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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2014

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 000-55020

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 (Address of Principal Executive Offices)	**08837** (Zip Code)

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

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

Title of each class	**Name of each exchange on which registered**

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $0.001 per share

(Title of Class)

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, 2013, was approximately $0. For purposes of the above statement only, all directors, executive officers and 10% shareholders are assumed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

The number of shares of the registrant's Common Stock outstanding as of September 19, 2014 was 22,273,397.

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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 a marketable product;
- Our ability to develop and commercialize our product;
- 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 FV-100 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 subsequent written and oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

PART I

ITEM 1. BUSINESS

Overview

We were incorporated in Delaware on May 15, 2013 for the purpose of holding certain FV-100 assets of Synergy Pharmaceuticals Inc., or Synergy. We were a majority-owned subsidiary of Synergy until February 18, 2014, the date Synergy completed the spinout of our shares of common stock. We are now an independent publicly traded company and Synergy retains no ownership interest in us.

On June 10, 2013, we and Synergy entered into a Contribution Agreement, as amended and restated on August 5, 2013, or the Contribution Agreement, to transfer to us the FV-100 assets, in exchange for the issuance to Synergy of 9,000,000 shares of our common stock representing 100% of the outstanding shares of our common stock as of immediately following such issuance. During the period from August 17, 2012 through September 30, 2013, Synergy made expenditures of $13,638 related to the research and development of FV-100. Pursuant to the Contribution Agreement, Synergy transferred ownership of all intellectual property rights acquired from Bristol-Myers Squibb Company, or 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. 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. There is no time limit to our assumed ongoing obligations under the BMS Agreement. During the period August 17, 2012 through June 10, 2013, there were no known material liabilities assumed by Synergy under the BMS Agreement and subsequently transferred to us pursuant to the Contribution Agreement.

On August 17, 2012, Synergy entered into the BMS Agreement, whereby Synergy acquired certain assets from BMS related to FV-100. The FV-100 assets acquired from BMS are licensed from University College Cardiff Consultants Limited, or Cardiff, pursuant to the terms of that certain Patent and Technology License Agreement, dated as of February 2, 2005, between Cardiff and Contravir Research Incorporated, or 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; (e) 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 (f) 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 under the Cardiff Agreement is equal to $550,000, of which $420,000 has been previously paid by CRI.

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.

FV-100

FV-100 is an orally available, small molecule nucleoside analogue prodrug 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. 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 post-herpetic neuralgia (PHN) (burning pain that follows healing of the shingles rash), and the time to lesion healing.

The primary endpoint for the FV-100 study was a 25% reduction in the severity and duration of shingles-related pain during the first 30 days as compared to valacyclovir. The trial missed its primary endpoint which was an endpoint developed by Inhibitex specifically for this trial called "burden of illness over the first 30 days" (BOI—30), as the results from the study did not meet statistical significance with respect to this endpoint. However, numerically favorable treatment differences with respect to the primary endpoint were observed, particularly in those patients that received 400 mg FV-100 relative to valacyclovir patients. Valacyclovir gave a BOI—30 of 118.0 days (6.25). In comparison, 400 mg FV-100 gave a BOI—30 of 110.3 days (6.08), which constitutes a 7% reduction over the value observed for valacyclovir over the first 30 days. As this was a Phase 2 study, we will be able to use this information to help design future clinical studies, as well as discussing future study designs with FDA and regulatory authorities worldwide. There were also favorable, non-statistically significant treatment differences observed for key secondary pain endpoints, including reduction in the severity and duration of shingles-associated pain over 90 days (a 14% relative reduction for 400 mg FV-100 as compared to valacyclovir), and the incidence of PHN (a 39% relative reduction for 400 mg FV-100 as compared to valacyclovir). The secondary endpoints were not, however, powered to demonstrate statistically significant treatment differences between the arms. FV-100 was generally well tolerated at both dose levels, and demonstrated a similar adverse event profile as compared to valacyclovir.

We are currently reviewing the clinical data from the Phase 2 trial and performing post hoc analyses, conducting additional market research, including unmet medical need, reimbursement, pricing, and competitive analyses, etc. We are also evaluating 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 are developing a comprehensive clinical strategy for future development of FV-100 which is being implemented in 2014. Typically, phase 2 clinical trials are conducted to explore efficacy and establish dose ranging data, and typically employ a number of statistical methods for evaluating efficacy on primary and secondary endpoints.

Inhibitex filed for an IND (IND 102,011) on March 19, 2008, which was approved by the FDA on April 20, 2008. This IND was transferred from Inhibitex to its new sponsor, Synergy, on August 27,

2012 and subsequently transferred to us in April 2014. As a result of this transfer, we will be able to run all clinical trials required to support FV-100 for the use in the treatment of shingles.

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. Therefore, shingles is typically not transmitted from one individual to the next, and only those individuals who have had chickenpox are generally at risk for shingles.

Although shingles can occur in any individual with a prior VZV infection, its incidence varies with its 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 increase. 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.

The symptoms associated with shingles generally include localized lesions (rash and blisters) and localized pain. In many cases the patient may notice localized pain prior to the appearance of any lesions; however, the first recognizable symptom of shingles is generally lesions that will continue to form for a week or two. Such lesions generally follow the path of nerves that emanate from the spinal cord around the torso (thoracic); however, the infection is also commonly found on the face, neck, lower back and in certain rare cases, systemically. Within several weeks, the lesions in the infected areas will typically begin to heal, and these dermatological symptoms generally will resolve within a month or less after the appearance of the first lesion. In rare instances, lesions may never appear, but pain will be present.

The pain associated with an episode of shingles is attributed to both the damage caused to the affected nerves by the replication of VZV and the inflammatory response associated with the infection. Pain symptoms are commonly described as a burning sensation, with bouts of stabbing and shooting pain, often set off by contact with the infected area. The majority of shingles patients experience such pain for several weeks in connection with their active infection, referred to as acute pain. For many patients, shingles-associated pain does not resolve when the lesions heal and the inflammation subsides, but, rather, continues for months, or possibly years. Persistent shingles-associated pain that lasts more than three to four weeks is referred to as sub-acute pain or neuralgia. Shingles-associated pain that persists more than three months is generally referred to as 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. Previous studies have established that additional risk factors for PHN include greater acute pain intensity, severity of the dermatological symptoms or lesions, and the presence and greater severity of the localized pain preceding the lesions or rash.

Valacyclovir, acyclovir and famciclovir are oral antivirals currently indicated and 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 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.

FV-100 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 efficacy analysis was conducted on the modified intent-to-treat population, which included all patients that received a dose of the drug except those whose lesions were PCR (-) for varicella zoster virus and PCR (+) for herpes simplex virus. Polymerase chain reaction, or PCR, is a test tube method using enzymes for the repeated coping of two strands of DNA genes of a particular gene sequence. PCR (-) for the varicella zoster virus means that the lesions did not contain DNA genes for that particular varicella zoster virus and PCR (+) for the herpes simplex virus indicates that the DNA genes are from the herpes simplex and not the herpes zoster virus. The efficacy endpoints were calculated using a statistical method of handling missing data called last observation carried forward methodology.

FV-100 Efficacy Summary

The primary endpoint for the study was a 25% reduction in the severity and duration of shingles-related pain during the first 30 days as compared to valacyclovir and the results obtained from the study demonstrate a lack of statistical significance. Shingles patients who received 200 mg or 400 mg FV-100 experienced numerically favorable treatment differences as compared to patients treated with valacyclovir, as measured by the primary endpoint (% of patients experiencing a 25% reduction in pain during the first 30 days following onset of treatment), of 3% and 7%, respectively. In addition, patients treated with 200 mg and 400 mg FV-100 experienced a relative reduction in the amount of shingles-associated pain over the first 90 days after lesion appearance compared to those treated with valacyclovir, of -4% and 14%, respectively (not statistically significant). Statistical significance at the 95% level ($p<0.05$) indicates that if you were to repeat the experiment, there would be only 5 chances in 100 the result could happen by coincidence. The levels of significance (0.05, 0.001, etc.) are arbitrarily set, however, the lack of statistical significance implies that the two treatments being compared are not different based on the design of the experiment. Further, 18% and 12% of the patients receiving 200 mg and 400 mg FV-100, respectively, developed PHN (% of patients reporting pain at 90 days following initiation of treatment) as compared to 20% of the valacyclovir-treated patients, resulting in relative treatment differences of 12% and 39%, respectively. Relative treatment differences reflect the percent difference between any FV-100 dose and the gold standard for treating shingles, valacyclovir. Effectively, this is the ratio of the percent of incidences of post-herpetic neuralgia reported for each treatment. In this case, 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.

The following table reflects the treatment outcomes among the three treatment arms with respect to the key shingles-associated pain endpoints on the modified intent-to-treat population:

	Primary Endpoint	Key Secondary Pain Endpoints	
Cohort (N)	30 Day Pain Score AUC ± S.E.	90 Day Pain Score AUC ± S.E.	Incidence of PHN (%)
3000 mg valacyclovir (N=109)	117.96 ± 6.25	229.59 ± 19.55	20.2
200 mg FV-100 (N=107)	114.49 ± 6.24	221.53 ± 19.51	17.8
400 mg FV-100 (N=113)	110.31 ± 6.08	196.94 ± 19.01	12.4

Area under the curve, or AUC, is a measure whereby daily scores are added up over the specified scoring period. Using a pain scale where 0 = no pain and 10 = worst possible pain, adding up the daily scores provides a measure of effectiveness where lower AUC numbers indicate lower pain scores over time. Post herpetic neuralgia, or PHN, is burning pain that follows healing of the shingles rash. Standard Error of the Mean, or S.E., refers to an estimate of the standard deviation which is computed from the sample of data being analyzed at that time.

FV-100 Safety Summary

A comparison of adverse events, or AE, 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. All three treatment arms showed a relatively low proportion of adverse events and serious adverse events, or SAE. In the 400 mg FV-100 dose group, the most common adverse events were headache (reported in 13% of patients) and nausea (9%); no patient discontinued because of headache and one patient terminated due to nausea (grade 1). The most common adverse events in the valacyclovir cohort were nausea (6%) and upper abdominal pain (5%).

The following table lists the summary of adverse event findings from the trial:

Number (%) of Patients Reporting:	200 mg FV-100 (N=117)	400 mg FV-100 (N=117)	3000 mg valacyclovir (N=116)
Any AE	46.2	54.7	42.2
Treatment-Related AEs	2	25.6	19.8
Discontinuation of Drug for AE	1.7	1.7	1.7
SAEs	0	4.3	3.4
Treatment-Related SAEs	0	0	1.7

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

Phase 1 Clinical Studies

In August 2008, an FV-100 Phase 1 single-ascending-dose clinical trial was completed. 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.

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. The EC 50 represents the concentration of drug that is required for 50% inhibition of viral replication *in vitro*.

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 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 exclusivity provisions of this law.

Pursuant to the Contribution Agreement, 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. 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.

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

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

or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we are taking to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or us, we may face costly litigation and the diversion of management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on 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 candidate. We intend to rely on contract manufacturers to produce all materials required to conduct preclinical studies and clinical trials under current good manufacturing practices ("cGMP"), with management and oversight of these activities by our management team. We have identified alternate sources of supply and other contract manufacturers that can produce materials for our preclinical and clinical trial requirements on a timely basis. However, if an existing or future contract 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.

Pharmaceutical Pricing and Reimbursement

In the U.S. and most foreign markets, any revenue associated with the sale of our product candidate, if approved for sale, will depend largely upon the availability of reimbursement from third-party payers. Third-party payers include various government health authorities such as The Centers for Medicare and Medicaid Services ("CMS"), which administers Medicare and Medicaid in the U.S., managed-care providers, private health insurers and other organizations. Third-party payers are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status of newly approved pharmaceutical products. Our products may ultimately not be considered cost-effective, and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to support a profitable operation or generate an appropriate return on our investment in product development.

The U.S. and foreign governments periodically propose and pass legislation designed to reduce the cost of healthcare and pharmaceutical products. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before our product candidate is ever approved for sale. In

addition, the adoption of new legislation could further limit reimbursement for pharmaceuticals. Further, an increasing emphasis on managed care in the U.S. has and will continue to increase the pressure on pharmaceutical pricing. The marketability of our products may suffer if the government and other third-party payers fail to provide adequate coverage and reimbursement rates for our product candidate.

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

Regulatory Matters

Overview

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

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

U.S. Regulatory Approval

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

- the completion of satisfactory preclinical studies under the FDA's good labor practices, or GLP, regulation;
- the submission and acceptance of an IND that must be reviewed by the FDA and become effective before human clinical trials may begin;
- obtaining the approval of an Institutional Review Board, or IRB, 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, orin vitro, evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain in vivo animal studies to assess its 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 Investigational New Drug application, or IND, which must be reviewed and become effective before we may begin any human clinical trials. An IND generally becomes effective approximately 30 days after receipt by the FDA, unless the FDA, within this 30-day time period, raises material concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. If our product candidate is placed on clinical hold, we may be required to resolve any outstanding issues to the satisfaction of the FDA before we could begin, or continue, clinical trials of such product candidate. Preclinical studies supportive of an IND generally take a year or more to complete, and there is no guarantee that an IND based on those studies will become effective, allowing human clinical testing to begin.

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

Clinical Trials

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

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

- *Phase 1:* After an IND becomes effective, Phase 1 human clinical trials can begin. A product candidate is typically introduced either into healthy human subjects or in some cases, patients with the medical condition for which the product candidate is intended to be used. Generally, the purpose of a Phase 1 trial is to assess a product candidate's safety and the ability of the human body to tolerate it at different dose levels. Absorption, metabolism, distribution and pharmacokinetic trials are also generally performed at this stage. Phase 1 trials typically evaluate these aspects of the investigational drug in both single doses, as well as multiple doses.

- *Phase 2:* During Phase 2 clinical trials, a product candidate is generally studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is

intended to be used in order to (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy or biologic activity of the product candidate for specific targeted diseases or medical conditions, and (iii) assess dose tolerance and determine the optimal dose for a subsequent Phase 2 or Phase 3 trial. Phase II trials generally involve patients who are divided into one or more groups that will get one of several dose levels of the product candidate, and a control group that is not treated with the product candidate but either receives a placebo or a drug already on the market for the same indication. Typically, two or more Phase 2 studies will be conducted for a product candidate prior to advancing to Phase 3.

- *Phase 3:* If and when one or more Phase 2 trials demonstrate that a specific dose or range of doses of a product candidate is potentially effective and has an acceptable safety profile, one or more Phase 3 trials may be undertaken to further demonstrate or confirm the clinical efficacy and safety of the investigational drug in an expanded patient population, with the goal of evaluating its overall risk-benefit relationship. Phase 3 trials are generally designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the product candidate's clinical efficacy. The successful demonstration of clinical efficacy and safety in one or more Phase 3 trials is typically a prerequisite to the filing of a NDA or BLA for a product candidate.

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

A company may request an "end-of-Phase 2 Meeting" with the FDA to assess the safety of the dose regimen to be studied in the Phase 3 clinical trial, to evaluate the planned design of a Phase 3 trial, and to identify any additional information that will be needed to support a NDA. If a Phase 3 clinical trial has been the subject of discussion at an "end-of-Phase2 Meeting," the trial sponsor may be eligible for a Special Protocol Assessment ("SPA"), by the FDA, a process by which the FDA, at the request of the sponsor, will evaluate the trial protocol and issues relating to the protocol within 45 days to assess whether it is deemed to be adequate to meet the scientific and regulatory requirements identified by the sponsor. If the FDA and the sponsor reach agreement on the design and size of a Phase 3 clinical trial intended to form the primary basis of an efficacy claim in a NDA or BLA, the FDA may reduce the understanding to writing. The SPA, however, is not a guarantee of product approval by the FDA, or approval of any permissible claims about the product.

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

Monitoring Board may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health or safety risk.

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

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

New Drug and Biologics License Applications

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

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

If the results of the FDA's evaluation of the NDA or BLA, and inspection of manufacturing facilities are favorable, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication. As a condition of NDA or BLA approval, the FDA may require post-approval testing, including Phase 4 trials, and

surveillance to monitor the drug's safety or efficacy and may impose other conditions, including labeling or distribution restrictions which can materially impact the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

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

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

Post-Approval Regulations

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

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

The labeling, advertising, promotion, marketing and distribution of an approved drug or biologic product must also comply with FDA and Federal Trade Commission ("FTC") requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving

the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing 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, 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.

Fast Track Drug Status

The FDA has developed "Fast Track" policies, which provide for the potential of an expedited review of a NDA or BLA. However, there is no assurance that the FDA will, in fact, accelerate the review process for a Fast Track product candidate. Fast Track status is provided for those new and novel therapies that are intended to treat persons with life-threatening and severely debilitating diseases where there is a defined unmet medical need, especially where no satisfactory alternative therapy exists or the new therapy appears to be significantly superior to existing alternative therapies. During the development of product candidates that qualify for this status, the FDA may expedite consultations and reviews of these experimental therapies. Fast Track status also provides for the potential for a "priority review", whereby the FDA agrees to reduce the time it takes to review a NDA or BLA. The FDA can base approval of a marketing application for a Fast Track product on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA generally requires as a condition of the approval of an application for certain Fast Track products, additional post-approval studies or Phase 4 clinical studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Further, Fast Track status allows for a rolling NDA or BLA submission, whereby portions of the application can be submitted to the FDA for review prior to the completion of the entire application. A rolling submission could result in a reduction in the length of time it would otherwise take the FDA to complete its review of the application. Fast Track status may be revoked by the FDA at any time if the clinical results of a trial fail to continue to support the assertion that the respective product candidate has the potential to address an unmet medical need. In addition, Fast Track status may be granted for a specific application of a drug candidate.

Foreign Regulatory Approval

Outside of the U.S., our ability to market any of our existing or future product candidates will also be contingent upon receiving marketing authorizations from the appropriate foreign regulatory authorities whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally includes risks that are similar to the FDA approval process described above. The requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals may vary widely from country to country and differ from that required for FDA approval.

Employees

At June 30, 2014, we had three employees. Our operations were previously conducted on a contract basis under a Shared Services Agreement with Synergy, or SSA, dated July 8, 2013,under which Synergy would provide and/or make available to us various administrative, financial, accounting, legal, insurance, facility, information technology, laboratory, real estate and other services to be provided by, or on behalf of, Synergy, together with such other services as may be mutually and reasonably agreed.

In consideration for such services, we paid fees to Synergy for the services provided, and those fees were generally in amounts intended to allow the party providing services to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the SSA were employees and/or independent contractors of Synergy and were not under our direction or control. These personnel costs were comparable to those arrived at on an arm's-length basis and were based upon the allocated percentages of time spent by Synergy personnel performing services for us under the shared services agreement. We also reimbursed Synergy for direct out-of-pocket costs incurred by Synergy for third party services provided to us.

Effective April 1, 2014, we terminated the SSA.

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.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will 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 June 30th , 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 refer to the Jumpstart Our Business Startups Act of 2012 in this Annual Report on Form 10-K as the "JOBS Act," and references to "emerging growth company" have the meaning associated with it in the JOBS Act.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this annual report, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have incurred losses since inception, anticipate that we will incur continued losses for the foreseeable future and our independent registered public accounting firm's report, contained herein, includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern, indicating the possibility that we may not be able to operate in the future.

As of June 30, 2014 and 2013, we had an accumulated deficit of $5.4 million and $0.1 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 of FV-100, 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 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 candidate, or continue our development programs.

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

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

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

- the progress of the development of FV-100;
- the number of product candidates we pursue;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- general market conditions for offerings from biopharmaceutical companies;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and
- our revenues, if any, from successful development and commercialization of our product candidate.

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

In preparing our consolidated financial statements, our management determined that our disclosure controls and procedures and internal controls were ineffective as of June 30, 2014 and if they continue to be ineffective could result in material misstatements in our financial statements.

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. As of June 30, 2014, our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to accounting controls and procedures in the future, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent auditors addressing these assessments. If 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.

Our prospects are largely dependent on the success of FV-100, which was the subject of a Phase II clinical trial that failed to meet its primary endpoints. While we seek to determine the implications, if any, of the Phase II results on our FV-100 product candidate and consider 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 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 FV-100 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 FV-100 through preclinical studies and clinical trials, have these product candidate approved for sale by the FDA or regulatory authorities in other countries, and ultimately have this product candidate successfully commercialized by us or a strategic collaborator. We cannot assure you that the results of our ongoing preclinical studies or clinical trials will support or justify the continued development of our product candidate, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidate.

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

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

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidate. 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 candidate may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidate demonstrates a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application, or NDA or a biologics license application, or BLA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

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

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

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

If the results of preclinical studies or clinical trials for our product candidate, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidate, which could materially harm our business.

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

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidate, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;
- regulatory authorities (including an Institutional Review Board) or IRBs 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 or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and
- the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidate demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

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

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. As of the date hereof, we have not entered into any contracts with third party vendors for any studies to be conducted. 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 and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the preclinical studies and clinical trials of our product candidate may be delayed or prove unsuccessful. Further, the FDA may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

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

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staffs 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 Biosceinces, 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 candidate.

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

The product 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 candidate is also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidate' safety and efficacy before they can be approved for the targeted indications. Our product candidate has not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidate we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidate, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 clinical trials. In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidate based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidate through clinical development, and ultimately commercialize them, may:

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

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

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

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes

typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks.

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

Our lead product candidate, FV-100, is a chemical compound, also referred to as a small molecule. We have limited experience in the discovery, development and manufacturing of these small molecule antiviral compounds. In order to successfully develop this product candidate, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of 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 candidate, we need to retain or attract certain personnel, consultants or advisors with experience in the drug development activities of small molecules that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, 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 candidate.

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

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

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

our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidate.

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

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

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

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

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

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among

jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidate or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

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

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

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

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

We, 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 candidate will be successful in clinical trials or receive regulatory approval. Further, our product candidate may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidate, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market 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 candidate, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidate are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

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

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

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

Administering any product candidate to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidate and could result in the FDA or other regulatory authorities denying further development or approval of our product candidate for any or all targeted indications. Ultimately, 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 defends against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

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

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre-clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for our product candidate currently under development. Any approvals we may obtain may not cover all 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 candidate for the claimed intended uses. Following any regulatory approval of our product candidate, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to 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 candidate is unable to compete effectively with marketed drugs targeting similar indications as our product candidate, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any shingles 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 successful in completing drug development for their product candidates and obtain approval from the FDA, they could limit the demand for FV-100.

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

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

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively in the shingles drug market 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. If our product candidate is approved by the FDA, we intend to market that product through our own sales force. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidate in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidate, we may not be able to commercialize our product candidate which would negatively impact our ability to generate revenue.

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

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

If the manufacturers upon whom we rely fail to produce FV-100, 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 FV-100, 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 of FV-100 or other 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 of FV-100 or other 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 FV-100 or other 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 FV-100 or other 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 candidate in commercial quantities, which would prevent us from commercializing our product candidate.

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

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

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

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

If our product candidate is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on 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 candidate 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 candidate, 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 candidate may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

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

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed product.

If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidate do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidate could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidate;
- our contract manufacturers failing to manufacture our product candidate according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidate. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidate. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated current good marketing practices or cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidate could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

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

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

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, FV-100 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 the treatment of chronic shingles-associated pain and the prevention of staphylococcal infections. Some of the large pharmaceutical companies that currently market products that would compete with our product candidate, 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 FV-100 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 FV-100 if successfully developed and approved, will compete directly or indirectly with existing generic drugs. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on competing patented drugs.

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

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

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

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

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have product liability insurance coverage for our clinical trials in the amount of $5.0 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 Candidate

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

Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to shareholders, or otherwise provide any competitive advantages in its intended indication or market.

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

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

If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidate, or otherwise fail to establish marketing and sales capabilities, we may not be able to successfully commercialize our products.

We currently have no infrastructure to support the commercialization of our product candidate, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if our product candidate is successfully developed and ultimately approved for sale, our future profitability will depend largely on our ability to access or develop suitable marketing and sales capabilities. We anticipate that we will need to establish relationships with other companies, through license and collaborations agreements, to commercialize our product candidate in the U.S. and in other countries around the world. To the extent that we enter into these license and collaboration agreements, or marketing and sales arrangements with other companies to sell, promote or market our products in the U.S. or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, will depend largely on their efforts, which may not be successful. In the event we develop a sales force and marketing capabilities, this may result in us incurring significant costs before the time that we may generate any significant product revenues. We may not be able to

attract and retain qualified third parties or marketing or sales personnel, or be able to establish marketing capabilities or an effective sales force.

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

In the U.S. and most foreign markets, our product revenues, and therefore the inherent value of our product candidate, will depend largely upon the reimbursement rates established by third-party payers for such product candidate or products. Such third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. These third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products, services and pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs or pharmaceutical products. Further, the comparative effectiveness of new compounds over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by these payers to establish reimbursement rates. We may also need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. We cannot assure you that any products we successfully develop will be reimbursed in part, or at all, by any third-party payers in any countries.

Domestic and foreign governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical drugs. In some foreign markets, governmental agencies control prescription drugs' pricing and profitability. In the U.S. significant changes in federal health care policy have been recently approved and will mostly likely result in reduced reimbursement rates in the future. We expect that there will continue to be federal and state proposals to implement more governmental control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products domestically. Cost control initiatives could decrease the price that we receive for any of our product candidates that may be approved for sale in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceutical products may change before our product candidate is approved for sale, which could further limit or eliminate reimbursement rates for our product candidate.

If any product candidate that we develop independently or through collaborations is approved but does not gain meaningful acceptance in its intended market, we are not likely to generate significant revenues or become profitable.

Even if our product candidate is successfully developed and we or a collaborator obtain the requisite regulatory approvals to commercialize it in the future, it may not gain market acceptance or utilization among physicians, patients or third party payers. The degree of market acceptance that our product candidate may achieve will depend on a number of factors, including:

- the therapeutic efficacy or perceived benefit of the product relative to existing therapies, if they exist;
- the timing of market approval and existing market for competitive drugs;
- the level of reimbursement provided by payers to cover the cost of the product to patients;
- the net cost of the product to the user or payer;
- the convenience and ease of administration of our product;
- the product's potential advantages over existing or alternative therapies;

- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, prevalence and severity of negative side effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA.

There can be no assurance that physicians will choose to prescribe or administer our product, if approved, to the intended patient population. If our product does not achieve meaningful market acceptance, or if the market for our product proves to be smaller than anticipated, we may not generate significant revenues or ever become profitable.

Even if we or a collaborator achieve market acceptance for our product, we may experience downward pricing pressure on the price of our product due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

Pressure from social activist groups and future government regulations, whose goal it is to reduce the cost of drugs, particularly in less developed nations, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our product in the future.

We may be unable to successfully develop a product candidate that is the subject of collaboration if our collaborator does not perform, terminates our agreement, or delays the development of our product candidate.

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

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

- may re-evaluate the importance and their support for developing our product candidate pipeline due to a change in management, business operations or financial strategy.

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

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

Our success, competitive position and future revenues will depend in part on our ability and the ability of Cardiff, the licensor of the FV-100 assets, to obtain and maintain patent protection for our products, 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. Under the Cardiff Agreement, we hold certain exclusive patent rights for our FV-100 assets, including licensed rights under U.S. patents and U.S. patent applications as well as licensed rights under foreign patents and patent applications owned by Cardiff.

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 candidate.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate". The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, United States Patent and Trademark Office, or USPTO, interference proceedings and related legal and administrative proceedings, both in the U.S. and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the U.S. are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to our product candidate may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding in the USPT office, or similar proceedings in other countries to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the 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 Agreement, Cardiff 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. Therefore, our commercial success will depend to a large extent on our ability to maintain and comply with our obligations under the Cardiff Agreement. The Cardiff Agreement provides Cardiff with the right to terminate the Cardiff 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 to Cardiff or future licensors, 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 FV-100 assets. The loss of our license with Cardiff with respect to the FV-100 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 Agreement and BMS 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.

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

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or impose ongoing requirements for potentially costly post-approval studies. FV-100 and other 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 FV-100 and/or other 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 FV-100 or other 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 FV-100 or other product candidates and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

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

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

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

We will need to increase the size of our organization, and we may experience difficulties in managing growth since we no longer rely upon Synergy for providing various services to us.

We are a small company with three employees as of June 30, 2014. All management services being provided to us other than the services of Mr. James Sapirstein, our chief executive officer, and William Hornung, our chief financial officer were provided by our former majority shareholder, Synergy, under our Shared Services Agreement, or SSA. Effective April 1, 2014, we terminated the SSA with Synergy. As a result, all executive officer positions other than Mr. Sapirstein were provided by various employees of Synergy under the SSA and we are now required to find suitable candidates who can fill their roles. To continue our clinical trials and commercialize our product candidate, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our planned clinical trials and capital raising efforts, we plan to add additional employees to assist us with our clinical programs. Our future financial performance and our ability to

commercialize our product candidate and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

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

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

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

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

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

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

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

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

products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

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

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.

Until recently, we depended on Synergy to provide us with certain services for our business. We may be unable to provide these services ourselves or obtain substitute arrangements with other third parties.

We were a controlled subsidiary of Synergy until February 18, 2014. All administrative services required by us for the operation of our business were provided by Synergy, including services related to insurance and risk management, accounting and human resources. On July 8, 2013, we entered into the shared services agreement with Synergy, effective May 16, 2013. Under the SSA, Synergy provided us with certain transition services until we were able to build our own capabilities in the transition areas. Effective April 1, 2014, we terminated the shared services agreement with Synergy. As a result, we are now required to provide these services ourselves or to obtain substitute arrangements with other third parties. We may be unable to provide these services because of financial or other constraints or be unable to implement substitute arrangements on a timely basis on terms that are favorable to us, or at all.

Risks Related to Our Common Stock

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.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, 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. 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. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

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

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

- our ability to integrate operations, technology, products and services;
- our ability to execute our business plan;
- operating results below expectations;
- our issuance of additional securities, including debt or equity or a combination thereof, which will be necessary to fund our operating expenses;
- announcements of technological innovations or new products by us or our competitors;
- loss of any strategic relationship;
- industry developments, including, without limitation, changes in healthcare policies or practices or third-party reimbursement policies;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- whether an active trading market in our common stock develops and is maintained.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

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

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

We expect that significant additional capital will be needed in the future to continue our planned operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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"Penny stock" rules may make buying or selling our securities difficult which may make our stock less liquid and make it harder for investors to buy and sell our securities.

If our shares of common stock continue to trade on the Over-the-Counter Bulletin Board or any quotation system maintained by OTC Markets, Inc, trading in our securities will be subject to the SEC's "penny stock" rules and it is anticipated that trading in our securities will continue to be subject to the penny stock rules for the foreseeable future. The SEC has adopted regulations that generally

define a penny stock to be any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. These rules require that any broker-dealer who recommends our securities to persons other than prior customers and accredited investors must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

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 June 30th , 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 FV-100. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

We expect that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 399 Thornall Street, First Floor, Edison, New Jersey, 08837, at a cost of $10,336 per month. The term of our lease expires in 2019. This lease started August 15, 2014.

ITEM 3. LEGAL PROCEEDINGS

We are not currently involved in any legal proceedings, however, from time to time, we may become a party to various legal actions and complaints arising in the ordinary course of business. In addition to commitments and obligations in the ordinary course of business, we are subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. It is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information and Holders

Our common stock is 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 OTCBB on September 19, 2014 was $1.15 per share.

Fiscal 2014	High	Low
Fourth Quarter	$ 2.35	$ 1.11
Third Quarter (beginning February 10, 2014)	$ 2.96	$ 0.75

Holders of Record

As of September 19, 2014, there were approximately 447 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, 2014.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Stockholders	—	$ —	—
Equity Compensation Plans Not Approved by Stockholders	2,341,270	$ 1.61	—
Total	2,341,270		

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with "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.

JOBS Act

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified

reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

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

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

We may take advantage of these provisions 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.

Business Overview

We are 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 reactivation of varicella zoster virus (VZV).

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. Preclinical studies, including wash-out studies in VZV-infected human embryonic lung cells following exposure to FV-100 or acyclovir, conducted by Inhibitex and specific cellular antiviral activity experiments comparing FV-100 to acyclovir conducted by Balzarini et al (Biochimica et Biophysica Acta, 1587 pages 287-295) 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 post-herpetic neuralgia (PHN) (burning pain that follows healing of the shingles rash), and the time to lesion healing.

The primary endpoint for the FV-100 study was a 25% reduction in the severity and duration of shingles-related pain during the first 30 days as compared to valacyclovir. The trial missed its primary endpoint which was an endpoint developed by Inhibitex specifically for this trial called "burden of illness over the first 30 days" (BOI—30), as the results from the study did not meet statistical significance with respect to this endpoint. However, numerically favorable treatment differences with respect to the primary endpoint were observed, particularly in those patients that received 400 mg FV-100 relative to valacyclovir patients. Valacyclovir gave a BOI—30 of 118.0 days (6.25). In comparison, 400 mg FV-100 gave a BOI—30 of 110.3 days (6.08), which constitutes a 7% reduction over the value observed for valacyclovir over the first 30 days. As this was a Phase 2 study, we will be able to use this information to help design future clinical studies, as well as discussing future study designs with FDA and regulatory authorities worldwide. There were also favorable, non-statistically significant treatment differences observed for key secondary pain endpoints, including reduction in the severity and duration of shingles-associated pain over 90 days (a 14% relative reduction for 400 mg FV-100 as compared to valacyclovir), and the incidence of PHN (a 39% relative reduction for 400 mg FV-100 as compared to valacyclovir). The secondary endpoints were not powered to demonstrate statistically significant treatment differences between the arms. FV-100 was generally well tolerated at both dose levels, and demonstrated a similar adverse event profile as compared to valacyclovir.

We are currently reviewing the clinical data from the Phase 2 trial and performing post hoc analyses, conducting additional market research, including unmet medical need, reimbursement, pricing, and competitive analyses, etc. We are also evaluating 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 are developing a comprehensive clinical strategy for future development of FV-100 which is being implemented in 2014. Inhibitex filed for an IND (IND 102,011) on March 19, 2008, which was approved by the FDA on April 20, 2008. This IND was transferred from Inhibitex to its new sponsor, Synergy, on August 27, 2012 and was subsequently transferred to us in April 2014. As a result of this transfer, we will be able to run all clinical trials required to support FV-100 for the use in the treatment of shingles.

Separation from Synergy Pharmaceuticals Inc.

On August 8, 2013, Synergy announced that it intended to separate its FV-100 assets from the remainder of its businesses through a pro rata distribution of the common stock of an entity holding the assets and liabilities associated with the FV-100 product candidate. We were incorporated in

Delaware on May 15, 2013 for the purpose of holding such businesses and were previously a subsidiary of Synergy.

On January 28, 2014, the Synergy board of directors approved the distribution of the 9,000,000 issued and outstanding shares of our common stock currently held by Synergy on the basis of 0.0986 shares of our common stock for each share of Synergy common stock held on the record date. On January 28, 2014, Synergy declared a dividend of our common stock. On the distribution date of February 18, 2014, Synergy stockholders of record as of the close of business on February 6, 2014 received .0986 shares of our common stock for every 1 share of Synergy common stock they held. None of our fractional shares were issued. Synergy stockholders received cash in lieu of fractional shares.

We are no longer a wholly-owned subsidiary of Synergy and Synergy retains no ownership interest in us.

We will incur increased costs as a result of becoming an independent, publicly-traded company, primarily from higher charges than in the past from Synergy for shared services and from establishing or expanding the corporate support for our businesses, including information technology, human resources, treasury, tax, risk management, accounting and financial reporting, investor relations, legal, procurement and other services. In the first year following the separation, these annual operating costs are estimated to be significantly higher than the general corporate expenses historically allocated from Synergy to us.

We do not anticipate that increased costs solely from becoming an independent, publicly traded company will have an adverse effect on our growth rate in the future.

FINANCIAL OPERATIONS OVERVIEW

From May 15, 2013 (inception) through June 30, 2014, we have sustained cumulative net losses of approximately $5.4 million. From inception through June 30, 2014, 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.

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 2 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, 2014 we had $1.8 million in cash. Net cash used in operating activities was $1.4 million for the year ended June 30, 2014. As of June 30, 2014 we had an accumulated deficit of $5.4 million. These financial statements have been prepared under the assumption that we will continue as a going concern. Our ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, 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. We will be required to raise additional capital within the next year to continue the development and commercialization of current product candidate and to continue to fund operations at the current cash expenditure levels. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that impact our ability to conduct business. If we are unable to raise additional capital when required or on acceptable terms, we may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of its product candidate; (ii) seek collaborators for product its candidate 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, notes 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, is recorded as a derivative liability under the provisions of FASB ASC 815 *Derivatives and Hedging ("ASC 815")* upon issuance. Subsequently the liability is adjusted to fair value as of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statement of operations under the caption "Change in fair value of derivative liabilities."

The fair value of warrants deemed to be derivative instruments is determined using 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 use model-derived valuations where significant value drivers are unobservable to third parties to determine the fair value and accordingly classify such warrants in Level 3 per ASC 820. At June 30, 2014, the fair value of

such warrants was $4,475,345 which we classified as a long term derivative liability on our balance sheets. There were no warrants recorded as derivative liabilities as of June 30, 2013.

Property, equipment and depreciation

As of June 30, 2014, our property and equipment consisted primarily of computer equipment As of June 30, 2013 we had no property or equipment. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets will be 2 to 5 years for equipment and furniture and fixtures. Leasehold improvements will be depreciated over the remaining useful life of the lease. Expenditures for repairs and maintenance are charged to operations as incurred. We will periodically evaluate whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable.

Income Taxes

We have not filed any Federal tax returns since May 15, 2013 (inception). The amount of any tax liability that could arise since inception is undetermined at this time, however, we believe that because we have sustained losses since inception, the amount of any tax liability, if any, that could arise would be immaterial to the our financial statements. Any interest or penalties would be recorded in its statement of operations. We intend to record a valuation allowance against any deferred tax assets upon the filing of its tax returns to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. As a result there are no income tax benefits reflected in the consolidated statements of operations to offset pre-tax losses.

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 Topic 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, regulatory and scientific consulting fees, as well as contract research, insurance and FDA consultants, are accounted for in accordance with ASC Topic 730-10-55-2, Research and Development.

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 Topic 730, Research and Development 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. We had no recorded prepaid research and development costs of June 30, 2014 and 2013.

Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, ("ASC Topic 260") for all periods presented. In accordance with this guide, 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. Diluted weighted-average shares are the same as basic weighted-average shares because there were no shares issuable pursuant to the exercise of stock options or warrants as of June 30, 2013. As of June 30, 2013 we had no outstanding stock options or warrants. For the year ended June 30, 2014, outstanding stock options and warrants have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive. For additional information, see Note 10 to the consolidated financial statements included in *Item 8: Financial Statements and Supplementary Data* of this report.

OFF-BALANCE SHEET ARRANGEMENTS

We had no off-balance sheet arrangements as of June 30, 2014.

RESULTS OF OPERATIONS

Comparison of Year Ended June 30, 2014 and period from May 15, 2013 (inception) thru June 30, 2013

	Year ended June 30, 2014	Period from May 15, 2013 (inception) thru June 30, 2013	Change
Revenues	$ —	$ —	$ —
Costs and Expenses:			
General and administrative	1,357,863	17,740	1,340,123
Research and development	314,246	122,427	191,819
Loss from operations	(1,672,109)	(140,167)	(1,531,942)
Other income (expense):			
Change in fair value of warrant liability	(3,595,788)	—	(3,595,788)
Interest expense	(12,945)	(328)	(12,617)
Total other income (expense)	(3,608,733)	(328)	(3,608,405)
Net loss	$ (5,280,842)	$ (140,495)	$ (5,140,347)

We had no revenues during the year ended June 30, 2014 or during the period from May 15, 2013 (inception) thru June 30, 2013 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 year ended June 30, 2014 amounted to $0.3 million, which were primarily scientific advisory fees and clinical data storage. Research and development expenses during the period May 15, 2013 (Inception) to June 30, 2013 amounted to $122,427 were primarily scientific advisory fees and clinical data storage.

General and administrative expenses for the year ended June 30, 2014 amounted to $1.4 million, which were primarily corporate legal and accounting services related to patent maintenance, Form 10 filings and independent accounting review and audit of our interim financial statements and SEC filings. General and administrative expenses during the period May 15, 2013 (Inception) to June 30, 2013 amounted to $17,740, which were primarily corporate legal and accounting services related to the formation of the Company, patent maintenance and independent audit of our financial statements.

Net loss for the year ended June 30, 2014 was approximately $5.3 million which was a result of the operating expenses discussed above, and a loss resulting from the change in fair value of derivative instruments—warrants of $3.6 million during the current year. Net loss for the period May 15, 2013 (Inception) to June 30, 2013 was $140,495.

Liquidity and Capital Resources

The following table summarizes our cash flows for the year ended June 30, 2014 and the period ended June 30, 2013:

	Year ended June 30, 2014	Period from May 15, 2013 (inception) to June 30, 2013
Net cash (used in) provided by:		
Operating activities	$ (1,363,079)	$ (13,284)
Investing activities	(15,847)	—
Financing activities	3,109,967	100,000
Net increase (decrease) in cash	$ 1,731,041	$ 86,716

As of June 30, 2014, we had $1.8 million in cash. Net cash used in operating activities was approximately $1.4 million for the year ended June 30, 2014. Net cash provided from financing activities was $3.1 million for the year ended June 30, 2014, which represented primarily the net proceeds from the February 2014 equity financing. As of June 30, 2014, we had working capital of $1.5 million, as compared to a working capital deficit of $0.1 million as of June 30, 2013.

On June 5, 2013, we entered into a Loan and Security Agreement with Synergy pursuant to which Synergy agreed to lend us up to five hundred thousand dollars ($500,000) for working capital purposes (the "Loan Agreement"). On November 18, 2013, we entered into an amendment to the Loan Agreement with Synergy pursuant to which Synergy agreed to increase the aggregate amount available to us under the Loan Agreement from five hundred thousand dollars ($500,000) to one million dollars ($1,000,000). As of June 30, 2014, borrowings under the Note were zero. On March 27, 2014, we paid Synergy an aggregate of $461,236, which represented all principal and accrued and unpaid interest that was due and payable on the Note.

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. 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. Based upon our analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" we have determined that the units issued in connection with this financing transaction must be recorded as derivative liabilities upon issuance and marked to market on a quarterly basis.

Operating and Capital Expenditure Requirements

As of June 30, 2014, we had an accumulated deficit of $5.4 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. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We will be required to raise additional capital 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.

Our audited financial statements as of June 30, 2014 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report on our June 30, 2014 financial statements that included an explanatory paragraph referring to our recurring losses from operations and stockholder's deficit; and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, 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.

Contractual Obligations and Commitments

We have no material long-term contractual cash obligations as of June 30, 2014.

Purchase Commitments

We have no material non-cancelable purchase commitments with contract manufacturers or service providers as we have generally contracted on a cancelable basis.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CONTRAVIR PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of ContraVir Pharmaceuticals, Inc. as of June 30, 2014 and 2013 and the related statements of operations, changes in stockholders' deficit, and cash flows for the period May 15, 2013 (inception) through June 30, 2013 and for the year ended June 30, 2014. 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 financial statements referred to above present fairly, in all material respects, the financial position of ContraVir Pharmaceuticals, Inc. at June 30, 2014 and 2013, and the results of its operations and its cash flows for the period May 15, 2013 (inception) through June 30, 2013 and for the year ended June 30, 2014, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered losses from operations, has a stockholders' deficit 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/BDO USA, LLP

New York, New York

September 29, 2014

CONTRAVIR PHARMACEUTICALS, INC.

Balance Sheets

	June 30, 2014	June 30, 2013
Assets		
Current assets:		
Cash	$ 1,817,757	$ 86,716
Prepaid expenses	164,421	—
Total current assets	1,982,178	86,716
Property and equipment, net	14,526	—
Other assets	4,200	—
Total assets	$ 2,000,904	$ 86,716
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 243,896	$ 3,617
Accrued expenses	207,915	40,000
Due to Synergy	6,928	83,266
Demand note payable to Synergy and accrued interest	—	100,328
Total current liabilities	458,739	227,211
Derivative financial instruments, at estimated fair value—warrants	4,475,345	—
Total liabilities	4,934,084	227,211
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Preferred stock—$0.001 par value per share. Authorized 20,000,000 shares, none issued and outstanding	—	—
Common stock—$0.001 par value per share; 120,000,000 shares authorized, 18,479,279 and 9,000,000 shares issued and outstanding at June 30, 2014 and 2013, respectively	1,848	900
Additional paid-in capital	2,486,309	(900)
Accumulated deficit	(5,421,337)	(140,495)
Total stockholders' deficit	(2,933,180)	(140,495)
Total liabilities and stockholders' deficit	$ 2,000,904	$ 86,716

See accompanying notes to financial statements.

CONTRAVIR PHARMACEUTICALS, INC.

Statements of Operations

	Year ended June 30, 2014	For the period May 15, 2013 (inception) thru June 30, 2013
Revenue	$ —	$ —
Costs and Expenses:		
General and administrative	1,357,863	17,740
Research and development	314,246	122,427
Loss from operations	(1,672,109)	(140,167)
Other income (expense):		
Change in fair value of derivative instruments—warrants	(3,595,788)	—
Interest expense	(12,945)	(328)
Total other income (expense)	(3,608,733)	(328)
Net loss	$ (5,280,842)	$ (140,495)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.41)	$ (0.02)
Weighted average common shares outstanding, basic and diluted	12,817,944	9,000,000

See accompanying notes to financial statements.

CONTRAVIR PHARMACEUTICALS, INC.

Statements of Changes in Stockholders' Deficit

For the Period From May 15, 2013 (date of inception) to June 30, 2014

	Stockholders' Deficit				
	Common Stock				
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, May 15, 2013 (date of inception)	—	$ —	$ —	$ —	$ —
Issuance of restricted stock	9,000,000	900	(900)	—	—
Net loss	—	—	—	(140,495)	(140,495)
Balance, June 30, 2013	9,000,000	900	(900)	(140,495)	(140,495)
Issuance of common stock via private placement	9,485,294	949	3,224,051	—	3,225,000
Fees and expenses associated with private placement	—	—	(15,033)	—	(15,033)
Stock-based compensation expense	—	—	195,226	—	195,226
Partial shares returned associated with Synergy's distribution of the Company's common stock	(6,015)	(1)	—	—	(1)
Fair value of warrants issued in connection with private placement, reclassified to derivative liability	—	—	(879,557)	—	(879,557)
Stock options granted in excess of authorized limit	—	—	(37,478)	—	(37,478)
Net loss	—	—	—	(5,280,842)	(5,280,842)
Balance, June 30, 2014	18,479,279	$ 1,848	$ 2,486,309	$ (5,421,337)	$ (2,933,180)

See accompanying notes to unaudited condensed financial statements.

CONTRAVIR PHARMACEUTICALS, INC.

Statements of Cash Flows

	Year ended June 30, 2014	For the period May 15, 2013 (inception) thru June 30, 2013
Operating activities:		
Net loss	$ (5,280,842)	$ (140,495)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	195,226	—
Change in fair value of derivative instrument—warrants	3,595,788	—
Depreciation	1,321	—
Interest expense on note payable	—	328
Changes in operating assets and liabilities:		
Accounts payable, accrued expenses and due to Synergy	294,049	126,883
Prepaid expenses and other assets	(168,621)	—
Net cash used in operating activities	(1,363,079)	(13,284)
Investing activities:		
Purchase of property and equipment	(15,847)	—
Net cash used in investing activities	(15,847)	—
Financing activities:		
Issuance of common stock via private placement	3,225,000	—
Fees and expenses—private placement	(15,033)	—
Borrowings under demand note payable to Synergy	350,000	100,000
Repayment of demand note payable to Synergy	(450,000)	—
Net cash provided by financing activities	3,109,967	100,000
Net increase (decrease) in cash and cash equivalents	1,731,041	86,716
Cash—beginning of period	86,716	—
Cash—end of period	$ 1,817,757	$ 86,716
Supplemental disclosure of cash flow information:		
Cash paid for taxes		

	$ —	$ —
Cash paid for interest	$ 12,945	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Value of warrants classified to derivative-net	$ 4,475,345	$ —

See accompanying notes to financial statements.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements

June 30, 2014

1. Business Overview

ContraVir Pharmaceuticals Inc. ("ContraVir" or the "Company") 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".

2. Basis of Presentation and Going Concern

Separation from Synergy Pharmaceuticals Inc.

On August 8, 2013, Synergy Pharmaceuticals Inc. ("Synergy") announced that it intended to separate its FV-100 assets from the remainder of its businesses through a pro rata distribution of the common stock of the entity holding the assets and liabilities associated with the FV-100 product candidate. ContraVir was incorporated in Delaware on May 15, 2013 for the purpose of holding such businesses as a wholly owned subsidiary of Synergy.

On January 28, 2014, the Synergy board of directors approved the distribution of the 9,000,000 issued and outstanding shares of ContraVir's common stock currently held by Synergy on the basis of 0.0986 shares of our common stock for each share of Synergy common stock held on the record date. On January 28, 2014, Synergy declared a dividend of ContraVir common stock. On the distribution date of February 18, 2014, Synergy stockholders of record as of the close of business on February 6, 2014 received .0986 shares of ContraVir common stock for every 1 share of Synergy common stock they held. Fractional shares were not issued. Synergy stockholders received cash in lieu of fractional shares.

ContraVir is no longer a wholly owned subsidiary of Synergy.

Going Concern

As of June 30, 2014 ContraVir had $1,817,757 in cash. Net cash used in operating activities was $1,363,079 for the year ended June 30, 2014. Net loss for the year ended June 30, 2014 was $5,280,842, of which $3,595,788 is attributable to a change in fair value of derivative instruments-warrants (non-cash). As of June 30, 2014, ContraVir had working capital of $1,523,439 whereas on June 30, 2013 ContraVir had a working capital deficit of $140,495.

These financial statements have been prepared under the assumption that the Company will continue as a going concern. ContraVir's ability to continue as a going concern is dependent upon its ability to obtain additional equity or debt financing, 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.

ContraVir will be required to raise additional capital within the next year to continue the development and commercialization of its current product candidate and to continue to fund operations at its current cash expenditure levels. ContraVir cannot be certain that additional funding will be available on acceptable terms, or at all. Any debt financing, if available, may involve restrictive covenants that impact ContraVir's ability to conduct business. If ContraVir is unable to raise additional capital when required or on acceptable terms, ContraVir may have to (i) significantly delay, scale back or discontinue the development and/or commercialization of its product candidate; (ii) seek collaborators for product its candidate 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

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

2. Basis of Presentation and Going Concern (Continued)

of rights to technologies, product candidates or products that ContraVir would otherwise seek to develop or commercialize ourselves on unfavorable terms.

On May 13, 2014, the Company filed a registration statement on Form S-1 with the SEC for a public offering of shares of its common stock and the Company has retained an underwriter for this proposed offering. As of the date of the filing of this report, the offering was not yet completed and there can be no assurance that this offering will be successful.

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, 2014 and 2013, the amount of cash was approximately $1.8 million and $0.1 million, respectively, consisting of checking accounts held at U.S. commercial banks. Cash is maintained at financial institutions and, at times, balances may exceed federally insured limits. We have never experienced losses related to these balances.

Fair Value of Financial Instruments

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.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

2. Basis of Presentation and Going Concern (Continued)

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, notes 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. See Note 7, Derivative Financial Instruments, for additional information.

Property, equipment and depreciation

As of June 30, 2014 ContraVir had $14,526 of property and equipment, consisting primarily of computer equipment. Expenditures for additions, renewals and improvements will be capitalized at cost. Depreciation will generally be computed on a straight-line method based on the estimated useful lives of the related assets. The estimated useful lives of the major classes of depreciable assets will be 2 to 5 years for equipment and furniture and fixtures. Leasehold improvements will be depreciated over the remaining useful life of the lease. Expenditures for repairs and maintenance are charged to operations as incurred. ContraVir will periodically evaluate whether current events or circumstances indicate that the carrying value of its depreciable assets may not be recoverable.

Income Taxes

ContraVir has not filed any Federal tax returns since May 15, 2013 (inception). The amount of any tax liability that could arise since inception is undetermined at this time, however, the Company believes that because it has sustained losses since inception, the amount of any tax liability, if any, that could arise would be immaterial to the ContraVir's financial statements. Any interest or penalties would be recorded in its statement of operations within other income (expense). ContraVir recorded a valuation allowance against any deferred tax assets upon the filing of its tax returns to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. As a result there are no income tax benefits reflected in the consolidated statements of operations to offset pre-tax losses.

Contingencies

In the normal course of business, ContraVir 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 FASB ASC Topic 450, Accounting for Contingencies, ("ASC Topic 450"), ContraVir 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. ContraVir, in accordance with this guidance, does not recognize gain contingencies until realized. As of June 30, 2014, ContraVir has not recorded any accruals related to loss contingencies.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

2. Basis of Presentation and Going Concern (Continued)

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, regulatory and scientific consulting fees, as well as contract research, insurance and FDA consultants, are accounted for in accordance with ASC Topic 730-10-55-2, Research and Development. 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.

ContraVir 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.

Also as prescribed by ASC Topic 730, Research and Development 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. ContraVir had no recorded prepaid research and development costs as of June 30, 2014 and 2013.

Loss Per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, Earnings per Share, ("ASC Topic 260") for all periods presented. In accordance with this guide, 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.

3. Recent Accounting Pronouncements

In June 2014, FASB issued ASU No. 2014-10, "Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation" ("ASU 2014-10"). ASU 2014-10 eliminates the accounting and reporting differences in U.S. GAAP between development stage entities and other operating entities, including the presentation of inception-to-date financial statement information and the development stage entity financial statement label. FASB guidance related to Risks and Uncertainties and FASB guidance utilized to determine if an entity is a variable interest entity now apply to entities that have not commenced planned principal operations. These changes will provide more consistent consolidation analysis and decisions among reporting entities. While these amendments are retrospectively effective for annual reporting periods beginning after December 15, 2014, early adoption is permitted for any annual reporting period or interim period for which the entity's financial statements have not yet been issued. The Company has elected early adoption in the current period. The Company's adoption of this standard did not have a significant impact on its financial position, results of operations or cash flows.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

4. Stockholders' Deficit

On February 4, 2014, ContraVir 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. The Company 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. Based upon our analysis of the criteria contained in ASC Topic 815-40, "Derivatives and Hedging—Contracts in Entity's Own Equity" 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. Upon the issuance of these warrants the fair value of $879,557 was recorded as derivative liability-warrants. See Note 11 for additional information regarding these warrants.

5. Accounting for Shared-Based Payments

ASC Topic 718*"Compensation—Stock Compensation"* 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.

ContraVir accounts for stock options issued to non-employees based on the fair value of the stock option, if that value is more reliably measurable than the fair value of the consideration or services received. The Company accounts for stock options issued and vesting 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. Accordingly the fair value of these options is being "marked to market" quarterly until the measurement date is determined.

ASC Topic 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 ContraVir's accumulated deficit position, no excess tax benefits have been recognized. ContraVir accounts for stock options granted to employees and non-employees based on the fair market value of the instrument, using the Black-Scholes option pricing model based on assumptions for expected stock price volatility, term of the option, risk-free interest rate and expected dividend yield, at the grant date.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

5. Accounting for Shared-Based Payments (Continued)

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 has reserved 1,500,000 shares of common stock issuable pursuant to the Plan. During the year ended June 30, 2014 the Company issued 841,270 options over the authorized number of options in the Plan. As per ASC Topic 815-40, the options have been accounted for as liabilities and recorded at fair value with the changes in fair value being recorded in the Company's statement of operations. Once stockholder approval is obtained to increase the number of authorized shares, the liability will then be reversed into additional paid in capital. The Company has recorded the $37,478 liability for this amount in accrued expenses.

For the year ended June 30, 2014, ContraVir recorded the following stock based compensation expense:

	Year ended June 30, 2014
General and administrative	$ 150,161
Research and development	45,065
Total stock based compensation expense	$ 195,226

No stock based compensation expense was recorded during the period ended June 30, 2013, as there were no options granted as of that date.

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, 2013	—	$—	$ —	$ —	—
Granted	2,341,270	$0.11 - $2.37	$ 1.61	$ 633,200	2.95 years
Exercised	—	—	—	—	—
Forfeited	—	—	—	—	—
Balance outstanding, June 30,2014	2,341,270	$0.11 - $2.37	$ 1.61	$ 633,200	2.95 years
Exercisable at June 30, 2014	230,000	$0.37	$ 0.37	$ 170,200	0 years

The weighted average grant date fair value per share of all options granted during the year ended June 30, 2014 is $0.88 per share.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

5. Accounting for Shared-Based Payments (Continued)

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

	Year Ended June 30, 2014
Stock price	$0.11 - $2.37
Risk-free interest rate	1.89% - 2.48%
Dividend yield	—
Expected volatility	88% - 90%
Expected term (in years)	5 - 9.7 years

Stock Price—Effective February 27, 2014, stock price is the closing market price of the Company's common stock. Prior to that date, there was no public market for the stock. Management believes that the best alternative indication of stock value is what Synergy paid for the FV-100 Product, in an arms-length transaction, to BMS on August 17, 2012, or $1,000,000. Thus $1,000,000 divided by the 9,000,000 shares then outstanding resulted in a stock price of $0.11 per share.

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—ContraVir has had no stock options exercised since inception. The expected option term represents the period that stock-based awards are expected to be outstanding based on the simplified method provided in Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment* , ("SAB No. 107"), which averages an award's weighted-average vesting period and expected term for "plain vanilla" share options. Under 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 Topic 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.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

5. Accounting for Shared-Based Payments (Continued)

Forfeitures—ASC Topic 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. ContraVir estimated future unvested option forfeitures based on the historical experience of its former parent.

The unrecognized compensation cost related to authorized non-vested stock options outstanding at June 30, 2014, net of expected forfeitures, was approximately $1.2 million to be recognized over a weighted-average remaining vesting period of approximately 2.6 years.

6. Income Taxes

At June 30, 2014, ContraVir estimates it has net operating loss carry forwards ("NOLs") aggregating approximately $1.4 million, which, if not used, begin to expire in 2033. The utilization of these NOLs may become subject to limitations based on future changes in ownership of ContraVir pursuant to Internal Revenue Code Section 382.

ContraVir records a valuation allowance against deferred tax assets to the extent that it is more likely than not that some portion, or all of, the deferred tax assets will not be realized. Due to the substantial doubt related to ContraVir's ability to continue as a going concern and utilize its deferred tax assets, a valuation allowance for the full amount of the deferred tax assets has been established at June 30, 2014. As a result of this valuation allowance there are no income tax benefits reflected in the accompanying statements of operations to offset pre-tax losses.

ContraVir has no uncertain tax positions subject to examination by the relevant tax authorities as of June 30, 2014 because no tax returns have yet been filed for the period May 15, 2013 (inception) to June 30, 2014. ContraVir will file U.S. and state income tax returns in jurisdictions with varying statutes of limitations.

7. Derivative Financial Instruments

Effective February 4, 2014, the Company adopted provisions of ASC Topic 815-40, "Derivatives and Hedging: Contracts in Entity's Own Equity" ("ASC Topic 815-40"). ASC Topic 815-40 clarifies the determination of whether an instrument issued by an entity (or an embedded feature in the instrument) is indexed to an entity's own stock, which would qualify as a scope exception under ASC Topic 815-10.

Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, ContraVir has determined that certain warrants issued in connection with sale of its common stock must be classified as derivative instruments. In accordance with ASC Topic 815-40, the fair value of these warrants is being re-measured at each balance sheet date and any resultant changes in fair value is being recorded in the Company's statement of operations.

ContraVir's warrants issued during the year ended June 30, 2014 contained a price protection clause which variable term required the Company to use a binomial model to determine fair value. The

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

7. Derivative Financial Instruments (Continued)

range of assumptions used to determine the fair value of the warrants at period end during the year ended June 30, 2014 was as follows:

	Year ended June 30, 2014
Estimated fair value of ContraVir common stock	$1.11
Expected warrant term (years)	5.60 years
Risk-free interest rate	1.77%
Expected volatility	88%
Dividend yield	—

In the Binomial model, the assumption for estimated fair value of the stock is 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 the 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 SAB 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.

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

Date	Description	Warrants	Derivative Instrument Liability
7/1/2013	Balance of derivative financial instruments liability	—	$ —
6/30/2014	Fair value of new warrants issued	4,742,648	$ 879,557
6/30/2014	Change in fair value of warrants recognized as other expense in the statement of operations	—	$ 3,595,788
6/30/2014	Balance of derivative financial instruments liability	4,742,648	$ 4,475,345

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

7. Derivative Financial Instruments (Continued)

ContraVir 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, 2014:

Description	Balance as of June 30, 2013	Quoted Prices in Active Markets for Identical Assets and Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Balance as of June 30, 2014
Derivative liabilities related to Warrants	$ —	$ —	$ —	$ 4,475,345	$ 4,475,345

The unrealized gains or losses on the derivative liabilities are recorded as a change in fair value of derivative liabilities in the Company's statement of operations. 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. At each reporting period, the Company reviews the assets and liabilities that are subject to ASC Topic 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.

8. Loan and Demand Note Payable

On June 5, 2013, ContraVir entered into a Loan and Security Agreement with Synergy pursuant to which Synergy agreed to lend ContraVir up to five hundred thousand dollars ($500,000) for working capital purposes (the "Loan Agreement"). Also on June 5, 2013, August 29, 2013, October 18, 2013 and January 9, 2014, pursuant to the Loan Agreement, Synergy made an advance to ContraVir of $100,000, $100,000, $150,000 and $100,000, respectively, under a promissory note (the "Note"). The Note bears interest at six percent (6%) per annum and such interest shall be paid on the 15th of each of January, March, June and September, beginning September 15, 2013. The Note matures on the earlier of June 10, 2014 or the date that the entire principal amount and interest shall become due and payable by reason of an event of default under the Note or otherwise. In addition, Synergy has the right to demand payment of the unpaid principal amount and all accrued but unpaid interest thereon at any time after August 4, 2013, upon providing us fifteen (15) days prior written notice. In connection with the Loan Agreement, ContraVir granted Synergy a security interest in all of its assets, including its intellectual property, until the Note is repaid in full. On November 18, 2013, ContraVir entered into an amendment to the Loan Agreement with Synergy pursuant to which Synergy agreed to increase the aggregate amount available to us under the Loan Agreement from five hundred thousand dollars ($500,000) to one million dollars ($1,000,000). On March 27, 2014, ContraVir paid $450,000 to Synergy in full repayment of the Note.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

9. Due to Synergy

On July 8, 2013, ContraVir entered into a Shared Services Agreement, as amended and restated August 5, 2013, with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy has provided and/or made available to us various administrative, financial, accounting, insurance, office, information technology and other services to be provided by, or on behalf of, Synergy, together with such other services as reasonably requested by us. In consideration for such services, we have paid fees to Synergy for the services provided, and those fees will generally be in amounts intended to allow the party providing services to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the Shared Services Agreement are employees and/or independent contractors of Synergy and are not under our direction or control. These personnel costs are based upon the actual percentages of time spent by Synergy personnel performing services for us under the Shared Services Agreement. ContraVir reimburses Synergy for direct out-of-pocket costs incurred by Synergy for third party services provided to the Company. Effective April 1, 2014, ContraVir terminated the Shared Services Agreement with Synergy. During the year ended June 30, 2014 and the period from inception thru June 30, 2013, shared services provided by Synergy totaled $101,462 and $83,266, respectively.

As of June 30, 2014 and 2013, the balances due to Synergy on shared services and allocated expenses are comprised of the following amounts:

	June 30, 2014	June 30, 2013
Legal, patent and corporate	$ —	$ 45,787
Salaries and benefits	—	16,703
Financial advisory fees	—	10,000
Insurance	—	2,934
Temporary labor	1,454	2,550
Rent, utilities, and property taxes	5,474	3,363
Other	—	1,929
Total Shared Services	$ 6,928	$ 83,266

10. Loss per Share

Basic and diluted net loss per share is presented in conformity with ASC Topic 260, *Earnings per Share*, ("ASC Topic 260") for all periods presented. In accordance with ASC Topic 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.

CONTRAVIR PHARMACEUTICALS, INC.

Notes to Financial Statements (Continued)

June 30, 2014

10. Loss per Share (Continued)

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

	Year ended June 30, 2014	For the period May 15, 2013 (inception) thru June 30, 2013
Net loss	$ (5,280,842)	$ (140,495)
Weighted average common shares outstanding	12,817,944	9,000,000
Net loss per share of common stock—basic and diluted	$ (0.41)	$ (0.02)

The following outstanding securities at June 30, 2014 and 2013 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Year ended June 30, 2014	For the period May 15, 2013 (inception) thru June 30, 2013
Options	2,341,270	—
Warrants	4,742,648	—
Total	7,083,918	—

11. Subsequent Events

On August 20, 2014, Contravir Pharmaceuticals, Inc., consummated its offer to exchange an aggregate 4,742,648 outstanding common stock purchase warrants owned by certain investors in the Company for an aggregate of 3,794,118 shares of common stock. The warrants were exercisable at $0.37 per share.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Evaluation of Disclosure Controls and Procedures

Our chief executive officer and chief financial officer evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, as of June 30, 2014, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are not effective, due to weaknesses in our financial closing process. We intend to implement remedial measures designed to address the ineffectiveness of our disclosure controls and procedures.

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, 2014 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, 2014.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers and Directors

Set forth below is certain information with respect to the individuals who are our directors and executive officers as of September 19, 2014:

Name	Age	Position
Gary S. Jacob	67	Chairman of the Board of Directors
James Sapirstein	53	Chief Executive Officer and Director
William Hornung	46	Chief Financial Officer
John P. Brancaccio	66	Director
Christopher McGuigan	56	Director
Timothy Block	59	Director

Gary S. Jacob, Ph.D. has served as our Chairman of the Board of Directors since March 19, 2014, and earlier served as our Chief Executive Officer from May 15, 2013 until March 19, 2014. Dr. Jacob is currently the Chairman of the Board, President and Chief Executive Officer of Synergy Pharmaceuticals Inc., a biopharmaceutical company, where he has held various positions since July 2008. Dr. Jacob served as Chief Executive Officer of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013 and a director from October 2004 until January 2013. Dr. Jacob currently serves as a director of Trovagene, Inc., a diagnostics company. Dr. Jacob has over twenty-five years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England.

James Sapirstein has served as our Chief Executive Officer and a Director since March 19, 2014. Mr. Sapirstein was the chief executive officer of Alliqua Therapeutics at Alliqua Inc., where he helped lead the transformation of transdermal wound care and drug delivery technology into a premier wound care organization from October 2012 to February 2014. Mr. Sapirstein was the chief executive officer of Tobira Therapeutics, a New Jersey based biopharmaceutical company focused on the development of novel HIV and infectious disease compounds, from October 2006 to April 2011. From June 2002 until May 2005, Mr. Sapirstein was Executive Vice President for Serono Laboratories where he led a team of over 100 professionals to rebuild a struggling HIV and pediatric growth hormone business. Mr. Sapirstein also served in the Global Marketing group at Gilead, beginning in 2000 where he led and developed the global marketing strategy for its flagship HIV drug, Viread as well as played a key role in the development of the drug combination strategy that resulted in Gilead's acquisition of Triangle's nucleoside portfolio. He held a number of positions at Hoffmann-LaRoche, including Product Director and International Operations Manager, and was actively involved with numerous product launches including several antivirals. In 1996, he became the Director of International Marketing of the Infectious Disease Division at Bristol Myers Squibb (BMS). Mr. Sapirstein directed the international HIV product marketing strategy at BMS and was an integral part of the international development and launch of a number of infectious disease products while at BMS.

William Hornung has served as our Chief Financial Officer since June 23, 2014. From April 2012 until March 2014, Mr. Hornung served as the Vice President of Finance for PTC Therapeutic, a public biotechnology company. From February 2009 until March 2012, Mr. Hornung served as Controller of

PTC Therapeutics. Mr. Hornung received his Bachelor of Science from The William Paterson State University of NJ in 1992.

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

Christopher McGuigan, Ph.D. has served as a director of our company since May 15, 2013 and as a director of Synergy Pharmaceuticals, Inc. since July 2008. Since 1995, Dr. McGuigan has been Professor of Medicinal Chemistry, Welsh School of Pharmacy, Cardiff University, UK. He is also Executive Chair of the Life Sciences Hub Wales, LTD, and Chari of the National Research Network in Health and Life Sciences for the Welsh Government. Dr. McGuigan is immediate past president of the International Society for Antiviral Research. Dr. McGuigan has over 220 publications and 50 patent applications. Dr. McGuigan was Chairman of Departmental Research Committee and Director of Research, Head of Medicinal Chemistry. Dr. McGuigan currently serves as a director of Synergy, Inc. and Tiziana Life Sciences (London). Dr. McGuigan's experience in developing new drug agents from discovery to human clinical trials, with three of his agents reaching human clinical trials, qualifies him to serve as a director of our company.

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

Director Independence

Our securities are not listed on a national securities exchange or in an inter-dealer quotation system that requires that a majority of our board of directors be independent. As of the date of this Annual Report, our board of directors has determined that a majority of the board consists of members who are currently "independent" as that term is defined under current listing standards of NASDAQ.

Committees of the Board of Directors

Audit Committee

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

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

Compensation Committee

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

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

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity, excluding Synergy, that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance/Nominating Committee

The Corporate Governance/Nominating Committee has responsibility for assisting the board of directors in, among other things, effecting board organization, membership and function including identifying qualified board nominees; effecting the organization, membership and function of board committees including composition and recommendation of qualified candidates; establishment of and subsequent periodic evaluation of successor planning for the chief executive officer and other executive officers; development and evaluation of criteria for Board membership such as overall qualifications, term limits, age limits and independence; and oversight of compliance with the Corporate Governance Guidelines. The Corporate Governance/Nominating Committee shall identify and evaluate the

qualifications of all candidates for nomination for election as directors. Potential nominees are identified by the Board of Directors based on the criteria, skills and qualifications that have been recognized by the Corporate Governance/Nominating Committee. While our nomination and corporate governance policy does not prescribe specific diversity standards, the Corporate Governance/Nominating Committee and its independent members seek to identify nominees that have a variety of perspectives, professional experience, education, differences in viewpoints and skills, and personal qualities that will result in a well-rounded Board of Directors.

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

Section 16(a) Beneficial Ownership Reporting Compliance

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

Based on a review of the copies of such forms received, we believe that during 2013, all filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were complied with.

Code of Business Conduct and Ethics

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

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

Other Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any bankruptcy or criminal proceedings, nor have there been any judgments or injunctions brought against any of our directors or executive officers during the last ten years that we consider material to the evaluation of the ability and integrity of any director or executive officer.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

Prior to February 18, 2014, we were a majority-owned subsidiary of Synergy. Our Compensation Committee is currently reviewing all aspects of compensation and intends to adopt an appropriate structure for our executive compensation arrangements. As of the date hereof, the Compensation Committee has not reviewed our executive compensation arrangements and the specifics of our compensation programs and policies have not yet been determined.

The following table contains compensation information for our prior Chief Executive Officer and certain other executive officers who were the most highly compensated expected officers for the fiscal year ended June 30, 2014.

Name & Principal Position	Year	Salary(2)	Bonus	Options granted(3)	Total
Gary S. Jacob Chairman of the Board and former Chief Executive Officer(1)	2014	$ —	$ —	$ 274,248	$ 274,248
James Sapirstein, Chief Executive Officer(4)	2014	$ 86,174	$ —	$ 1,172,074	$ 1,258,248
William Hornung, Chief Financial Officer(5)	2014	$ 4,889	$ —	$ 75,278	$ 80,167

(1) Effective October 1, 2013, Dr. Jacob was elected Chairman of the Board. Effective March 19, 2014, Dr. Jacob resigned his position as Chief Executive Officer of the Company. Dr. Jacob agreed to payment in the form of stock options in lieu of salary.

(2) On July 8, 2013, we entered into a Shared Services Agreement, as amended and restated August 5, 2013, with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy has provided and/or made available to us various administrative, financial (including payroll functions), insurance, facility, information technology, and other services. In consideration for such services, we have paid fees to Synergy for the services provided, and those fees were in amounts intended to allow the party providing services to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the Shared Services Agreement are employees and/or independent contractors of Synergy and are not under our direction or control. These personnel costs are based upon the actual percentages of time spent by Synergy personnel performing services for us under the Shared Services Agreement. We have also reimbursed Synergy for direct out-of-pocket costs incurred by Synergy for third party services provided to us. For the periods ended June 30, 2014 and 2013, shared services provided by Synergy totaled $101,462 and $83,266, respectively. Effective April 1, 2014, we terminated the shared services agreement with Synergy.

(3) Represents the fair value of incentive stock options granted during the year ended June 30, 2014 using the Black-Scholes model for computing stock based compensation expense as of the date of grant.

(4) James Sapirstein was hired in March 2014. On March 19, 2014, we issued options to purchase 1,000,000 shares of our common stock to James Sapirstein, our newly hired Chief Executive Officer. These option vest over 4 years, expire on March 19, 2024 and have an exercise price of $2.31 per share.

(5) William Hornung was hired in June 2014. On June 23, 2014, we issued options to purchase 100,000 shares of our common stock to William Hornung, our newly hired Chief Financial Officer. These options vest over 3 years, expire on June 23, 2024 and have an exercise price of $1.70 per share.

Outstanding Equity Awards as of June 30, 2014

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Gary S. Jacob	—	30,000	$ 0.11	10/02/2023
Chairman of the Board and	200,000	—	0.37	1/24/2024
former Chief Executive Officer	—	300,000	2.31	3/19/2024
James Sapirstein,	—	1,000,000	2.31	3/19/2024
Chief Executive Officer				
William Hornung,	—	100,000	1.70	6/23/2024
Chief Financial Officer				

Director Compensation

During the year ended June 30, 2014, our non-employee directors received the following compensation for their services on the board and its committees:

Name	Cash Fees	Option Awards	Total
John P. Brancaccio	$ —	$ 50,762	$ 50,762
Christopher McGuigan	—	284,331	284,331
Timothy Block	—	43,000	43,000

- Directors have agreed to forgo cash based compensation for their services on the board and its committees until the cash position of the Company improves. As of June 30, 2014, we have recorded a liability of approximately $0.1 million related to Director Fees.
- On March 12, 2014, the Board of Directors determined that compensation for our non-employee directors will be comprised of an annual cash retainer and an annual equity award in the form of stock options. In addition, we expect to grant new directors, including the directors who will be joining our board, a one-time equity award in the form of stock options in connection with their election to the board. Since the end of our fiscal year ended June 30, 2013, we have granted the following options to our non-employee directors:
  - On October 2, 2013 we issued options to purchase (i) 30,000 shares of our common stock at an exercise price of $0.11 per share to Gary Jacob, our Chairman of the Board, for services rendered (ii) 30,000 shares of our common stock at an exercise price of $0.11 per share to John Brancaccio, a director, for services rendered, (iii) 30,000 shares of our common stock at an exercise price of $0.11 per share to Christopher McGuigan, a director, for services rendered.
  - On November 26, 2013, we issued options to purchase 30,000 shares of our common stock at an exercise price of $0.11 per share to Timothy Block, a director, for services rendered.
  - On January 24, 2014, we issued options to purchase (i) 200,000 shares of our common stock at an exercise price of $0.37 per share to Gary Jacob, our Chairman of the Board, for services rendered (ii) 30,000 shares of our common stock at an exercise price of $0.37 per share to John Brancaccio, a director, for services rendered, (iii) 10,000 shares of our

common stock at an exercise price of $0.37 per share to Timothy Block, a director, for services rendered, and (iv) 250,000 shares of our common stock at an exercise price of $0.37 per share to Christopher McGuigan, a director, pursuant to his consulting agreement.

- On March 12, 2014, we issued options to purchase (i) 21,897 shares of our common stock at an exercise price of $2.37 per share to John Brancaccio, a director, for services rendered, (ii) 19,777 shares of our common stock at an exercise price of $2.37 per share to Timothy Block, a director, for services rendered, and (iii) 16,596 shares of our common stock at an exercise price of $2.37 per share to Christopher McGuigan, a director, for services rendered.

- On March 19, 2014, we issued options to purchase 300,000 shares of our common stock at an exercise price of $2.31 per share to Gary Jacob, our Chairman of the Board, for services rendered.

- On April 3, 2014, we issued options to purchase 15,000 shares of our common stock at an exercise price of $2.35 per share to both John Brancaccio and Timothy Block, directors, for services rendered.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of September 19, 2014, by:

- our named executive officers;

- each of our directors;

- all of our current directors and executive officers as a group; and

- each stockholder known by us to own beneficially more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of September 19, 2014, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 22,273,397 shares of common stock outstanding on September 19, 2014.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless

otherwise indicated, the address for each director and executive officer listed is: c/o ContraVir Pharmaceuticals, Inc., 399 Thornall Street, First Floor, Edison, New Jersey, 08837.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned
Directors and Executive Officers		
James Sapirstein	0	*
William Hornung	0	*
Gary S. Jacob(1)	232,935	1.05
Bernard F. Denoyer	1,030	*
John Brancaccio	2,015	*
Christopher McGuigan	0	*
Timothy Block	0	*
All current executive officers and directors as a group (6 persons)	235,980	1.06*

* Represents beneficial ownership of less than 1%.

(1) Consists of 32,935 shares of common stock and 200,000 shares of common stock issuable upon exercise of outstanding stock options.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Agreements with Synergy

Loan and Security Agreement

On June 5, 2013, ContraVir entered into a Loan and Security Agreement with Synergy pursuant to which Synergy agreed to lend ContraVir up to five hundred thousand dollars ($500,000) for working capital purposes (the "Loan Agreement"). Also on June 5, 2013, August 29, 2013, October 18, 2013 and January 9, 2014, pursuant to the Loan Agreement, Synergy made an advance to ContraVir of $100,000, $100,000, $150,000 and $100,000, respectively, under a promissory note (the "Note"). The Note bears interest at six percent (6%) per annum and such interest shall be paid on the 15th of each of January, March, June and September, beginning September 19, 2013. The Note matures on the earlier of June 10, 2014 or the date that the entire principal amount and interest shall become due and payable by reason of an event of default under the Note or otherwise. In addition, Synergy has the right to demand payment of the unpaid principal amount and all accrued but unpaid interest thereon at any time after August 4, 2013, upon providing us fifteen (15) days prior written notice. In connection with the Loan Agreement ContraVir granted Synergy a security interest in all of its assets, including its intellectual property, until the Note is repaid in full. On November 18, 2013, we entered into an amendment to the Loan Agreement with Synergy pursuant to which Synergy agreed to increase the aggregate amount available to us under the Loan Agreement from five hundred thousand dollars ($500,000) to one million dollars ($1,000,000). On March 27, 2014, we paid $461,236 to Synergy in full repayment of the advance, including accrued but unpaid interest thereon. As of the date of this Annual Report, we have not taken any further advances under the Loan Agreement.

Shared Services Agreement

On July 8, 2013, we entered into a Shared Services Agreement, as amended and restated August 5, 2013, with Synergy, effective May 16, 2013. Under the Shared Services Agreement, Synergy has provided and/or made available to us various administrative, financial (including internal audit and payroll functions), legal, insurance, facility, information technology, laboratory, real estate and other

services to be provided by, or on behalf of, Synergy, together with such other services as reasonably requested by us. In consideration for such services, we have paid fees to Synergy for the services provided, and those fees will generally be in amounts intended to allow the party providing services to recover all of its direct and indirect costs incurred in providing those services. The personnel performing services under the Shared Services Agreement are employees and/or independent contractors of Synergy and are not under our direction or control. These personnel costs are based upon the actual percentages of time spent by Synergy personnel performing services for us under the Shared Services Agreement. We will also reimburse Synergy for direct out-of-pocket costs incurred by Synergy for third party services provided to us. For the periods ended June 30, 2014 and 2013, shared services provided by Synergy totaled $101,462 and $83,266, respectively. Effective April 1, 2014, we terminated the shared services agreement with Synergy.

Consulting Agreement

On January 23, 2014 we entered into a three year consulting agreement with Chris McGuigan, Ph.D. for scientific and technical advisory services. Dr. McGuigan is a director of our company and was instrumental in the early development of our 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.

Director Independence

Our securities are not listed on a national securities exchange or in an inter-dealer quotation system that requires that a majority of our board of directors be independent. As of the date of this Annual Report, our board of directors has determined that a majority of the board consists of members who are currently "independent" as that term is defined under current listing standards of NASDAQ.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

The aggregate fees billed and unbilled for the fiscal years ended June 30, 2014 and 2013 for professional services rendered by our principal accountants for the audits of our annual financial statements on Form 10 and Form 10-K, the review of our financial statements included in our quarterly reports on Form 10-Q and consultations and consents were approximately $247,000 and $84,000, respectively.

Audit Related Fees

There were no fees billed for the fiscal year ended June 30, 2014 and 2013 for audit related fees by our principal accountants.

Tax and Other Fees

There were no fees billed for the fiscal year ended June 30, 2014 and 2013 for professional services rendered by our principal accountants for tax compliance.

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of ContraVir Pharmaceuticals, Inc. appearing on page F-1 of this report.

(a)(2) Financial Statement Schedules

Not applicable.

(b) EXHIBITS

Exhibit Number	Exhibit Description
3.1	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).
3.2	By-Laws of ContraVir Pharmaceuticals, Inc. (filed as Exhibit 3.2 to the Company's registration statement on Form 10-12G which was filed with the Securities and Exchange Commission on August 8, 2013 and incorporated herein by reference).
4.1	Promissory Note, dated June 5, 2013, issued by ContraVir Pharmaceuticals, Inc. to Synergy Pharmaceuticals Inc. By-Laws of ContraVir Pharmaceuticals, Inc. (filed as Exhibit 4.1 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).
4.2	Form of Warrant issued to the investors in the February 2014 private placement (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2014 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	Shared Services Agreement, dated July 8, 2013, as amended and restated August 5, 2013, by and between Synergy Pharmaceuticals Inc. and ContraVir Pharmaceuticals, Inc. (filed as Exhibit 10.2 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).
10.3	Loan and Security Agreement, dated June 5, 2013, between Synergy Pharmaceuticals Inc. and ContraVir Pharmaceuticals, Inc. (filed as Exhibit 10.3 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).
10.4	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).†

Exhibit Number	Exhibit Description
10.5	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) †
10.6	Amendment No. 1 to Loan and Security Agreement, dated November 18, 2013, by and between Synergy Pharmaceuticals Inc. and ContraVir Pharmaceuticals, Inc. (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 19, 2013 and incorporated herein by reference).
10.7	First Amendment to Patent and Technology License Agreement, effective as of March 27, 2007, by and between University College Cardiff Consultant Limited and Contravir Research Incorporated (filed as Exhibit 10.7 to the Company's registration statement on Form 10-12G/A which was filed with the Securities and Exchange Commission on December 24, 2013 and incorporated herein by reference).
10.8	Form of securities purchase agreement by and among ContraVir Pharmaceuticals, Inc. and the investors in the February 2014 private placement (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2014 and incorporated herein by reference).
10.9	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.)
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	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended March 31, 2014, filed on, formatted in Extensible Business Reporting Language (XBRL): (i) the Statements of Operations, (ii) the Balance Sheets, (iii) the Statement of Stockholders Equity (iv) the Statements of Cash Flows and (v) the Notes to Financial Statements tagged as blocks of text.

† 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.

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 29, 2014

CONTRAVIR PHARMACEUTICALS, INC.

By: /s/ JAMES SAPIRSTEIN

James Sapirstein
Chief Executive Officer and Director
(Principal Executive Officer)

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 29, 2014
/s/ WILLIAM HORNUNG William Hornung	Chief Financial Officer (Principal Financial and Accounting Officer)	September 29, 2014
Gary S. Jacob, PhD.	Chairman, Board of Directors	September 29, 2014
John Brancaccio	Director	September 29, 2014
Christopher McGuigan	Director	September 29, 2014
Timothy Block	Director	September 29, 2014

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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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. 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

   c. 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 29, 2014

/s/ JAMES SAPIRSTEIN

James Sapirstein
Chief Executive Officer
(Principal Executive Officer)

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Exhibit 31.2

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

I, William Hornung, 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, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. 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

   c. 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 29, 2014

/s/ WILLIAM HORNUNG

William Hornung
Chief Financial Officer
(Principal Financial Officer)

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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, 2014, 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 29, 2014

/s/ JAMES SAPIRSTEIN

Chief Executive Officer
(Principal Executive Officer)

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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, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, William Hornung, 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 29, 2014

/s/ WILLIAM HORNUNG

Chief Financial Officer
(Principal Financial Officer)

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