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 fiscal year ended June 30, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of December 31, 2015, was approximately $41,943,614.

The number of shares of the registrant's Common Stock outstanding as of September 26, 2016 was 53,655,682.

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Documents Incorporated by Reference:

Portions of our Proxy Statement for the 2016 Annual Meeting of Stockholders, to be filed within 120 days of June 30, 2016, are incorporated by reference in Part III. Such Proxy Statement, except for the parts therein which have been specifically incorporated by reference, shall not be deemed "filed" for the purposes of this Annual Report on Form 10-K.

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Cautionary Note Regarding Forward-Looking Statements

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

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

- Market conditions;
- Our capital position;
- Our ability to compete with larger better financed pharmaceutical companies;
- New and alternative approaches to the treatment of shingles;
- 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.

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PART I

ITEM 1. BUSINESS

Overview

Overview

We are a biopharmaceutical company focused on the development of antiviral drugs with a primary emphasis on the treatment of Hepatitis B virus ("HBV") infections. We are developing two compounds to treat HBV infection, CMX157 and CRV431. CMX157 is a highly potent oral prodrug of tenofovir. Prodrugs are designed to improve the characteristics of drugs, such as better efficacy, lower pill burden, improved safety, etc. Another prodrug of tenofovir, Viread®, is approved for the treatment of HIV and HBV infections. CRV431 is a novel drug candidate also designed or the treatment of HBV infection. We are also developing an antiviral asset known as FV-100. FV-100 is an orally available, small molecule compound being developed for the prevention of post-herpetic neuralgia (PHN) and treatment of herpes zoster infection and acute zoster-associated pain. Herpes zoster, otherwise known as shingles, is an infection caused by the reactivation of varicella zoster virus or VZV, the cause of Chickenpox. We were incorporated in Delaware on May 15, 2013.

On December 18, 2014, we, and Chimerix, Inc.("Chimerix"), entered into a Licensing Agreement pursuant to which we licensed CMX157 from Chimerix for further clinical development and commercialization. CMX157 is a highly potent lipid analog of the antiviral drug tenofovir DF (Viread®). CMX157 is an oral prodrug of tenofovir. Prodrugs are designed to improve the characteristics of drugs, such as better efficacy, lower pill burden, improved safety, etc. Another prodrug of tenofovir, Viread®, is licensed for the treatment of HIV and HBV.

On June 10, 2016, we completed an acquisition of Ciclofilin Pharmaceuticals, Inc., a Delaware corporation ("Ciclofilin"), in accordance with certain Agreement and Plan of Merger dated May 26, 2016. At the closing of the Merger we acquired all of the outstanding equity interests in Ciclofilin in exchange for Ciclofilin having the right to receive future milestone payments. These milestone payments, if received, will be allocated among the holders of Ciclofilin common stock and certain creditors who converted their debt into equity immediately prior to the Closing. The milestone payments will consist of up to $17 million cash and up to 10% of ContraVir's issued and outstanding common stock as of June 10, 2016, and will be paid upon the achievement of certain developmental and/or regulatory milestones related to CRV431, Ciclofilin's lead development candidate.

CMX157

CMX157 is a lipid prodrug of tenofovir that utilizes a proprietary technology developed by Chimerix. The proprietary technology is utilized to covalently modify a drug molecule with a lipid side-chain that mimics a naturally occurring phospholipid component of cell membranes. The lipid-conjugated molecule can then utilize natural uptake pathways to achieve oral bioavailability, enhance uptake into cells, avoid many toxicities, and yield higher intracellular concentrations of drug with lower levels of free drug circulating in the blood. Chimerix tested CMX157 in a Phase 1 trial in 2010. It was a randomized, double blind, placebo controlled, single dose escalation study conducted in healthy volunteers. The purpose of the study was to evaluate the safety, tolerability, and pharmacokinetics of CMX157.

Data from the Phase 1 study showed that CMX157 was both safe and well tolerated. The data generated from the study support the notion that CMX157 may have a better safety profile than Viread® as the novel structure of CMX157 resulted in a high intracellular concentration of the active antiviral agent tenofovir diphosphate and decreased levels of circulating tenofovir, which means there is decreased potential for the renal and bone side effects associated with Viread® (TDF).

We have licensed CMX157 from Chimerix in exchange for an upfront payment of 120,000 shares of our preferred stock, valued at $1.2 million (time of the deal). We intend to develop CMX157 for the treatment of chronic HBV infection. A recently issued composition of matter patent for CMX157 provides intellectual property protection to at least 2031.

The decision to develop CMX157 for Hepatitis B has been taken because we do not see a large opportunity to grow the HIV market with new compounds, even though CMX157 is 200 times more potent than tenofovir in vitro. We believe the Hepatitis B market is poised for exceptional growth. CMX157 is 97 times more potent than TDF in vitro and thus potentially allows for a lower dose to achieve similar results in future head to head clinical studies. The lower dose may also

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allow for a better safety profile than TDF. The strategy for CMX157 is to develop the compound to serve as a critical backbone therapy in future HBV curative combination therapies.

We have completed a Phase 1b safety and pharmacokinetic study in 2016. Data from the Phase 1b study demonstrate that CMX157 was safe and well tolerated by healthy volunteers in all five dosing groups, receiving 5, 10, 25, 50 or 100 mg orally per day. In addition to demonstrating an excellent safety profile, plasma levels of CMX157 and tenofovir showed a favorable, dose-dependent pharmacokinetic profile. In 2016 we have also initiated a Phase 2a multiple ascending dose clinical trial. The study will enroll 60 treatment-naïve patients with chronic HBV infection and compare CMX157 to TDF. The sequential dose escalation consists of 10 patients per cohort receiving four weeks of a once-daily dose of either 5, 10, 25, 50 or 100 mg of CMX157, and two patients per cohort receiving 300 mg of TDF, the standard dose of TDF.

We will be seeking to submit an Investigational New Drug application ("IND") to support initiation of our HBV clinical development program at the beginning of 2017.

CRV431

CRV431 is a novel drug candidate designed to target a class of proteins called cyclophilins, of which there are many types. 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. And, specific host cyclophilins (e.g., cyclophilin A, B, C, D) play a role in the life cycle of certain viruses, including for example, HBV, HIV, and hepatitis C virus ("HCV") infections. CRV431 has been developed to inhibit the role of host cyclophilins and therefore interfere in the propagation of these viruses. 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. In a non-alcoholic steatohepatitis (NASH) mouse model, CRV431 demonstrated anti-fibrotic potential, thus addressing an important concern of the downstream effects of chronic HBV infection and liver disease. Both animal models confirmed that CRV431 is orally active and appeared to be well tolerated.

Market Opportunities

The hepatitis B virus (HBV) is a member of the hepadnavirus family that causes both acute and chronic liver infections. Transmission of the virus occurs by exposure to infected blood or bodily fluids, with the most typical modes being sexual contact, blood transfusion, re-use of contaminated syringes, and transmission from mother to child during childbirth.

Acute infection with the hepatitis B virus typically results in a loss of appetite, nausea, vomiting, body aches, mild fever, and jaundice. More than 90% of adults infected with the hepatitis B virus will recover and be completely free of the virus within six months. A vaccine to prevent hepatitis B infection has been available in the U.S. for over 30 years. It is administered as a series of three shots and is now believed to offer indefinite protection against infection (Van Damme *et al*., 2007). The vaccine is both safe and effective, with over one billion doses administered worldwide since its introduction, with less than 1% of vaccinated children developing chronic infection.

Nevertheless, it is estimated that approximately 350-400 million people worldwide have a chronic, lifelong infection. According to the World Health Organization, the likelihood of developing a chronic hepatitis B infection is highly dependent upon the age when the infection occurs (WHO fact sheet N°204):

- 80-90% of infants infected during the first year of life develop chronic infections;
- 30-50% of children infected before the age of six develop chronic infections;
- Less than 5% of otherwise healthy adults will develop chronic infection;

Chronic HBV infection is associated with significant morbidity and mortality. If left untreated, 15-40% of chronically infected individuals will develop serious complications, such as hepatitis B associated liver cirrhosis or cancer (AASLD, 2009). Globally, there were 750 thousand HBV-related deaths in 2010 (Lavancy 2004), primarily due to end stage liver disease and liver cancer. Complications due to chronic HBV infection currently represent 5% to 10% of cases of liver transplantation.

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Limitations of current therapies

Two different types of drugs are utilized in the treatment of chronic HBV infection: conventional or pegylated interferon alpha (INF or PEG-INF) and nucleoside/nucleotide analogs (NAs). Treatment is dependent upon: serum HBV DNA levels, serum ALT levels, and severity of liver disease. NAs available for the treatment of chronic HBV infection include:

- Nucleoside analogs: clevudine, emtricitabine, entecavir, lamivudine, telbivudine
- Nucleotide analogs: adefovir and tenofovir.

NAs are quite effective at inhibiting HBV replication; however, these treatments are not curative and require lifelong dosing. With the exception of tenofovir and entecavir, long-term treatment with these NAs is associated with a high risk of developing drug resistance. Entecavir is less effective in patients who had previously been treated with lamivudine (PI), a widely used treatment for HBV. Long-term treatment with the currently licensed prodrug of tenofovir, Viread®, is associated with kidney and bone and toxicity (Scaglione et al., 2012)(PI).

Tenofovir is a NA inhibitor of reverse transcriptase, an enzyme that has diverse functions during HBV replication (Jones et al., 2013). Tenofovir was originally synthesized in the mid 1980's and was initially shown to have anti-HIV activity. However, due to its very limited bioavailability, the compound did not have the potential for widespread use. Tenofovir disoproxil fumarate (TDF) is a prodrug of tenofovir that was developed to allow for oral administration. TDF was approved by the FDA for the treatment of HIV in 2001 and for the treatment of chronic HBV infection in 2008. The drug is marketed under the name Viread® by Gilead Sciences, or Gilead. Gilead has developed tenofovir alafenamide fumarate (TAF) as a follow-on compound to TDF. In both HIV and HBV clinical studies, TAF exhibits similar antiviral activity to TDF but at much lower concentrations of tenofovir in the blood. The lower blood concentration of tenofovir following metabolism of TAF supports the notion that kidney and bone toxicity will be reduced compared to treatment with TDF (Ruane et al., 2013, Agarwal et al., 2015 and Sax et al., 2015). Gilead has tested TAF in clinical trials for chronic HBV and its NDA is currently under review with the FDA.

A critical limitation of current therapies is the inability to achieve control of the infection in the vast majority of patients without lifelong treatment. HBV exists in the liver as viral cccDNA. The infected person is unable to eliminate this persistent form of the virus despite available therapies. This underscores the need for combination therapy with new classes of agents to eradicate HBV. New mechanisms of action are being identified to attack the virus at different parts of its lifecycle. Combinations of agents with complimentary mechanisms of action that attack the virus at different parts of its lifecycle will be needed to achieve a cure. It is our intention to develop CMX157, the prodrug of a well established anti-HBV nucleotide analog, tenofovir, to be a pivotal component of a curative combination therapy for HBV.

The drive to find meaningful combination therapy for the treatment of chronic HBV infection stems from the generally accepted principle that a functional cure should address: 1) reduction of HBV DNA; 2) reduction in expression of HBeAg and HBsAg; 3) development of anti-HBsAg antibodies; and 4) reduction/elimination of cccDNA. CMX157 has been primarily developed to reduce HBV DNA (viral load). Layering CRV431 on top of CMX157 is a strategy that begins to address this need for combination therapy to target multiple stages of the HBV life cycle, as preliminary findings indicate CRV431 suppresses HBV DNA and suppresses both HBeAg and HBsAg.

License Agreement

Under the terms of the License Agreement, we licensed CMX157 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.

FV-100

FV-100 is an orally available, small molecule nucleoside analogue prodrug of CF-1743 that we are developing for the prevention of post-herpetic neuralgia (PHN) and treatment of herpes zoster infection and acute zoster-associated pain. Herpes zoster, otherwise known as shingles, is an infection caused by the reactivation of varicella zoster virus or VZV. VZV is responsible for producing the infectious disease known as chicken pox in individuals upon initial exposure to the virus. After the initial infection, the virus can remain dormant in nerve cells for many years and if reactivated, causes a painful rash

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called shingles. FV-100 is being developed specifically for the prevention of post-herpetic neuralgia and treatment of acute herpes zoster associated pain. Nucleoside analogs are capable of disrupting replication of the virus. FV-100 is a pro-drug of CF-1743, which enables us to take advantage of FV-100's more rapid absorption compared to CF-1743 when taken orally. Published preclinical studies demonstrate that FV-100 is significantly more potent against VZV than currently marketed compounds acyclovir, valacyclovir, and famciclovir, the FDA-approved drugs used for the treatment of shingles. Preclinical studies, including wash-out studies in VZV-infected human embryonic lung cells following exposure to FV-100 or acyclovir, conducted by Inhibitex Inc., or Inhibitex, and specific cellular antiviral activity experiments comparing FV-100 to acyclovir conducted by Balzarini et al (Biochim Biophys Acta . 2002 Jul 18; 1587(2-3):287-95. Chemotherapy of varicella-zoster virus by a novel class of highly specific anti-VZV bicyclic pyrimidine nucleosides (Balzarini J 1, McGuigan C.) further demonstrate that FV-100 has a more rapid onset of antiviral activity, and may fully inhibit the replication of VZV more rapidly than these drugs at significantly lower concentration levels. In addition, pharmacokinetic data from completed Phase 1 and 2 clinical trials suggest that FV-100 has the potential to demonstrate antiviral activity when dosed orally once-a-day at significantly lower blood levels than valacyclovir, acyclovir, and famciclovir.

A Phase 2 clinical trial for FV-100 in shingles patients was conducted by Inhibitex and completed in December 2010. This trial represented the first evaluation of FV-100 in shingles patients, and was a well-controlled double blind study comparing two different doses of FV-100 to an active control dose of valacyclovir. A total of 350 patients, aged 50 years and older, were enrolled in one of three treatment arms: 200 mg FV-100 administered once daily; 400 mg FV-100 administered once daily; and 1,000 mg valacyclovir administered three times per day. In addition to further evaluating its safety and tolerability, the main objectives of the trial were to evaluate the potential therapeutic benefit of FV-100 in reducing the severity and duration of shingles-related pain, the incidence of PHN (pain that follows healing of the shingles rash), and the time to lesion healing.

We conducted an extensive review of the clinical data from the completed Phase 2 trial. We also conducted additional market research (including unmet medical need), reimbursement, pricing, and competitive landscape analyses, etc. Based upon these comprehensive analyses, we had an End of Phase 2 (EoP2) meeting with the FDA from which we were allowed to have FV-100 enter a Phase 3 clinical trial without the need to conduct any additional dose-range finding Phase 2 studies. In parallel to the Phase 3 initiation during the second quarter of 2015, Study 008, a drug-drug interaction trial was conducted during January-March, 2015. The study's objective was to highlight any potential drug interactions with compounds which are metabolized using the liver's CYP450 pathway. This is a very common trial in virology and in drug development overall.

We are currently conducting a Phase 3 study that will compare FV-100 to valacyclovir (Valtrex®) with the reduction in the incidence of shingles-associated pain, PHN, as a primary endpoint. It is a multi-center, randomized, double-blind, parallel-group, comparative study in up to 200 centers in the U.S. The study is comprised of three arms: FV-100 400mg QD, FV-100 400mg BID, and valacyclovir 1000mg TID. Approximately 825 patients are expected to be analyzed for a seven-day treatment period, and follow up through day 120.

Market Opportunity for the Treatment of Shingles

VZV, a DNA virus and a member of the herpes virus group, is the virus that causes both chickenpox and herpes zoster, or shingles. Chickenpox, the initial infection caused by VZV in an individual, generally occurs during childhood and it is caused by exposure to another individual with an active infection. After the chickenpox infection subsides, VZV remains latent in the individual's nerves including dorsal root and cranial nerve ganglia, and can re-emerge later in life. The majority of shingles patients experience pain for several weeks in connection with their active infection. For many patients, the shingles-associated pain does not resolve when the lesions heal and continues for months, possibly years. Shingles-associated pain that persists more than three months is referred to as post-herpetic neuralgia ("PHN") which is the most common and clinically relevant complication of shingles. Approximately 15-20% of all shingles patients experience PHN, although the incidence of PHN is more prevalent in patients over 50 years of age.

Although shingles can occur in any individual with a prior VZV infection, its incidence varies with key risk factors, which are advanced age, immune status and being female. Shingles is largely a disease of the aged or aging, with over 50% of all cases occurring in individuals over the age of 60, and approximately 80% occurring in individuals over the age of 40. A study in 2007 based upon data from 2000 implied that there were approximately 1 million new shingles cases that year. Due to the aging of the population in many industrialized countries, as well as the increasing use of immunosuppressive agents in transplant patients, patients receiving immune suppressants for autoimmune diseases such rheumatoid arthritis and the increased numbers of immunosuppressed patients from cancer therapy, the incidence of shingles has increased and is expected to continue to rise. A recent study from the Centers for Disease Control investigating medical claims data from MarketScan® databases from 1993-2006 indicated that the crude incidence of shingles cases increased 259% over that period

of time. Furthermore, a study conducted by the Mayo Clinic suggests that the recurrence rate for shingles is approximately 6.2%, which reflects a much higher rate than prior studies which assessed a shorter follow-up period. It is estimated that approximately 20-30% of all persons in the U.S. will suffer from shingles at some point during their lifetime.

Valacyclovir, acyclovir and famciclovir are oral antivirals currently approved by the FDA, and regulatory agencies in many other countries, for the treatment of shingles. These generically available drugs are referred to as "pan-herpetic" drugs, as they are used to treat infections caused by various herpes viruses, including herpes simplex 1 and 2, and VZV. Unlike those drugs, FV-100 only demonstrates antiviral activity against VZV, and not the other herpes viruses. Based upon an analysis by data compiled by IMS Health, Inc. ("IMS") on our behalf, and a recent utilization study of the use of Valtrex® from 1994-2009 conducted by the FDA as well as other market research we have independently conducted, we estimate that 15-30% of the nearly 17 million retail prescriptions written for valacyclovir, acyclovir and famciclovir combined in 2009 were for the treatment of herpes zoster.

Limitations of Current Therapies

Data from various clinical trials conducted in the 1990's demonstrate that a seven day administration of valacyclovir, acyclovir, or famciclovir, beginning within 72 hours from the first appearance of a shingles-related rash or lesion, can lessen the duration of the dermatological symptoms associated with shingles and the average duration of shingles-related pain. However, these currently approved antiviral drugs, when used to treat shingles, have a number of limitations, including the following:

- *No Approved Label for the Reduction of shingles-Associated Pain and PHN.* Currently, there are no antiviral therapies indicated for the reduction of shingles-related pain or the prevention PHN. There is also no cure for PHN *per se*; rather, treatment of PHN is accomplished through analgesics, narcotics and pain management. The most commonly prescribed medications to treat PHN are opioids, antidepressants, anticonvulsants, or topical lidocaine or capsaicin patches. Previously published clinical data demonstrate that antiviral therapy can reduce the duration of shingles-related pain, and we believe a more potent, faster acting anti-VZV compound, such as FV-100, has the potential to more rapidly inhibit the replication of VZV, thus reducing shingles-related nerve damage and further reducing shingles-associated pain and PHN. We believe an antiviral therapy that can further reduce the severity and/or duration of shingles-associated pain and the prevalence of PHN may have a competitive advantage relative to the currently available shingles therapies.

- *Inconvenient Dosing.* Due to their pharmacokinetic properties and lower potency against VZV, current pan-herpetic oral antiviral therapies require shingles patients to take three to five oral doses each day for seven to ten days. Specifically, current dosing regimens for the treatment of shingles are as follows: valacyclovir—1,000 mg, three times per day; famciclovir—500 mg, three times per day; and acyclovir—800 mg, five times per day. Such dosing regimens are inconvenient and can result in non-compliance since patients tend to forget to take multiple doses, particularly if more frequent than twice daily, resulting in less than optimal treatment outcomes. We believe that an effective therapy that can be administered via a more convenient, once-a-day oral administration may have a competitive advantage relative to current shingles therapies.

- *The Dosage of Currently Available Antiviral Drugs for shingles Must be Adjusted for Patients with Insufficient Renal Function.* Although current pan-herpetic oral antiviral therapies have been shown to be generally safe and well tolerated in shingles patients, dosing of valacyclovir, famciclovir and acyclovir must be adjusted for certain patients with insufficient renal (kidney) function to avoid potential adverse events. Preclinical and clinical data to-date suggests that FV-100 is primarily

metabolized and excreted via the liver and not through the kidney. Accordingly, we currently believe that the dosing of FV-100 will not need to be adjusted for patients with insufficient renal function. We believe that an oral antiviral therapy that has a similar or better safety profile to valacyclovir, famciclovir and acyclovir, and is not required to be adjusted for patients with insufficient renal function, may have a competitive advantage over currently approved shingles therapies.

We believe there is a significant unmet medical need for a more potent, faster acting, low dose once-daily oral antiviral agent, such as FV-100, which has the potential to further reduce the incidence, severity, and duration of shingles-associated pain and prevent PHN.

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FV-100 Clinical Trials

Prior to the formation of our company, the following clinical trials were completed.

Phase 1.

In August 2008, a FV-100 Phase 1 single-ascending-dose clinical trial was completed in August 200. The blinded, placebo-controlled trial evaluated the safety and pharmacokinetics of four doses of FV-100 in six cohorts of healthy volunteers (100, 200, 400, and 800 mg, as well as a two 400 mg food effect groups). Each cohort consisted of six subjects that received FV-100 and two that received placebo. There were no serious adverse events observed and the compound appeared to be generally well tolerated in the trial. In addition, pharmacokinetic data demonstrated that all doses evaluated in the trial maintained plasma levels of CF-1743, the active form of FV-100, which exceeded its EC50 for at least 24 hours. The EC 50 represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*

In January 2009, a blinded, placebo-controlled Phase 1 trial conducted by Inhibitex was completed to evaluate single and multiple doses of FV-100 in healthy subjects 65 years of age and older. One dose cohort consisted of 12 healthy subjects, ten of whom received a single administration of 400 mg of FV-100 and two of whom received placebo, and the second cohort also consisted of 12 healthy subjects, ten of whom received 400 mg of FV-100 administered twice daily for seven consecutive days and two of whom received placebo. The results of this trial demonstrated no significant safety differences between these subjects and those from the multiple ascending dose trial.

In February 2009, a Phase I trial was completed by Inhibitex. The trial, a blinded, placebo-controlled multiple-ascending-dose study, was designed to evaluate the safety and pharmacokinetics of five oral doses of FV-100 (100, 200, 400 and 800 mg administered once daily and 400 mg administered twice daily, each for seven days) in healthy subjects aged 18 to 55. Each dose cohort consisted of six subjects that received FV-100 and two that received placebo. The results of the trial demonstrated that there were no serious adverse events and FV-100 appeared to be generally well tolerated at all dose levels. Further, pharmacokinetic data demonstrated that all doses studied maintained mean plasma levels of CF-1743, the active form of FV-100, which exceeded its EC 50 for at least 24 hours, supporting the evaluation of once-daily dosing of FV-100 in future clinical trials.

Phase 2.

A Phase 2 clinical trial of FV-100 was completed by Inhibitex in December 2010. The trial was a well-controlled, double-blind study comparing two different doses of FV-100 to an active control (valacyclovir). A total of 350 patients, aged 50 years and older who had shingles-associated pain and presented to the clinic within 72 hours of appearance of their first shingles lesion, were equally randomized to one of three treatment arms: 200 mg FV-100 administered once-daily for seven days; 400 mg FV-100 administered once-daily for seven days; or 1,000 mg valacyclovir administered three times per day for seven days. In addition to further evaluating its safety and tolerability, the objectives of the trial were to evaluate the potential therapeutic benefit of FV-100 in reducing: (i) the severity and duration of shingles-associated pain, (ii) the incidence of PHN, (iii) the time to lesion crusting and healing, and (iv) the use of concomitant pain medications, as compared to valacyclovir.

The primary endpoint for the Phase 2 study was a 25% reduction in the severity and duration of shingles-related pain during the first 30 days as compared to valacyclovir. The results obtained from the study did not demonstrate a statistically significant reduction. Shingles patients who received 200 mg or 400 mg FV-100 experienced numerically favorable treatment differences as compared to patients treated with valacyclovir. Both doses of FV-100 resulted in lower incidences of PHN when compared to valacyclovir. For patients receiving valacyclovir, the time to lesion crusting was faster than those patients receiving FV-100; however, no differences were noted among the treatment arms on time to full lesion healing. The three treatment arms were well-balanced with regard to demographics and baseline shingles-associated pain levels.

FV-100 Safety Summary

Adverse events, ("AE"), means any reported sign or symptom reported by the patient that began following the initiation of therapy. Serious adverse events ("SAE") means any adverse event that is life threatening, requires hospitalization or is considered a significant clinical event according to the treating physician.

A comparison of AE and SAE among the three treatment arms in the Phase 2 trial demonstrated that the overall tolerability and side effect profile of both doses of FV-100 was comparable to valacyclovir.

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License Agreement

The FV-100 assets acquired from BMS are licensed from Cardiff pursuant to the terms of that certain Patent and Technology License Agreement, dated as of February 2, 2005, between Cardiff and CRI, an entity with no prior relationship with us, as amended March 27, 2007, or the Cardiff Agreement.

The Cardiff Agreement shall remain in full force and effect until the date upon which the last of the last patent or the last continuation or extension to any patents within the Patent Rights (as defined in the Cardiff Agreement) expires. Any milestone and/or royalty payment under the Cardiff Agreement shall be payable for as long as the Cardiff Agreement is in effect. The Cardiff Agreement may be terminated in its entirety, for among other reasons and in the following manner as set forth below: (a) automatically by Cardiff, if we become bankrupt or insolvent and/or if our business shall be placed in the hands of a receiver, assignee, or trustee; (b) upon ninety (90) calendar days written notice from Cardiff, if we breach or default (i) on the payment or report obligations or use of name obligations or (ii) on any other obligation under the Cardiff Agreement, subject to a ninety (90) calendar-day cure period; (c) if we have defaulted or been in excess of one (1) month late on its payment obligations pursuant to the terms of the Cardiff Agreement on any two (2) occasions in a twelve (12) month period, subject to a cure period; (d) upon one hundred twenty (120) calendar days written notice from us if any particular patent or patents included in Patent Rights and which account for at least thirty (30%) percent of the total royalty to Cardiff, is or are irrevocably adjudicated to be invalid; or (e) upon ninety (90) calendar days written notice from us if Cardiff is in breach of Section 11.1 (Confidential Information and Publication) unless, before the end of the such ninety (90) calendar-day notice period, Cardiff has cured the default or breach to our reasonable satisfaction and so notifies us, stating the manner of the cure.

The terms of the Cardiff Agreement provided in consideration for a license of all of Cardiff's rights in any technical information, know-how, processes, procedures, compositions, devices, methods, formulae, protocols, techniques related to the FV-100 Assets, or the Patent Rights. The Cardiff Agreement provided for an initial base payment of $270,000, which has previously been paid by CRI, subsequent milestone payments covering (i) initiation of a clinical trial at each phase, (ii) marketing (FDA) approval and (iii) on achieving the milestone of aggregate net sales in three different tiers, as well as a low single digit royalty based on net sales. The total aggregate amount of milestone payments that could be payable to Cardiff by us under the Cardiff Agreement is equal to $400,000.

The terms of the BMS Agreement provided for an initial base payment of $1 million, subsequent milestone payments covering (i) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales. The total aggregate amount of milestone payments that could be payable to BMS under the BMS Agreement is equal to $9 million. The duration of any milestone payment obligation owed to BMS shall continue until the earliest of (i) payment, in full, of all milestone payments as required under the BMS Agreement, (ii) our determination using commercially reasonable standards consistent with the exercise of prudent scientific and business judgment and consistent with those standards used by us for its other therapeutic products at a similar stage of development and with similar commercial potential, to terminate the development of the FV-100 assets, and (iii) the tenth (10th) anniversary of the date of the BMS Agreement, The duration of any royalty payment obligation to BMS shall commence on the date of the first commercial sale of the FV-100 assets in a country until the expiration of any claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction of any of our patents or any other patent covering the use or sale of the FV-100 assets in such country. The transactions contemplated by the BMS Agreement closed on August 17, 2012 and neither party can terminate the remaining obligations owed under the BMS Agreement.

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, 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.

Pursuant to the Contribution Agreement, entered into between us and Synergy on August 5, 2013, Synergy transferred ownership of all intellectual property rights acquired from BMS, including all historical research, clinical study protocols, data, results and patents related to the FV-100 assets as well as assumed the obligations of Synergy, including all liabilities of Synergy, under the BMS Agreement. These obligations include among other things, (i) all liabilities of BMS and Synergy related to the FV-100 assets, including all accounts payable, legal, environmental, tax, or warranty claims and all other liabilities of Synergy of whatever kind and nature, direct or indirect, absolute or contingent, known or unknown, whether or not accrued, arising out of or relating to the FV-100 assets or the ownership, sale or lease of any of the FV-100 assets, including any claim, action, suit, arbitration, inquiry, proceeding or investigation by or before any governmental entity, and (ii) the payment of any milestone or royalty payment to BMS under the BMS Agreement. During the period August 17, 2012 through June 10, 2013, there were no material liabilities assumed by Synergy under the BMS Agreement and subsequently transferred to us pursuant to the Contribution Agreement.

The FV-100 assets acquired by us from Synergy are licensed from Cardiff pursuant to the terms of the Cardiff Agreement which we assumed from Synergy. Cardiff and Rega Foundation ("Rega") were originally the joint owners of the Patent Rights. Pursuant to the terms of an agreement, dated September 24, 1998, as amended December 23, 2004, Cardiff received from Rega an exclusive, irrevocable worldwide license to manufacture, use, sell, or otherwise deal in or with products utilizing the Patent Rights, including the right to grant sublicenses thereunder. Synergy assumed the obligations under the Cardiff Agreement from BMS pursuant to the terms of the BMS Agreement. BMS assumed the obligations under the Cardiff agreement from Inhibitex upon its acquisition of Inhibitex in January 2012. Inhibitex assumed the obligations under the Cardiff Agreement upon its acquisition of FermaVir Pharmaceuticals, Inc. ("FermaVir") in September 2010. FermaVir was the successor to CRI in a merger consummated in August 2005. As of June 30, 2014, we currently license from Cardiff the three issued United States patents related to FV-100 which we acquired from Synergy pursuant to the Contribution Agreement. One of these patents covers the composition-of-matter of FV-100 and was issued on December 11, 2012 and will expire in 2028. The other two cover the precursor and close analogs of FV-100 and were issued on October 26, 2001 and June 3, 2003 and will both expire in 2018. In addition we currently license from Cardiff 38 granted foreign patents which cover composition-of-matter of FV-100 and expire in 2027. These foreign patents cover Australia, Austria, Belgium, Bulgaria, China, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Monaco, Netherlands, New Zealand, Pakistan, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Turkey, United Kingdom and the Russian Federation. We also own 5 pending foreign applications which cover the composition of matter of FV-100. We also own 45 additional foreign patents that cover the precursor and close analogs of FV-100. We also currently license from Cardiff 6 foreign applications and 1 US application pending, which cover the FV-100 process and polymorph composition.

The CMX-157 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 CMX-157. 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 CMX-157. One of these patents covers a composition of matter of a stable crystalline salt of CMX-157 and was issued on

April 14, 2015 and will expire in 2031. The other United States patent covers methods of use of CMX-157 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 CMX-157 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 CMX-157 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 CMX-157. We also directly license from Chimerix 21 additional pending foreign patent applications and 4 pending US patent applications which cover methods of use of CMX-

157. 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 CMX-157. Four of the issued patents cover a composition of matter of CMX-157 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 CMX-157 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 CMX-157 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.

On June 13, 2016 we completed our merger with Ciclofilin Pharmaceuticals, Inc. ("CPI") acquiring all of its outstanding equity interests. Ciclofilin's lead asset is CPI-431-32, which is in development against hepatitis B virus (HBV). CPI-431-32 strengthens ContraVir's HBV portfolio, which also contains CMX157, a highly potent HBV antiviral that works through a complementary mechanism. On February 14, 2014, CPI, through its wholly owned subsidiary 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") including a royalty of 2.5% of net sales by CPC or its licensee(s). The amount payable under the foregoing royalty obligation is uncapped.

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

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

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to

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develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable n 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 FV-100, CMX157, 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

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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,

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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

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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

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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 the company 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,

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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.

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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 June 30, 2016, we had fifteen 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 339 Thornall Street, First Floor, Edison, New Jersey. Our telephone number is (732) 902-4000.

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.

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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 June 30, 2016 and 2015, we had an accumulated deficit of $44.6 and $27.6 million, respectively. We expect to incur significant and increasing operating losses for the next several years as we expand our research and development efforts, 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, our independent registered public accounting firm has included in its report an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. 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 proposed 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;

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- 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 prospects are partially dependent on the success of FV-100, which was the subject of a Phase II clinical trial that failed to meet its primary endpoints. FV-100 has now moved into a Phase III, pivotal trial program. While we seek to improve the clinical results with the Phase II program there is the possibility that the results on our FV-100 product candidate may or may not lead to other potential strategic pathways; there can be no assurance we will be able to successfully advance or develop our FV-100 product candidate and if we are unable to further develop or obtain regulatory approval, our business will be materially harmed.

In December 2010, Inhibitex, a previous owner of the FV-100 assets, announced that in a pivotal Phase II clinical trial of FV-100, an oral antiviral compound being developed to treat herpes zoster, more commonly referred to as shingles, failed to meet its primary endpoint. Since we received the FV-100 assets from Synergy, we have not engaged in any clinical study of FV-100 or materially advanced the development of FV-100. We are currently conducting various analyses of our preclinical and clinical data related to FV-100, as well as analyzing the various lots of clinical trial material used in the Phase II trials in an effort to determine whether the results of the Phase II trial were a consequence of one or more factors, including the potency and consistency of the clinical trial material, the change in the dosing schedule, and selection of the patient population studied and the appropriateness of the primary efficacy endpoint used in the clinical trial to determine the effectiveness of the treatments. If we are unable to successfully advance or develop our FV-100 product candidate, it will have a material adverse effect on our business.

Our product candidate CMX157 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;

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- 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 actual or perceived therapeutic benefits of FV-100 are not sufficiently different from existing generic drugs currently used to treat shingles or reduce or prevent shingles-associated pain and PHN, we may terminate the development of FV-100 at any time, or our ability to generate significant revenue from the sale of FV-100, if approved, may be limited and our potential profitability could be harmed.

Valacyclovir, famciclovir and acyclovir are existing generic drugs currently marketed to treat shingles patients. Generic drugs are compounds that have no remaining patent protection, and generally have an average selling price substantially lower than drugs that are protected by patents and intellectual property rights. Unless a patented drug can differentiate itself from generic drugs treating the same condition or disease in a clinically meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on patented drugs. Accordingly, if at any time we believe that FV-100 may not provide meaningful therapeutic benefits, perceived or real, over these existing generic drugs, we may delay or terminate its future development. We cannot provide any assurance that later-stage clinical trials of FV-100 will demonstrate any meaningful therapeutic benefits over existing generic drugs sufficient to justify its continued development. Further, if we successfully develop FV-100 and it is approved for sale, we cannot assure you that any real or perceived therapeutic benefits of FV-100 over generic drugs will result in it being, accepted for sale by insurance company or hospital formularies, prescribed by physicians or commanding a price higher than the existing generic drugs.

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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

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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. To the best of our knowledge, the following companies are potential competitors as we develop FV-100: Epiphany Biosciences, Inc., Astellas Pharma US, Inc., GlaxoSmithKline plc and Janus Pharmaceuticals, Inc. Specifically, we are aware that valomaciclovir is being developed by Epiphany Pharmaceuticals and has completed Phase IIb clinical trials for VZV infections. To our knowledge, other potential competitors are in earlier stages of development for VZV infections. 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 FV-100.

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.

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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 lead product candidates, FV-100 and CMX157, 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 James Sapirstein, our Chief Executive Officer. The loss of services of Mr. Sapirstein or one or more of our other members 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.

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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.

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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, as a newly formed entity, 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.

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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.

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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, FV-100 intends to compete with at least 4 currently approved prescription therapies for the treatment of shingles, acyclovir, valacyclovir and famiciclovir. In addition, Zostavax®, a live attenuated varicella zoster virus VZV vaccine, is available and may reduce the overall incidence of shingles. We also believe other companies are developing products that will compete with FV-100 should they be approved by the FDA. For example, valomaciclovir is being developed by Epiphany Pharmaceuticals and has completed Phase IIb clinical trials for VZV infections. To our knowledge, other potential competitors are in earlier stages of development. If potential competitors are

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successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for FV-100.

If approved and commercialized, CMX157 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 CMX157.

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 FV100 and CMX157, 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 FV-100 or other 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.

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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.

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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, FV-100, CMX157, 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. For example, FV-100 may compete with products for the treatment shingles, shingles-associated pain and the prevention of post-herpetic neuralgia. Some of the large pharmaceutical companies that currently market products that would compete with our product candidates, if approved, include, but are not limited to multiple large generic companies such as GlaxoSmithKline and Merck.

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.

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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.

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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.

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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.

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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

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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 USPT 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 Cardiff or Chimerix Agreements, each 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 Cardiff and Chimerix. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under the Agreements. The Agreements provide 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 FV100 and CMX157 assets. The loss of our license with Cardiff with respect to the FV100 assets, and potentially 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 Cardiff, BMS, and Chimerix Agreement each 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.

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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 receives regulatory approval, it may still face future development and regulatory difficulties.

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

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

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

In the future, we may seek to commercialize our product 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

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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 15 employees as of June 30, 2016. 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,

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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.

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.

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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 June 30, 2016 and 2015 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 June 30, 2016 and 2015, our management has determined that we had material weaknesses in our control environment and in the period end financial close and reporting process. If additional material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our Common Stock could drop significantly.

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

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

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- 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.

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.

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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 $1.0 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 FV100 and CMX157. 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.

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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 4,000 square feet of leased space at 399 Thornall Street, First Floor, Edison, New Jersey, 08837.

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.

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PART II

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

Market Information and Holders

As of February 27, 2015, our common stock began trading on The NASDAQ Capital Market under the symbol "CTRV." Prior to that date, our common stock was traded on the Over-the-Counter Bulletin Board, or OTCBB, under the symbol "CTRV." Prior to February 18, 2014, there was no public market for our common stock. The closing price of our common stock on The NASDAQ Capital Market on September 16, 2016 was $1.18 per share.

Fiscal 2016	High	Low
Fourth Quarter	$ 1.18	$ 0.82
Third Quarter	$ 1.74	$ 0.88
Second Quarter	$ 4.72	$ 1.51
First Quarter	$ 5.75	$ 2.09

Fiscal 2015	High	Low
Fourth Quarter	$ 5.13	$ 3.00
Third Quarter	$ 5.15	$ 1.76
Second Quarter	$ 2.65	$ 0.65
First Quarter	$ 1.75	$ 0.91

Holders of Record

As of September 16, 2016, there were approximately 464 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 June 30, 2016.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))
Equity Compensation Plans Approved by Stockholders	5,204,478	$ 1.59	1,295,522
Equity Compensation Plans Not Approved by Stockholders	—	—	—
Total	5,204,478	$ 1.59	1,295,522

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Business Overview

We are a biopharmaceutical company focused on the development of antiviral drugs with a primary emphasis on the treatment of Hepatitis B virus ("HBV") infections. We are developing two compounds to treat HBV infection, CMX157 and CRV431. CMX157 is a highly potent oral lipid prodrug of tenofovir. Prodrugs are designed to improve the characteristics of drugs, such as better efficacy, lower pill burden, improved safety, etc. Another prodrug of tenofovir, Viread®, is approved for the treatment of HIV and HBV infections. CRV431 is a novel drug candidate also designed for the treatment of HBV infection. CRV431 is a novel drug candidate also designed for the treatment of HBV infection. CRV431, a non-immunosuppressive analog of cyclosporine that we acquired through our merger with Ciclofilin Pharmaceuticals Inc. CRV431 has been designed to target enzymes ("cyclophilins") that play a key role in the HBV viral life cycle. We are also developing an antiviral asset known as FV-100, FV-100 is an orally available, small molecule compound being developed for the prevention of post-herpetic neuralgia (PHN) and treatment of herpes zoster infection and acute zoster-associated pain. Herpes zoster, otherwise known as shingles, is an infection caused by the reactivation of varicella zoster virus or VZV, the cause of Chickenpox.

CMX 157

CMX157 is a novel lipid acyclic nucleoside phosphonate that delivers high intracellular concentrations of the active antiviral agent tenofovir diphosphate. CMX157's novel structure results in decreased circulating levels of tenofovir (TFV), lowering systemic exposure and thereby reducing the potential for renal side effects. It has completed a Phase 1 clinical trial in healthy volunteers, demonstrating a favorable safety, tolerability and drug distribution profile. We intend to develop CMX157 for Hepatitis B (HBV).

We have licensed CMX157 from Chimerix in exchange for an upfront payment of 120,000 shares of our preferred stock, valued at $1.2 million (time of the deal). We intend to develop CMX157 for the treatment of chronic HBV infection. We are planning to meet with the FDA to discuss an appropriate clinical plan for CMX157 and to initiate a Phase 2 clinical trial testing the compound in HBV patients in the next 12-18 months. A recently issued composition of matter patent for CMX157 provides intellectual property protection to at least 2031.

The decision to develop CMX157 for Hepatitis B has been taken because we do not see a large opportunity to grow the HIV market with new compounds, even though CMX157 is 200 times more potent than tenofovir in vitro. We believe the Hepatitis B market is poised for exceptional growth. CMX157 is 4.5 times more potent than PDFtenofovir in vitro and thus potentially allows for a lower dose to achieve similar results in future head to head clinical studies. The lower dose may also allow for a better safety profile than TDF. The strategy for CMX157 is to develop the compound to serve as a critical backbone therapy in future HBV combination therapies. We will be seeking to submit an Investigational New Drug application ("IND") to support an initiation of our HBV clinical development program at the end of 2015.

CRV 431

CRV431 is a novel drug candidate designed to target a class of proteins called cyclophilins, of which there are many types. 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. And, specific host cyclophilins (e.g., cyclophilin A, B, C, D) play a role in the life cycle of certain viruses, including for example, HBV, HIV, and hepatitis C virus ("HCV") infections. CRV431 has been developed to inhibit the role of host cyclophilins and therefore interfere in the propagation of these viruses. CRV431 does not directly target the virus and, as such, should be less susceptible to drug resistance, borne from viral mutations.

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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. In a non-alcoholic steatohepatitis (NASH) mouse model, CRV431 demonstrated anti-fibrotic potential, thus addressing an important concern of the downstream effects of chronic HBV infection and liver disease. Both animal models confirmed that CRV431 is orally active

and appeared to be well tolerated.

FV-100

FV-100 is an orally available, small molecule, nucleoside analogue pro-drug of CF-1743 that we are developing for the treatment of herpes zoster, which is an infection caused by the reactivation of varicella zoster virus or VZV. VZV is responsible for producing the infectious disease known as chicken pox in individuals upon initial exposure to the virus. After the initial infection, the virus can remain dormant in nerve endings for many years and if reactivated, causes a painful rash called shingles. FV-100 is being developed specifically for the treatment of shingles. Nucleoside analogs are capable of disrupting replication of the virus. FV-100 is a pro-drug of CF-1743, which enables us to take advantage of FV-100's more readily absorbed properties compared to CF-1743 when given orally. FV-100 is then broken down to the active moiety, CF-1743, upon entry into the blood stream. Published preclinical studies demonstrate that FV-100 is significantly more potent against VZV than currently marketed compounds acyclovir, valacyclovir, and famciclovir, the FDA-approved drugs used for the treatment of shingles. We conducted an extensive review of the clinical data from the completed Phase 2 trial, including performing post-hoc analyses. We performed additional market research (including unmet medical need), reimbursement, pricing, and competitive landscape analyses, etc. We also evaluated a number of clinical, regulatory and commercial pathways for the potential future development of FV-100. Based upon the analyses of the completed Phase 2 study coupled with the additional market research, we approached the FDA to discuss our clinical development program and requested an End of Phase 2 (EoP2) meeting. The meeting was granted and the result was a streamlined development plan for FV-100 that allowed us to proceed directly into a Phase 3 trial without the need to conduct any additional Phase 2 studies. We had satisfied these criteria and initiated Protocol 007 during 2Q/2015.

In parallel to the Phase 3 initiation, Study 008, a drug-drug interaction trial was conducted during January-March, 2015. The study's objective was to highlight potential drug interactions with compounds which are metabolized using the CYP450 pathway. This is a very common trial in virology and in drug development overall.

FINANCIAL OPERATIONS OVERVIEW

From inception through June 30, 2016, we have an accumulated deficit of approximately $44.6 million. From inception through June 30, 2016, we have not generated any revenue from operations and expect to incur additional losses to perform further research and development activities and do not currently have any commercial biopharmaceutical products. We do not expect to have such for several years, if at all.

On February 4, 2014, we entered into a securities purchase agreement with accredited investors to sell securities and raise gross proceeds of $3,225,000 in a private placement and incurred expenses of approximately $15,000 related to this placement. We sold 9,485,294 units to the investors with each unit consisting of one share of our common stock and one warrant to purchase an additional one half share of our common stock. The purchase price paid by the investor was $0.34 for each unit. The warrants expire after six years and are exercisable at $0.37 per share. On August 20, 2014, the warrants were exchanged for common stock.

On October 14, 2014, we closed a private offering of Series A Convertible Preferred Stock (the "Series A") and issued 900,000 shares of Series A preferred at $10.00 per share, generating gross proceeds of approximately $9,000,000. We also granted the purchaser the option to purchase up to an additional 350,000 shares of Series A prior to February 28, 2015. The Series A are classified as permanent equity in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity*. We issued an additional 50,000 shares of Series A preferred at $10.00 per share on December 23, 2014, an additional 30,000 shares of Series A preferred at $10.00 per share on February 10, 2015 and an additional 270,000 shares on February 26, 2015, generating aggregate gross proceeds of $3,500,000.

On December 17, 2014, we issued 120,000 of Series B Convertible Preferred Stock (the "Series B") in exchange for an exclusive license for further clinical development and commercialization of CMX157 from Chimerix, Inc.

On October 7, 2015, we entered into an underwriting agreement related to the public offering and sale of 5,000,000

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shares of common stock and warrants to purchase up to 3,000,000 shares of common stock, at a fixed combined price to the public of $3.00 under our current 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 $4.25 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 were $15,000,000, before deducting the underwriting discount and other offering expenses payable of approximately $1,474,000. If the warrants were exercised in full, we would receive additional proceeds of approximately $12,750,000.

On April 4, 2016, the Company closed on a public offering of 4,929,578 shares of its common stock and warrants to purchase up to 2,464,789 shares of common stock, at a fixed combined price to the public of $1.42 under the Company's current 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 $1.70 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 $7,000,000, before deducting the underwriting discount and other offering expenses payable by the Company of approximately $700,000. If the warrants were exercised in full, ContraVir would receive additional proceeds of approximately $4,200,000.

Our product development efforts are thus 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 June 30, 2016 we had $7.4 million in cash. Net cash used in operating activities was $16.6 million for the year ended June 30, 2016. Net loss for the year ended June 30, 2016 was $17.0 million. As of June 30, 2016 we had an accumulated deficit of $44.6 million. As of June 30, 2016, ContraVir had working capital of $2.8 million, whereas on June 30, 2015 ContraVir had working capital of $3.3 million. We expect to incur losses for the next several years as we expand our research, development and clinical trials of FV-100, CMX157 and CRV143. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

These 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 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 are marked to market at the end of each reporting period.

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 FASB 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 certain warrants with a price protection clause deemed to be derivative instruments was determined using a Binomial option-pricing model using varying assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus used model-derived valuations where significant value drivers were unobservable to third parties to determine the fair value and accordingly classified such warrants in Level 3 per ASC 820. This derivative liability was extinguished when the warrants were converted into common stock in August 2014.

The fair value of the warrants, issued in connection with the October 2015 and April 2016 common stock offerings deemed to be derivative instruments due to the 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 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 June 30, 2016, the fair value of such warrants was $2,115,965 which we classified as a long term derivative liability on our balance sheets. As of June 30, 2015, all previously issued warrants deemed to be derivative instruments were exchanged for shares of common stock of the Company.

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 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.

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 June 30, 2016 and 2015 ContraVir had prepaid research and development costs of $354,542 and $425,699, 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, 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. ContraVir has a limited trading history in its 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 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 us for annual reporting periods beginning after December 15, 2017, with early adoption permitted. We are currently evaluating the impact that this guidance will have on our results of operations, financial position and cash flows.

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

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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.

Business Combinations

We account for business acquisitions, such as our acquisition of Ciclofilin in June of 2016, under the acquisition method of accounting as indicated in the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") 805, "Business Combinations", which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquired business; and establishes the acquisition date as the fair value measurement point. Accordingly, we recognize assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities and non-controlling interest in the acquiree, based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, we recognize and measure goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

Contingent consideration assumed in a business combination is remeasured at fair value each reporting period and any change in the fair value from either the passage of time or events occurring after the acquisition date, is recorded in results from operations.

The acquisition of Ciclofilin closed on June 10, 2016, wherein our results of operations were impacted by 20 days in our 2016 fiscal year and are included from the acquisition date in the financial statements for all businesses acquired.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2016.

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RECENT ACCOUNTING PRONOUNCEMENTS

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

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. We are currently evaluating

the impact that this guidance will have on our results of operations, financial position and cash flows.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- *Contracts with customers*—including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).

- *Significant judgments and changes in judgments*—determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.

- *Certain assets*—assets recognized from the costs to obtain or fulfill a contract.

In August 2015, the FASB issued updated guidance deferring the effective date of the revenue recognition standard. In March, April and May 2016, the FASB issued additional updated guidance, which clarifies certain aspects of the ASU and the related implementation guidance issued by the FASB-IASB Joint Transition Resource Group for Revenue Recognition. This guidance is effective for us for annual reporting periods beginning after December 15, 2017. We are currently evaluating the impact that this guidance will have on our results of operations, financial position and cash flows.

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:

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- 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 for up to five years 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 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 Years Ended June 30, 2016 and 2015:

	Year ended		
	June 30, 2016	June 30, 2015	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
Research and development	15,019,277	8,403,579	6,615,698
General and administrative	5,786,208	5,556,400	229,808
Loss from operations	(20,805,485)	(13,959,979)	(6,845,506)
Other income/(expense):			
Change in fair value of warrant liability	3,806,847	(387,898)	4,194,745
Total other income/(expense)	3,806,847	(387,898)	4,194,745
Net loss	$ (16,998,638)	$ (14,347,877)	(2,650,761)

We had no revenues during the years ended June 30, 2016 and 2015, 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, 2016 and 2015 amounted to $15.0 million and $8.4 million, respectively. The increase of $6.6 million is primarily due to an increase of $3.6 million in development plan costs for FV-100, $4.2 million of costs for CMX157 and an increase of $1.2 million in salaries and benefits and consulting fees from higher employee headcount and consultants. These increases were partially offset by a decrease of $0.6 million in stock-based compensation expense, primarily due to the decrease in fair value of the awards granted to non-employees, which are subject to remeasurement each reporting period, $1.2 million of expense recorded in the prior year associated with the Chimerix transaction and a decrease of $0.6 million in other R&D related expenses.

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General and administrative expenses for the years ended June 30, 2016 and 2015 amounted to $5.8 million and $5.6 million, respectively. The increase of $0.2 million is

primarily due to an increase of $0.6 million for legal, investor relations and public relations expenses, an increase of $0.3 million in consulting fees, partially offset by a decrease in stock-based compensation expense of $0.7 million, primarily as a result of a decrease in the fair value of awards granted to non-employees, which are subject to remeasurement each reporting period, and the reversal of previously recognized expense for unvested stock options due to employee terminations.

In the years ended June 30, 2016 and 2015, we had income of $3.8 million and a loss of $0.4 million, respectively, related to a change in the fair value of our warrant liabilities. This change in fair value of the derivative liabilities primarily due to a decrease in the Company's 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.

Net loss for the years ended June 30, 2016 and 2015 was $17.0 million and $14.3 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 years ended June 30, 2016 and 2015:

	Year ended	
	June 30, 2016	June 30, 2015
Net cash (used in) provided by:		
Operating activities	$ (16,555,098)	$ (9,672,556)
Investing activities	(502,206)	(83,269)
Financing activities	19,898,079	12,501,233
Net increase in cash	2,840,775	$ 2,745,408

As of June 30, 2016, we had $7.4 million in cash, as compared to $4.6 million as of June 30, 2015. Net cash used in operating activities was approximately $16.6 million for the year ended June 30, 2016, as compared to $9.7 million for the year ended June 30, 2015. This cash was primarily used to continue development of FV-100, development of CMX157 as well as general and administrative costs and expenses. Additionally, the cash used in operations included a decrease of $3.8 million related to the non cash change in fair market value of our warrant liability, partially offset by $0.9 million of non-cash stock-based compensation expense. As of June 30, 2016, we had working capital of $2.8 million, as compared to $3.3 million as of June 30, 2015.

Net cash used in investing activities for the year ended June 30, 2016 includes $0.5 million of cash used to acquire Ciclofilin in June 2016.

Net cash provided by financing activities for the year ended June 30, 2016 primarily consisted of net proceeds of $19.9 million from two equity offerings, described further below. Net cash provided by financing activities for the year ended June 30, 2015 primarily consisted of net proceeds of $12.5 million from the issuance of preferred stock.

On April 4, 2016 we closed on a public offering of 4,929,578 shares of our common stock and warrants to purchase up to 2,464,789 shares of common stock, at a fixed combined price to the public of $1.42 under our current 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 $1.70 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 us were $7.0 million, before deducting the underwriting discount and other offering expenses payable by us of approximately $0.7 million.

On October 7, 2015, we entered into an underwriting agreement related to the public offering and sale of 5,000,000 shares of common stock and warrants to purchase up to 3,000,000 shares of common stock, at a fixed combined price to the public of $3.00 under our current 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 $4.25 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 us were $15 million, before deducting the underwriting discount and other offering expenses payable by the Company of approximately $1.5 million.

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We issued 1,250,000 shares of Convertible A Preferred Stock during the year ended June 30, 2015 at $10.00 per share, aggregating gross proceeds of $12.5 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, including our Phase 3 clinical trial of FV-100, 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.

As of June 30, 2016, we have not made any sales under the Agreement.

Operating and Capital Expenditure Requirements

As of June 30, 2016, we had an accumulated deficit of $44.6 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 FV-100, CMX157 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 June 30, 2016 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 our ability to continue as a going concern without additional capital becoming available 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 its self on unfavorable terms.

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Contractual Obligations and Commitments

We have no material long-term contractual cash obligations as of June 30, 2016, other than an operating lease for our office space and a capital lease for equipment. 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	$ 407,117	$ 128,043	$ 262,501	$ 16,573	$ —
Capital lease	10,410	10,410	—	—	—

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of ContraVir Pharmaceuticals, Inc. and its subsidiaries ("the Company") as of June 30, 2016 and 2015 and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the years then ended. These 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ContraVir Pharmaceuticals, Inc. and its subsidiaries at June 30, 2016 and 2015, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 financial statements, the Company has suffered losses from operations and will continue to incur large 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.

/s/BDO USA, LLP

Woodbridge, New Jersey

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

	June 30, 2016	June 30, 2015
Assets		
Current Assets:		
Cash	$ 7,403,940	$ 4,563,165
Prepaid expenses	491,045	681,249
Total Current Assets	7,894,985	5,244,414
Property and equipment, net	80,848	81,441
In-process research and development	3,190,000	—
Goodwill	1,870,924	—
Other assets	69,955	51,344
Total Assets	$ 13,106,712	$ 5,377,199
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,252,243	$ 1,481,393
Accrued expenses	820,894	456,722
Current portion of capital lease	10,410	—
Total Current Liabilities	5,083,547	1,938,115
Contingent consideration	3,320,000	—
Deferred tax liability	1,269,620	—
Derivative financial instruments, at estimated fair value—warrants	2,115,965	—
Total Liabilities	11,789,132	1,938,115
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 $10.00 per share, issued and outstanding 1,250,000 and 1,250,000 shares at June 30, 2016 and 2015, respectively	12,500,000	12,500,000
Series B convertible preferred stock, stated value $10.00 per share, issued and outstanding 120,000 and 120,000 shares at June 30, 2016 and 2015, respectively	1,200,000	1,200,000
Common stock—$0.0001 par value per share; 120,000,000 shares authorized, 32,231,241 and 22,276,730 shares issued and outstanding at June 30, 2016 and 2015, respectively	3,224	2,228
Additional paid in capital	32,226,851	17,350,713
Accumulated deficit	(44,612,495)	(27,613,857)
Total Stockholders' Equity	1,317,580	3,439,084
Total Liabilities and Stockholders' Equity	$ 13,106,712	$ 5,377,199

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

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	Year ended June 30, 2016	June 30, 2015
Revenues	$ —	$ —
Costs and Expenses:		
Research and development	15,019,277	8,403,579
General and administrative	5,786,208	5,556,400
Total Operating Expenses	20,805,485	13,959,979
Loss From Operations	(20,805,485)	(13,959,979)
Other Income (Expense):		
Change in fair value of derivative instruments—warrants	3,806,847	(387,898)
Total Other Income (Expense)	3,806,847	(387,898)
Comprehensive Loss	(16,998,638)	(14,347,877)
Series A and B convertible preferred stock beneficial conversion feature accreted as a dividend	—	(7,844,643)
Comprehensive Loss Attributable to Common Shareholders	$ (16,998,638)	$ (22,192,520)
Weighted Average Common Shares Outstanding		
Basic and Diluted	27,060,326	21,754,623
Net loss per Common Share		
Basic and Diluted	$ (0.63)	$ (1.02)

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

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

For the years ended June 30, 2016 and 2015

	Preferred Stock, Series A $0.0001 par value		Preferred Stock, Series B $0.0001 par value		Common Stock, $0.0001 par value		Additional Paid in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Par Value			
Balance July 1, 2014	—	$ —	—	$ —	18,479,279	$ 1,848	$ 2,486,309	$ (5,421,337)	$ (2,933,180)
Stock-based compensation expense	—	—	—	—	—	—	2,118,187	—	2,118,187
Stock options granted in excess of authorized limit	—	—	—	—	—	—	(81,689)	—	(81,689)
Reversal of stock option liability upon increase in authorized number of shares	—	—	—	—	—	—	119,167	—	119,167
Restricted common shares issued in exchange of warrants	—	—	—	—	3,794,118	380	4,862,863	—	4,863,243
Issuance of Series A preferred shares	1,250,000	12,500,000	—	—	—	—	—	—	12,500,000
Issuance of Series B preferred shares	—	—	120,000	1,200,000	—	—	—	—	1,200,000
Beneficial conversion feature accreted as deemed dividend	—	—	—	—	—	—	7,844,643	(7,844,643)	—
Stock option exercise	—	—	—	—	3,333	—	1,233	—	1,233
Net loss	—	—	—	—	—	—	—	(14,347,877)	(14,347,877)
Balance June 30, 2015	1,250,000	$ 12,500,000	120,000	$ 1,200,000	22,276,730	$ 2,228	$ 17,350,713	$ (27,613,857)	$ 3,439,084
Issuance of common stock, net	—	—	—	—	9,929,578	993	19,862,993	—	19,863,986
Fair value of warrants issued in connection with common stock offering, reclassified to derivative liability	—	—	—	—	—	—	(5,922,812)	—	(5,922,812)
Stock option exercise	—	—	—	—	24,933	3	34,090	—	34,093
Stock-based compensation expense	—	—	—	—	—	—	901,867	—	901,867
Net loss	—	—	—	—	—	—	—	(16,998,638)	(16,998,638)
Balance June 30, 2016	1,250,000	$ 12,500,000	120,000	$ 1,200,000	32,231,241	$ 3,224	$ 32,226,851	$ (44,612,495)	$ 1,317,580

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

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

	Year ended	
	June 30, 2016	June 30, 2015
Cash Flows From Operating Activities:		
Net loss	$ (16,998,638)	$ (14,347,877)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	901,867	2,118,187
Stock issued for license expense	—	1,200,000
Change in fair value of derivative instrument—warrants	(3,806,847)	387,898
Depreciation	21,525	16,355
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	3,135,022	1,516,855
Prepaid expenses and other assets	191,973	(563,974)
Net Cash Used In Operating Activities	(16,555,098)	(9,672,556)
Cash Flows From Investing Activities:		
Acquisition of business, net of cash acquired	(495,603)	—
Purchase of property and equipment	(6,603)	(83,269)
Net Cash Used In Investing Activities	(502,206)	(83,269)
Cash Flows From Financing Activities:		
Proceeds from the issuance of preferred stock	—	12,500,000
Proceeds from the issuance of common stock and warrants, net	19,863,986	—
Issuance of common stock via stock option exercise	34,093	1,233
Net cash provided by financing activities	19,898,079	12,501,233
Net Increase In Cash	2,840,775	2,745,408
Cash at beginning of period	4,563,165	1,817,757
Cash at end of period	$ 7,403,940	$ 4,563,165
Supplementary Disclosure Of Cash Flow Information:		
Cash paid for taxes	$ —	$ —
Supplementary Disclosure Of Non-Cash Financing Activities:		
Value of warrants exchanged for common stock	$ —	$ 4,863,243
Fair value of warrants issued in conjunction with common stock offering	$ 5,922,812	$ —
Deemed dividend on preferred stock beneficial conversion feature	$ —	$ 7,844,643

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CONTRAVIR PHARMACEUTICALS, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

1. Business Overview

ContraVir Pharmaceuticals Inc. ("ContraVir", "Company "we," "us," or similar pronouns) is a biopharmaceutical company focused primarily on the clinical development of FV-100 to treat herpes zoster (HZ), or shingles, which is an infection caused by the reactivation of varicella zoster virus (VZV) or "chickenpox", and CMX157 to treat Hepatitis B (HBV).

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 Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The results of operations for the year ended June 30, 2016 include the results of Ciclofilin from the closing date of the Merger on June 10, 2016.

Principles of Consolidation

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

Going Concern

As of June 30, 2016, ContraVir had $7.4 million in cash. Net cash used in operating activities was $16.6 million for the year ended June 30, 2016. Net loss for the year ended June 30, 2016 was $17.0 million. As of June 30, 2016 we had an accumulated deficit of $44.6 million. As of June 30, 2016, ContraVir had working capital of $2.8 million, whereas on June 30, 2015 ContraVir had working capital of $3.3 million. The Company expects to incur losses for the next several years as it expands its research, development and clinical trials of FV-100, CMX157 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 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 financial statements without additional capital becoming available to attain further operating efficiencies and, ultimately, to generate revenue. The 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 our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of one or more product candidates; (ii) seek collaborators for product candidates at an

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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 its self 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 June 30, 2016 and 2015, the amount of cash was approximately $7.4 million and $4.6 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.

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Warrants

The Company 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 FASB 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 certain warrants with a price protection clause deemed to be derivative instruments was determined using a Binomial option-pricing model using varying assumptions regarding volatility of our common share price, remaining life of the warrant, and risk-free interest rates at each period end. We thus used model-derived valuations where significant value drivers were unobservable to third parties to determine the fair value and accordingly classified such warrants in Level 3 per ASC 820. This derivative liability was extinguished when the warrants were converted into common stock in August 2014.

The fair value of the warrants, issued in connection with the October 2015 and April 2016 common stock offerings deemed to be derivative instruments due to the 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 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 June 30, 2016, the fair value of such warrants was $2,115,965 which we classified as a long term derivative liability on our balance sheets. As of June 30, 2015, all previously issued warrants deemed to be derivative instruments were exchanged for shares of common stock of the Company.

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.

Property, equipment and depreciation

As of June 30, 2016 and 2015, the Company had $80,848 and $81,441, respectively, of property and equipment, consisting primarily of computer equipment and equipment under capital lease. 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 years ended June 30, 2016 and 2015 was $21,525 and $16,355, 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 June 30, 2016 and 2015.

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 No. 2012-02, *Intangibles — Goodwill and Other*

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(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.

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 June 30, 2016.

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.

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, 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 June 30, 2016.

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.

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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, 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 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 June 30, 2016 and 2015, the Company had prepaid research and development costs of $354,542 and $425,699, 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

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outflows from operating activities. Due to ContraVir's accumulated deficit position, no excess tax benefits have been recognized. 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. The Company is currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

Foreign Exchange

The functional currency of ContraVir and ContraVir Research Inc. is the U.S. dollar. The functional currency of Ciclofilin 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 June 30, 2016.

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 June 30, 2016.

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. Due to the net losses incurred 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 were anti-dilutive, thus, basic and dilutive net loss per share are the same.

Business Combinations

The Company accounts for its business acquisitions, such as our acquisition of Ciclofilin in June of 2016, under the acquisition method of accounting as indicated in FASB ASC 805, "Business Combinations", which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquired business; and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities and non-controlling interest in the acquiree, based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

Contingent consideration assumed in a business combination is remeasured at fair value each reporting period and any change in the fair value from either the passage of time or events occurring after the acquisition date, is recorded in results from operations.

The acquisition of Ciclofilin closed on June 10, 2016, wherein the Company's results of operations were impacted by 20 days in the 2016 fiscal year and are included from the acquisition date in the financial statements for all businesses acquired.

4. Recent Accounting Pronouncements

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

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

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*. This guidance requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This guidance also requires an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. Qualitative and quantitative information is required about:

- *Contracts with customers*—including revenue and impairments recognized, disaggregation of revenue and information about contract balances and performance obligations (including the transaction price allocated to the remaining performance obligations).

- *Significant judgments and changes in judgments*—determining the timing of satisfaction of performance obligations (over time or at a point in time), and determining the transaction price and amounts allocated to performance obligations.

- *Certain assets*—assets recognized from the costs to obtain or fulfill a contract.

In August 2015, the FASB issued updated guidance deferring the effective date of the revenue recognition standard. In March, April and May 2016, the FASB issued additional updated guidance, which clarifies certain aspects of the ASU and the related implementation guidance issued by the FASB-IASB Joint Transition Resource Group for Revenue Recognition. This guidance is effective for the Company for annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact that this guidance will have on its results of operations, financial position and cash flows.

5. Business Combination

Acquisition of Ciclofilin Pharmaceuticals, Inc.

On June 10, 2016, ContraVir completed its acquisition of 100% of the common stock of Ciclofilin. The transaction provided ContraVir with a product candidate, CRV431, that is in pre-clinical stage development, targeted at treating hepatitis B. CRV431 belongs to a known drug class of cyclophilin inhibitors derived from cyclosporine A, and was designed specifically to optimize potency and selectivity against HBV.

The acquisition-date fair value of the consideration transferred is as follows:

	At June 10, 2016
Cash	$ 300,000
Notes receivable settled upon closing of transaction	200,000
Contingent consideration	3,320,000
Total consideration	$ 3,820,000

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On April 12, 2016, Ciclofilin issued $200,000 of convertible 1% Notes payable to ContraVir with a maturity date of October 12, 2016. This Note was to be repaid upon the earlier of i) a change in control event or ii) October 12, 2016. In the event of a change of control event in which ContraVir was the acquirer, any amount due from ContraVir to Ciclofilin at closing would be set-off by the principal amount. The Note was effectively settled upon closing of the transaction, with the settlement amount equal to the carrying amount. There was no impact to ContraVir's consolidated statements of operations as a result of the settlement and the settlement amount is included in total consideration above.

The contingent consideration represents the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones as described below. The contingent consideration was estimated based on a probability-weighted discounted cash flow model, which is an income approach.

Milestone Event under the ContraVir Merger Agreement	Milestone Payment to Stockholders
Upon receipt of Phase I Positive Data from the Phase I trial of CRV431 in humans	(1) Such number of validly issued, fully paid and non-assessable shares of Buyer Common Stock equal to 2.5% of the issued and outstanding Buyer Common Stock on the Closing Date and (2) $1,000,000 by wire transfer of immediately available funds.
Upon receipt of Phase II Positive Data from a proof of concept clinical trial (whether an HBV-positive Phase I clinical trial or a separate Phase II clinical trial, or otherwise) of CRV431 in humans	(1) Such number of validly issued, fully paid and non-assessable shares of Buyer Common Stock equal to 7.5% of the issued and outstanding Buyer Common Stock on the Closing Date and (2) $3,000,000 by wire transfer of immediately available funds.
Upon initiation of a Phase III trial of CRV431	$5,000,000
Upon the acceptance by the U.S. Food and Drug Administration of a new drug application for CRV431	$8,000,000

The transaction was accounted for as a business combination under the acquisition method of accounting. Accordingly, the tangible and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized is attributable primarily to strategic opportunities related to leveraging Tribute's existing infrastructure. Goodwill is not deductible for tax purposes.

The following table summarizes the estimated preliminary fair values of the assets acquired and liabilities assumed at the date of acquisition:

	At June 10, 2016
Cash	$ 4,397
Tax receivable	5,504

Prepaid rent		1,769
Property, plant and equipment, net		14,329
Other assets		13,107
In-process research and development		3,190,000
Current portion of capital lease		(10,410)
Deferred tax liability		(1,269,620)
Total net assets acquired	$	1,949,076
Goodwill		1,870,924
Total consideration	$	3,820,000

The purchase price allocation has been prepared on a preliminary basis and is subject to change as additional

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information becomes available concerning the fair value and tax basis of the assets acquired and liabilities assumed. Any adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the June 10, 2016 acquisition date.

Acquired In-Process Research and Development

Acquired IPR&D is the estimated fair value of the CRV431 asset at the acquisition date. The Company determined that the estimated fair value of CRV431 was $3,190,000 as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset's projected incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of CRV431 under the MPEEM, the Company used probability-weighted, projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by clinical-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to CRV431 and then reduced by a contributory charge on requisite assets employed. Contributory assets included working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through 2040. The resultant cash flows were then discounted to present value using a weighted-average cost of capital for companies with profiles substantially similar to that of ContraVir, which the Company believes represent the rate that market participants would use to value the assets. The Company compensated for the phase of development of the program by applying a probability factor to the estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, including the indication in which development of CRV431 will be pursued, the time and resources needed to complete the development and regulatory approval of CRV431, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain regulatory approvals to conduct clinical studies, failure of clinical studies, delay or failure to obtain required market clearances, and intellectual property litigation.

Deferred Income Tax Liability

The Company recorded a $1,269,620 deferred income tax liability resulting from the acquisition reflecting the tax impact of the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset 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 CRV431.

The operating results of Ciclofilin for the period from June 10, 2016 to June 30, 2016, including an operating loss of $69,138, have been included in the consolidated financial statements as of and for the year ended June 30, 2016. The Company incurred approximately $214,000 in transaction costs in connection with the acquisition, which were included in general and administrative expenses within the consolidated statements of operations for the year ended June 30, 2016.

The following supplemental unaudited pro forma information presents the Company's financial results as if the acquisition of Ciclofilin had occurred on July 1, 2014:

	Year Ended June 30,	
	2016 (Unaudited)	2015 (Unaudited)
Total revenues, net	$ —	$ 113,786
Net loss	$ (18,912,149)	$ (15,106,340)
Basic and diluted net loss per share	$ (0.70)	$ (1.05)

The above unaudited pro forma information was determined based on the historical GAAP results of ContraVir and Ciclofilin. The unaudited pro forma condensed consolidated results are provided for informational purposes only and are not necessarily indicative of what ContraVir's consolidated results of operations actually would have been if the acquisition was completed on July 1, 2014 or what the consolidated results of operations will be in the future. The pro forma condensed consolidated net loss includes pro forma adjustments relating to the following significant recurring and non-recurring items directly attributable to the business combination:

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(i) Elimination of interest expense of $67,533 and $47,629 for the years ended June 30, 2016 and 2015 related to Ciclofilin's convertible notes that were converted to equity as part of the acquisition.

(ii) Elimination of $414,444 of stock-based compensation expense recorded by Ciclofilin in the year ended June 30, 2016 for the automatic acceleration of vesting of restricted stock awards upon the merger with ContraVir, considered a change in control.

(iii) Elimination of approximately $214,000 of transaction related costs incurred by ContraVir for the year ended June 30, 2016.

6. Stockholders' Equity and Derivative Liability — Warrants

Exchange of Warrants for Restricted Stock

On August 20, 2014, ContraVir consummated its offer (the "Offer") to exchange an aggregate 4,742,648 outstanding common stock purchase warrants (the "Warrants") owned by the February 4, 2014 investors in the Company for an aggregate 3,794,118 shares of restricted common stock. The Warrants were revalued on August 20, 2014, immediately prior to conversion, increasing the liability by $387,898 to $4,863,243 which was recorded in the change in fair value of derivative instruments- warrants on the statement of operations. The liability was extinguished when the restricted shares were issued that had a fair value of $4,552,924 (using $1.20 per share, which was the stock price on August 20, 2014) by recording the offset to additional paid in capital.

ContraVir's warrants contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. The range of assumptions used to determine the fair value of the warrants on August 20, 2014 was as follows:

	August 20, 2014
Estimated fair value of ContraVir common stock	$1.20
Expected warrant term (years)	5.46 years
Risk-free interest rate	1.75%
Expected volatility	88%
Dividend yield	—

In the Binomial model, the assumption for estimated fair value of the stock was based on a Black-Scholes based apportionment of the unit price paid for the shares and warrants issued in ContraVir's recent private placement, which resulting stock prices were deemed to be arms-length negotiated prices. 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. The warrants have a transferability provision and based on guidance provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* , ("SAB No. 107"), for instruments issued with such a provision, ContraVir used the full contractual term as the expected term of the warrants. The risk free rate is based on the U.S. Treasury security rates for maturities consistent with the expected remaining term of the warrants.

Series A and Series B Preferred Stock Issuances

On October 14, 2014, the Company's Board of Directors authorized the sale and issuance of up to 1,250,000 shares of Series A Convertible Preferred Stock (the "Series A"). Also on October 14, 2014, the Company closed a private offering of the Series A and issued 900,000 shares of Series A preferred shares at a stated value of $10.00 per share, generating gross proceeds of approximately $9,000,000. The Company also granted the purchaser of the Series A and their assignees the option to purchase up to an additional 350,000 shares of Series A prior to February 28, 2015. The purchaser elected to purchase an additional 50,000, 30,000 and 20,000 shares on December 23, 2014, February 10, 2015, and February 26, 2015 generating additional gross proceeds of $500,000, $300,000 and $200,000, respectively. On February 26, 2015, assignees of the purchaser elected to purchase 250,000 shares, generating additional gross proceeds of $2,500,000.

On December 15, 2014, the Company's Board of Directors authorized the issuance of 120,000 shares of Series B Convertible Preferred Stock (the "Series B") in connection with the Company's exclusive license agreement with Chimerix, Inc., entered into December 17, 2014. (See License Agreement discussion in Note 13). The stated and estimated value of these shares was $10.00 per share based on calculating the value of the series B on a converted-basis less the discount received on the conversion price compared to the stock price on date of issuance.

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There are no stated dividends or redemption features associated with the Series A and B. The Series A and B have voting rights on an as converted basis. Each share of the Series A and B 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 A conversion price is currently $0.48 and the Series B conversion price is currently $1.12, based on 70% of the five day average common share price preceding the date of settlement. If the Company sells common stock or equivalents at an effective price per share that is lower than the conversion price, the Preferred holders conversion price may be reduced to the lower conversion price. The preferred stock is automatically convertible into common stock in the event of a fundamental transaction to the Company. Based on these facts, the Series A and B are classified as permanent equity.

Beneficial Conversion Feature- Series A and Series B Preferred Stock

Each share of Series A is convertible into shares of common stock, at any time at the option of the holder at a conversion price of $0.48 per share. On October 14, 2014, December 23, 2014, February 10, 2015 and February 26, 2015, the date of issuances of the Series A, the publicly traded common stock prices were $0.65, $2.09, $4.50 and $4.50 per share, respectively. Each share of Series B is convertible into shares of common stock at any time at the option of the holder at a conversion price of $1.12 per share. On December 17, 2014, the date of the Series B agreement, the publicly traded common stock price was $1.79 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 A and Series B 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 A and Series B shares was $7.8 million and the preferred stock was further discounted by this amount. The beneficial conversion amount of $7.8 million was then accreted back to the preferred stock as a dividend charged to accumulated deficit as the preferred stock was 100% convertible immediately.

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, including the Phase 3 clinical trial of FV-100, 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).

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.

As of June 30, 2016, the Company has not made any sales under the Agreement.

Common Stock and Warrant Offering

On October 7, 2015, the Company entered into an underwriting agreement related to the public offering and sale of 5,000,000 shares of common stock and warrants to purchase up to 3,000,000 shares of common stock, at a fixed combined price to the public of $3.00 under the Company's current 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 $4.25 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.

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The Company also granted the Underwriters a 45-day option to purchase up to an additional 750,000 additional shares of common stock and additional warrants to purchase up to 450,000 shares of common stock at $3.00, 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 measure the warrants at issuance and to remeasure the liability as of June 30, 2016:

	October 13, 2015	June 30, 2016
Price of ContraVir common stock	$2.76	$1.04
Expected warrant term (years)	5.00 years	4.28 years
Risk-free interest rate	1.36%	0.86%
Expected volatility	76%	75%
Dividend yield	—	—

On April 4, 2016, the Company closed on a public offering of 4,929,578 shares of its common stock and warrants to purchase up to 2,464,789 shares of common stock, at a fixed combined price to the public of $1.42 under the Company's current 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 $1.70 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 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.

Similar to the terms of the warrants issued in October 2015, 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 classifed 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

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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 June 30, 2016:

	April 4, 2016	June 30, 2016
Price of ContraVir common stock	$1.16	$1.04
Expected warrant term (years)	5.00 years	4.76 years
Risk-free interest rate	1.22%	1.01%
Expected volatility	76%	76%
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
7/1/2014	Balance of derivative financial instruments liability	4,742,648	$ 4,475,345
	Change in fair value of warrants immediately prior to conversion, recognized as change in fair value of derivative instruments - warrants in the statement of operations	—	387,898
	Amounts reclassified to additional paid in capital	(4,742,648)	(4,863,243)
6/30/2015	Balance of derivative financial instruments liability	—	—
	Issuance of warrants on October 13, 2015	3,000,000	4,384,523
	Issuance of warrants on April 4, 2015	2,464,789	1,538,289
	Change in fair value of warrants for the year ended June 30, 2016	—	(3,806,847)
6/30/2016	Balance of derivative financial instruments liability	5,464,789	$ 2,115,965

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 June 30, 2016. There were no such liabilities as of June 30, 2015.

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)
Derivative liabilities related to warrants	$ (2,115,965)	$ —	$ —	$ (2,115,965)
Contingent consideration	(3,320,000)	$ —	$ —	$ (3,320,000)

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 years ended June 30, 2016 and 2015. 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.

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As discussed in Note 5, contingent consideration was recorded for the acquisition of Ciclofilin on June 10, 2016. The contingent consideration represented the acquisition date fair value of potential future payments, to be paid in cash and Company stock, upon the achievement of certain milestones and was estimated based on a probability-weighted discounted cash flow model. At June 30, 2016, there was no change in fair value of the contingent consideration from its initial value as of June 10, 2016.

	Acquisition-related Contingent Consideration
Liabilities	
Balance at June 30, 2015	$ —
Contingent consideration recorded in acquisition	3,320,000
Change in fair value recorded in earnings	—
Balance at June 30, 2016	$ 3,320,000

8. Indefinite-lived Intangible Assets and Goodwill

IPR&D

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

	June 30, 2016	June 30, 2015
IPR&D asset:		
CRV431	$ 3,190,000	$ —

Goodwill

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

	Amount
Goodwill balance at June 30, 2015	$ —
Goodwill from acquisition of Ciclofilin on June 10, 2016	1,870,924
Goodwill balance at June 30, 2016	$ 1,870,924

9. Accrued Liabilities

The Company's accrued expenses consist of the following:

	Year ended June 30, 2016	Year ended June 30, 2015
Research and development	$ 177,197	$ 279,682
Professional fees	80,984	60,000
Payroll and related costs	489,823	94,891
Legal fees	8,441	9,091
Other	64,449	13,058
Total accrued expenses	$ 820,894	$ 456,722

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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 typically will vest after three years of continuous service from the grant date and will have a contractual term of ten years. ContraVir had initially reserved 1,500,000 shares of common stock issuable pursuant to the Plan. As of September 30, 2014, the Company had issued 841,270 options over the authorized number of options in the Plan. As per ASC Topic 815-40, the options were accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company's statement of operations. Stockholder and Board approval was obtained on December 2, 2014 to increase the number of authorized shares to 6,500,000. Immediately prior to approval, the liability was revalued, and an additional expense was recorded. Upon approval, the cumulative liability of $119,167 was reversed into additional paid-in capital. As of June 30, 2016, the Company had 1,295,522 shares of common stock available for

grant under the Plan.

The Company classifies stock-based compensation expense in its statement of operations in the same 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 June 30, 2016	Year ended June 30, 2015
General and administrative	$ 839,200	$ 1,476,474
Research and development	62,667	641,713
Total stock-based compensation expense	$ 901,867	$ 2,118,187

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, July 1, 2014	2,341,270	$0.11 - $2.37	$ 1.61		9.65 years
Granted	1,779,808	$1.50 - $3.83	$ 1.95		
Exercised	(3,333)	—	$ 0.37		
Forfeited	—	—			
Balance outstanding, June 30, 2015	4,117,745	$0.11 - $3.83	$ 1.76		9.04 years
Granted	1,275,000	$0.92 - $4.38	$ 1.05		
Exercised	(24,933)	$0.11 - $2.20	$ 1.37		
Forfeited	(163,334)	$1.50 - $3.60	$ 1.86		
Balance outstanding, June 30, 2016	5,204,478	$0.11 - $4.38	$ 1.59		8.12 years
Vested awards and those expected to vest at June 30, 2016	5,113,838	$0.11 - $4.38	$ 1.59	$ 648,126	8.10 years
Vested and exercisable at June 30, 2016	2,183,140	$0.11 - $3.83	$ 1.51	$ 530,015	7.01 years

The weighted-average grant-date fair value of options granted to employees during the years ended June 30, 2016 and 2015 was $0.76 and $1.36 per share. The total fair value of shares vested during the year ended June 30, 2016 was $1.3 million. The total fair value of shares vested during the year ended June 30, 2015 was $1.6 million. Included within the above table are 1,335,734 non-employee options outstanding as of June 30, 2016, of which 655,999 are unvested as of June 30, 2016 and therefore subject to remeasurement. The remeasurement impact for the year ended June 30, 2016 was negative due to the decreases 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 June 30, 2016, the unrecognized compensation cost related to non-vested stock options outstanding, net of expected forfeitures, was approximately $2.6 million to be recognized over a weighted-average remaining vesting period of

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approximately 2.18 years.

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.

	Year Ended June 30, 2016	Year Ended June 30, 2015
Stock price	$1.10	$1.90
Risk-free interest rate	1.35%	1.71%
Dividend yield	—	—
Expected volatility	81%	87%
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 June 30, 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.

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 has not recorded a current or deferred income tax expense or benefit since its inception.

The Company's loss before income taxes was $16,998,638 and $14,347,877 for the years ended June 30, 2016 and 2015, respectively, and was generated entirely in the United States and Canada.

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:

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	Year Ended June 30, 2016	Year Ended June 30, 2015
Federal net operating loss ("NOL")	$ 11,330,100	$ 4,580,100
State NOL	1,965,700	800,200
Canadian NOL	179,200	—
Stock Compensation & Other	949,700	776,900
Deferred tax valuation allowance	(14,424,700)	(6,157,200)
Net deferred tax asset	$ —	$ —
Deferred tax liability (In-Process R&D)	(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 June 30, 2016 and June 30, 2015. The Company has recorded a net deferred tax liability of $1,269,600 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 by $8.3 million and $4.7 million for the years ended June 30, 2016 and 2015 due primarily to the generation of net operating losses during the periods.

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

	Year Ended June 30, 2016	Year Ended June 30, 2015
U.S. statutory income tax rate	34.0%	34.0%
State income taxes, net of federal benefit	6.9	5.5
Warrant liability	7.6	(0.9)
Valuation allowance	(48.5)	(38.6)
Effective tax rate	—	—

As of June 30, 2016 and June 30, 2015, the Company had U.S. federal and state net operating loss carryforwards of $33.3 million and $13.5 million, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in June 2034. As of June 30, 2016 and June 30, 2015, the Company also had foreign net operating loss carryforwards of $0.7 and $0.1, respectively, which may be available to offset future income tax liabilities and will begin to expire at various dates starting in June 2034.

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. Although the detailed study of Sec. 382 has not been completed, it is more likely than not that an ownership change under Sec. 382 has not occurred through the Series A and Series B Preferred Stock Issuances.

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 IRS and state authorities.

The Company had no unrecognized tax benefits or related interest and penalties accrued through June 30, 2016.

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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 to the beneficial conversion feature on this instrument for the periods in which the preferred stock is outstanding. The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Year ended June 30, 2016	Year ended June 30, 2015
Numerator:		
Net loss	$ (16,998,638)	$ (14,347,877)
Preferred stock deemed dividend	—	(7,844,643)
Net loss attributable to common stockholders	$ (16,998,638)	$ (22,192,520)
Denominator:		

Weighted average common shares outstanding	27,060,326	21,754,623
Net loss per share of common stock—basic and diluted	$ (0.63)	$ (1.02)

The following outstanding securities at June 30, 2016 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year ended June 30, 2016	Year ended June 30, 2015
Common shares issuable upon conversion of Series A preferred stock	26,041,667	26,041,667
Common shares issuable upon conversion of Series B preferred stock	1,071,429	1,071,429
Stock options	5,204,478	4,117,745
Warrants	5,464,789	—
Total	37,782,363	31,230,841

The liability classified warrants disclosed above been excluded from the computation of diluted earnings per share because their exercise price 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 CMX157 from Chimerix for further clinical development and commercialization. CMX157 is a highly potent analog of the antiviral drug tenofovir DF (Viread®). Under the terms of the agreement, ContraVir licensed CMX157 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

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stage, has not yet reached technological feasibility and has no alternative use. As of September 28, 2016, no amounts had been accrued related to the payments Chimerix is eligible to receive.

License Agreement with University College Cardiff Consultants Limited ("Cardiff")

On June 10, 2013, the Company and Synergy entered into a Contribution Agreement, as amended and restated on August 5, 2013, or the Contribution Agreement, to transfer to the Company the FV-100 assets, in exchange for the issuance to Synergy of 9,000,000 shares of the Company's common stock representing 100% of the outstanding shares of the Company's common stock as of immediately following such issuance. Pursuant to the Contribution Agreement, Synergy transferred ownership of all intellectual property rights acquired from Bristol-Myers Squibb ("BMS") including all historical research, clinical study protocols, data, results and patents related to the FV-100 assets as well as assumed the obligations of Synergy, including all liabilities of Synergy, under the asset purchase agreement, dated August 17, 2012, by and between Synergy and BMS, or the BMS Agreement.

The FV-100 assets acquired from BMS are licensed from Cardiff pursuant to the terms of that certain Patent and Technology License Agreement, dated as of February 2, 2005, between Cardiff and CRI, an entity with no prior relationship with us, as amended March 27, 2007, or the Cardiff Agreement.

The Cardiff Agreement shall remain in full force and effect until the date upon which the last of the last patent or the last continuation or extension to any patents within the Patent Rights (as defined in the Cardiff Agreement) expires. Any milestone and/or royalty payment under the Cardiff Agreement shall be payable for as long as the Cardiff Agreement is in effect. The Cardiff Agreement may be terminated in its entirety, for among other reasons and in the following manner as set forth below: (a) automatically by Cardiff, if we become bankrupt or insolvent and/or if our business shall be placed in the hands of a receiver, assignee, or trustee; (b) upon ninety (90) calendar days written notice from Cardiff, if we breach or default (i) on the payment or report obligations or use of name obligations or (ii) on any other obligation under the Cardiff Agreement, subject to a ninety (90) calendar-day cure period; (c) if we have defaulted or been in excess of one (1) month late on its payment obligations pursuant to the terms of the Cardiff Agreement on any two (2) occasions in a twelve (12) month period, subject to a cure period; (d) upon one hundred twenty (120) calendar days written notice from us if any particular patent or patents included in Patent Rights and which account for at least thirty (30%) percent of the total royalty to Cardiff, is or are irrevocably adjudicated to be invalid; or (e) upon ninety (90) calendar days written notice from us if Cardiff is in breach of Section 11.1 (Confidential Information and Publication) unless, before the end of the such ninety (90) calendar-day notice period, Cardiff has cured the default or breach to our reasonable satisfaction and so notifies us, stating the manner of the cure.

The terms of the Cardiff Agreement provided in consideration for a license of all of Cardiff's rights in any technical information, know-how, processes, procedures, compositions, devices, methods, formulae, protocols, techniques related to the FV-100 Assets, or the Patent Rights. The Cardiff Agreement provided for an initial base payment of $270,000, which has previously been paid by CRI, subsequent milestone payments covering (i) initiation of a clinical trial at each phase, (ii) marketing (FDA) approval and (iii) on achieving the milestone of aggregate net sales in three different tiers, as well as a low single digit royalty based on net sales. The total aggregate amount of milestone payments that could be payable to Cardiff by the Company under the Cardiff Agreement is equal to $400,000 as follows:

Milestone payments upon occurrence of the following events:

- Upon initiation of a Phase 3 clinical trial for a licensed product, $150,000
- Upon approval of the first NDA for any licensed product, $250,000

The terms of the BMS Agreement provided for an initial base payment of $1 million, subsequent milestone payments of $3 million and $6 million, respectively, covering (i) marketing (FDA) approval and (ii) on achieving the milestone of aggregate net sales equal to or greater than $125 million, as well as a single digit royalty based on net sales. The total aggregate amount of milestone payments that could be payable to BMS under the BMS Agreement is equal to $9 million. The duration of any milestone payment obligation owed to BMS shall continue until the earliest of (i) payment, in full, of all milestone payments as required under the BMS Agreement, (ii) our determination using commercially reasonable standards consistent with the exercise of prudent scientific and business judgment and consistent with those standards used by us for its other therapeutic products at a similar stage of development and with similar commercial potential, to terminate the development of the FV-100 assets, and (iii) the tenth (10th) anniversary of the date of the BMS Agreement, The duration of any royalty payment obligation to BMS shall commence on the date of the first commercial sale of the FV-100 assets in a country until the expiration of any claim of an issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of

competent jurisdiction of any of our

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patents or any other patent covering the use or sale of the FV-100 assets in such country. The transactions contemplated by the BMS Agreement closed on August 17, 2012 and neither party can terminate the remaining obligations owed under the BMS Agreement. No milestone payments have been made under this agreement. As of September 28, 2016, no amounts had been accrued related to the remaining payments BMS is eligible to receive.

Contractual Obligations

In August 2014, the Company entered into a lease for corporate office space in Edison, New Jersey. Rent expense for the years ended June 30, 2016 and 2015 was $139,797 and $119,747. Upon acquisition of Ciclofilin on June 10, 2016, the Company also leases space in Edmonton, Canada on a lease on a month to month basis.

The following table summarizes annual rental payments for each of the following fiscal years ended June 30:

2017	$	128,043
2018		130,181
2019		132,320
2020		16,573
2021 and thereafter		—
Total	$	407,117

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.

Consulting Agreement

On January 23, 2014, the Company entered into a three year consulting agreement with Chris McGuigan, Ph.D. for scientific and technical advisory services. Dr. McGuigan was a director of the company and was instrumental in the early development of the FV-100 drug candidate. His total compensation under the agreement is a grant of 250,000 common stock options, at an exercise price of $0.37 per share, vesting over three years. Upon his death in March 2016, this consulting agreement was terminated. The Company's Board of Directors authorized the immediate vesting of his unvested stock options outstanding under this consulting agreement and extended the exercise term from 90 days to four years. The modification to this consulting agreement resulted in an expense of $49,534 recorded in Research & Development expense.

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 CMX157. The Company incurred expenses related to the agreement of approximately $127,500 and $2,000 in 2016 and 2015, respectively.

The Company is a party to a Master Services Agreement dated June 19, 2014 with Clinical Supplies Management, Inc. ("CSM"), pursuant to which CSM provides the Company with pharmaceutical and clinical supply management services in support of clinical research programs. James Sapirstein, the CEO of ContraVir, is a director of CSM which is a private company. For the years ended June 30, 2016 and 2015, the Company incurred expenses related to services performed by CSM of approximately $550,000 and $510,000, respectively. As of June 30, 2016 there was an outstanding payables balance of $69,833.

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 360,000 stock options which vest in 10,000 increments on a monthly basis over 3 years.

15. Subsequent events

Certain holders of the Company's preferred stock elected to convert approximately 1,000,000 shares of Series A Preferred Stock into approximately 21.4 million shares of the Company's common stock.

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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 June 30, 2016, 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 intend to implement remedial measures designed to address these material weaknesses.

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 June 30, 2016. 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 the following material weaknesses in internal control over financial reporting as of June 30, 2016. 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 June 30, 2016, 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

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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 June 30, 2016 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 June 30, 2016.

ITEM 9B. OTHER INFORMATION

None.

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PART III

Certain information required by Part III is omitted from this Report on Form 10-K since we intend to file our definitive Proxy Statement for our next Annual Meeting of Stockholders, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended (the 2016 Proxy Statement), no later than October 28, 2016, and certain information to be included in the 2016 Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding our directors, executive officers and corporate governance will be included in our 2016 Proxy Statement and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item regarding executive compensation will be included in our 2016 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding security ownership of certain beneficial owners and management will be included in our 2016 Proxy Statement and is incorporated herein by reference.

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

The information required by this item regarding certain relationships and related transactions and director independence will be included in our 2016 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item regarding principal accounting fees and services will be included in our 2016 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of ContraVir Pharmaceuticals, Inc. appearing on page 61 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).

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Exhibit Number	Exhibit Description
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).
3.2	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).
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).

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Exhibit Number	Exhibit Description
10.5	Executive Agreement, dated March 19, 2014, between ContraVir Pharmaceuticals, Inc. and James Sapirstein (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 20, 2014 and incorporated herein by reference.)*.
10.6	Executive Agreement, dated April 1, 2016, between ContraVir Pharmaceuticals, Inc. and John Cavan (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 31, 2016 and incorporated herein by reference.)*
10.7	Form of Stock Purchase Agreement (filed as Exhibit 10.1 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.)
10.8	Executive Agreement, dated January 19, 2015, between ContraVir Pharmaceuticals, Inc. and Dr. John Sullivan-Bolyai (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 15, 2015 and incorporated herein by reference.)*
10.9	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). †
10.10	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).*
10.11	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.)*
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.

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: September 28, 2016

CONTRAVIR PHARMACEUTICALS, INC.

By: /s/ JAMES SAPIRSTEIN
James Sapirstein
Chief Executive Officer and Director
(Principal Executive Officer)

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KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, James Sapirstein, 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/ JAMES SAPIRSTEIN James Sapirstein	Chief Executive Officer and Director (Principal Executive Officer)	September 28, 2016
/s/ JOHN CAVAN John Cavan	Chief Financial Officer (Principal Financial and Accounting Officer)	September 28, 2016
/s/ GARY S. JACOB, PHD. Gary S. Jacob, PhD.	Chairman, Board of Directors	September 28, 2016
/s/ JOHN BRANCACCIO John Brancaccio	Director	September 28, 2016
/s/ ARNOLD LIPPA Arnold Lippa	Director	September 28, 2016
/s/ TIMOTHY BLOCK Timothy Block	Director	September 28, 2016
/s/ THOMAS ADAMS Thomas Adams	Director	September 28, 2016

Exhibit 21.1

LIST OF SUBSIDIARIES

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

ContraVir Pharmaceuticals, Inc.
399 Thornall Street, First Floor
Edison, New Jersey 08837

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 No. 333-202625 and Form S-8 No. 333-203867 of ContraVir Pharmaceuticals, Inc. of our report dated September 28, 2016, relating to the consolidated financial statements, which appears in this Form 10-K for the year ended June 30, 2016. 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

September 28, 2016

Exhibit 31.1

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

I, James Sapirstein, 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: September 28, 2016

/s/ JAMES SAPIRSTEIN
James Sapirstein
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: September 28, 2016

/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 June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James Sapirstein, 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: September 28, 2016

/s/ JAMES SAPIRSTEIN
James Sapirstein
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 June 30, 2016, 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.

Dated: September 28, 2016

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