,942)
Repayment of principal of debt financing	668,942
Balance at December 31, 2018	$ (1,440,000)

Contingent consideration was related to the acquisition of Ciclofilin and recorded on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model utilizing a discount rate of 6.5% and a stock price of $0.28. 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 100,737 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.

	Acquisition-related Contingent Consideration
Liabilities	
Balance at June 30, 2017	$ 3,410,000
Change in fair value recorded in earnings	(30,000)
Balance at December 31, 2017	3,380,000
Settlement of first clinical milestone	(1,055,398)
Change in fair value recorded in earnings	265,398
Balance at December 31, 2018	$ 2,590,000

8. Indefinite-lived Intangible Assets and Goodwill

IPR&D

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

	December 31, 2018	December 31, 2017
CRV431	$ 3,190,000	$ 3,190,000

Goodwill

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

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

9. Accrued Liabilities

The Company's accrued expenses consist of the following:

	Year ended December 31, 2018	For the transition period Ended December 31, 2017
Payroll and related costs	$ 280,235	$ 539,063
Research and development	184,120	322,842
Professional fees	151,812	75,934
Legal fees	34,072	81,550
Other	11,182	27,309
Total accrued expenses	$ 661,421	$ 1,046,698

During the year ended December 31, 2018, the Company paid approximately $1.3 million of severance costs. Approximately $36,000 of severance payments remaining as of December 31, 2018 are included in accrued payroll and related costs.

10. Accounting for Share-Based Payments

On June 3, 2013, ContraVir adopted the 2013 Equity Incentive Plan (the "Plan"). Stock options granted under the Plan will typically vest after three years of continuous service from the grant date and will have a contractual term of ten years. Stockholder and Board approval was obtained on December 2, 2014 to increase the number of authorized shares to 812,500 and on December 14, 2016 Stockholder and Board approval was obtained to increase the number of authorized shares to 962,500. Stockholder and Board approval was obtained on February 21, 2018 to increase the number of authorized shares to 1,337,500. As of December 31, 2018 and December 31, 2017, the Company had 694,904 and 109,851 shares of common stock, respectively, available for grant under the Plan.

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified. ContraVir recorded the following stock-based compensation expense for the periods shown:

	Year ended December 31, 2018	For the transition Period ended December 31, 2017
General and administrative	$ 271,644	$ 509,072
Research and development	(37,134)	236,669
Total stock-based compensation expense	$ 234,510	$ 745,741

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, June 30, 2017	810,148	$ 0.88 – $30.64	$ 12.32	301,011	7.72 years
Granted	45,000	$ 2.96 - $4.96	$ 4.16		
Cancelled	(2,500)	$ 4.00 - $4.96	$ 4.48		
Balance outstanding, December 31, 2017	852,648	$ 0.88 - $30.64	$ 11.84	5,958	7.00 years
Forfeited	(126,184)	$ 2.96 - $16.08	$ 9.44		
Cancelled	(83,868)	$ 4.64 - $20.48	$ 1.82		
Balance outstanding, December 31, 2018	642,596	$ 0.88 - $30.64	$ 12.32		6.02 years
Vested awards and those expected to vest at December 31, 2018	639,940	$ 0.88 - $30.64	$ 12.66	—	6.06 years
Vested and exercisable at December 31, 2018	616,115	$ 0.88 - $30.64	$ 12.82	—	6.02 years

There were no stock options issued during the year ended December 31, 2018. The weighted-average grant-date fair value of options granted to employees during the transition period ended December 31, 2017 and the year ended June 30, 2017 was $2.64 and $7.44 per share, respectively. The total fair value of shares vested during the year ended December 31, 2018 was $1.1 million. Included within the above table are 0.2 million non-employee options outstanding as of December 31, 2018, of which approximately 19,000 are unvested as of December 31, 2018 and therefore subject to remeasurement. The remeasurement impact for the year ended December 31, 2018 was negative due to a decrease in the Company's stock price, which resulted in a decrease in the related expense recognized.

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

As of December 31, 2018, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was approximately $0.1 million to be recognized over a weighted-average remaining vesting period of approximately 1.24 years.

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

	For the transition period ended December 31, 2017	Year Ended June 30, 2017
Stock price	$ 4.16	$ 11.12
Risk-free interest rate	1.64%	1.86%
Dividend yield	—	—
Expected volatility	73.05%	79.18%
Expected term (in years)	6 years	6 years

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

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

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

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

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

stock options, and therefore used a simple average of the vesting period and the contractual term for options granted as permitted by SAB No. 107.

Forfeitures—ASC 718 requires forfeitures to be estimated at the time of grant and revised if necessary, in subsequent periods if actual forfeitures differ from those estimates. At April 1, 2016, the Company determined that it had sufficient history of issuing stock options and decreased its estimated forfeiture rate from 10%, which was based on the historical experience of its former parent, to 3%, which is the Company's actual historical forfeiture rate. The forfeiture rate was 10% through the end of the 3rd fiscal quarter ended March 31, 2016 and was then 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 year ended December 31, 2018, the transition period ended December 31, 2017, and year ended June 30, 2017. The Company will continue to analyze the forfeiture rate on at least an annual basis or when there are any identified triggers that would justify immediate review.

11. Income Taxes

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

The Company's loss before income taxes was $9,985,295, $9,458,852, and $16,799,053 for the year ended December 31, 2018, the transition period ended December 31, 2017 and the fiscal year ended June 30, 2017, respectively, and was generated entirely in the United States and Canada.

The income tax benefit for the year ended December 31, 2018, the transition period ended December 31, 2017 and June 30, 2017 was $0.5 million, $1.9 million and $1.9 million, respectively. The income tax benefits resulted from the sale of state net operating losses totaling $0, $1.5 million, and $1.9 million, respectively, and adjustments to the deferred tax liability resulting from the 2017 Tax Act. The 2017 Tax Act changed the Net Operating Loss carryforwards' period to now have an indefinite life and the Company recorded a $0.5 million adjustment during the year ended December 31, 2018 and a $0.4 million adjustment during the transition period ended December 31, 2017. The Company has sold a portion of its state NOLs and Research and Development credits in prior years under the State of New Jersey's Technology Business Tax Certificate Transfer Program and plans to sell additional NOLs and credits under the same program later in 2019. In connection with the preparation of the unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2018 the Company identified a $0.5 million reduction to the Company's deferred tax liabilities that should have been recorded to the valuation allowance to reflect the adjustment allowed by the 2017 Tax Act to utilize indefinite deferred tax liabilities as a source of income against indefinite lived portions of the Company's deferred tax assets in conjunction with the evaluation of the amount of valuation allowance needed. This adjustment was determined to be immaterial and was corrected as an out of period adjustment recorded in the quarter ended March 31, 2018.

Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets are comprised of the following:

	As of December 31, 2018	As of December 31, 2017	As of June 30, 2017
Federal net operating loss ("NOL")	$ 13,600,500	$ 12,054,400	$ 17,050,000
State NOL	2,116,300	1,148,800	1,597,000
Canadian NOL	1,978,500	1,140,000	560,300
Research and development credits	1,043,300	696,400	522,300
Stock Compensation & Other	1,206,300	1,000,100	1,232,500
Deferred tax asset valuation allowance	(19,348,600)	(16,039,700)	(20,962,100)
Total Deferred Tax Asset	$ 596,300	$ —	$ —
Deferred tax liability (In-Process R&D)	$ (957,000)	$ (896,700)	$ (1,269,600)
Total Deferred Tax Liability	$ (957,000)	$ —	$ —
Net Deferred Tax Liability	$ (360,700)	$ (896,700)	$ (1,269,600)

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2018, December 31, 2017, and June 30, 2017. The Company has recorded a net deferred tax liability of

$360,700 related to in-process research and development as a result of the acquisition of Ciclofilin. It is the Company's position that the acquired in-process research and development is an indefinite-lived intangible asset and is not available as a source of income to support the realization of deferred tax assets.

The valuation allowance increased/(decreased) by $3.3 million and ($5.0) million for the year ended December 31, 2018 and the transition period ended December 31, 2017, respectively, due primarily to the generation of net operating losses during the periods and also adjustments due to the December 22, 2017 enactment of the tax reform law.

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

	Year Ended December 31, 2018	For the transition period ended December 31, 2017
U.S. statutory income tax rate	21.0%	34.0%
State income taxes, net of federal benefit	7.3	(6.6)
Sale of New Jersey tax benefits	—	16.9
Research and development credits	(3.7)	1.9
Net operating loss	—	—
Warrant liability	10.9	3.9
Rate change	—	(78.3)
Foreign Tax Differential	1.7	—
Other	(1.6)	—
Valuation allowance	(30.3)	49.1
Effective tax rate	5.3%	20.9%

As of December 31, 2018, December 31, 2017, and June 30, 2016, the Company had U.S. federal and state net operating loss carryforwards of $88.3 million, $73.6 million, and $77.0 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2032. As of December 31, 2018, December 31, 2017, and June 30, 2017, the Company also had foreign net operating loss carryforwards of $7.5 million, $4.3 million, and $2.1 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in December 2033. The Company also had federal and state research and development tax credit carry forwards of approximately $1.0 million as of December 31, 2018, which will begin to expire in December 2036.

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

The Company files income tax returns in the United States, Canada and various state jurisdictions. The Company's federal and state income tax returns from the year of incorporation, 2013, and forward remain subject to examination by the Internal Revenue Service ("IRS") and state authorities.

The Company had no unrecognized tax benefits or related interest and penalties accrued through December 31, 2018. The Company would record the effects of interest and penalties as a component of income tax expense.

12. Loss per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, ("ASC 260") for all periods presented. In accordance with ASC 260, basic and diluted net loss per common share was determined by dividing net loss applicable to common stockholders by the weighted-average common shares outstanding during the period. In addition, the net loss attributable to common stockholders' is adjusted for the preferred stock deemed dividends related accretion of beneficial conversion feature and other discount on this instrument for the periods in which the preferred stock is outstanding. The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

Basic net (loss) income per common share	Year ended December 31, 2018	For the transition period ended December 31, 2017	Year ended June 30, 2017
Numerator:			
Net loss attributable to common stockholders — basic	$ (17,901,146)	$ (7,511,092)	$ (14,891,050)
Denominator:			
Basic weighted average common shares outstanding	12,871,530	9,678,329	7,286,304
Net loss per share of common stock—basic	$ (1.39)	$ (0.78)	$ (2.04)
Diluted net (loss) income per common share			
Numerator:			
Net loss attributable to common stockholders - basic	$ (17,901,146)	$ (7,511,092)	$ (14,891,050)
Less: reversal of gain on warrants	—	—	(2,698,015)
Net loss attributable to common stockholders - diluted	$ (17,901,146)	$ (7,511,092)	$ (17,589,065)
Denominator:			
Basic weighted average common shares outstanding	12,871,530	9,678,329	7,286,304
Effect of dilutive securities			
Exercise of warrants	—	—	6,023
Weighted average shares used to compute diluted net loss per share	12,871,530	9,678,329	7,292,327
Net loss per share of common stock—diluted	$ (1.39)	$ (0.78)	$ (2.41)

The following outstanding securities at December 31, 2018, December 31, 2017, and June 30, 2017 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year ended December 31, 2018	For the transition period ended December 31, 2017	Year ended June 30, 2017
Common shares issuable upon conversion of Series A preferred stock	222,867	270,867	270,867
Common shares issuable upon conversion of Series C preferred stock	1,273,548	—	—
Stock options	642,596	852,648	810,148
Warrants — liability classified	7,559,798	1,426,849	676,849
Warrants — equity classified	279,381	—	—
Total	9,978,190	2,550,364	1,757,864

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

13. Commitments and Contingencies

License Agreement with Chimerix, Inc.

On December 17, 2014, the Company entered into an exclusive license agreement with Chimerix pursuant to which the Company has licensed TXL™ from Chimerix for further clinical development and commercialization. TXL™ is a highly potent analog of the antiviral drug tenofovir DF (Viread®). Under the terms of the agreement, ContraVir licensed TXL™ from Chimerix in exchange for an upfront payment consisting of 120,000 shares of ContraVir Series B Convertible Preferred Stock. In addition, Chimerix is eligible to receive up to approximately $20 million in clinical, regulatory and initial commercial milestone payments in the United States and Europe, as well as royalties and additional milestone payments based on commercial sales in those territories. Either party may terminate the License Agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy or insolvency of the other party. The Company may also terminate the License Agreement without cause on a country by country basis upon sixty days' prior written notice to Chimerix.

The fair value of the Preferred B shares exchanged for the license was determined to be equal to the amount paid per share of the Series A, as the provision of the Preferred B shares were the same as the Preferred A Shares, based on an arm's length transaction. Therefore, the fair value of the Preferred B shares issued was $10 per share or $1.2 million. The cost of the license was classified as a research and development expense in the amount of $1.2 million as the compound is early stage, has not yet reached technological feasibility and has no alternative use. As of December 31, 2018, no amounts are due to Chimerix based on the Company's assessment regarding the probability as to whether the related milestones will be achieved.

On September 30, 2016 Chimerix converted all shares of Series B Preferred Stock into approximately 134,000 shares of the Company's common stock.

Contractual Obligations

In August 2014, the Company entered into a lease for corporate office space in Edison, New Jersey. In December 2017, the Company entered into an amendment to the lease for corporate office space in Edison, New Jersey expanding the office footprint and extending the lease for an approximate 5 year period. Rent expense for the year ended December 31, 2018, the transition period ending December 31, 2017 and year ended June 30, 2017 was $289,504, $101,732, and $183,716, respectively. The Company also leases office and research laboratory space in Edmonton, Canada that is currently on a month to month basis.

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

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

Employment Agreements

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

14. Related Party Transactions

One of the Company's Directors, Timothy Block, is President of the Baruch S. Blumberg Institute ("Blumberg Institute"). On May 29, 2015, the Company entered into a Sponsored Research Agreement ("Agreement") with Blumberg Institute, pursuant to which the Company is sponsoring research by investigators affiliated with the Blumberg Institute with respect to TXL™. The Company incurred expenses related to the agreement of approximately $50,000, $50,000, and $75,000 for the year ended December 31, 2018, the transition period ended December 31, 2017, and fiscal year ended June 30, 2017, respectively.

On June 1, 2016, the Company entered into a consulting agreement with Gabriele Cerrone, one of the Company's principal stockholders. The agreement is for a term beginning on June 1, 2016 and expires on June 1, 2019. Pursuant to the consulting agreement Mr. Cerrone is paid $10,000 per month. Either party may terminate the agreement at any time upon 30 days prior written notice. On June 16, 2016, Mr. Cerrone was issued 45,000 stock options which vest in 1,250 increments on a monthly basis over 3 years. The Company terminated the consulting agreement with Mr. Cerrone effective as of August 4, 2018.

15. Year Ended December 31, 2017 Comparative Data (Unaudited)

	For the year ended December 31, 2017
Revenues	$ —
Costs and Expenses:	
Research and development	13,368,165
General and administrative	7,277,951
Loss From Operations	(20,646,116)
Other Income (Expense):	
Change in fair value of derivative instruments—warrants and contingent consideration	5,618,598
Loss before income taxes	(15,027,518)
Income tax benefit	1,947,760
Net loss	$ (13,079,758)
Weighted Average Common Shares Outstanding	
Basic and Diluted	9,678,329
Net loss per Common Share	
Basic and Diluted	$ (1.35)

16. Subsequent Events

The Company made a cash redemption payment on the debt to IRT on January 10, 2019 totaling $312,500. The Company also made redemption payments on the debt to IRT on February 14, 2019 and February 28, 2019 utilizing company stock totaling 541,143 shares with a redemption value of $100,000.

On February 27, 2019, the Company received a letter from Nasdaq indicating that, based upon the Company's continued non-compliance with the Minimum Bid Price Rule as well as the fact that the Company has not yet held an annual meeting of shareholders within twelve months of the end of the Company's fiscal year end, the Company's common stock would be subject to delisting unless the Company timely requests a hearing before a Nasdaq Hearings Panel (the "Panel"). The Company timely requested a hearing before the Panel and were granted a meeting, scheduled to occur on April 11, 2019. The request will stay any further action by Nasdaq at least pending the issuance of a decision following the hearing and the expiration of any additional extension that may be granted by the Panel. The Company is considering all of its options to regain compliance; however, there can be no assurance that the Panel will grant the Company's request for continued listing or that the Company will be able to evidence compliance with the continued listing criteria within the period of time that the Panel may grant it to do so.

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, 2018, 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. We are committed to the remediation of the material weaknesses described below, 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 utilizing the services of external consultants for non-routine and\or technical accounting issues as they arise. As we continue our evaluation and improve our internal control over financial reporting, management may identify and take additional measures to address control deficiencies. We cannot assure you that we will be successful in remediating the material weaknesses in a timely manner.

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, 2018. 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, 2018. 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, 2018, 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 reconciled to the underlying supporting schedules and accounting records.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to exemptions provided to issuers that are non-accelerated filers or qualify as an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

Changes in Internal Control over Financial Reporting

As required by Rule 13a-15(d) of the Exchange Act, our management, including our principal executive officer and our principal financial officer, conducted an evaluation of the internal control over financial reporting to determine whether any changes occurred during the quarter ended December 31, 2018 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, 2018.

ITEM 9B. OTHER INFORMATION

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers, Directors and Key Employees

The following table sets forth the names and ages of the members of our Board of Directors and our executive officers and the positions held by each as of March 07, 2019.

Name	Age	Present Position with ContraVir Pharmaceuticals, Inc.
Gary S. Jacob	71	Chairman of the Board of Directors
Dr. Robert T. Foster	60	Chief Executive Officer
John Cavan	60	Chief Financial Officer
John P. Brancaccio	70	Director
Timothy Block	64	Director
Arnold Lippa	72	Director
Thomas Adams	76	Director

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

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

John Cavan has served as our Chief Financial Officer since April 1, 2016. From January 2016 to April 2016, Mr. Cavan served in the capacity of Interim CFO. Prior to joining ContraVir, Mr. Cavan was a consultant with The Pine Hill Group from February 2012 to March 2016 where he was instrumental in completing multiple strategic and financial transactions, including initial public offerings, business combinations and strategic transactions. Prior to his role with the Pine Hill Group, from June 2006 until February

2012, he served as Chief Accounting Officer at Stemline Therapeutics, Inc. and as Vice President and Chief Accounting Officer at Aegerion Pharmaceuticals, Inc. where he was instrumental in the company's initial public offering, through which Aegerion achieved a $2 billion market capitalization. He has also held financial positions within the healthcare industry at AlgoRx Pharmaceuticals, Inc. and Alpharma. Mr. Cavan served in a variety of financial and operational positions early in his career during tenures with large multinational public companies, including Sony, American Express, International Specialty Products (an Ashland Company) and Nestlé U.S.A. Mr. Cavan currently serves on the Board of Directors of Vantage Health Systems.

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

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

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

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

Directorships

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

Family Relationships

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

Board Responsibilities and Structure

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

Board of Directors Meetings

During the year ended December 31, 2018, our Board met 15 times, including telephonic meetings, the Audit Committee met 4 times, the Compensation Committee met 1 time and the Corporate Governance/Nominating Committee did not meet. All directors attended 100% of the aggregate number of meetings of the Board, all of the Audit Committee members attended 100% of the Audit Committee meetings and all of the Compensation Committee members attended 100% of the Compensation Committee meetings.

Information Regarding Board Committees

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

Audit Committee

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

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

Compensation Committee

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

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

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee was, during the year ended December 31, 2018, an officer or employee of ours, was formerly an officer of ours or had any relationship requiring disclosure by us under Item 404 of Regulation S-K. No interlocking relationship as described in Item 407(e)(4) of Regulation S-K exists between any of our executive officers or Compensation Committee members, on the one hand, and the executive officers or compensation committee members of any other entity, on the other hand, nor has any such interlocking relationship existed in the past.

Corporate Governance/Nominating Committee

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

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

Communications with our Board of Directors

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

Based on a review of the copies of such forms received, we believe that during the annual period ended December 31, 2018, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

Code of Business Conduct and Ethics

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

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

Item 11. Executive Compensation.

Summary Compensation Table

The following table contains compensation information for our Chief Executive Officer and certain other executives who were the most highly compensated executive officers for the year ended December 31, 2018, the six-month transition period ended December 31, 2017 and the fiscal year ended June 30, 2017.

Name & Principal Position	Year	Salary	Bonus(1)	Stock In Lieu of Cash Bonus	Options granted(2)	Non-equity incentive plan compensation(1)(3)	Other	Total
James Sapirstein, R.Ph.	December 2018	$ 380,000	$ —	$ 199,179	$ —	$ —	$ 835,335(4)	$ 1,414,514
Former Chief Executive Officer	December 2017	$ 240,000	$ —	$ —	$ —	$ —	$ —	$ 240,000
	June 2017	$ 410,000	$ —	$ —	$ 610,995	$ 228,940	$ —	$ 1,249,935
Theresa Matkovits, Ph.D.	December 2018	$ 249,129	$ 28,490	$ 34,331	$ —	$ —	$ 116,563(5)	$ 428,513
Former Executive Vice President	December 2017	$ 153,414	$ —	$	$ 11,769	$ —	$ —	$ 165,183
	June 2017	$ 275,000	$ —	$	$ —	$ 64,870	$ —	$ 339,870
Dr. Robert Foster	December 2018	$ 312,345	$ —	$ 62,244	$ —	$ —	$ —	$ 374,589
Chief Executive Officer(6)								
John Sullivan-Bolyai, M.D.	December 2018	$ —	$ —	$ 34,622	$ —	$ —	$ —	$ 34,622
Former Chief Medical Officer(7)	December 2017	$ 166,400	$ —	$ —	$ —	$ —	$ —	$ 166,400
	June 2017	$ 332,800	$ —	$ —	$ 102,904	$ —	$ —	$ 435,704

(1) Bonus and non-equity incentive compensation amounts are for performance during the year ended December 31, 2018, the transition period ending December 31, 2017, and fiscal year 2017, as applicable, whether or not paid in the year the compensation was earned.

(2) Our named executive officers will only realize compensation to the extent the fair market value of our common stock is greater than the exercise price of such stock options. The grant date fair value of option awards granted in 2017 is in

accordance with ASC Topic 718, or ASC 718. For information regarding assumptions underlying the valuation of equity awards, see Note 10 of the Notes to Consolidated Financial Statements.

(3) Represents cash incentive payments earned based upon the achievement of corporate objectives established by our Board of Directors for performance during December 31, 2018, the Transition period ending December 31, 2017, and fiscal year June 30, 2017.

(4) On October 18, 2018, we entered into a Separation Agreement and General Release with James Sapirstein, our former Chief Executive Officer (the "Sapirstein Agreement") pursuant to which, among other things, we paid Mr. Sapirstein 18 months of salary as per his employment agreement and agreed to pay 18 months of COBRA health benefit payments totaling approximately $0.8 million, in exchange for a general release.

(5) On October 15, 2018 we entered into a Settlement Agreement and General Release with Theresa Matkovits, our former Chief Operating Officer (the "Matkovits Agreement") pursuant to which, among other things, Ms. Matkovits was paid three months of salary plus three months of COBRA health benefit payments in exchange for a general release amounting to approximately $0.1 million.

(6) The full year U.S. dollar salary shown is paid in Canadian dollars and reflects both Dr. Foster's pre and post change in salary effective on October 1, 2018 based upon his updated executive agreement in connection with his election to be the CEO of ContraVir Pharmaceuticals which was effective December 12, 2018. The US dollar amount is calculated using the current exchange rate on the date each payroll is drawn, which is disclosed as salary.

(7) Dr. Sullivan-Bolyai stepped down as Chief Medical Officer in December 2017.

Employment Agreements

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

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

On May 25, 2017, we entered into an Amended and Restated Executive Agreement (the "Sapirstein Agreement") with James Sapirstein, our Chief Executive Officer. The term of the Sapirstein Agreement commenced on May 25, 2017 and ended on October 18, 2018. Pursuant to the Sapirstein Agreement, Mr. Sapirstein's current base compensation is $480,000 per year. Mr. Sapirstein was eligible to receive a cash bonus of up to 50% of his base salary per year based on meeting certain performance objectives and bonus criteria.

On October 18, 2018, we entered into a Separation Agreement and General Release with James Sapirstein, our former Chief Executive Officer (the "Sapirstein Agreement") pursuant to which, among other things, we paid Mr. Sapirstein 18 months of salary as per his employment agreement, extended the period to exercise his vested stock options from 90 days to two years, and agreed to pay 18 months of COBRA health benefit payments totaling approximately $0.8 million, in exchange for a general release.

On June 1, 2015, we entered into an executive agreement with Theresa Matkovits Ph.D. effective June 1, 2015, under which Dr. Matkovits serves as Executive Vice President — Drug Development of the Company. Pursuant to the terms of her employment agreement, Dr. Matkovits receives an annual salary of $275,000. She was eligible to receive a cash bonus of up to 28% of her base salary upon achievement of performance milestones.

On October 15, 2018 we entered into a Settlement Agreement and General Release with Theresa Matkovits, our former Chief Operating Officer (the "Matkovits Agreement") pursuant to which, among other things, Ms. Matkovits was paid three months of salary, we extended the period to exercise her vested stock options from 90 days to two years, and agreed to pay three months of COBRA health benefit payments in exchange for a general release amounting to approximately $0.1 million.

On January 13, 2015, we entered into an executive agreement with John Sullivan-Bolyai, M.D., MPH, effective January 19, 2015, under which he served as Chief Medical Officer of the Company until December 2017. Pursuant to the terms of his employment agreement, Dr. Sullivan-Bolyai received an annual salary of $320,000. He also received 16,875 options with an exercise price of $20.48 which vest over three years. He was eligible to receive a cash bonus of up to 25% of his base salary upon achievement of performance milestones. Dr. Sullivan-Bolyai stepped down as Chief Medical Officer in December 2017.

Outstanding Equity Awards as of December 31, 2018

	Number of Securities Underlying Unexercised Options (#)		Option Exercise	Option Expiration
Name	Exercisable	Unexercisable	Price ($)	Date(1), (2)
James Sapirstein,	125,000	—	18.48	10/15/2020
Former Chief Executive Officer	60,416	—	12.00	10/15/2020
	18,750	—	28.80	10/15/2020
	41,666	—	7.92	10/15/2020
	13,079	—	11.44	10/15/2020
	13,079	—	11.44	10/15/2020
Theresa Matkovits,	6,250	—	30.64	10/12/2020
Former Executive Vice President	833	—	7.60	10/12/2020
	2,083	—	7.92	10/12/2020
	1,041	—	4.64	10/12/2020
Dr. Robert Foster	6,250	6,250	7.36	6/10/2026
Chief Executive Officer				

(1) Per the Separation Agreement and General Release with James Sapirstein, his vested options expiration date has been extended from 90 days to 2 years, resulting in a probable to probable modification of his stock options. The modification did not have a material impact on stock compensation expense.

(2) Per the Separation Agreement and General Release with Theresa Matkovits, her vested options expiration date has been extended from 90 days to 2 years, resulting in a probable to probable modification of her stock options. The modification did not have a material impact on stock compensation expense.

Per the consulting agreement with John Sullivan-Bolyai, M.D., our former Chief Medical Officer, his options continued to vest while he remained a consultant to the Company. Upon the termination of his consulting agreement, effective August 1, 2018, his vesting of options ceased and all his vested options were forfeited following the 90 day exercise period.

Director Compensation

During year ended December 31, 2018, our non-employee directors received the following compensation for their services on the Board and its committees:

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

As of December 31, 2018, we have recorded a liability of approximately $82,000 related to director fees, of which approximately $82,000 was paid in January 2019.

(1) No options grants were issued during the year ended December 31, 2018.
(2) As of December 31, 2018, Dr. Jacob held 126,875 option awards of which 126,875 are exercisable.
(3) As of December 31, 2018, Mr. Brancaccio held 25,081 option awards of which 25,081 are exercisable.
(4) As of December 31, 2018, Dr. Lippa held 9,687 option awards of which 9,687 grants are exercisable.
(5) As of December 31, 2018, Dr. Block held 21,210 option awards of which 21,210 are exercisable.
(6) As of December 31, 2018, Dr. Adams held 5,625 option awards of which 3,750 are exercisable.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 07, 2019 by:

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

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of March 07, 2019, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 17,179,331 shares of common stock outstanding on March 07, 2019.

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

Beneficial Owner	Number of Shares Beneficially Owned	Shares of common stock issuable upon exercise of stock options	Shares of common stock issuable upon exercise of warrants	Percentage of Common Stock Beneficially Owned
Directors and Executive Officers				
John Cavan	20,993	11,557	8,625	*
Dr. Robert Foster	18,092	6,250	—	*
Gary S. Jacob	4,116	126,875	8,625	*
John Brancaccio	251	25,081	1,725	*
Timothy Block	—	21,210	—	*
Arnold Lippa	—	9,687	8,625	*
Thomas Adams	—	3,750	—	*
All current executive officers and directors as a group (7 persons)	43,452	204,410	27,600	1.6%

*Represents beneficial ownership of less than 1%.

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

None

Item 14. Principal Accountant Fees and Services.

Independent Registered Public Accountants' Fees

Audit Fees

The aggregate fees billed and unbilled for the year ended December 31, 2018, the transition period ended December 31, 2017 and the fiscal year ended June 30, 2017 for professional services rendered by our principal accountants for the audits of our annual financial statements on Form 10-K and Form 10-KT, the review of our financial statements included in our quarterly reports on Form 10-Q, services associated with other SEC filings, and consents were approximately $318,000, $105,000, and $298,800, respectively.

Tax and Other Fees

There was approximately $40,000 billed for the year ended December 31, 2018, $31,000 billed for the transition period ended December 31, 2017, and $21,400 billed for the fiscal year ended June 30, 2017 for professional services rendered by our principal accountants for tax compliance. There were no other fees billed for the year ended December 31, 2018, the transition period ended December 31, 2017 years ended June 30, 2017.

Audit Committee's Pre-Approval Policies and Procedures

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of ContraVir Pharmaceuticals, Inc. appearing on page 55 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	Controlled Equity Offering℠ Sales Agreement dated March 9, 2015 between ContraVir Pharmaceuticals, Inc. and Cantor Fitzgerald & Co. (filed as Exhibit 1.2 to the Company's registration statement on Form S-3 which was filed with the Securities and Exchange Commission on March 9, 2015 and incorporated herein by reference).
3.1(a)	Certificate of Incorporation of ContraVir 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 ContraVir 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 ContraVir 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 ContraVir 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).
3.2	By-Laws of ContraVir Pharmaceuticals, Inc. (filed as Exhibit 3.2 to the Company's registration statement on Form 10-12G which was filed with the Securities and Exchange Commission on August 8, 2013 and incorporated herein by reference).
4.1	Secured Convertible Promissory Note, dated May 8, 2018, by and between ContraVir Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 4.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
4.2	Warrant Agency Agreement, dated as of July 2, 2018, by and between the Company and Philadelphia Stock Transfer, Inc. (filed as Exhibit 4.1 to the Company's Form 8-K which was filed with the Securities and Exchange Commission on July 5, 2018 and incorporated herein by reference).
10.1	Amended and Restated Contribution Agreement, dated June 10, 2013, as amended and restated August 5, 2013, by and between Synergy Pharmaceuticals Inc. and ContraVir Pharmaceuticals, Inc. (filed as Exhibit 10.1 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).
10.2	Asset Purchase Agreement dated August 17, 2012 between Synergy Pharmaceuticals Inc. and Bristol-Myers Squibb Company (filed as Exhibit 10.4 to the Company's registration statement on Form 10-12G/A which was filed with the Securities and Exchange Commission on November 21, 2013 and incorporated herein by reference).†
10.3	Patent and Technology License Agreement, dated as of February 2, 2005, between University College Cardiff Consultant Limited and ContraVir Research Incorporated, an entity with no prior relationship with the Company, as amended March 27, 2007 (filed as Exhibit 10.5 to the Company's registration statement on Form 10-12G/A which was filed with the Securities and Exchange Commission on November 21, 2013 and incorporated herein by reference)†
10.4	First Amendment to Patent and Technology License Agreement, effective as of March 27, 2007, by and between University College Cardiff Consultant Limited and ContraVir Research Incorporated (filed as Exhibit 10.7 to the Company's registration statement on Form 10-12G/A which was filed with the Securities and Exchange Commission on December 24, 2013 and incorporated herein by reference).
10.5	License Agreement effective as of December 2014 by and between Chimerix, Inc. and ContraVir Pharmaceuticals, Inc. (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 12, 2015 and incorporated herein by reference). †
10.6	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).*
10.7	Executive Agreement, dated June 10, 2016, between ContraVir 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.)*
10.8	Securities Purchase Agreement, dated May 8, 2018, by and between ContraVir Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 10.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
10.9	Security Agreement, dated May 8, 2018, by and between ContraVir Pharmaceuticals, Inc. and Iliad Research and Trading, L.P. (filed as Exhibit 10.2 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on May 15, 2018 and incorporated herein by reference).
10.10	Settlement Agreement and General Release between ContraVir Pharmaceuticals, Inc. and Theresa Matkovits dated as of October 15, 2018 (filed as Exhibit 10.1 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on November 15, 2018 and incorporated herein by reference).
10.11	Separation Agreement and General Release between ContraVir Pharmaceuticals, Inc. and James Sapirstein dated as of October 18, 2018 (filed as Exhibit 10.2 to the Company's Form 10-Q which was filed with the Securities and Exchange Commission on November 15,, 2018 and incorporated herein by reference)..
14.1	Code of Business Conduct and Ethics (filed as Exhibit 14.1 to the Company's Transition Report on Form 10-KT filed with the Securities and Exchange Commission on March 26, 2018 and incorporated herein by reference)

21.1	List of Subsidiaries
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm
24	Power of Attorney (included on signature page hereto)
31.1	Certification of Chief Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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

* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

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

Date: March 13, 2019

CONTRAVIR 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 13, 2019
/s/ JOHN CAVAN John Cavan	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2019
/s/ GARY S. JACOB, PHD. Gary S. Jacob, PhD.	Chairman, Board of Directors	March 13, 2019
/s/ JOHN BRANCACCIO John Brancaccio	Director	March 13, 2019
/s/ ARNOLD LIPPA Arnold Lippa	Director	March 13, 2019
/s/ TIMOTHY BLOCK Timothy Block	Director	March 13, 2019
/s/ THOMAS ADAMS Thomas Adams	Director	March 13, 2019

Exhibit 21.1

LIST OF SUBSIDIARIES

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

ContraVir Pharmaceuticals, Inc.
Edison, New Jersey 08837

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 No. 333-225041, Form S-3 Nos. 333-202625 and 333-229534 and Form S-8 Nos. 333-203867 and 333-215662 of ContraVir Pharmaceuticals, Inc. of our report dated March 13, 2019, relating to the consolidated financial statements, which appears in this Form 10-K. Our report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP
Woodbridge, New Jersey

March 13, 2019

Exhibit 31.1

Certification of Principal Executive Officer of ContraVir 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 ContraVir 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 13, 2019

/s/ ROBERT FOSTER
Dr. Robert Foster
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer of ContraVir 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 ContraVir 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 13, 2019

/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 ContraVir Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018, 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 13, 2019

/s/ ROBERT FOSTER
Dr. Robert Foster
Chief Executive Officer
(Principal Executive Officer)

Exhibit 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

In connection with the Annual Report of ContraVir Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2018, 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 13, 2019

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