

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 December 31, 2016.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission file number: 000-21088

VICAL INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
10390 Pacific Center Court, San Diego, California
(Address of principal executive offices)

Registrant's telephone number, including area code: (858) 646-1100

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

93-0948554
(I.R.S. Employer
Identification No.)
92121-4340
(Zip Code)

Title of each class

Common Stock, \$0.01 par value

Name of each exchange on which registered

The Nasdaq Capital Market

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 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 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.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the last sale price of the registrant's common stock reported on the Nasdaq Capital Market on June 30, 2016, was approximately \$36,468,133.

The number of shares of common stock outstanding as of February 28, 2017, was 11,093,663.

Documents Incorporated by Reference:

Document

Proxy Statement for the Annual Meeting of
Stockholders to be held May 25, 2017

Part of Form 10-K

Part III

VICAL INCORPORATED

FORM 10-K
INDEX

PART I.		
ITEM 1.	Business	3
ITEM 1A.	Risk Factors	18
ITEM 1B.	Unresolved Staff Comments	30
ITEM 2.	Properties	30
ITEM 3.	Legal Proceedings	30
ITEM 4.	Mine Safety Disclosures	30
PART II.		
ITEM 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	31
ITEM 6.	Selected Financial Data	32
ITEM 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	33
ITEM 7A.	Quantitative and Qualitative Disclosures About Market Risk	40
ITEM 8.	Financial Statements and Supplementary Data	41
ITEM 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	65
ITEM 9A.	Controls and Procedures	65
ITEM 9B.	Other Information	66
PART III.		
ITEM 10.	Directors, Executive Officers and Corporate Governance	66
ITEM 11.	Executive Compensation	66
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	66
ITEM 13.	Certain Relationships and Related Transactions, and Director Independence	66
ITEM 14.	Principal Accounting Fees and Services	66
PART IV.		
ITEM 15.	Exhibits and Financial Statement Schedules	67
Signatures		70

FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, the research and development of biopharmaceutical products, the timing of on-going clinical trials and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products. Actual results could differ materially from those discussed in this Annual Report on Form 10-K. Factors that could cause or contribute to such differences include, but are not limited to, those identified in Item 1A entitled “Risk Factors” beginning on page 18 of this report, as well as those discussed in our other filings with the Securities and Exchange Commission, or SEC, including our Quarterly Reports on Form 10-Q. As a result, you are cautioned not to unduly rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

ITEM 1. BUSINESS**Overview**

We research and develop biopharmaceutical products, including those based on our patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases.

We currently have three active, independent or partnered, development programs in the area of infectious disease comprised of:

- An ongoing Phase 3 trial of ASP0113 for prevention of cytomegalovirus, or CMV, reactivation in hematopoietic stem cell transplant, or HCT, recipients in collaboration with Astellas Pharma Inc., or Astellas. Astellas has completed enrollment in the Phase 3 clinical trial and expects top-line data to be available in the first quarter of 2018.
- An ongoing Phase 2 trial of VCL-HB01, our Vaxfectin[®]-formulated therapeutic DNA vaccine for reduction of lesion recurrences caused by herpes simplex virus type 2, or HSV-2, infection. This randomized, double-blind, placebo-controlled trial will evaluate the efficacy and safety of VCL-HB01 in approximately 225 healthy adults aged 18 to 50 years with symptomatic genital HSV-2 infection at up to 15 U.S. clinical sites. Subjects will receive a four-dose vaccination series, and will be evaluated for genital herpes lesion recurrences over a 12-month period after vaccination. The primary endpoint for the study is annualized lesion recurrence rate.
- An ongoing first-in-human Phase 1 trial of VL-2397. This randomized, double-blind, placebo-controlled trial is intended to evaluate safety, tolerability and pharmacokinetics of VL-2397 in healthy volunteers. The study design is composed of seven single ascending dose cohorts followed by four multiple ascending dose cohorts. Dosing was completed in October 2016. Safety follow-ups and pharmacokinetic sampling was completed in 2016. Preliminary results point to a favorable safety and pharmacokinetic profile for VL-2397. We expect to present the full data set at an upcoming scientific conference in 2017. The U.S. Food and Drug Administration, or FDA, has granted us Fast Track, qualified infectious disease product, or QIDP, and orphan drug designations for VL-2397 for the treatment of invasive aspergillosis. This fungal infection represents a sizable unmet need in immunocompromised patients due to a high mortality despite available antifungal therapies. We are working actively with our expert advisors and the FDA to design a Phase 2 safety and efficacy study to evaluate VL-2397 in the treatment of patients with invasive aspergillosis.

Available Information

We were incorporated in Delaware in 1987. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website at www.vical.com as soon as reasonably practicable after such reports and amendments are electronically filed with or furnished to the SEC. We also make available copies of our news releases and other financial information about us on our website.

Our Core Technology

The key discovery leading to our core DNA delivery technology was that muscle tissues can take up polynucleotide genetic material, such as DNA or RNA, directly, without the use of viral components or other delivery vehicles or technologies, and subsequently express the proteins encoded by the genetic material for periods ranging from weeks to more than a year. Our approach typically involves designing and constructing closed loops of DNA called plasmids. These plasmids contain a DNA segment encoding the protein of interest, as well as short segments of DNA that control protein expression. Plasmids can be manufactured using uniform methods of fermentation and processing. This could result in faster development and production times than technologies that require development of product-specific manufacturing processes.

Since the initial discovery of our DNA delivery technology, our researchers have improved the design of our plasmids to increase efficiency of gene expression and immunogenicity. We own broad patent rights in the United States and in key foreign markets to certain non-viral polynucleotide delivery technologies. Our patents and patent applications cover, for example, specific DNA constructs and formulations of gene-based product candidates, methods for producing pharmaceutical-grade DNA, and several families of lipid molecules and their uses in DNA delivery. Benefits of our DNA

delivery technologies may include the following, which may enable us to offer novel treatment alternatives for diseases that are currently poorly addressed:

- *Broad Applicability* . Our DNA delivery technologies may be useful in vaccines for infectious diseases, in which the expressed protein induces an immune response, and for therapeutic protein delivery, in which the expressed protein is a therapeutic agent;
- *Convenience* . Our DNA-based biopharmaceutical product candidates are intended to be administered on an outpatient basis;
- *Safety* . Our product candidates contain no infectious components that may cause unwanted immune responses, infections, or malignant and permanent changes in the targeted cells' genetic makeup;
- *Repeat Administration* . Our product candidates contain no infectious components that may preclude multiple dosing with a single product or use in multiple products;
- *Ease of Manufacturing* . Our DNA product candidates are manufactured using uniform fermentation and purification procedures; and
- *Cost-Effectiveness* . Our DNA delivery technologies may be more cost-effective than other approaches. They may also cause fewer potential side effects, which may reduce per patient treatment costs.

DNA Technology

Our DNA delivery technology is currently being developed by us and our partners in the area of infectious disease:

Infectious Diseases

DNA vaccines use portions of the genetic code of a pathogen to cause the host to produce proteins of the pathogen that may induce an immune response. Compared with conventional vaccines that use live, weakened, or killed pathogens to produce an immune response, this method potentially offers superior safety and ease of manufacturing, as well as convenient storage and handling characteristics. DNA vaccines have the potential to induce potent T-cell responses against target pathogens as well as trigger production of antibodies. Over the past decade, many scientific publications have documented the effectiveness of DNA vaccines in contributing to immune responses in dozens of species, including fish, nonhuman primates and humans. We believe important steps in the validation of DNA vaccines occurred in 2005 when our licensee Aqua Health received Canadian approval to market its proprietary product, Apex[®]-IHN, a DNA vaccine to protect farm-raised salmon against infectious hematopoietic necrosis virus, or IHNV, and again in late 2009, when our licensee Merial received approval from the U.S. Department of Agriculture, or USDA, to sell a therapeutic DNA vaccine, ONCEPT[®], designed to aid in extending the survival time of dogs with oral melanoma.

Vaccines are generally recognized as the most cost-effective approach for infectious disease healthcare. However, the technical limitations of conventional vaccine approaches have constrained the development of effective vaccines for many diseases. Development of vaccines based on conventional methods requires significant infrastructure in research and manufacturing. In addition, the safety risks associated with certain conventional vaccine approaches may offset their potential benefits. We believe our potential vaccine products may be simpler to manufacture than vaccines made using live viruses or protein subunit approaches, including those involving mammalian, avian or insect cell, or egg-based, culture procedures. In addition, our DNA delivery technologies may accelerate certain aspects of vaccine product development such as nonclinical evaluation and manufacturing.

In the broader vaccine marketplace, it is important to note a changing dynamic. Traditionally, vaccines have been predominantly focused on the pediatric market, intended to protect children from diseases that could cause them serious harm. Today, there is a growing interest in vaccines against diseases that may affect adolescents and adults, which include both sexually transmitted diseases and infections that strike opportunistically, such as during pregnancy or in immunocompromised individuals. We believe our technologies, because of their potential safety and development timeline advantages, could be ideally suited for this new generation of vaccines.

Manufacturing Process Development

The bacterial fermentation process typically used for DNA vaccines produces a closed loop of DNA, called a plasmid, which must include DNA sequences required in the manufacturing process. Conventional vaccine development and manufacturing methods require prolonged effort after the emergence of a new pathogen for production of even a single dose

for testing. Current DNA vaccine development and manufacturing processes allow initial production of vaccines in as little as three months after selection of a gene sequence associated with a pathogen, but quantities are limited by the batch-processing capacity of available manufacturing equipment.

Business Strategy

There are three basic elements to our business strategy:

Develop Products Independently

We currently focus our resources on the independent development of infectious disease vaccines and other therapeutic products for infectious disease targets. The selection of targets for our independent development programs is driven by three key criteria: the complexity of the product development program, competition, and commercial opportunities. We intend to retain significant participation in the commercialization of any independently developed proprietary DNA vaccines and therapeutics that receive regulatory approval, although we may choose to enlist the support of partners to accelerate product development and commercialization.

Vaccines are perceived by government and medical communities as an efficient and cost-effective means of healthcare. According to the Centers for Disease Control and Prevention, or CDC, "Vaccines are among the very best protections we have against infectious diseases." In the infectious disease area, we are currently focusing our resources on the development of DNA-based vaccines against CMV and HSV-2. We are also focusing our resources on VL-2397, a therapeutic antifungal product candidate we in-licensed from Astellas. We believe our technologies may lead to the development of novel preventive or therapeutic products for infectious disease targets. DNA vaccines may help combat diseases for which conventional vaccine methods have been unsuccessful.

Expand the Applications of Our Technologies through Strategic Collaborations

We collaborate with major pharmaceutical and biotechnology companies and government agencies, providing us access to complementary technologies or greater resources. These collaborations are intended to provide us with mutually beneficial opportunities to expand or advance our product pipeline and serve significant unmet medical needs. We license our intellectual property to other companies to leverage our technologies for applications that may not be appropriate for our independent product development.

Pursue Contract Manufacturing Opportunities

We selectively pursue contract manufacturing opportunities to leverage our infrastructure and expertise in DNA manufacturing, to support advancement and application of our technologies by others, and to provide revenues that contribute to our independent research and development efforts.

Product Development

We, together with our licensees and collaborators, are currently developing a number of DNA-based vaccines and other therapeutics for the prevention or treatment of infectious diseases. The table below summarizes our current active independent programs and corporate collaborations.

Product/Concept	Intended Use	Development Status ¹	Lead Developer
Independent Programs			
VCL-HB01 therapeutic vaccine for HSV-2	Prevent and protect against lesion recurrence	Phase 2	Vical
VL-2397 antifungal	Treatment of invasive fungal infections	Phase 1	Vical
CyMVectin™ prophylactic vaccine for CMV	Prevent fetal transmission during pregnancy	Preclinical	Vical
Corporate Collaborations			
ASP0113 therapeutic vaccine for CMV	Protect against reactivation of infection after HCT	Phase 3	Astellas
ONCEPT® therapeutic cancer vaccine encoding human tyrosinase	Adjunct treatment to increase survival time of dogs with oral melanoma	Marketed in the United States	Merial

¹ “Preclinical” (or “nonclinical”) indicates that a specific product candidate in a nonclinical setting has shown functional activity that is relevant to a targeted medical need, and is advancing toward initial human clinical testing. “Phase 1” clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. “Phase 2” clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the product candidate. “Phase 3” clinical trials involve large scale, multi-center, comparative trials that are conducted with patients afflicted with a target disease to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling.

Programs Targeting Infectious Diseases

Herpes Simplex Virus - 2

In June 2015, we announced top-line results from our Phase 1/2 trial of our Vaxfectin® -formulated therapeutic vaccine for HSV-2. A total of 165 HSV-2-infected patients were enrolled in the trial. The randomized, double-blind, placebo-controlled trial evaluated safety, tolerability and efficacy in otherwise healthy HSV-2-infected patients aged 18 to 50 years who had experienced two to nine genital herpes recurrences within the prior year. This trial tested the effectiveness of two HSV-2 vaccines, a monovalent vaccine and VCL-HB01, a bivalent vaccine, by comparing the viral shedding rate pre-vaccination (baseline) to the viral shedding rate post-vaccination of each subject. In addition to this primary efficacy endpoint, this trial also evaluated several secondary outcome measures, including genital lesion rate change from baseline, the HSV viral load (or copy numbers) change from baseline, as well as the immunological responses over time from baseline.

Neither the monovalent nor VCL-HB01 met the primary endpoint (reduction of viral shedding from baseline). However, VCL-HB01-vaccinated patients achieved statistically significant reductions in the clinically meaningful secondary endpoint of genital lesion rate at 3 months after their final dose. All patients were also followed for safety for 12 months after their final vaccine dose. In addition, we collected clinical efficacy data including lesion rate at up to nine months after their final dose. VCL-HB01 continued to achieve statistically significant reductions in the clinically meaningful secondary endpoint of genital lesion rate when compared to the pre-vaccination period at the nine-month time point after the patients’ final dose. Neither the placebo nor the monovalent vaccine groups achieved statistical significance on this endpoint at nine months after vaccination.

In September 2016, we announced the initiation of a Phase 2 trial of VCL-HB01, our Vaxfectin® -formulated, therapeutic DNA vaccine for HSV-2 infection. The randomized, double-blind, placebo-controlled trial will evaluate the efficacy and safety of the vaccine in approximately 225 healthy adults aged 18 to 50 years with symptomatic genital HSV-2 infection at up to 15 U.S. clinical sites. Subjects will receive a four-dose vaccination series, and will be evaluated for lesion

recurrences over a 12-month period after vaccination. The primary endpoint for the study is annualized lesion recurrence rate.

About HSV-2

HSV-2 is a member of the herpes virus family and is the leading cause of recurrent genital herpes worldwide. About 400 million people aged 15-49 years are living with HSV-2 worldwide, and about 20 million are newly infected every year. About one in six adults 14 to 49 years of age in the United States are infected with HSV-2. Even higher infection rates are evident in developing countries, with further complications in people also infected with HIV. HSV-2 infections are permanent and result in periodic virus shedding. There is no approved vaccine for HSV-2. Although antiviral regimens have become a standard of care in developed countries, we believe their inconvenience and cumulative cost underscore the need for safe, new approaches to reducing HSV-2 lesions, shedding, and transmission.

CMV Vaccines

CMV is a ubiquitous herpes virus that can cause serious complications in two distinct patient populations: immunocompromised transplant patients and children who were congenitally infected during pregnancy. We are currently developing two CMV vaccines to address the unmet needs in each of these two populations: ASP0113 (TransVax™; in collaboration with Astellas) and CyMVectin™. ASP0113 is designed to serve the first patient population by preventing CMV reactivation or infection in HCT recipients. In 2011, we licensed the right to develop and commercialize ASP0113 to Astellas. CyMVectin™ is designed to serve the second, much larger patient population by preventing CMV infection during pregnancy and thereby precluding maternal-fetal CMV transmission, congenital CMV infection, and related birth defects. We believe congenital CMV represents a major commercial opportunity and could potentially lead to universal vaccination.

Prior to licensing ASP0113 to Astellas, we completed a multicenter Phase 2 trial in 94 CMV-seropositive HCT recipients (14 donor-recipient pairs and 80 recipient-only subjects), randomized 1:1 to vaccine or placebo. Subjects enrolled were 18-65 years of age and had been diagnosed with selected leukemias or lymphomas. Enrollment in the trial was completed in November 2008 and a one-year follow up was completed in November 2009. In 2010, we released 12 month post-transplant data, and showed that significant reductions were achieved for key viral reactivation metrics. The final study results were published in *The Lancet Infectious Diseases* in January 2012.

The FDA and European Medicines Agency has designated ASP0113 as an orphan drug for the prevention of clinically significant CMV viremia, CMV disease and associated complications in at-risk transplant populations. Orphan drug designation provides certain tax benefits for qualifying expenses in the U.S. and can result in extended marketing exclusivity both in the U.S. and Europe.

We initially developed ASP0113 as a pathway to establish a CMV vaccine proof of concept in a relatively small patient population. We decided to specifically target HCT patients who are at very high risk of CMV reactivation. Therefore we designed a vaccine that would primarily induce a cellular immune response. ASP0113 is a plasmid DNA vaccine that induces both T-cell and antibody responses by expressing two antigens: phosphoprotein 65, or pp65, and glycoprotein B, or gB. The tegument protein, pp65, is a major antigen recognized by T cells in CMV-infected individuals. The gB protein is a major surface antigen of CMV and a primary target of neutralizing antibodies. The gB protein is also a major CMV antigen recognized by both CD4⁺ and CD8⁺ T cells in CMV-seropositive subjects. Induction of gB-specific T cells following DNA vaccination may provide an additional antiviral mechanism that could act to reduce CMV replication and viral loads shortly after infection. The vaccine is formulated with poloxamer CRL1005, which has been shown in nonclinical studies by us and others to enhance gene expression and immune responses.

In 2013, our licensee, Astellas, initiated two ASP0113 clinical trials including a global Phase 3 registration trial of ASP0113. This 1:1 randomized, double-blind, placebo-controlled trial enrolled CMV seropositive subjects undergoing HCT procedures. Randomization was stratified by donor-recipient relatedness and donor CMV serostatus. The trial enrolled 515 subjects and the primary endpoint is a composite of overall mortality and CMV end organ disease which will be assessed at one year after transplantation. Treatment and follow-up for each subject will continue for one year following enrollment. An independent committee has been appointed to adjudicate all cases of CMV end organ disease and data collection is in progress. Enrollment of the Phase 3 trial was completed in September 2016 and top-line data are expected to be available in the first quarter of 2018. During the course of the trial, an independent statistician conducted six futility analyses based upon viral load. The last of these analyses has now been completed and the trial continues as planned.

Astellas also completed a Phase 2 trial of ASP0113 in approximately 140 solid organ transplant recipients. This global, randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy of ASP0113 compared to placebo as measured by the incidence of CMV viremia in CMV-seronegative subjects receiving a kidney from a CMV-seropositive donor. In September 2016, we and Astellas announced top-line results from the study which demonstrated that the trial did not meet its primary endpoint, which was the proportion of patients having CMV viremia defined as a plasma viral load of ≥ 1000 IU/mL by central laboratory assay through one year after first injection of study drug. Additionally, the secondary endpoints of CMV-associated disease and CMV-specific antiviral therapy, which were evaluated by an independent, blinded adjudication committee, were similar in both treatment groups. Based on these results, Astellas has informed us that they do not plan to pursue further clinical development of ASP0113 in kidney transplant patients.

CyMVectin™

CMV is the most common congenital infection in the United States and a leading cause of birth defects. If a woman becomes infected with CMV for the first time during pregnancy, the manifestations of congenital infection can be very severe and there are no treatment options available. CyMVectin™ is designed to prevent CMV infection prior to pregnancy. We believe this may ultimately reduce birth defects caused by CMV.

CyMVectin™ consists of plasmid DNA that encodes the CMV gB antigen and a plasmid DNA that encodes the CMV pp65. The product is formulated with our proprietary lipid-based adjuvant Vaxfectin®. Vaxfectin® has been shown in clinical and/or nonclinical studies by us and others to enhance immune responses, particularly antibody responses, to expressed immunogens. A recombinant gB protein-based vaccine, developed by others, has shown some protection against maternal CMV infection in a Phase 2 clinical trial, so we believe a vaccine strategy for CMV prevention can be successful. In addition, prior maternal CMV infection is associated with a reduction of risk of congenital infection. Nonclinical studies performed in rabbit, guinea pig and mouse models have demonstrated the ability to induce high titers of gB-specific antibodies in animals receiving the gB plasmid. Rabbit studies of Vaxfectin®-formulated gB plasmid DNA demonstrated an approximately 10-fold enhancement of gB when compared to gB plasmid DNA in phosphate-buffered saline. Similarly, mouse studies also demonstrated this added benefit of Vaxfectin® as an adjuvant. The results of these and prior published studies provide support that immune responses can be induced by DNA vaccination and that formulation with Vaxfectin® enhances those immune responses. Phosphoprotein 65 is a major CMV tegument protein that is among the most widely recognized CMV antigens by both CD4+ and CD8+ T cells in CMV-seropositive subjects. Induction of pp65-specific T cells following vaccination may provide an additional antiviral mechanism that could limit the spread of CMV infection by reducing CMV replication and viral loads. A repeat dose safety study in rabbits with Vaxfectin®-formulated gB and pp65 plasmids supports the conduct of an initial safety study in humans under an allowed Investigational New Drug application, or IND.

About CMV

CMV infects over 50% of adults in the United States by age 50. Although most healthy people who are infected by CMV after birth are asymptomatic, CMV can affect certain high-risk groups, including immunocompromised individuals and congenitally-infected infants. Significant mortality and morbidity are observed in the immunocompromised populations, especially HCT recipients. In CMV-seropositive HCT recipients, the incidence of CMV reactivation in the first three months following transplantation is 50-70%, and these subjects are at increased risk for CMV end-organ disease. The incidence of CMV disease has been reduced to approximately 11% at one year after transplantation by the use of antiviral therapy, but currently available antiviral therapies are associated with drug toxicity, are costly, may lead to drug resistance and provide incomplete efficacy. Late-onset CMV reactivation may also occur after the initial 100-day period of heightened susceptibility. Despite current antiviral treatments that reduce the incidence of CMV disease, CMV-seropositive HCT recipients are still at increased risk of overall mortality as well as significant morbidities or mortalities from acute and chronic graft-versus-host disease, as well as other non-CMV infectious diseases.

Currently no vaccine is approved for the prevention of CMV infection. The only approved treatment for CMV in HCT patients is ganciclovir, although other antivirals are used off label, such as valganciclovir, foscarnet, and cidofovir. We believe a vaccine that enables the patient's immune system to control CMV infection, thereby reducing the need for antiviral therapy, would be a valuable therapeutic option for HCT recipients. The control of CMV in immunocompromised persons is primarily associated with T-cell mediated immune responses.

CMV-seropositive HCT recipients represent important populations for the prevention of CMV reactivation and reduction in antiviral therapy. Approximately 70,000 HCTs are performed annually throughout the world. We believe these populations represent a significant market potential for our ASP0113 vaccine.

CyMVectin™ was designed to prevent CMV infection prior to pregnancy. We believe this may ultimately reduce birth defects caused by CMV. In the United States, congenital infection occurs in about 1 in 150 live-born infants and results in permanent disabilities, including hearing loss, mental retardation and vision loss in approximately 5,000 children per year, and approximately 500 deaths annually. Congenital infection can also occur in CMV-seropositive women. Prior maternal CMV infection is associated with a reduction of the frequency and severity of congenital infection. Contact with infected young children is the primary source of infection for pregnant women, especially those exposed to children in daycare environments.

DNA vaccine induction of CMV-specific antibodies and T-cell responses may prevent or limit CMV infection in women during pregnancy, which could impact congenital CMV transmission and the incidence of newborns suffering from the morbidities or mortality inflicted by CMV infections. We believe that there is a significant market potential for our CyMVectin™ vaccine, as there are more than 30 million CMV seronegative women of childbearing age (10 to 49 years) in the United States.

Antifungal Program

In March 2016, we initiated a Phase 1 clinical trial of our novel antifungal candidate, VL-2397. The randomized, double-blind trial evaluated safety, tolerability and pharmacokinetics of VL-2397 at single and multiple ascending doses in otherwise healthy volunteers at one U.S. clinical site. We intend to develop VL-2397 as a front-line therapy for invasive pulmonary aspergillosis which may represent a meaningful commercial opportunity within the global market for systemic antifungals. The FDA granted us Fast Track, orphan drug and QIDP designation for VL-2397 for the treatment of invasive aspergillosis.

VL-2397 represents a potential new class of antifungal compound to address invasive aspergillus infections, which are major causes of morbidity and mortality in immunocompromised patients, including transplant recipients. In preclinical studies to date, it has demonstrated faster fungicidal activity than marketed drugs and activity against azole-resistant fungal pathogens. Current treatment options have limited efficacy, as approximately 50-60% of allogeneic hematopoietic stem cell transplant recipients with invasive aspergillosis infections die within 12 weeks. Over the past 30 years, only one new class of antifungal drugs (echinocandins) has been introduced.

Other Infectious Disease Programs

Ebola

In January 2015, we and AnGes MG, Inc., or AnGes, announced a collaboration to develop and commercialize an equine polyclonal antibody therapy for patients afflicted with Ebola virus disease. We developed and provided to AnGes a DNA vaccine encoding the glycoprotein antigen of the 2014 Zaire strain of Ebola virus, formulated with our proprietary Vaxfectin® adjuvant. AnGes received the right to exclusively develop and commercialize the equine polyclonal antibody therapy in Japan and will be responsible for all development costs. We received an upfront payment and are eligible to receive royalties on net sales and a percentage of payments received by AnGes under any sub-licensing agreements. Characterization studies of the equine polyclonal antibodies are ongoing.

Government Collaborations

We have developed several vaccines targeting other diseases including dengue, malaria, anthrax, severe acute respiratory syndrome, or SARS, West Nile virus, or WNV, and Ebola. We have performed nonclinical work and completed a Phase 1 clinical trial targeting anthrax. The Naval Medical Research Center, or NMRC, has completed a Phase 1 study of a tetravalent (serotypes 1, 2, 3, and 4) dengue DNA vaccine formulated with Vaxfectin®. The National Institutes of Health, or NIH, has completed Phase 1 clinical trials using our vaccines targeting SARS, WNV and Ebola. Due to the lack of commercial opportunities and government funding, we do not plan on further developing these vaccines at this time.

Adjuvant Development

DNA Vaccines with Vaxfectin®

Vaxfectin® is our proprietary, cationic lipid formulation optimized to increase the immune response to vaccines. Vaxfectin® formulations have demonstrated safety and adjuvant activity in DNA vaccine applications in multiple animal models, including nonhuman primates. Studies of Vaxfectin®-formulated DNA vaccines against CMV and measles have shown enhanced immunogenicity in rodents and nonhuman primates. Vaxfectin®-formulated DNA vaccines have also been

tested in approximately 200 healthy human subjects receiving influenza , dengue , or HSV-2 vaccines, and collectively, these Phase 1 trials indicate favorable safety profiles of these vaccines. We believe Vaxfectin® is an important potentiator of both antibody and T-cell mediated immune responses to DNA vaccines.

Other Vaxfectin® Applications

In 2013, we entered into a nonexclusive license with Bristol-Myers Squibb Company, or BMS, for our patented platform DNA immunization technology and our Vaxfectin® adjuvant for use in the production of antibodies. Under the agreement, BMS is using our technology to generate antibodies with potential therapeutic uses in humans. We also agreed to provide specified quantities of our Vaxfectin® adjuvant to BMS from time to time.

Collaboration and Licensing Agreements

We have entered into various arrangements with corporate, academic, and government collaborators, licensors, licensees, and others. In addition to the agreements summarized below, we conduct ongoing discussions with potential collaborators, licensors and licensees.

Out-licensing

Astellas . In July 2011, we entered into license agreements with Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of gB, and/or pp65, including ASP0113 but excluding CyMVectin™. Under the agreements, Astellas is responsible for the worldwide development and commercialization of products in the licensed field, at its expense, and has agreed to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize at least one licensed product for use in certain immunocompromised patients in the licensed field in the United States and certain other major markets.

Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of \$25.0 million in 2011. We received an additional \$10.0 million in 2012 upon finalization of the trial design for a Phase 3 registration trial of ASP0113 in HCT recipients. We are also entitled to receive additional cash payments potentially totaling \$65.0 million for achievement of certain milestones through commercial launch and to receive double-digit royalties on net sales of products, and we have an option to co-promote ASP0113 in the United States. Under the terms of a supply and services agreement entered into by us and Astellas on the same date, we agreed to perform certain development and regulatory activities, at Astellas' expense, and to supply licensed products to Astellas, at Astellas' expense, for use in development and initial commercialization activities in the licensed field. During the years ended December 31, 2016, 2015 and 2014, we recognized \$1.5 million, \$1.8 million and \$1.6 million, respectively, related to the license fee and know-how, and \$12.5 million, \$14.7 million and \$13.3 million, respectively, of revenue related to contract services and product delivered.

In August 2012, we amended our license and supply agreements with Astellas to, among other things, (i) extend the time period that we are obligated to supply licensed products for commercial use to Astellas, at Astellas' expense, (ii) modify the allocation of \$65.0 million of milestone payments among certain milestones through commercial launch and (iii) modify the structure of the royalties on net sales from a fixed double-digit royalty to escalating tiered double-digit royalties.

As of December 31, 2016, the aggregate potential milestone payments that we were eligible to receive under each of our out-license agreements with Astellas was equal to approximately \$65.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. Because the milestones are highly contingent and we have limited control over whether the development and regulatory milestones will be achieved, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be received, or when. Many of the milestone events are related to progress in clinical trials which will take several years to achieve.

We are also eligible to receive royalty payments under our out-license agreements based on net sales of any products which incorporate the out-licensed technology. The royalties in our out-license agreements with Astellas are based on percentages of net sales in the double-digit range. Our receipt of any royalty payments under the out-license agreements is contingent upon the licensee successfully developing and commercializing products incorporating the licensed technology, and we have limited control over our licensees' efforts in this regard. Consequently, we are not in a position to reasonably estimate when or to what extent we will receive any royalty payments under our out-license agreements.

Merial. In 2004, we granted an exclusive license to Merial for use of our core DNA delivery technology in a therapeutic vaccine designed to aid in extending survival time of dogs with oral melanoma. Under the agreement, Merial is responsible for research and development activities. In March 2009, Merial received approval from the USDA to market the DNA vaccine, now called ONCEPT®. Merial pays royalties to us on sales of the vaccine.

In-licensing

Astellas. In March 2015, we entered into a license agreement with Astellas, granting us exclusive worldwide license to develop and commercialize our novel antifungal candidate, VL-2397. As consideration for the rights under the license, we issued 86,121 shares of our common stock to Astellas and made an up-front payment of \$250,000 in cash. The license agreement provides for potential development, regulatory and sales milestone payments totaling up to \$99.0 million, as well as tiered single-digit royalty payments based on net sales of licensed products. The royalty payments are subject to reduction on a country-by-country basis in certain circumstances where there is not exclusivity in the country. We are responsible for the worldwide development, manufacturing and commercialization of licensed products, at our cost, and we are required to use commercially reasonable efforts with respect to such development and commercialization activities.

The license agreement, unless terminated earlier, will continue until expiration of our royalty obligations with respect to licensed products. Either party may terminate the license agreement earlier if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party's insolvency. Astellas may terminate the license agreement earlier if we or any of our affiliates or sublicensees oppose or challenge any of the licensed patents. We may terminate the license agreement on a country-by-country basis for reasonable scientific, regulatory, commercial, financial, ethical or other reasons.

CytRx. In 2001, we entered into an exclusive agreement with CytRx Corporation, or CytRx, which grants us rights to use or sublicense CytRx's poloxamer technology to enhance viral or non-viral delivery of polynucleotides in all nonexcluded preventive and therapeutic human and animal health applications, including CMV. In addition, the agreement permits our use of CytRx's technology to enhance the delivery of proteins in prime-boost vaccine applications that involve the use of polynucleotides. As part of the agreement, we made a \$3.8 million up-front payment and agreed to make potential future milestone and royalty payments. As of December 31, 2016, we had paid CytRx \$5.4 million under the agreement.

The agreement with CytRx expires upon the expiration of our royalty obligations, unless earlier terminated as set forth in the agreement. Each party may terminate the agreement early upon the bankruptcy or insolvency of, or the material breach of the agreement by, the other party, upon prior written notice to the other party. Subject to certain conditions, we may terminate the agreement early upon prior written notice to CytRx.

City of Hope. In 2003, we licensed from the City of Hope on an exclusive basis various U.S. patents that provide protection for CMV-related polynucleotide based vaccines, including TransVax™ and CyMVectin™ vaccine candidates. The agreement expires upon the last to expire of the patent rights licensed by us under the agreement, unless earlier terminated as set forth in the agreement. The City of Hope may terminate the agreement early, in accordance with notice provisions set forth in the agreement, if we cease to operate, fail to make payments when due or materially breach the agreement. Subject to certain conditions, we may terminate the agreement early at any time upon prior written notice to the City of Hope. We are also obligated to pay a low double-digit percentage of any payments we receive from the sub-license of products that incorporate the licensed technology. As of December 31, 2016, we had paid the City of Hope \$5.7 million under the agreement.

As of December 31, 2016, the aggregate potential milestone payments that we could be obligated to pay under our active in-license agreements with Astellas, City of Hope and CytRx, total approximately \$106.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. Although we believe that some of the milestones contained in the in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are highly contingent and we have limited control over whether the regulatory milestones will be achieved, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under these in-license agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

Under these in-license agreements, we may also be obligated to pay royalties based on net sales of any products which incorporate the in-licensed technology. These royalties are based on percentages of net sales in the single digit range. We may also be obligated to make payments under our in-license agreements with the City of Hope based on amounts we receive from sub-licensees, if any. Our obligations to pay any royalty payments under our in-license agreements are

contingent upon the successful development and commercialization of products incorporating the in-licensed technology. Before any products incorporating the in-licensed technology may be sold, such products must be approved by U.S. or foreign regulatory authorities, which will require a substantial amount of additional research and development. Even if such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. Consequently, we are not in a position to reasonably estimate when or to what extent we will be obligated to pay any royalties under our in-licensing agreements.

Intellectual Property

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, inventions, and improvements to our inventions that we consider important to the development of our business. We believe we have a comprehensive patent portfolio in the United States and in key foreign markets. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

Our patents and patent applications cover, for example, specific DNA constructs and formulations of gene-based product candidates, methods for producing pharmaceutical-grade DNA, and several families of lipid molecules and their uses in DNA delivery, as described more fully below:

- *Core DNA Delivery Technology.* We either co-owned or had rights to issued U.S. patents covering our core DNA delivery technology, including patents on methods of administering DNA sequences for the purposes of expressing therapeutic proteins or for inducing immune responses and the administration of DNA sequences into blood vessels and the heart. These patents are now expired, but we maintain patents covering specific product applications as described below.
- *Lipid Technologies.* We are the sole assignee of issued U.S. patents covering numerous examples of cationic lipid compounds that are used to facilitate delivery of plasmids to some tissues. Our HSV-2 therapeutic vaccine candidate, our Vaxfectin® adjuvant, as well as our CyMVectin™ prophylactic vaccine candidate are protected in-part by lipid technology and/or lipid compound patents that extend up to March 24, 2020. Patent protection of these key lipids also has been obtained in Europe, Canada and Japan. Under the Hatch-Waxman Act, a U.S. patent term extension for up to 5 years may be available under certain conditions.
- *Specific DNA Products.* We have patents covering specific product applications of our technologies. To date, we have received patents in the United States, Europe, Canada and Japan, relating to codon-optimized polynucleotide-based vaccines against human CMV infection. The patents expire between December 19, 2023, and May 12, 2025. These patents further protect both our ASP013 therapeutic vaccine candidate for CMV as well as our CyMVectin™ prophylactic vaccine candidate for CMV. Protection for our therapeutic vaccine candidate for HSV-2 is further augmented by issued patents in the U.S. and Japan and other foreign counterparts pending in Australia, Canada, and Europe, all of which will expire on July 20, 2027. These patents are co-owned with the University of Washington. Under the Hatch-Waxman Act, a U.S. patent term extension for up to 5 years may be available under certain conditions.
- *Antifungal Technology.* We have been granted the exclusive right to Astellas patents which claim the composition of matter of, or any method of making or using, VL-2397. All of these issued U.S. patents and foreign counterparts will expire on March 13, 2029.

As of December 31, 2016, we were the assignee or co-assignee of 53 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated.

As of December 31, 2016, we were also prosecuting one pending patent application in the United States and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners.

See “Risk Factors—Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products,” and “The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.”

Commercialization and Manufacturing

Because of the broad potential applications of our technologies, we intend to develop and commercialize products both on our own and through our collaborators and licensees. We intend to develop and commercialize products in well-defined specialty markets, including infectious diseases. Where appropriate, we intend to rely on strategic marketing and distribution alliances.

We believe our plasmids can be produced in commercial quantities through uniform methods of fermentation and processing that are applicable to all plasmids. In addition, our formulations consist of components that are synthesized chemically using traditional, readily scalable organic synthesis procedures.

We produce and supply our own plasmids for all of our research needs and clinical trials and intend to produce sufficient supplies for all foreseeable clinical investigations. Our facility received a California Food and Drug Branch manufacturing facility license and began production in 2004. We also engage in contract manufacturing of plasmid investigational products for selected clients.

Competition

We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are actively engaged in infectious disease vaccine research and development. These include Sanofi, GlaxoSmithKline plc, MedImmune, Inc., a wholly owned subsidiary of AstraZeneca, Merck and Pfizer Inc., among others. We may also experience competition from companies that have acquired or may acquire technologies from companies, universities and other research institutions. These companies may develop proprietary technologies which may materially and adversely affect our business.

In addition, a number of companies are developing products to address the same diseases that we are targeting. For example, Roche, Sanofi, AiCuris GmbH & Co. KG in conjunction with Merck, Chimerix, Inc., and others have products or development programs for CMV treatment and prevention. GlaxoSmithKline plc, Genocera Biosciences, Inc. and others have products or development programs for HSV-2 treatment. If these or any other companies develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed.

Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive, or result in treatments or cures superior to ours.

Our competitive position will be affected by the disease indications addressed by our product candidates and those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these product candidates are likely to be significant competitive factors. Other important competitive factors will include the efficacy, safety, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

The FDA and other regulatory agencies may expand current requirements for public disclosure of DNA-based product development data, which may harm our competitive position with foreign and U.S. companies developing DNA-based products for similar indications.

Government Regulation***FDA Review and Approval***

Any products we develop will require regulatory clearances prior to clinical trials and additional regulatory approvals prior to commercialization. New gene-based products for vaccine or therapeutic applications are subject to extensive regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which we will have to comply are uncertain at this time due to the novelty of the gene-based products and indications, or uses, that are

currently under development. In the United States, the Federal Food, Drug and Cosmetic Act and the Public Health Service Act and their implementing regulations govern, among other things, biopharmaceutical testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and other promotional practices.

Obtaining FDA approval is a costly and time-consuming process. Generally, FDA approval requires that preclinical studies be conducted in the laboratory and in animal model systems to gain preliminary information on efficacy and to identify any major safety concerns. The results of these studies are submitted as a part of an IND which the FDA must review and allow before human clinical trials can start. The IND includes a detailed description of the proposed clinical investigations.

A company must submit an IND for each proposed product and must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients.

To obtain FDA approval prior to marketing a biopharmaceutical product in the United States typically requires several phases of clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical trials are the means by which experimental treatments are tested in humans, and are conducted following preclinical testing. Clinical trials may be conducted within the United States or in foreign countries. If clinical trials are conducted in foreign countries, the products under development as well as the trials are subject to regulations of the FDA and/or its counterparts in the other countries. Upon successful completion of clinical trials, approval to market the treatment for a particular patient population may be requested from the FDA in the United States and/or its counterparts in other countries.

Clinical trials for therapeutic products are normally done in three phases. Phase 1 clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the drug. Phase 3 clinical trials involve large scale, multi-center, comparative trials that are conducted to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling. In some special cases where the efficacy testing of a product may present a special challenge to testing in humans, such as in the case of a vaccine to protect healthy humans from a life-threatening disease that is not a naturally occurring threat, effectiveness testing may be required in animals.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, a Biologics License Application, or BLA, is required. If the product is classified as a new drug, a New Drug Application, or NDA is required. The NDA or BLA must include results of product development activities, preclinical studies, and clinical trials in addition to detailed chemistry, manufacturing and control information.

Applications submitted to the FDA are subject to an unpredictable and potentially prolonged approval process. Despite good-faith communication and collaboration between the applicant and the FDA during the development process, the FDA may ultimately decide, upon final review of the data, that the application does not satisfy its criteria for approval or requires additional product development or further preclinical or clinical studies. Even if FDA regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Before marketing clearance for a product can be secured, the facility in which the product is manufactured must be inspected by the FDA and must comply with the FDA's current Good Manufacturing Practices, or cGMP, regulations. In addition, after marketing clearance is secured, the manufacturing facility must be inspected periodically for cGMP compliance by FDA inspectors, and, if the facility is located in California, by inspectors from the Food and Drug Branch of the California Department of Health Services.

In addition to the FDA requirements, the NIH has established guidelines for research involving human genetic materials, including recombinant DNA molecules. The FDA cooperates in the enforcement of these guidelines, which apply to all recombinant DNA research that is conducted at facilities supported by the NIH, including proposals to conduct clinical research involving gene therapies. The NIH review of clinical trial proposals and safety information is a public process and often involves review and approval by the Recombinant DNA Advisory Committee of the NIH.

Sponsors of clinical trials are required to register, and report results for, all controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation. Trial registration may require public disclosure of confidential commercial development data resulting in the loss of competitive secrets, which could be commercially detrimental.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for such drug or biological product for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

We received QIDP, and Fast Track designation for VL-2397 for the treatment of invasive aspergillosis. If VL-2397 for the treatment of invasive aspergillosis is approved by FDA, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded. FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill an unmet medical need. This designation allows for companies to interact with the FDA review team frequently to discuss critical development issues such as study design, required safety data necessary to support approval, and structure and content of an application. Additionally, should the FDA determine that a Fast Track product may be effective after their preliminary evaluation of clinical data submitted by a sponsor, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application, known as a "rolling" submission.

Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

We may also be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These additional healthcare regulations could affect our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors. Such laws potentially applicable to our operations include:

- The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully, directly or indirectly, overtly or covertly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act or ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation.
- Federal false claims and false statement laws, including the federal civil False Claims Act and whistleblower or *qui tam* actions, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, require certain types of individuals and entities to protect the privacy, security, and electronic exchange of certain patient data.
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third party payors, including private insurers. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Further, we may be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers and healthcare entities, or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

are found to be in violation of any of these federal, state, local or foreign laws or regulations, we may be subject to penalties, including without limitation, administrative or civil penalties, imprisonment, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, or the curtailment or restructuring of our operations.

Reimbursement and Health Reform

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate that receives regulatory approval. In the United States and markets in other countries, sales of our product candidates, if approved, will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for drugs. Further, third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication.

Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product.

The United States and some foreign jurisdictions are considering or have enacted legislative and regulatory proposals to contain healthcare costs, as well as to improve quality and expand access. For example, in March 2010, ACA, was signed into law that included a number of provisions of importance to the pharmaceutical industry. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011 was enacted, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that may be charged for any of our product candidates, if approved.

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Employees

As of December 31, 2016, we had 73 full-time employees, including 7 with doctorate degrees and one medical doctor. Of these full-time employees, 53 were engaged in, or directly supporting, research and development and manufacturing activities, and 20 were in general and administrative positions. A significant number of our management and other employees have prior experience with pharmaceutical and/or biotechnology companies. None of our employees is covered by collective bargaining agreements, and our management considers relations with our employees to be good.

Executive Officers of the Registrant

Our executive officers and other executives are as follows:

Name	Age ¹	Position
Vijay B. Samant ²	64	President, Chief Executive Officer and Director
Keith D. Hall	55	Vice President, Operations
Mammen P. Mammen, Jr., M.D.	53	Vice President, Clinical Vaccines
Anthony A. Ramos ²	50	Vice President Finance, Chief Accounting Officer
Larry R. Smith, Ph.D. ²	56	Vice President, Vaccine Research

¹ As of December 31, 2016.

² Executive officer.

Vijay B. Samant joined us as President and Chief Executive Officer in November 2000. Previously, he held various positions at Merck from 1977 to 2000. From 1998 to 2000, he was Chief Operating Officer of the Merck Vaccine Division. From 1990 to 1998, he served in the Merck Manufacturing Division as Vice President of Vaccine Operations, Vice President of Business Affairs and Executive Director of Materials Management. From 1977 to 1990, Mr. Samant held a variety of positions of increasing responsibility in manufacturing, process engineering, production planning and control, business development and loss prevention in several Merck operating divisions. Mr. Samant holds a bachelor's degree in chemical engineering from the University of Bombay, India, an M.S. degree in chemical engineering from Columbia University and an S.M. degree from the Sloan School of Management at MIT. Mr. Samant currently serves on the Board of

Directors for AmpliPhi Biosciences and was a member of the board of directors of Raptor Pharmaceutical Corporation from 2011 to 2014. Mr. Samant was a member of the Board of Trustees for the National Foundation for Infectious Diseases and the International Vaccine Institute in Seoul, South Korea from 2008 to 2012. Mr. Samant was also a Director of the Aeras Global TB Vaccine Foundation from 2001 to 2010.

Keith D. Hall joined us as Director Quality Control and Assay Development in February 2003 and was named Vice President, Operations in April 2016. From 2000 to 2003 he served as Director of Manufacturing for Aegenix in Houston, TX where he oversaw drug substance and product manufacture, and the design, construction and commissioning of a recombinant human lactoferrin bulk drug substance manufacturing facility in Italy. From 1994 to 2000 he served as Senior Manager, Quality Control and Analytical Development for Valentis/GeneMedicine in The Woodlands, TX. Prior to 1994, Mr. Hall served in various development and manufacturing positions of increasing responsibilities at Hybritech and Amgen. He earned a master's degree in business administration from the C.T. Bauer College of Business at the University of Houston, and a bachelor's degree in microbiology from the University of California at Santa Barbara.

Mammen P. Mammen, Jr., M.D. joined us as Vice President, Clinical Vaccines, in November 2012. Prior to joining us, he served as Infectious Disease Consultant and Chief, Pandemic Warning Team, U.S. Department of Defense, Fort Detrick, Maryland. From 2006 to 2010, he served as the Army's Product Manager for vaccines in Advanced Development against dengue, hepatitis E, and HIV viruses for the U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland. As Chief, Department of Virology, the Armed Forces Research Institute of Medical Sciences, Thailand, from 2001 to 2006, Dr. Mammen managed a number of the Army's FDA-regulated vaccine studies. Dr. Mammen received his M.D. degree from the Pennsylvania State University College of Medicine and is Board-certified in Infectious Diseases. He has been elected as Fellow by the Infectious Disease Society of America and the American College of Physicians. He received his Internal Medicine and Infectious Disease clinical training from the Walter Reed Army Medical Center. He earned a B.A. degree in mathematics from Williams College. Dr. Mammen has authored or co-authored nearly 50 scientific publications spanning multiple emerging and re-emerging infectious diseases.

Anthony A. Ramos joined us as Corporate Controller in February 2005 and was named Chief Accounting Officer in July 2010 and Vice President of Finance in December 2013. From January 1999 until joining Vical, Mr. Ramos held various positions at Copper Mountain Networks, Inc., a publicly held network communications company, most recently as Vice President of Finance with broad responsibilities in finance, accounting, treasury, risk management and corporate governance. From April 1996 until joining Copper Mountain Networks, Mr. Ramos was Accounting Manager at Viasat, Inc., a publicly held digital communications company, where he held accounting and financial reporting responsibilities. From January 1990 until joining Viasat, Mr. Ramos served as an audit manager at PricewaterhouseCoopers LLP, where his clients included life sciences, computer software and telecommunications companies as well as government contractors. Mr. Ramos received his bachelor's degree in business administration and accounting from San Diego State University and is a Certified Public Accountant.

Larry R. Smith, Ph.D. joined us as Executive Director, Vaccinology in September 2003, and was named Vice President, Vaccine Research in October 2006. Prior to joining Vical, Dr. Smith was Director of Viral Vaccines Research at Wyeth Vaccines, where he oversaw the immunogenicity testing of various viral vaccines including a number of recombinant viral vectors. Prior to joining Wyeth in 1996, Dr. Smith was a Scientific Investigator at Immune Response, where he identified autoreactive T-cell targets in psoriasis and multiple sclerosis which led to the clinical testing of several therapeutic vaccine candidates. Dr. Smith received a B.S. degree in biology from Purdue University, a Ph.D. in microbiology and immunology from the University of Texas Medical Branch, and was a postdoctoral fellow in the Immunology Department at Scripps Clinic and Research Foundation.

ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Annual Report on Form 10-K, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

None of our independently developed product candidates has been approved for sale, and we have a limited number of independently developed product candidates in clinical trials. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

All of our independently developed product candidates are either in research or development. We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Limited data exist regarding the efficacy of DNA vaccines or therapeutics compared with conventional vaccines or therapeutics. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, we may stop development and regulatory authorities will not approve them. For example, in 2013 we ceased development of Allovectin[®], an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial.

We initiated a Phase 2 clinical trial of VCL-HB01, our HSV-2 vaccine in September 2016, but the results of the Phase 2 clinical trial may not be positive and the favorable results or trends observed in our previously completed Phase 1/2 clinical trial may not continue in the Phase 2 clinical trial. In addition, in March 2016, we initiated a Phase 1 clinical trial of our novel antifungal, VL-2397. The Phase 2 clinical trial of VCL-HB01, our Phase 1 clinical trial of VL-2397 and any future trials, if any, may not demonstrate sufficient safety or efficacy to support further product development. Because we have a limited number of independent clinical-stage product candidates, if we experience a significant delay, set-back or failure in the development of any of our product candidates, it could have a material adverse impact on our business prospects.

All of the product candidates we are developing independently will require significant costs to advance through the development stages. If such product candidates are advanced through clinical trials, the results of such trials may not support approval by the FDA or comparable foreign agencies. Even if approved, our products may not be commercially successful, particularly if they do not gain market acceptance among physicians, patients, healthcare payers and relevant medical communities. If we fail to develop and commercialize our product candidates, we may be forced to curtail or cease operations.

Our clinical trials or those of our partners may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. We and our licensees have in the past suffered significant setbacks in advanced clinical trials due to lack of efficacy, notwithstanding promising results in earlier trials. For example, in 2013 we ceased development of Allovectin[®], an investigational intratumoral cancer immunotherapy, following negative results from a Phase 3 trial. In June 2015, we announced that our HSV-2 product candidates did not meet the primary endpoint in a Phase 1/2 clinical study. In September 2016, we and Astellas announced ASP0113 did not meet its primary endpoint in a Phase 2 clinical study evaluating the safety and efficacy of ASP0113 versus placebo in kidney transplant patients receiving an organ from a CMV-seropositive donor. Most product candidates that commence clinical trials are never approved as products.

There are a number of factors that could cause a clinical study to fail or be delayed, including:

- the clinical study may produce negative or inconclusive results;
- regulators, monitoring boards or other entities may require that we hold, suspend or terminate clinical research for safety, ethical or regulatory reasons, including adverse events reported during the trial;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical studies;
- enrollment in our clinical studies may be slower than we anticipate;
- the cost of our clinical studies may be greater than we anticipate; and

- the supply or quality of our product candidates or other materials necessary to conduct our clinical studies may be insufficient, inadequate or delayed.

In addition, even if clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as sufficient to demonstrate that a product is safe and efficacious, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

We are dependent on our out-license agreements with Astellas to further develop and commercialize ASP0113. The failure to maintain these agreements, or the failure of Astellas to perform its obligations under these agreements, could negatively impact our business.

Pursuant to the terms of our out-license agreements with Astellas, we granted to Astellas exclusive worldwide rights to develop and commercialize certain products, including ASP0113 but excluding CyMVectin™, for the control and prevention of CMV infection in immunocompromised patients, including transplant recipients and transplant donors, and pursuant to the terms of our supply and services agreement with Astellas, we are obligated to perform certain development activities and supply Astellas with its product requirements for development and initial commercialization activities. Consequently, our ability to generate any revenues from ASP0113 depends on Astellas' ability to develop, obtain regulatory approvals for and successfully commercialize ASP0113. We have limited control over the amount and timing of resources that Astellas will dedicate to these efforts. For example, based on the results of the Phase 2 clinical trial evaluating ASP0113 in kidney transplant patients, Astellas has informed us that they do not plan to pursue further clinical development of ASP0113 in solid organ transplant indications.

We are subject to a number of other risks associated with our dependence on our out-license agreements with Astellas, including:

- Astellas may not comply with applicable regulatory guidelines with respect to developing or commercializing ASP0113, which could adversely impact sales or future development of ASP0113;
- We and Astellas could disagree as to future development plans and Astellas may delay, fail to commence or stop future clinical trials or other development;
- There may be disputes between us and Astellas, including disagreements regarding the license agreements or supply agreement, that may result in (1) the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments, (2) the delay or termination of any future development or commercialization of ASP0113, and/or (3) costly litigation or arbitration that diverts our management's attention and resources;
- Astellas may not provide us with timely and accurate information regarding development, sales and marketing activities or supply forecasts, which could adversely impact our ability to comply with our service and supply obligations to Astellas and manage our own inventory of ASP0113, as well as our ability to generate accurate financial forecasts;
- Business combinations or significant changes in Astellas' business strategy may adversely affect Astellas' ability or willingness to perform its obligations under our license agreements;
- Astellas may not properly defend our intellectual property rights, or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential litigation;
- The royalties we are eligible to receive from Astellas may be reduced based upon Astellas' and our ability to maintain or defend our intellectual property rights and the presence of generic competitors;
- Limitations on our or an acquirer's ability to maintain or pursue development or commercialization of products that are competitive with ASP0113 could deter a potential acquisition of us that our stockholders may otherwise view as beneficial; and
- If Astellas is unsuccessful in developing, obtaining regulatory approvals for or commercializing ASP0113, we may not receive any additional milestone or royalty payments under the license agreements and our business prospects and financial results may be materially harmed.

The out-license agreements and supply and services agreement are subject to early termination, including through Astellas' right to terminate upon advance notice to us if Astellas reasonably determines that further development and/or commercialization will not be beneficial for Astellas. If the agreements are terminated early, we may not be able to find another collaborator for the commercialization and further development of ASP0113 on acceptable terms, or at all, and we may be unable to pursue continued development or commercialization of ASP0113 on our own.

Our revenues partially depend on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If our other collaborators or licensees do not successfully develop and commercialize products covered by these arrangements, or if we are unable to find collaborators or licensees in the future, we may not be able to derive revenues from these arrangements, we may lose opportunities to validate our DNA delivery technologies, or we may be forced to curtail our development and commercialization efforts in these areas.

In addition to our out-license agreements with Astellas, we have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues partially depend upon the ability of these collaborators and licensees to successfully develop and commercialize products covered by these arrangements. In addition, our licensee Astellas has product candidates in advanced stages of clinical development, for which we believe regulatory approval would provide important further validation of our DNA delivery technologies. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that our collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators or licensees to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our DNA delivery technologies, or force us to curtail or cease our development and commercialization efforts in these areas.

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies. If we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

We licensed rights to patents and know-how for VL-2397 from Astellas pursuant to an in-license agreement that contains obligations to pay Astellas regulatory and sales milestone payments relating to VL-2397, as well as royalties on net sales of VL-2397. If we fail to make a required payment to Astellas or otherwise materially breach our in-license agreement with Astellas and do not cure the failure within the required time period, Astellas may be able to terminate the license to the VL-2397 patents and know-how, which would have a material adverse effect on our business, financial condition and results of operations.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$9.0 million, \$9.2 million and \$16.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had incurred cumulative net losses totaling approximately \$413.9 million. Moreover, we expect that our net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. Currently our revenues are largely dependent on manufacturing and research services performed under our license agreement with Astellas. That revenue may decrease once the ASP0113 trials are complete or in the event that the development of the ASP0113 program ceases. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. 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, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

In October 2016, we also entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we may issue and sell up to \$10.0 million of shares of our common stock from time to time. To date we have not sold any shares of our common stock under the ATM Agreement. However, BP is not obligated to sell any shares that we may request to be sold, and any attempt to sell shares under this facility, if made, may not be successful or generate sufficient proceeds to meet our capital requirements.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials;
- The amount of our legal expenses and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us and our collaborators and licensees from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees, including Astellas, are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources.

U.S. or foreign regulations evolve and could prevent or delay regulatory approval of our products or limit our and our collaborators and licensees' ability to develop and commercialize our products. Delays could:

- Impose costly procedures on our activities and those of our collaborators and licensees;
- Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;
- Diminish any competitive advantages that we or our products attain; or
- Otherwise negatively affect our results of operations and cash flows.

We have no experience in filing a BLA or an NDA with the FDA. Because these applications must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

The FDA and comparable foreign regulatory bodies will regulate separately each product containing a particular gene depending on its intended use. Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

We anticipate that we would commercially manufacture the drug substance for the ASP0113 program if it is approved for marketing. Therefore, our manufacturing facilities will have to be approved by the FDA pursuant to inspections conducted after we submit an application for regulatory approval. If we cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our manufacturing facilities. If the FDA does not approve our facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, our ability to develop, obtain regulatory approval for or market our product candidates will be adversely affected.

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product or a product class, including 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 product class, our collaborators and licensees or us, including requiring withdrawal of a product from the market. Our product candidates will also be subject to ongoing FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. If we or our collaborators and licensees fail to maintain regulatory compliance after receiving marketing approval, we or our collaborators and licensees may be unable to market our products and our business could suffer.

Adverse events or the perception of adverse events in the field of gene therapy, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

The commercial success of some of our product candidates will depend in part on public acceptance of the use of gene therapy for preventing or treating human diseases. Serious adverse events, including patient deaths, have occurred in clinical trials utilizing viral delivery systems to deliver therapeutic genes to the patient's targeted cells. Although none of our current products or studies utilize viral delivery systems, these adverse events, as well as any other adverse events in the field of gene therapy that may occur in the future, may negatively influence public perception of gene therapy in general. If public perception is influenced by claims that gene therapy is unsafe, our product candidates may not be accepted by the general public or the medical community.

Future adverse events in gene therapy or the biotechnology industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials. In addition,

any adverse events that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, although we do not believe our vaccine candidates could cause the diseases they are designed to protect against, a temporal relationship between vaccination and disease onset could be perceived as causal. Some of our products are designed to stimulate immune responses, and those responses, if particularly strong or uncontrolled, could result in local or systemic adverse events, including latent adverse events.

Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

As of December 31, 2016, we were the assignee or co-assignee of 53 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

As of December 31, 2016, we were also prosecuting one pending patent application in the United States and in foreign countries that cover various aspects of our proprietary technologies, not including patent applications for which we are a co-assignee and that are being prosecuted by our partners.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Others may also challenge or seek to circumvent or invalidate our patents. In that event, the rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

In addition, the Leahy-Smith America Invents Act, or AIA, was signed into law on September 16, 2011, and significantly changed certain aspects of the United States patent laws. These changes include, but are not limited to, authorizing fee setting authority to the United States Patent Office, transitioning the United States to a first-inventor-to-file patent system, expanding the scope of prior art that may be utilized against a pending patent application, and adding post-patent grant proceedings before the Patent Office in which third parties may challenge the validity of the granted patent. It is not clear, what, if any, impact the AIA will have on the cost of prosecuting our patent applications, our ability to obtain patents based on our patent applications, and our ability to enforce or defend our issued or granted United States patents. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Some components of our gene-based product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our and our collaborators', including Astellas', success will depend in part on our, or our collaborators', ability to obtain patent protection for our products and processes, both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. If we or, as applicable, our commercialization partners, including Astellas pursuant to its first right to enforce patents licensed to it under our license agreements, choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. Moreover, if a competitor were to file a patent application claiming technology also invented by us or our collaborators or licensees, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We or our collaborators or licensees may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our collaborators or licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we or our collaborators or licensees could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we or our collaborators or licensees could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we or our collaborators or licensees may have to obtain licenses to test, use or market these products. Our business will suffer if we or our collaborators or licensees are not able to obtain licenses at all or on terms commercially reasonable to us or them and we or they are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us.

The internet site ClinicalTrials.gov provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to achieve our business objectives.

We are highly dependent on our principal scientific, manufacturing, clinical, regulatory and management personnel, including Vijay B. Samant, our President and Chief Executive Officer. The loss of the services of these individuals might significantly delay or prevent the achievement of our objectives. We do not maintain "key person" life insurance on any of our personnel. We depend on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We face competition for qualified individuals from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. To pursue our product development plans, we may need to hire additional management personnel and additional scientific personnel to perform research and development, as well as additional personnel with expertise in clinical trials, government regulation and manufacturing. However, due to the reasons noted above, we may not be successful in hiring or retaining qualified personnel and therefore we may not be able to achieve our business objectives.

We have limited experience in manufacturing our product candidates in commercial quantities. We may not be able to comply with applicable manufacturing regulations or produce sufficient product for contract or commercial purposes.

The commercial manufacturing of vaccines and other biological products is a time-consuming and complex process, which must be performed in compliance with the FDA's cGMP regulations. We may not be able to comply with the cGMP regulations, and we have in the past encountered and may in the future encounter delays, disruptions or quality control problems in our manufacturing process. In addition, we may need to complete the installation and validation of additional large-scale fermentation and related purification equipment to produce the quantities of product expected to be required for commercial purposes. We have limited experience in manufacturing at this scale. We will also depend on third parties for any commercial scale filling of product vials. Moreover, our manufacturing processes may be disrupted if we do not extend the lease for our existing facility or find adequate replacement space sufficiently in advance of the expiration of our current lease term in December 2018. Noncompliance with the cGMP regulations, the inability to complete the installation or validation of additional large-scale equipment, the inability to secure adequate space to conduct our manufacturing activities or other problems with our manufacturing process may limit or delay the development or commercialization of our product candidates, and cause us to breach our contract manufacturing service arrangements or our obligations under our agreements with collaborators, including our obligations under our supply and services agreement with Astellas.

We currently depend on third parties to conduct our clinical trials and may initially depend on third parties to manufacture our product candidates commercially.

We rely on third parties, including clinical research organizations, medical institutions and contract laboratories, to perform critical services for us in connection with our clinical trials. These third parties are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol and applicable regulations, including good clinical practices established by the FDA and foreign regulatory authorities, which govern the conduct, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that trial subjects are adequately informed of the potential risks associated with participating in clinical trials. Our reliance on third parties does not relieve us of the responsibility to ensure these requirements are met. These third parties may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or applicable good clinical practice regulations, our clinical trials may not meet regulatory requirements or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials. These risks also apply to the development activities of our collaborators and licensees, and we do not control our collaborators' and licensees' research and development, clinical trials or regulatory activities.

We may also initially depend on collaborators, licensees or other third parties to manufacture our product candidates in commercial quantities. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the commercial manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. Our dependence on third parties for the commercial manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical industry experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

If we fail to comply with federal and state healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and its qui tam or whistleblower provisions, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- Government health administration authorities;
- Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;
- Private health coverage insurers;
- Managed care organizations; and
- Other organizations.

If we fail to obtain appropriate reimbursement, we could be prevented from successfully commercializing our potential products. There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. In the United States, the Federal government passed comprehensive healthcare reform legislation, the ACA, in 2010, which Congress is currently considering legislation to repeal or replace. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the ACA that are repealed. We cannot assure that any future healthcare reform legislation will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Additionally, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials and biological materials. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We could incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate plus additional coverage specific to the foreign countries where our clinical trials are being conducted, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2014, to December 31, 2016, our stock price has ranged from \$2.21 to \$17.90. The following factors, among others, could have a significant impact on the market price of our common stock:

- The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;
- The success of our collaborators and licensees, including Astellas, in the development or commercialization of our product candidates;
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;
- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- Our cash balances, need for additional capital, and access to capital.

We are at risk of future securities class action litigation due to our past and expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Even if such claims are not successful, any litigation could result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we recently completed a private placement of common stock to AnGes, immediately following which AnGes owned approximately 18.6% of our outstanding shares. In connection with the private placement, AnGes agreed to vote all of its shares in accordance with the recommendations of our board of directors on any matter brought before our stockholders for a vote, subject to certain limitations. This voting provision may also discourage or prevent attempts by other stockholders to replace members of our board of directors or engage in acquisition activities that our board of directors does not determine to be in the best interests of our stockholders.

The issuance of preferred stock could adversely affect our common stockholders.

We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants and our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 68,400 square feet of manufacturing, research laboratory and office space at a single site in San Diego, California. In July 2016, the term of the lease was extended for 16 months through December 2018.

ITEM 3. LEGAL PROCEEDINGS

We prosecute our intellectual property estate vigorously to obtain the broadest valid scope for our patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or our financial condition is not subject to reasonable estimates.

In the ordinary course of business, we may become a party to additional lawsuits involving various matters. We are unaware of any such lawsuits presently pending against us which, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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

Our common stock is listed on the Nasdaq Capital Market under the symbol VICL and until January 25, 2016 was listed on the Nasdaq Global Select Market. The following table presents quarterly information on the range of high and low sales prices for our common stock during the periods presented.

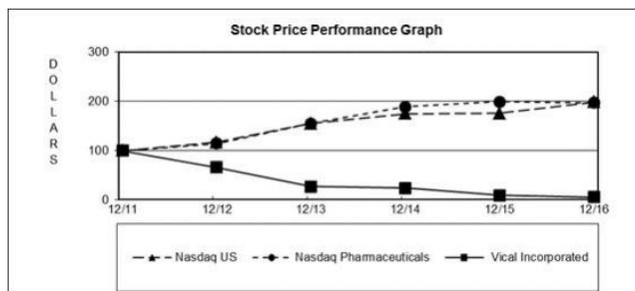
<u>2016</u>		<u>High</u>		<u>Low</u>
First Quarter	\$	4.70	\$	2.81
Second Quarter		4.80		3.58
Third Quarter		4.57		2.84
Fourth Quarter		3.15		2.21
<u>2015</u>		<u>High</u>		<u>Low</u>
First Quarter	\$	11.90	\$	8.52
Second Quarter		15.50		6.80
Third Quarter		7.20		4.20
Fourth Quarter		5.35		3.38

As of February 28, 2017, there were approximately 137 stockholders of record of our common stock and 11,093,663 shares of our common stock outstanding. We have never declared or paid any dividends and do not expect to pay any dividends in the foreseeable future. We did not repurchase any of our common stock in the fourth quarter of 2016.

Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following table compares total stockholder returns for Vical over the last five years to the Nasdaq U.S. and Foreign Index and the Nasdaq Pharmaceutical Stocks Index assuming a \$100 investment made on December 31, 2011. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.



ITEM 6.

SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data derived from our audited financial statements. The information presented should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Contract revenue	\$ 12,804	\$ 18,860	\$ 13,304	\$ 5,846	\$ 6,176
License and royalty revenue	1,727	2,090	1,913	1,872	11,343
Total revenues	14,531	20,950	15,217	7,718	17,519
Operating expenses:					
Research and development	10,355	11,061	11,467	14,558	17,340
Manufacturing and production	6,291	10,927	10,824	12,698	13,055
General and administrative	7,062	8,366	9,552	11,814	10,557
Total operating expenses	23,708	30,354	31,843	39,070	40,952
Loss from operations	(9,177)	(9,404)	(16,626)	(31,352)	(23,433)
Investment and other income, net	204	166	134	114	534
Net loss	(8,973)	(9,238)	(16,492)	(31,238)	(22,899)
Net loss per share (basic and diluted)	\$ (0.90)	\$ (1.01)	\$ (1.86)	\$ (3.60)	\$ (2.66)
Weighted average shares used in per share calculation	10,019	9,175	8,879	8,684	8,597
Balance Sheet Data (at end of period):					
Cash, cash equivalents, marketable securities, long-term investments, including restricted	\$ 40,978	\$ 42,006	\$ 49,123	\$ 55,477	\$ 86,082
Working capital	40,722	40,336	46,129	54,434	80,230
Total assets	52,284	49,914	57,979	66,353	96,522
Long-term obligations, less current portion	-	359	856	1,288	1,657
Total stockholders' equity	45,139	45,393	51,922	61,412	89,086

Overview

We research and develop biopharmaceutical products, including those based on our patented DNA delivery technologies, for the prevention and treatment of serious or life-threatening diseases. We currently have three active product development programs, independent or partnered, in the clinical testing stage in the area of infectious disease comprised of:

- An ongoing Phase 3 trial of ASP0113 for prevention of CMV reactivation in HCT recipients in collaboration with Astellas. Astellas has completed enrollment in the Phase 3 clinical trial and expects top-line data to be available in the first quarter of 2018.
- An ongoing Phase 2 trial of VCL-HB01, our Vaxfectin[®]-formulated, therapeutic DNA vaccine for reduction of lesion recurrences caused by HSV-2 infection. This randomized, double-blind, placebo-controlled trial will evaluate the efficacy and safety of VCL-HB01 in approximately 225 healthy adults aged 18 to 50 years with symptomatic genital HSV-2 infection at up to 15 U.S. clinical sites. Subjects will receive a four-dose vaccination series, and will be evaluated for recurrences over a 12-month period after vaccination. The primary endpoint for the study is annualized lesion recurrence rate.
- An ongoing first-in-human Phase 1 trial of VL-2397. This randomized, double-blind, placebo-controlled trial is intended to evaluate safety, tolerability and pharmacokinetics of VL-2397 in healthy volunteers. The study design is composed of seven single ascending dose cohorts followed by four multiple ascending dose cohorts. Dosing was completed in October 2016. Safety follow-ups and pharmacokinetic sampling was completed in 2016. Preliminary results point to a favorable safety and pharmacokinetic profile for VL-2397. We expect to present the full data set at an upcoming scientific conference in 2017. The FDA has granted us Fast Track, QIDP and orphan drug designations for VL-2397 for the treatment of invasive aspergillosis. This fungal infection represents a sizable unmet need in immunocompromised patients due to a high mortality despite available antifungal therapies. We are working actively with our expert advisors and the FDA to design a Phase 2 efficacy study to evaluate VL-2397 in the treatment of patients with invasive aspergillosis.

In addition, we have licensed complementary technologies from leading research institutions and biopharmaceutical companies.

Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We earn revenues by performing services under research and development contracts, grants, manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we have received approximately \$274.1 million in revenues from these sources. Revenues by source for each of the three years ended December 31, 2016, were as follows (in millions):

Source	2016	2015	2014
Astellas contract	\$ 12.5	\$ 14.7	\$ 13.3
IPPOX contract	—	4.1	—
Other contracts	0.3	0.1	—
Total contract revenue	12.8	18.9	13.3
Astellas license	1.5	1.8	1.6
AnGes license	—	0.1	—
Other royalties and licenses	0.2	0.2	0.3
Total royalty and license revenues	1.7	2.1	1.9
Total revenues	\$ 14.5	\$ 21.0	\$ 15.2

Research, development, manufacturing and production costs by major program, as well as other expenses for each of the three years ended December 31, 2016, were as follows (in millions):

Program	2016	2015	2014
CMV	9.2	13.1	14.8
HSV-2	3.6	3.1	4.8
VL-2397	3.4	3.4	—
Other research, development, manufacturing and production	0.4	2.4	2.7
Total research, development, manufacturing and production	\$ 16.6	\$ 22.0	\$ 22.3

Since our inception through December 31, 2016, we estimate that we have spent approximately \$561 million on research, development, manufacturing and production. Our current independent development focus is on a DNA vaccine for CMV, a vaccine to treat HSV-2, and other clinical and preclinical targets. These programs, excluding ASP0113 which we licensed to Astellas, will require significant additional funds to advance through development to commercialization. From inception through December 31, 2016, we have spent approximately \$21 million on our HSV-2 program, \$117 million on our CMV programs and \$7 million on our VL-2397 program.

We have other product candidates in the research stage. It can take many years to develop product candidates from the initial decision to screen product candidates, perform preclinical and safety studies, and perform clinical trials leading up to possible approval of a product by the FDA or comparable foreign agencies. The outcome of the research is unknown until each stage of the testing is completed, up through and including the registration clinical trials. Accordingly, we are unable to predict which potential product candidates we may proceed with, the time and cost to complete development, and ultimately whether we will have a product approved by the FDA or comparable foreign agencies.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to manufacturing activities, costs related to our facilities, and possible advancement toward commercialization activities.

Critical Accounting Policies and Estimates

The preparation and presentation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and informed estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, they are inherently uncertain and actual results may differ materially from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, contract services and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Certain of our revenue is generated through manufacturing contracts and stand-alone license agreements.

Contract Manufacturing Revenue

Revenue associated with contract manufacturing services is recognized once the service has been rendered and/or upon shipment (or passage of title) of the product to the customer. On occasion, we recognize revenue on a "bill-and-hold" basis. Revenue is recognized for such "bill-and-hold" arrangements in accordance with the authoritative guidance, which requires, among other things, the existence of a valid business purpose for the arrangement, that the "bill-and-hold"

arrangement is at the request of the customer, that title and risk of ownership pass to the customer, that the product is complete and ready for shipment, a fixed delivery date that is reasonable and consistent with the customer's business practices, that the product has been separated from our inventory, and that no further performance obligations by us exist.

Multiple-element arrangements

We have entered into multiple-element arrangements. In order to account for the multiple-element arrangements, we identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

The delivered item(s) must have value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in our control.

A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, we use our best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. If facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the license is identified as a separate unit of accounting and the amounts allocated to the license are recognized upon the delivery of the license, assuming the other revenue recognition criteria have been met. However, if the amounts allocated to the license through the relative selling price allocation exceed the upfront license fee, the amount recognized upon the delivery of the license is limited to the upfront fee received. If facts and circumstances dictate that the license does not have standalone value, the transaction price, including any upfront license fee payments received, are allocated to the identified separate units of accounting and recognized as those items are delivered.

The terms of our license and collaboration agreements provide for milestone payments upon achievement of certain regulatory and commercial events. We recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) The consideration relates solely to past performance, and 3) The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us.

Contract Services, Grant and Royalty Revenue

We recognize revenue from contract services and federal government research grants during the period in which the related expenditures are incurred and related payments for those services are received or collection is reasonably assured. Royalties to be received based on sales of licensed products by our partners incorporating our licensed technology are recognized when received.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and

clinical trials, facilities costs and amortization of intangible assets. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due for licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty of the technology or product being successful;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Capitalization and Valuation of Long-Lived and Intangible Assets

Intangible assets with finite useful lives consist of capitalized costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to research and development expense.

Intangible assets and long-lived assets are evaluated for impairment at least annually or whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

- A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- A significant negative industry or economic trend.

In the event we determine that the carrying value of intangible assets or long-lived assets is not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets. As of December 31, 2016, our largest group of intangible assets with finite lives included issued patents and patents pending for our DNA delivery technology, consisting of intangible assets with a net carrying value of approximately \$0.8 million.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 1 of the Notes to Financial Statements included in this Annual Report on Form 10-K.

Results of Operations

Year Ended December 31, 2016, Compared to Year Ended December 31, 2015

Total Revenues. Total revenues decreased \$6.4 million, or 30.6%, to \$14.5 million in 2016 from \$20.9 million in 2015. Our contract revenue decreased by \$6.1 million which was primarily the result of the recognition of \$4.1 million of non-recurring revenue related to our contract manufacturing agreement with the IPPOX Foundation to manufacture HIV-antigen plasmid DNA in 2015. The remaining decrease was primarily due to the deferred recognition of contract revenue in 2016 related to drug manufacturing under our ASP0113 license agreement with Astellas.

Research and Development Expenses. Research and development expenses decreased \$0.7 million, or 6.4%, to \$10.4 million for 2016 from \$11.1 million for 2015. This decrease was primarily due to the recognition of \$1.7 million in expenses related to the in-license of ASP2397 in 2015, which was partially offset by an increase in clinical trial costs related to our ongoing HSV-2 Phase 2 clinical trial in 2016.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased \$4.6 million, or 42.4%, to \$6.3 million for 2016 from \$10.9 million for 2015. This decrease was primarily due to a \$6.3 million net increase in deferred contract costs capitalized, which was partially offset by an increase in wages, equipment and scientific supplies.

General and Administrative Expenses. General and administrative expenses decreased \$1.3 million, or 15.6%, to \$7.1 million for 2016 from \$8.4 million for 2015. This decrease was primarily due to a decrease in employee stock based compensation and legal fees related to the securities class action litigation that was concluded in 2015.

Investment and Other Income. Investment and other income increased \$38,000, or 22.9%, to \$204,000 for 2016 from \$166,000 for 2015. This increase was primarily the result of an increase in yields realized on short-term investments during the year ended December 31, 2016.

Year Ended December 31, 2015, Compared to Year Ended December 31, 2014

Total Revenues. Total revenues increased \$5.7 million, or 37.7%, to \$20.9 million in 2015 from \$15.2 million in 2014. Our contract revenue increased by \$5.6 million which was primarily the result of the recognition of \$4.1 million of revenue related to our contract manufacturing agreement with the IPPOX Foundation to manufacture HIV-antigen plasmid DNA. The remaining increase was primarily related to an increase in billable activities under our ASP0113 license agreement with Astellas.

Research and Development Expenses. Research and development expenses decreased \$0.4 million, or 3.5%, to \$11.1 million for 2015 from \$11.5 million for 2014. This decrease was primarily due to a decrease in HSV-2 clinical trial costs combined with a decrease in stock-based compensation, which was partially offset by license payments made to Astellas for the in-license of VL-2397.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$0.1 million, or 1.0%, to \$10.9 million for 2015 from \$10.8 million for 2014. This increase was primarily due to a net increase in deferred contract costs recognized under various contract manufacturing agreements when compared to 2014.

General and Administrative Expenses. General and administrative expenses decreased \$1.2 million, or 12.4%, to \$8.4 million for 2015 from \$9.6 million for 2014. This decrease was primarily due to a decrease in legal fees related to the recently completed securities class action litigation and a decrease in employee stock based compensation.

Investment and Other Income. Investment and other income increased \$32,000, or 23.9%, to \$166,000 for 2015 from \$134,000 for 2014. This increase was primarily the result of an unrealized gain recognized on auction rate securities during the year ended December 31, 2015.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. From our inception through December 31, 2016, we have received approximately \$274.1 million in revenues from performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$433.2 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted securities, totaled \$41.0 million at December 31, 2016, compared with \$42.0 million at December 31, 2015. The decrease in our cash, cash equivalents and marketable securities for the year ended December 31, 2016, was due primarily to the use of cash to fund our operations, which was offset by \$7.8 million received from the sale of common stock to AnGes.

Net cash used in operating activities was \$8.4 million and \$6.9 million for the years ended December 31, 2016 and 2015, respectively. The increase in net cash used in operating activities for the year ended December 31, 2016, compared with the prior year period, was primarily the result of the timing of accounts payable disbursements and the collection of receivables.

Net cash used in investing activities was \$ 7.7 million and \$ 0.1 million for the years ended December 31, 2016 and 2015, respectively. The increase in net cash used in investing activities for the year ended December 31, 2016, compared with the prior year, was primarily the result of purchases of marketable securities.

Net cash provided by (used in) financing activities was \$7.7 million and \$(20,000) for the years ended December 31, 2016 and 2015, respectively. The increase in net cash provided by financing activities for the year ended December 31, 2016, compared with the prior year period, was the result of \$7.7 million in net proceeds received from the sale of common stock to AnGes in August 2016.

A discussion of our exposure to auction rate securities is included in Part II, Item 7A of this Annual Report on Form 10-K under the heading "Quantitative and Qualitative Disclosures About Market Risk."

In the long-term, we expect to incur substantial additional research and development expenses, manufacturing and production expenses, and general and administrative expenses, including increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. For example, in August 2016, we sold 1,841,420 shares of our common stock to AnGes in a private placement for gross proceeds of approximately \$7.8 million. We currently have on file an effective shelf registration statement that allows us to raise up to \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. In October 2016, we also entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we may issue and sell up to \$10.0 million of shares of our common stock from time to time. Under the ATM Agreement, we may deliver placement notices that will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the ATM Agreement, BP may sell the shares only by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made directly through the Nasdaq Capital Market, on any other existing trading market for our common stock or to or through a market maker. BP will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares in accordance with the terms of the ATM Agreement and any applicable placement notice. The ATM Agreement may be terminated by us upon prior notice to BP or by BP upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse effect on our Company. We have no obligation to sell any shares under the ATM Agreement, and both we and BP may at any time suspend the sale of shares under the ATM Agreement. To date we have not sold any shares of our common stock under the ATM Agreement.

Despite our current shelf registration statement and the ATM Agreement, additional financing through these or other means may not be available on favorable terms or at all. If additional financing is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash needs at least through December 31, 2018.

Contractual Obligations and Off-Balance Sheet Arrangements

The following table sets forth our contractual obligations, including all off-balance sheet arrangements, as of December 31, 2016 (in thousands):

	Payment Due by Period				
	Total	Less than 1 Year	2-3 Years	4-5 Years	After 5 Years
Contractual Obligations ¹					
Operating lease obligations	\$ 6,212	\$ 3,377	\$ 2,835	\$ —	\$ —
Unconditional purchase obligations ²	969	969	—	—	—
Total contractual obligations	<u>\$ 7,181</u>	<u>\$ 4,346</u>	<u>\$ 2,835</u>	<u>\$ —</u>	<u>\$ —</u>

¹ Certain long-term liabilities reflected on our balance sheet are not presented in this table because they are already reflected in operating lease commitments or do not require cash settlement in the future.

² Unconditional purchase obligations represent contractual commitments entered into for goods and services in the normal course of our business. The purchase obligations do not include potential severance payment obligations to our executive officers. For information regarding these severance arrangements, refer to the final paragraph in this Item 7.

Under our license agreements with Astellas, we are required to make certain payments to the City of Hope and CytRx in connection with the development and commercialization of our products licensed by Astellas. In addition, certain technology license agreements require us to make other payments if we or our sublicensees advance products through clinical development. For programs developed with the support of U.S. government funding, the U.S. government may have rights to resulting products without payment of royalties to us.

We may be required to make future payments to our licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under our in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that we could be required to pay under our active in-license agreements in place at December 31, 2016, is approximately \$106.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

In addition, we have undertaken certain commitments under license agreements with collaborators, and under indemnification agreements with our officers and directors. Under the license agreements with our collaborators, we have agreed to continue to maintain and defend the patent rights licensed to the collaborators and, in the case of our agreements with Astellas, have agreed to undertake certain development and manufacturing activities. Under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have employment agreements that contain severance arrangements with our chief executive officer, or CEO, and our four other executives. Under the agreement with our CEO, we are obligated to pay severance if we terminate the CEO's employment without "cause," or if the CEO resigns for "good reason," as defined in the agreement, within the periods set forth therein. The severance for the CEO consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, the CEO receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 18 months from the date of termination. In the event that the termination occurs within 24 months of a "change in control," as defined in the agreement, the severance for the CEO consists of a lump sum payment equal to 24 months of base salary at the then-current rate, the payment of health insurance premiums for 18 months, plus a

payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. Under the agreements with our other four executives, we are obligated to pay severance if we terminate the executive's employment without "cause," or if the executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance for the other executives consists of a lump-sum payment equal to 12 months of base salary at the then-current rate, including the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, the executive receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 12 months from the date of termination. In the event that the termination occurs within 12 months of a "change in control," as defined in the agreements, the severance for the other executives consists of a lump sum payment equal to 18 months of base salary at the then-current rate, the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The maximum payments due under these employment agreements would have been \$3.6 million if each such officer was terminated at December 31, 2016.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, marketable securities and long-term investments. The average maturity of our investments, excluding our auction rate securities, is approximately six months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a 12-month time horizon, a 6-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$257,000 lower than the reported fair value of our investments at December 31, 2016.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of December 31, 2016, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At December 31, 2016, the auction rate security we held maintained a Standard and Poor's credit rating of A-. Our auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed or mature.

Since February 2008, there has been insufficient demand at auction for our auction rate security held at December 31, 2016. As a result, this security is currently not liquid, and we could be required to hold it until it is redeemed by the issuer or to maturity. As of December 31, 2016, we had recognized \$0.5 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of December 31, 2016, we had recorded cumulative unrealized gains of \$0.2 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of December 31, 2016. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics.

In the event we need to access the funds that are not currently liquid, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them until 2038 when they mature. We do not anticipate a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate these investments on an ongoing basis for impairment. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of these investments will affect our ability to execute our current business plan.

INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	42
Balance Sheets	43
Statements of Operations	44
Statements of Comprehensive Loss	45
Statements of Stockholders' Equity	46
Statements of Cash Flows	47
Notes to Financial Statements	48

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Vical Incorporated

We have audited the accompanying balance sheets of Vical Incorporated as of December 31, 2016 and 2015, and the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. 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. We were not engaged to perform an audit of the Company's 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, and 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 Vical Incorporated at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles .

/s/ Ernst & Young LLP

San Diego, California

March 10, 2017

VICAL INCORPORATED
BALANCE SHEETS
(in thousands, except per share data)

	December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,069	\$ 13,450
Marketable securities, available-for-sale	30,552	23,258
Restricted cash	3,311	3,246
Receivables and other assets	8,935	4,544
Total current assets	47,867	44,498
Long-term investments	2,046	2,052
Property and equipment, net	1,173	1,873
Intangible assets, net	810	1,300
Other assets	388	191
Total assets	\$ 52,284	\$ 49,914
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,127	\$ 3,912
Deferred revenue	3,018	250
Total current liabilities	7,145	4,162
Long-term liabilities:		
Deferred rent	—	359
Commitments and contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.01 par value, 160,000 shares authorized, 11,052 and 9,154 shares issued and outstanding at December 31, 2016 and 2015, respectively	111	92
Additional paid-in capital	458,881	450,166
Accumulated deficit	(413,878)	(404,905)
Accumulated other comprehensive income	25	40
Total stockholders' equity	45,139	45,393
Total liabilities and stockholders' equity	\$ 52,284	\$ 49,914

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Revenues:			
Contract revenue	\$ 12,804	\$ 18,860	\$ 13,304
License and royalty revenue	1,727	2,090	1,913
Total revenues	14,531	20,950	15,217
Operating expenses:			
Research and development	10,355	11,061	11,467
Manufacturing and production	6,291	10,927	10,824
General and administrative	7,062	8,366	9,552
Total operating expenses	23,708	30,354	31,843
Loss from operations	(9,177)	(9,404)	(16,626)
Other income:			
Investment and other income, net	204	166	134
Net loss	\$ (8,973)	\$ (9,238)	\$ (16,492)
Basic and diluted net loss per share	\$ (0.90)	\$ (1.01)	\$ (1.86)
Weighted average shares used in computing basic and diluted net loss per share	10,019	9,175	8,879

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Net loss	\$ (8,973)	\$ (9,238)	\$ (16,492)
Other comprehensive (loss) gain:			
Unrealized (loss) gain on available-for-sale and long-term marketable securities:			
Unrealized (loss) gain arising during holding period, net of tax benefit of \$0, \$32 and \$0 for years ended December 31, 2016, 2015 and 2014, respectively	(15)	52	(23)
Other comprehensive (loss) gain	(15)	52	(23)
Total comprehensive loss	\$ (8,988)	\$ (9,186)	\$ (16,515)

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF STOCKHOLDERS' EQUITY
FOR EACH OF THE THREE YEARS IN THE PERIOD ENDED DECEMBER 31, 2016
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Number of Shares	Amount				
Balance at January 1, 2014	8,678	\$ 87	\$ 440,489	\$ (379,175)	\$ 11	\$ 61,412
Net loss	—	—	—	(16,492)	—	(16,492)
Other comprehensive loss	—	—	—	—	(23)	(23)
Issuance of common stock	329	3	3,920	—	—	3,923
Issuance of common stock underlying restricted stock units net of shares withheld to settle withholding taxes	26	1	(58)	—	—	(57)
Non-cash compensation expense related to grant of equity based compensation	—	—	3,159	—	—	3,159
Balance at December 31, 2014	<u>9,033</u>	<u>\$ 91</u>	<u>\$ 447,510</u>	<u>\$ (395,667)</u>	<u>\$ (12)</u>	<u>\$ 51,922</u>
Net loss	—	—	—	(9,238)	—	(9,238)
Other comprehensive income	—	—	—	—	52	52
Issuance of common stock	86	1	774	—	—	775
Issuance of common stock underlying restricted stock units net of shares withheld to settle withholding taxes	35	—	(20)	—	—	(20)
Non-cash compensation expense related to grant of equity based compensation	—	—	1,902	—	—	1,902
Balance at December 31, 2015	<u>9,154</u>	<u>\$ 92</u>	<u>\$ 450,166</u>	<u>\$ (404,905)</u>	<u>\$ 40</u>	<u>\$ 45,393</u>
Net loss	—	—	—	(8,973)	—	(8,973)
Other comprehensive loss	—	—	—	—	(15)	(15)
Issuance of common stock	1,841	18	7,735	—	—	7,753
Issuance of common stock underlying restricted stock units net of shares withheld to settle withholding taxes	57	1	(10)	—	—	(9)
Non-cash compensation expense related to grant of equity based compensation	—	—	990	—	—	990
Balance at December 31, 2016	<u>11,052</u>	<u>\$ 111</u>	<u>\$ 458,881</u>	<u>\$ (413,878)</u>	<u>\$ 25</u>	<u>\$ 45,139</u>

See accompanying notes to financial statements

VICAL INCORPORATED
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	\$ (8,973)	\$ (9,238)	\$ (16,492)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,117	1,159	1,663
Write-off of abandoned patents and licensed technology	374	230	350
Gain on sale of property and equipment	—	(1)	(15)
Compensation expense related to stock options and awards	990	1,902	3,159
Purchase of technology license with common stock	—	775	—
Changes in operating assets and liabilities:			
Receivables and other assets	(4,588)	(178)	412
Accounts payable and accrued expenses	557	(1,415)	1,635
Deferred revenue	2,768	250	(150)
Deferred rent	(633)	(432)	(368)
Net cash used in operating activities	<u>(8,388)</u>	<u>(6,948)</u>	<u>(9,806)</u>
Cash flows from investing activities:			
Maturities of marketable securities	30,652	20,183	10,556
Purchases of marketable securities	(38,134)	(20,114)	(22,643)
Purchases of property and equipment	(255)	(72)	(85)
Proceeds from the sale of property and equipment	—	3	15
Patent and licensed technology expenditures	—	(53)	(269)
Net cash used in investing activities	<u>(7,737)</u>	<u>(53)</u>	<u>(12,426)</u>
Cash flows from financing activities:			
Net proceeds from issuance of common stock	7,758	3	3,925
Payment of withholding taxes for net settlement of restricted stock units	(14)	(23)	(59)
Net cash provided by (used in) financing activities	<u>7,744</u>	<u>(20)</u>	<u>3,866</u>
Net decrease in cash and cash equivalents	(8,381)	(7,021)	(18,366)
Cash and cash equivalents at beginning of year	13,450	20,471	38,837
Cash and cash equivalents at end of year	<u>\$ 5,069</u>	<u>\$ 13,450</u>	<u>\$ 20,471</u>

See accompanying notes to financial statements

VICAL INCORPORATED
NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and Business Activity

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products, including those based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators and from contract manufacturing agreements. Most of the Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations.

Basis of Presentation

These financial statements are prepared in conformity with accounting principles generally accepted in the United States of America.

On May 25, 2016, the Company amended its certificate of incorporation to effect a one-for-ten (1:10) reverse stock split. This reverse stock split became effective as of the close of business on May 26, 2016. The reverse stock split had no effect on the par value of its common stock and did not reduce the number of authorized shares of common stock but reduced the number of outstanding shares of common stock by the one-for-ten ratio. Accordingly, the outstanding shares, stock award disclosures, net loss per share, and other per share disclosures for all periods presented have been retrospectively adjusted to reflect the impact of this reverse stock split.

The reverse stock split resulted in a proportionate adjustment to the per share exercise price and the number of shares of common stock issuable upon the exercise of outstanding stock options, the number of shares of common stock issuable upon the vesting of restricted stock units, or RSUs, and the number of shares of common stock eligible for issuance under the Company's stock incentive plan. No fractional shares were issued in connection with the reverse stock split. Each stockholder's percentage ownership and proportional voting power generally remained unchanged as a result of the reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make informed estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less and can be liquidated without prior notice or penalty. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities or the

amounts, net of tax, reclassified out of accumulated other comprehensive income (loss), if any, are determined on a specific identification basis.

Restricted Cash

The Company is required to maintain a letter of credit securing an amount equal to twelve months of the current monthly installment of base rent for the original term of the lease for its facilities, which ends on August 31, 2017. At December 31, 2016 and 2015, restricted cash of \$3.3 million and \$3.2 million, respectively, was pledged as collateral for the letter of credit. In July 2016, the term of the lease was extended for 16 months through December 2018. During the extended term the Company is required to maintain a letter of credit securing an amount equal to \$0.2 million.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, marketable securities and receivables. The Company invests its excess cash in debt instruments of financial institutions and of corporations with above average credit ratings, in U.S. government obligations, and in money market funds and certificates of deposits at financial institutions.

Property and Equipment

Property and equipment is recorded at cost and depreciation is computed using the straight-line method over the estimated useful lives of the assets. Assets acquired pursuant to capital lease arrangements and leasehold improvements are amortized using the straight-line method over the shorter of the life of the remaining lease term or the remaining useful life of the asset. Manufacturing equipment has estimated useful lives of 5 to 10 years. All other property and equipment have estimated useful lives of 3 to 5 years. Maintenance and repairs of property and equipment are expensed as incurred.

Intangible Assets

Intangible assets include certain costs related to patent applications. The Company capitalizes license fees paid to acquire access to proprietary technology if the technology is expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized using the straight-line method over the estimated useful life of the technology. Certain costs related to patent applications are amortized over the estimated economic lives of the patents, which is generally 20 years and typically commences at the time the patent application is filed. As of December 31, 2016, the weighted average amortization period of capitalized patent costs is approximately 8 years. Amortization expense for licensed technology and capitalized patent cost is included in research and development expenses.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment at least annually, quarterly for intangible assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset over the asset's estimated fair value and the loss recognized in current earnings. The Company recognized research and development expense of approximately \$0.4 million, \$0.2 million and \$0.4 million for the years ended December 31, 2016, 2015 and 2014, respectively, related to patents for which the value was deemed to be impaired.

Revenue Recognition

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Certain of the Company's revenue is generated through manufacturing contracts and stand-alone license agreements.

Contract Manufacturing Revenue

Revenue associated with contract manufacturing services is recognized once the service has been rendered and/or upon shipment (or passage of title) of the product to the customer. On occasion, the Company recognizes revenue on a "bill-and-hold" basis. Revenue is recognized for such "bill-and-hold" arrangements in accordance with the authoritative guidance, which requires, among other things, the existence of a valid business purpose for the arrangement, that the "bill-

and-hold” arrangement is at the request of the customer, that title and risk of ownership pass to the customer, that the product is complete and ready for shipment, a fixed delivery date that is reasonable and consistent with the customer’s business practices, that the product has been separated from the Company’s inventory, and that no further performance obligations by the Company exist.

Multiple-element arrangements

The Company has entered into multiple-element arrangements. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. The delivered item(s) must have value to the customer on a standalone basis and, if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the Company’s control.

A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company uses its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. If facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the license is identified as a separate unit of accounting and the amounts allocated to the license are recognized upon the delivery of the license, assuming the other revenue recognition criteria have been met. However, if the amounts allocated to the license through the relative selling price allocation exceed the upfront license fee, the amount recognized upon the delivery of the license is limited to the upfront fee received. If facts and circumstances dictate that the license does not have standalone value, the transaction price, including any upfront license fee payments received, are allocated to the identified separate units of accounting and recognized as those items are delivered.

The terms of the Company’s partnership agreements provide for milestone payments upon achievement of certain regulatory and commercial events. Under the Milestone Method, the Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) The consideration is commensurate with either the entity’s performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity’s performance to achieve the milestone, 2) The consideration relates solely to past performance, and 3) The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity’s performance or on the occurrence of a specific outcome resulting from the entity’s performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company.

Contract Services, Grant and Royalty Revenue

The Company recognizes revenues from contract services and federal government research grants during the period in which the related expenditures are incurred and related payments for those services are received or collection is reasonably assured. Royalties to be received based on sales of licensed products by the Company’s partners incorporating the Company’s licensed technology are recognized when received.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and clinical trials, facilities

costs and amortization of intangible assets. The Company accounts for its clinical trial costs by estimating the total cost to treat a patient in each clinical trial, and accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the site conducting the trial, and patient-related lab and other costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the number of treatments that a patient receives. Treatment periods vary depending on the clinical trial. The Company makes revisions to the clinical trial cost estimates in the current period, as clinical trials progress.

Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses for the production of plasmid DNA for use in the Company's research and development efforts. Manufacturing expenses related to manufacturing contracts are deferred and expensed when the related revenue is recognized. Deferred contract costs at December 31, 2016 and 2015 were \$5.5 million and \$0.1 million, respectively. Production expenses related to the Company's research and development efforts are expensed as incurred.

Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under RSUs, as the effect would be antidilutive. Common stock equivalents of 7,350, 33,720 and 46,267 for the years ended December 31, 2016, 2015 and 2014, respectively, were excluded from the calculation because of their antidilutive effect.

Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, restricted cash, marketable securities, receivables, accounts payable and accrued expenses at December 31, 2016 and 2015, are considered to approximate fair value because of the short term nature of those items.

Income Taxes

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits recorded by the Company as of the date of adoption in 2007. There are no unrecognized tax benefits included in the balance sheets that would, if recognized, affect the effective tax rate.

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement bases and the tax bases of assets and liabilities using enacted tax rates. A valuation allowance is established to reduce a deferred tax asset to the amount that is expected more likely than not to be realized.

Comprehensive Loss

Comprehensive loss consists of net loss and certain changes in equity that are excluded from net loss. Comprehensive loss for the years ended December 31, 2016, 2015 and 2014, has been reflected in the accompanying Statements of Comprehensive Loss. Accumulated other comprehensive income (loss), which is included in stockholders' equity, represents unrealized gains and losses on marketable securities.

Business Segments

The Company operates in one business segment, which is within the United States, and is dedicated to research and development of DNA delivery technology.

Stock-Based Compensation

The Company records its compensation expense associated with stock options and other forms of equity compensation based on their fair value at the date of grant using the Black-Scholes-Merton option pricing model. Stock-based compensation includes amortization related to stock option awards based on the estimated grant date fair value. Stock-based compensation expense related to stock options includes an estimate for forfeitures and the portion that is ultimately expected to vest is recognized ratably over the vesting period of the option. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. Stock-based compensation expense related to RSUs includes an estimate for forfeitures and the portion expected to vest is recognized ratably over the requisite service period. The expected forfeiture rate of all equity based compensation is based on observed historical patterns of the Company's employees and is estimated to be 8.75% annually for each of the years ended December 31, 2016, 2015 and 2014.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton valuation model using the assumptions noted in the following table. The expected life of options is based on the Company's observed historical exercise patterns. The expected volatility of stock options is based upon the historical volatility of the Company's stock commensurate with the expected life of the option. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	Year Ended December 31,		
	2016	2015	2014
Assumptions:			
Assumed risk-free interest rate	1.44%	1.34%	1.63%
Assumed volatility	72%	68%	73%
Average expected option life	4.5 years	4.5 years	4.5 years
Expected dividend yield	—	—	—

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance outlines a five-step process for revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards, and also requires enhanced disclosures regarding the nature, amount, timing and uncertainty of revenues and cash flows from contracts with customers. Major provisions include determining which goods and services are distinct and require separate accounting (performance obligations), how variable consideration (which may include change orders and claims) is recognized, whether revenue should be recognized at a point in time or over time and ensuring the time value of money is considered in the transaction price. The guidance allows for either full retrospective or modified retrospective adoption and will become effective for the Company in the first quarter of 2018.

The Company is in the process of evaluating the impact of adopting the new revenue guidance on the Company's financial position, results of operations, cash flows and related disclosures. Based on the Company's initial assessment, the Company plans to adopt this new standard using the modified retrospective method which may result in a cumulative effect adjustment as of the date of adoption. At this time, management does not expect the adoption of the new guidance to have a material impact on the revenue recognition related to contracts with remaining performance obligations upon the adoption of the standard. The impact on the Company's financial statements is not expected to be material because, based upon the preliminary analysis of material contracts under the new revenue recognition standard, management has determined the recognition and allocation of revenue upon the delivery or completion of the Company's performance obligations are consistent with those under the current revenue recognition model. The Company expects to complete its assessment process, including finalizing a transition method for adoption, by the end of the third quarter of 2017 and expects to complete its implementation process prior to the adoption of this ASU on January 1, 2018.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements—Going Concern." In connection with preparing financial statements for each annual and interim reporting period, ASU 2014-15 requires management to assess an entity's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016 and interim periods

thereafter. Early application is permitted. The adoption of this guidance had no impact on the Company's financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)." The new standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more than 12 months and will require both lessees and lessors to disclose certain key information about lease transactions. The standard will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is evaluating the effect that the adoption of the new guidance will have on its financial statements.

In March 2016, the FASB issued ASU 2016-09, "Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting." The amended guidance simplifies the accounting for share-based payment transactions. The amended guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company is evaluating the effect that the adoption of this new guidance will have on its financial statements.

2. Short-Term Marketable Securities

The following is a summary of short-term marketable securities classified as available-for-sale (in thousands):

	Amortized Cost	Unrealized Gain	Unrealized Loss	Market Value
December 31, 2016				
U.S. treasuries	\$ 23,295	\$ —	\$ 18	\$ 23,277
Certificates of deposit	7,275	—	—	7,275
	<u>\$ 30,570</u>	<u>\$ —</u>	<u>\$ 18</u>	<u>\$ 30,552</u>
December 31, 2015				
U.S. treasuries	\$ 7,027	\$ —	\$ 8	\$ 7,019
Corporate bonds	1,000	—	—	1,000
Certificates of deposit	15,239	—	—	15,239
	<u>\$ 23,266</u>	<u>\$ —</u>	<u>\$ 8</u>	<u>\$ 23,258</u>

At December 31, 2016, none of these securities were scheduled to mature outside of one year. There were no net realized gains (losses) on sales of available-for-sale securities for the years ended December 31, 2016, 2015 and 2014. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2016 and 2015.

3. Long-Term Investments

As of December 31, 2016, the Company held an auction rate security with a par value of \$2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated A- by Standard and Poor's as of December 31, 2016. The security continues to pay interest according to its stated terms.

The valuation of the Company's auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateral underlying the security investment, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, liquidity and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics. As of December 31, 2016, the inputs used in the Company's discounted cash flow analysis assumed an interest rate of 1.64%, an estimated redemption period of five years and a discount rate of 1.0%. Based on the valuation of the security, the Company has recognized cumulative losses of \$0.5 million as of December 31, 2016, none of which were realized during the year ended December 31, 2016. The losses, when recognized, are included in investment and other income. The market value of the security has partially recovered. Included in other comprehensive (loss) income are unrealized (losses) gains of \$(6,000), \$48,000 and \$(9,000) for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, the Company had recorded

cumulative unrealized gains of \$0.2 million. The resulting carrying value of the auction rate security at December 31, 2016, was \$2.0 million. Any future decline in market value may result in additional losses being recognized.

4. Fair Value Measurements

The Company measures fair value as an 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 at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Fair value measurements are based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash equivalents, marketable securities and long-term investments measured at fair value are classified in the table below in one of the three categories described above (in thousands):

December 31, 2016	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Certificates of deposit	\$ 7,275	\$ —	\$ —	\$ 7,275
Money market funds	1,171	—	—	1,171
U.S. treasuries	23,277	—	—	23,277
Auction rate securities	—	—	2,046	2,046
	<u>\$ 31,723</u>	<u>\$ —</u>	<u>\$ 2,046</u>	<u>\$ 33,769</u>

December 31, 2015	Fair Value Measurements			
	Level 1	Level 2	Level 3	Total
Certificates of deposit	\$ 15,239	\$ —	\$ —	\$ 15,239
U.S. treasuries	7,019	—	—	7,019
Corporate bonds	—	1,000	—	1,000
Auction rate securities	—	—	2,052	2,052
	<u>\$ 22,258</u>	<u>\$ 1,000</u>	<u>\$ 2,052</u>	<u>\$ 25,310</u>

The Company's investments in U.S. treasury securities, certificates of deposit and money market funds are valued based on publicly available quoted market prices for identical securities as of December 31, 2016. The Company determines the fair value of other government-sponsored enterprise related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company validates the valuations received from its primary pricing vendors for its level 2 securities by examining the inputs used in that vendor's pricing process and determines whether they are reasonable and observable. The Company also compares those valuations to recent reported trades for those securities. The Company did not adjust any of the valuations received from these third parties with respect to any of its level 2 securities at December 31, 2016. The valuation of the Company's investment in auction rate securities is more fully described in Note 3.

Activity for assets measured at fair value using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

Balance at December 31, 2015	\$	2,052
Total net realized gains included in earnings		—
Total net unrealized loss included in other comprehensive income		(6)
Net transfers in and/out of Level 3		—
Balance at December 31, 2016	\$	<u>2,046</u>
Amount of total losses for the period included in net loss attributable to the change in unrealized gains or losses relating to assets still held at December 31, 2016	\$	<u>—</u>

Total cumulative unrealized losses of \$0.5 million relate to Level 3 assets still held as of December 31, 2016, none of which were recognized during the years ended December 31, 2016, 2015 and 2014. The losses, when recognized, are included in investment and other income.

5. Other Balance Sheet Accounts

Property and equipment consisted of the following at December 31 (in thousands):

	2016	2015
Equipment	\$ 17,043	\$ 17,425
Leasehold improvements	8,144	8,048
	25,187	25,473
Less accumulated depreciation and amortization	(24,014)	(23,600)
	<u>\$ 1,173</u>	<u>\$ 1,873</u>

Depreciation and amortization of equipment and leasehold improvements for the years ended December 31, 2016, 2015 and 2014, was \$0.9 million, \$0.9 million and \$1.4 million, respectively.

Intangible assets consisted of the following at December 31 (in thousands):

	2016	2015
Patent application costs	\$ 1,500	\$ 2,252
Accumulated amortization patent costs	(690)	(952)
	<u>\$ 810</u>	<u>\$ 1,300</u>

Amortization of licensed technology rights and patent application costs for the years ended December 31, 2016, 2015 and 2014, was \$0.1 million, \$0.2 million and \$0.2 million, respectively. Estimated annual amortization for these assets is \$0.1 million for each of the years in the period from 2017 to 2021, and \$0.3 million being recognized thereafter.

Accounts payable and accrued expenses consisted of the following at December 31 (in thousands):

	2016	2015
Employee compensation	\$ 2,518	\$ 2,220
Clinical trial accruals	446	102
Accounts payable	326	733
Deferred rent	223	496
Other accrued liabilities	614	361
	<u>\$ 4,127</u>	<u>\$ 3,912</u>

6. Significant Contract , License and Royalty Agreements

Contracts

IPPOX

In April 2015, the Company entered into a \$4.1 million contract with the IPPOX Foundation to manufacture HIV-antigen plasmid DNA as a component of vaccine regimens to be evaluated in clinical trials for the prevention of HIV infection. IPPOX is a Swiss non-profit foundation that participates in the conduct of HIV vaccine clinical trials under the auspices of the Pox-Protein Public-Private Partnership, or P5, funded by the Bill & Melinda Gates Foundation and the U.S. National Institute of Allergy and Infectious Diseases, or NIAID. These plasmids were shipped and the related revenue of \$4.1 million was recognized in December 2015. This contract builds upon the Company's 2010 agreement with IPPOX to manufacture plasmid DNA for HIV vaccine clinical trials.

Astellas

In July 2011, the Company entered into license agreements with Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's know-how and intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of glycoprotein B and/or phosphoprotein 65, including ASP0113 but excluding CyMVectin™. Under the agreements, Astellas is responsible for the worldwide development and commercialization of products in the licensed field, at its expense, and has agreed to use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize at least one licensed product for use in certain immunocompromised patients in the licensed field in the United States and certain other major markets. Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of \$25.0 million.

In 2012, the Company received a \$10.0 million milestone payment upon finalization of the trial design for a Phase 3 registration trial of ASP0113 in hematopoietic stem cell transplant recipients. The Company is also entitled to receive additional cash payments potentially totaling \$65.0 million for achievement of certain milestones through commercial launch and to receive double-digit royalties on net sales of products. In addition, the Company has an option to co-promote ASP0113 in the United States. Under the terms of a supply and services agreement entered into by the Company and Astellas on the same date, the Company agreed to perform certain development and regulatory activities, at Astellas' expense, and to supply licensed products to Astellas, at Astellas' expense, for use in development and initial commercialization activities in the licensed field.

In August 2012, the Company amended its license and supply agreements with Astellas to, among other things, extend the time period that the Company is obligated to supply licensed products for commercial use to Astellas, at Astellas' expense, modify the allocation of \$65.0 million of milestone payments among certain milestones through commercial launch and modify the structure of the royalties on net sales from a fixed double digit royalty to tiered double digit royalties.

The Company identified the deliverables at the inception of the agreements. The Company has determined that the license and related know-how, the development and regulatory services and the drug product supply individually represent separate units of accounting, because each deliverable has standalone value. The best estimated selling prices for these units of accounting was determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotechnology industry and entity-specific factors, such as the terms of the Company's previous collaborative agreements, the Company's pricing practices and pricing objectives and the nature of the research and development services to be performed for the partner. The arrangement consideration was allocated to the deliverables based on the relative selling price method.

The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the licenses was limited to the extent of cash received. As a result, during the years ended December 31, 2016, 2015 and 2014, the Company recognized \$1.5 million, \$1.8 million and \$1.6 million, respectively, related to the license fee and know-how. The Company will recognize the amounts allocated to research and development services as revenues under the agreements as the related services are delivered and as reimbursements are received. During the years ended December 31, 2016, 2015 and 2014, the Company recognized \$10.1 million, \$8.7 million and \$7.8 million, respectively, of revenue related to contract services delivered. The Company will recognize as revenue the amounts allocated to the sales of drug product when the sale of that drug product has met all required specifications and the related title and risk of loss and damages have passed to Astellas. During the years ended December 31, 2016, 2015 and 2014, the Company recognized \$2.4 million, \$6.0 million and \$5.5 million, respectively, of revenue related to drug product delivered. The Company is eligible to receive additional cash payments upon the achievement of specified regulatory and commercial milestones. The Company has determined that each of the regulatory and commercial milestones meets the definition of a

milestone and that each milestone is substantive in accordance with the milestone method of revenue recognition. Accordingly, the Company expects to recognize such regulatory and commercial milestone payments as revenues under the agreements upon achievement of each milestone.

In-licensing Agreements

Astellas

In March 2015, the Company entered into a license agreement with Astellas which grants to the Company exclusive worldwide license to develop and commercialize a novel antifungal, VL-2397. As consideration for the rights under the license, the Company issued 86,121 shares of our common stock to Astellas and made an up-front payment of \$250,000 in cash. The License Agreement provides for potential development, regulatory and sales milestone payments totaling up to \$99.0 million, the vast majority of which are payable upon achievement of commercial and sales milestones, and single-digit royalties on net sales of commercial products. The Company is responsible for the worldwide development, manufacturing and commercialization of licensed products, at the Company's cost, and we are required to use commercially reasonable efforts with respect to such development and commercialization activities.

The license agreement, unless terminated earlier, will continue until expiration of Vical's royalty obligations with respect to licensed products. Either party may terminate the license agreement earlier if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party's insolvency. Astellas may terminate the license agreement earlier if Vical or any of its affiliates or sublicensees oppose or challenge any of the licensed patents. Vical may terminate the license agreement on a country-by-country basis for reasonable scientific, regulatory, commercial, financial, ethical or other reasons.

City of Hope

In 2003, the Company licensed from the City of Hope on an exclusive basis various U.S. patents that provide protection for CMV-related polynucleotide based vaccines, including TransVaxTM and CyMVectinTM vaccine candidates. The agreement expires upon the last to expire of the patent rights licensed by the Company under the agreement, unless earlier terminated as set forth in the agreement. The City of Hope may terminate the agreement early, in accordance with notice provisions set forth in the agreement, if the Company ceases to operate, fails to make payments when due or materially breaches the agreement. Subject to certain conditions, the Company may terminate the agreement early at any time upon prior written notice to the City of Hope. The Company is also obligated to pay a low double-digit percentage of any payments it receives from the sub-license of products that incorporate the licensed technology. The Company paid the City of Hope \$0.1 million under the agreement for each of the years ended December 31, 2016, 2015 and 2014.

CytRx

In 2001, the Company entered into an exclusive agreement with CytRx which grants to the Company the rights to use or sublicense CytRx's poloxamer technology to enhance viral or non-viral delivery of polynucleotides in all preventive and therapeutic human and animal health applications, including CMV. The agreement excludes applications for four infectious disease vaccine targets that had been licensed to Merck and prostate-specific membrane antigen. In addition, the agreement permits the Company's use of CytRx's technology to enhance the delivery of proteins in prime-boost vaccine applications that involve the use of polynucleotides. As part of the agreement, the Company made a \$3.8 million up-front payment and agreed to make potential future milestone and royalty payments. The license fee is fully amortized as of December 31, 2013. The Company paid CytRx \$0.1 million under the agreement for each of the years ended December 31, 2016, 2015 and 2014.

Milestone Payments

The Company may be required to make future payments to its licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under the Company's in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that the Company could be required to pay under its active in-license agreements in place at December 31, 2016, is approximately \$106.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of

the related products is obtained, the Company may be required to make royalty payments in addition to these milestone payments. Although the Company believes that some of the milestones contained in its in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent the Company is not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which the Company estimates will take several years to achieve.

7. Commitments and Contingencies

Facility Leases

The Company is currently leasing its facility which has approximately 68,400 square feet of manufacturing, research laboratory and office space. In July 2016, the term of the lease was extended for 16 months through December 2018. The Company has the option to renew the lease for three additional five-year periods beyond its expiration.

The lease related to the facility is treated as an operating lease. The minimum annual rent on the facility is subject to increases specified in the lease. The Company is also required to pay taxes, insurance and operating costs under the facility lease. The Company recognizes level monthly rent for its facility lease over the entire lease period. The monthly rent is calculated by adding the total rent payments over the entire lease period and then dividing the result by the total term of the lease. The \$0.2 million difference between the base rent paid and the rent expensed through December 31, 2016 is recorded as deferred rent in the balance sheet. Rent expense for the years ended December 31, 2016, 2015 and 2014 was \$2.6 million, \$2.8 million, and \$2.8 million, respectively.

At December 31, 2016, future minimum rental payments due under the Company's facilities lease were as follows (in thousands):

Year ending December 31,		
2017	\$	3,377
2018		2,835
2019		—
2020		—
2021		—
Thereafter		—
Total lease payments	\$	<u>6,212</u>

Other Contingencies

In late October and early November 2013, following the Company's announcement of the results of its Phase 3 trial of Allovectin[®] and the subsequent decline of the price of the Company's common stock, two putative securities class action complaints were filed in the U.S. District Court for the Southern District of California against the Company and certain of its current and former officers. On February 26, 2014, the two cases were consolidated into one action and a lead plaintiff and lead counsel were appointed ("Consolidation Order"). On May 12, 2014, the lead plaintiff filed a first amended consolidated complaint alleging that the defendants violated Section 10(b) and 20(a) of the Securities Exchange Act of 1934 by making materially false and misleading statements regarding our business prospects and the prospects for Allovectin[®], thereby artificially inflating the price of the Company's common stock. On June 9, 2014, the defendants filed a motion to dismiss the first amended complaint and a motion to strike certain allegations in the amended complaint. On March 9, 2015, the Court granted defendants' motion to dismiss the first amended complaint and terminated as moot defendants' motion to strike, or Order. The lead plaintiff was granted leave to amend his first amended complaint on or before March 25, 2015. The lead plaintiff chose not to amend his complaint and instead stipulated to an entry of judgment. On April 28, 2015, the Court entered final judgment dismissing the action, or Judgment. On May 28, 2015, the lead plaintiff appealed the Judgment to the U.S. Court of Appeals for the Ninth Circuit. That same day, another group of the Company's stockholders that had previously moved for appointment as lead plaintiff, or the Vical Investor Group, also appealed the Judgment, as well as the Consolidation Order, to the U.S. Court of Appeals for the Ninth Circuit. On August 3, 2015, the Vical Investor Group voluntarily dismissed its appeal. On October 8, 2015, the lead plaintiff-appellant filed an opening brief in support of his appeal. Defendants filed an answering brief on December 9, 2015. On January 27, 2016, lead plaintiff-appellant filed a motion to dismiss his appeal with prejudice, which was joined by defendants. On February 1, 2016, the Ninth Circuit granted the joint motion and dismissed the appeal.

In the ordinary course of business, the Company may become a party to additional lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, are deemed to be material to the Company's financial condition or results of operations.

The Company prosecutes its intellectual property vigorously to obtain the broadest valid scope for its patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or the Company's financial condition is not subject to reasonable estimates.

8. Stockholders' Equity

As of the date of this filing the Company has on file a shelf registration statement that allows it to raise up to an additional \$100.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. Specific terms of any offering under the shelf registration statements and the securities involved would be established at the time of sale.

In October 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which the Company may issue and sell up to \$10.0 million of shares of its common stock from time to time. Under the ATM Agreement, the Company may deliver placement notices that will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the ATM Agreement, BP may sell the shares only by methods deemed to be an "at the market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, including without limitation sales made directly through the Nasdaq Capital Market, on any other existing trading market for our common stock or to or through a market maker. BP will use commercially reasonable efforts consistent with its normal trading and sales practices to sell the shares in accordance with the terms of the ATM Agreement and any applicable placement notice. The ATM Agreement may be terminated by the Company upon prior notice to BP or by BP upon prior notice to us, or at any time under certain circumstances, including but not limited to the occurrence of a material adverse effect on the Company. The Company has no obligation to sell any shares under the ATM Agreement, and both the Company and BP may at any time suspend the sale of shares under the ATM Agreement. To date the Company has not sold any shares of its common stock under the ATM Agreement.

On August 1, 2016, the Company entered into a stock purchase agreement with AnGes MG, Inc., or AnGes, an existing stockholder, to purchase 1,841,420 shares of the Company's common stock in a private placement. The shares were sold at a price of \$4.24 per share. Gross proceeds totaled approximately \$7.8 million. The private placement closed on August 2, 2016. The shares are subject to a two-year lock-up period during which they may not be sold and AnGes has agreed to not increase its ownership position beyond 19.9% and to refrain from taking certain other actions with respect to the Company's stock, subject to certain conditions. AnGes is entitled to have a representative attend meetings of the Company's Board of Directors in a non-voting capacity and may in the future be entitled to have a representative appointed to the Company's Board of Directors, subject to certain conditions. AnGes has also agreed to vote its shares in accordance with the recommendations of the Company's Board of Directors for so long as it continues to hold a specified percentage of the Company's outstanding common stock. The Company also agreed under certain circumstances in the future to register the private placement shares for resale by AnGes.

In March 2015, the Company entered into license and stock purchase agreements with Astellas, granting the Company an exclusive worldwide license to develop and commercialize a novel antifungal, VL-2397, formally known as ASP2397. VL-2397 is a potential therapeutic for invasive fungal infections, including invasive aspergillosis. Astellas received 86,121 shares of unregistered Company common stock and \$250,000 in cash. The \$250,000 cash payment and the fair value of the common stock issued of \$775,094 were included in research and development expenses during the year ended December 31, 2015.

In April 2014, the Company entered into an At-the-Market Issuance Sales Agreement, or the Sales Agreement, with Meyers Associates, L.P. (doing business as Brinson Patrick, a division of Meyers Associates, L.P.), or Brinson Patrick, under which the Company could issue and sell up to \$25.0 million of shares of its common stock from time to time. During the year ended December 31, 2014, the Company sold 329,152 shares under the Sales Agreement and received gross proceeds of \$4,067,751. There were no shares sold during the year ended December 31, 2015. This agreement expired in May 2015.

9. Stock Based Compensation

The Company has a stock-based compensation plan which is described below. Total stock-based compensation expense of \$1.0 million, \$1.9 million and \$3.2 million was recognized for the years ended December 31, 2016, 2015 and 2014, respectively. Total stock-based compensation expense was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Research and development	\$ 290	\$ 392	\$ 785
Manufacturing and production	111	159	229
General and administrative	589	1,351	2,145
Total stock-based compensation expense	\$ 990	\$ 1,902	\$ 3,159
Cash received from RSU grants and options exercised	\$ 1	\$ 3	\$ 2

Stock Incentive Plan

The Company has a stock incentive plan, under which 2,370,000 shares of common stock, subject to adjustment as provided in the plan, are reserved for issuance to employees, non-employee directors and consultants of the Company. As of December 31, 2016 there were 1,988,797 shares reserved for future issuance under the plan. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25% on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan also limits the number of options that may be granted to any plan participant in a single calendar year to 1,300,000 shares.

The Company has granted RSUs to executive officers, other executives, and employees under the stock incentive plan. In 2015 and 2014 the Company granted RSUs covering an aggregate of 78,843, and 82,800 shares of common stock, respectively. There were no RSUs granted in 2016. These RSUs generally vest 25% on the first anniversary date of the grant, with the remaining rights vesting quarterly over the remaining three years and, once vested, allow the participants to acquire the underlying shares of common stock at par value. The participants are not entitled to sell or transfer any unvested RSUs and are not entitled to vote or receive dividends on any shares of common stock covered by the RSUs prior to the acquisition of such shares. Granted but unvested RSUs are forfeited at termination of employment. Compensation expense related to the RSUs for the years ended December 31, 2016, 2015, and 2014 was approximately \$0.3 million, \$0.8 million and \$1.1 million, respectively.

The following table summarizes stock option transactions under the Company's stock incentive plans for the years ended December 31, 2016, 2015 and 2014:

	Shares	Weighted Average Exercise Price
Outstanding December 31, 2013	840,419	\$ 31.50
Granted	188,961	\$ 13.99
Exercised	—	\$ —
Forfeited	(169,937)	\$ 36.91
Outstanding December 31, 2014	859,443	\$ 26.58
Granted	235,675	\$ 10.06
Exercised	—	\$ —
Forfeited	(149,534)	\$ 21.51
Outstanding December 31, 2015	945,584	\$ 23.27
Granted	339,975	\$ 3.51
Exercised	—	\$ —
Forfeited	(82,758)	\$ 24.37
Outstanding December 31, 2016	1,202,801	\$ 17.61
Vested and unvested options expected to vest as of December 31, 2016	1,166,012	\$ 18.00

The number of underlying shares and weighted average exercise price of options exercisable at December 31, 2016, 2015 and 2014, were 808,639 shares at \$23.43, 688,468 shares at \$26.81, and 603,717 shares at \$28.94, respectively. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2016, was 6.5 years and 5.4 years, respectively. The weighted average remaining contractual term of vested and unvested options expected to vest at December 31, 2016, was 6.4 years. The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2016 was \$0.0 million and \$0.0 million, respectively. As of December 31, 2016, the total unrecognized compensation cost related to unvested options was \$0.5 million, which is expected to be recognized over a weighted-average period of 1.39 years.

The weighted average grant-date fair value of options granted during the years ended December 31, 2016, 2015 and 2014, was \$1.85, \$5.08 and \$7.28 per share, respectively. There were no options exercised during the years ended December 31, 2016, 2015 or 2014. At December 31, 2016, there were 689,012 shares available for grant under the Company's stock incentive plans.

A summary of the outstanding RSUs as of December 31, 2016, and changes during the year then ended is presented below:

	Shares	Weighted Average Grant-Date Fair Value per Share
Unvested at December 31, 2015	104,074	\$ 12.55
Granted	—	\$ —
Vested	(59,568)	\$ 13.43
Cancelled	—	\$ —
Unvested at December 31, 2016	44,506	\$ 11.38

The aggregate grant-date fair value of RSUs granted during the years ended December 31, 2015 and 2014 was \$0.8 million, and \$1.2 million, respectively. There were no RSUs granted in 2016. As of December 31, 2016, the total unrecognized compensation cost related to unvested RSUs was \$0.1 million, which is expected to be recognized over a weighted average period of 1.27 years. The aggregate grant-date fair value of shares subject to RSUs vested during the years ended December 31, 2016, 2015 and 2014, was \$0.8 million, \$1.0 million and \$0.8 million, respectively. As of December 31, 2016, there were 52,477 shares of common stock underlying RSUs that were fully vested but the issuance of such shares has been deferred.

10. Income Taxes

At December 31, 2016, the Company had deferred tax assets of \$112.6 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax asset. Pursuant to Sections 382 and 383 of the Internal Revenue Code, or IRC, annual use of the Company's net operating loss and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company determined that such an ownership change occurred on December 29, 2006, as defined in the provisions of Section 382 of the IRC as a result of various stock issuances used to finance the Company's operations. Such ownership change resulted in annual limitations on the utilization of tax attributes, including net operating loss carryforwards and tax credits. The Company estimates that \$101.2 million of its net operating loss carryforwards were effectively eliminated under Section 382 for federal tax purposes. A portion of the remaining net operating losses limited by Section 382 become available each year. The Company also estimates that \$12.2 million of its research and development credits and other tax credits were effectively eliminated under Section 383 for federal purposes. The company's Section 382 analysis was completed through December 31, 2011. There is a risk that additional changes in ownership could have occurred since that date. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement bases and the tax bases of assets and liabilities using enacted tax rates. A valuation allowance is established to reduce deferred tax assets to the amount that is expected more likely than not to be realized.

Significant components of the Company's deferred tax assets as of December 31, 2016 and 2015 are listed below. A valuation allowance of \$112.6 million and \$120.8 million at December 31, 2016 and 2015, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain.

Amounts for the years ended December 31 were as follows (in thousands):

Deferred Tax Assets	2016	2015
Net operating losses	\$ 83,954	\$ 83,143
Credit carryovers	9,952	19,903
Depreciation and amortization	15,278	13,944
Accruals and reserves	701	609
Capital loss carryover	85	85
Other	2,677	3,114
Total deferred tax assets	112,647	120,798
Less valuation allowance	(112,647)	(120,798)
Net deferred tax assets	\$ —	\$ —

In November 2015, the FASB issued Accounting Standard Update No. 2015-17, "Balance Sheet Classification of Deferred Taxes", an update to ASC 740, Income Taxes ("Update"). Current GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the amendments in this Update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments in this Update.

For public business entities, the amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The FASB also decided to permit earlier application by all entities as of the beginning of any interim or annual reporting period. The FASB further provides that this Update may be applied to all deferred tax liabilities and assets retrospectively to all periods presented. The Company chose to adopt the Update in fiscal year ended December 31, 2015 and apply this Update on a prospective basis.

The reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows for the years ended December 31 (in thousands):

	2016	2015	2014
Computed "expected" tax benefit	\$ (3,051)	\$ (3,152)	\$ (5,607)
State income taxes, net of federal benefit	(534)	—	(444)
Tax effect of:			
Change in valuation allowance	(8,148)	(4,069)	5,102
Rate change	—	3,524	—
Expiration of prior year credits and net operating losses	692	786	675
Stock compensation	491	376	274
Uncertain tax positions	11,128	3,074	—
Other	(578)	(539)	—
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2016 and 2015, the Company had available federal net operating loss carryforwards of approximately \$315.9 million and \$311.3 million, respectively, which expire from 2018 through 2036. In addition, the Company had federal research and development credit and orphan drug credit carryforwards of \$26.3 million and \$26.3 million as of December 31, 2016 and 2015, respectively, to reduce future federal income taxes, if any. These carryforwards expire from 2018 through 2033 and are subject to review and possible adjustment by the Internal Revenue Service. The Company also has available California state net operating loss carryforwards of approximately \$269.5 million and \$272.8 million as of December 31, 2016 and 2015, respectively, which expire from 2017 to 2036. In addition, the Company had California research and development credits of approximately \$8.8 million as of December 31, 2016 and 2015 to reduce future California income tax, if any. The California research and development credits do not expire.

The Company generated windfall tax benefits from the settlement of certain stock awards. The tax benefit will be recorded as a credit to additional paid-in capital in the year the deduction reduces income taxes payable. The net operating loss carryforwards related to these windfall tax benefits of approximately \$1.6 million are included in the net operating loss carryforwards disclosed above.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to our unrecognized tax benefits (in thousands):

	2016	2015	2014
Beginning balance	\$ 4,340	\$ 582	\$ —
Increases related to prior year tax positions	12,332	3,758	—
Increases related to current year tax positions	873	—	582
Ending balance	<u>\$ 17,545</u>	<u>\$ 4,340</u>	<u>\$ 582</u>

As of December 31, 2016 and 2015, the Company had gross unrecognized tax benefits of \$17.5 million and \$4.3 million, respectively, none of which would affect the effective tax rate. The increase in 2016 related to prior year tax positions is primarily due to a change in our estimate of research and development and other tax credits that may not be sustained on audit. The Company does not anticipate any significant decreases in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company had no accrual for interest or penalties on its balance sheets at December 31, 2016 or December 31, 2015, and has not recognized interest and/or penalties in its statements of operations for any of the years ended December 31, 2016, 2015 or 2014.

The Company is subject to taxation in the United States and California. The Company's tax years for 1998 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and R&D credits.

11. Employee Benefit Plan

The Company has a defined contribution savings plan under section 401(k) of the IRC. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.1 million for each of the years ended 2016, 2015 and 2014.

12. Summary of (Unaudited) Quarterly Financial Information

The following is a summary of the Company's (unaudited) quarterly results of operations for the years ended December 31 (in thousands, except per share amounts):

2016:	March 31,	June 30,	Sept. 30,	Dec. 31,
Total revenues	\$ 4,604	\$ 4,122	\$ 2,642	\$ 3,163
Total operating expenses	7,114	5,443	5,213	5,938
Net loss	(2,423)	(1,255)	(2,523)	(2,772)
Basic and diluted net loss per share (1)	(0.26)	(0.14)	(0.24)	(0.25)
2015:	March 31,	June 30,	Sept. 30,	Dec. 31,
Total revenues	\$ 4,944	\$ 4,176	\$ 5,017	\$ 6,813
Total operating expenses	8,801	6,968	5,350	9,235
Net income (loss)	(3,821)	(2,762)	(300)	(2,355)
Basic and diluted net loss per share (1)	(0.42)	(0.30)	(0.03)	(0.26)

(1) Net income (loss) per share is computed independently for each quarter and the full year based upon respective shares outstanding. Therefore, the sum of the quarterly loss per share amounts may not equal the annual amounts reported.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. The evaluation of our disclosure controls and procedures included a review of the disclosure controls' and procedures' objectives, design, implementation and the effect of the controls and procedures on the information generated for use in this report. In the course of our evaluation, we sought to identify data errors, control problems or acts of fraud and to confirm the appropriate corrective actions, including process improvements, were being undertaken. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), as of December 31, 2016, the end of the period covered by this Annual Report on Form 10-K. Based on our evaluation under the framework in *Internal Control – Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Controls

There has been no change in our internal control over financial reporting during the three months ended December 31, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item and not included in Part I, Item 1 of this Annual Report on Form 10-K is incorporated by reference from our Proxy Statement for our 2016 Annual Meeting of Stockholders, or our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from our Proxy Statement.

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

The information required by this item is incorporated by reference from our Proxy Statement.

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

The information required by this item is incorporated by reference from our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from our Proxy Statement.

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**(a)(1) Financial Statements**

The following independent registered public accounting firms' reports and our financial statements are filed as part of this Annual Report:

Report of Independent Registered Public Accounting Firm
 Balance Sheets as of December 31, 2016 and 2015
 Statements of Operations for each of the three years in the period ended December 31, 2016
 Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2016
 Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2016
 Statements of Cash Flows for each of the three years in the period ended December 31, 2016
 Notes to Financial Statements

(2) Financial Statement Schedules

The schedules required to be filed by this item have been omitted because of the absence of conditions under which they are required, or because the required information is included in the financial statements or the notes thereto.

(3) Exhibits

See the list in paragraph (b) below. Each management contract or compensatory plan or arrangement required to be identified by this item is so designated in such list.

(b) Exhibits

Exhibit Number	Description of Document
3.1(i)(1)	Restated Certificate of Incorporation.
3.2(ii)(2)	Amended and Restated Bylaws of the Company.
3.3(i)(2)	Certificate of Amendment to Restated Certificate of Incorporation.
3.4(i)(3)	Certificate of Amendment to Restated Certificate of Incorporation.
3.4(i)(4)	Certificate of Amendment to Restated Certificate of Incorporation.
4.1(1)	Specimen Common Stock Certificate.
10.1(4) ^a	Amended and Restated Stock Incentive Plan of Vical Incorporated.
10.2(5) ^a	Form of Indemnity Agreement between the Company and its directors and officers.
10.3(6) ^a	Vical Incorporated Non-Employee Director Compensation Policy.
10.4(7) ^a	Form of Delayed Issuance Stock Purchase Election Agreement, as amended, under the Amended and Restated Stock Incentive Plan (with deferral election).
10.5(8) ^a	Form of Delayed Issuance Stock Purchase Election Agreement, as amended, under the Amended and Restated Stock Incentive Plan.
10.6(9) ^a	Restated employment letter dated January 9, 2009, between the Company and Vijay B. Samant.
10.7(10) ^a	Employment Agreement dated January 14, 2005, between the Company and Anthony A. Ramos.
10.8(11) ^a	Severance Agreement dated January 23, 2015, between the Company and Anthony A. Ramos.
10.9(12) ^a	Employment Agreement dated August 25, 2003, between the Company and Larry Smith.
10.10(13) ^a	Severance Agreement dated January 23, 2015, between the Company and Larry Smith.

Exhibit Number	Description of Document
10.11(14) ^b	U.S. License Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.12(15) ^b	Ex-U.S. License Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.13(16) ^b	Supply and Services Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.14(17)	Letter agreement dated July 12, 2011, related to the U.S. License Agreement dated July 12, 2011, between the Company and Astellas Pharma Inc.
10.15(18) ^b	1st Amendment dated August 6, 2012, to U.S. License Agreement Between Vical Incorporated and Astellas Pharma Inc.
10.16(19) ^b	1st Amendment dated August 6, 2012, to Ex-U.S. License Agreement Between Vical Incorporated and Astellas Pharma Inc.
10.17(20) ^b	1st Amendment dated August 6, 2012, to Supply and Services Agreement Between Vical Incorporated and Astellas Pharma Inc.
10.18(21) ^b	License Agreement dated March 24, 2015, between the Company and Astellas Pharma Inc.
10.19(22) ^b	Amendment No. 1 dated August 31, 2015, to License Agreement dated March 25, 2015, between the Company and Astellas Pharma Inc.
10.20(23) ^b	License Agreement dated December 7, 2001, between the Company and CytRx Corporation.
10.21(24)	Letter Agreement dated July 5, 2011, related to the License Agreement dated December 7, 2001, between the Company and CytRx Corporation.
10.22(25) ^b	Exclusive License Agreement dated February 3, 2003, between the Company and City of Hope.
10.23(26)	Letter agreement dated July 7, 2011, related to the Exclusive License Agreement dated February 3, 2003, between the Company and City of Hope.
10.24(27)	Lease dated January 30, 2002, between the Company and Kilroy Realty, L.P. a Delaware Limited Partnership.
10.25(28)	First Amendment dated July 15, 2016, to Lease dated January 30, 2002, between the Company and Kilroy Realty, L.P. a Delaware Limited Partnership.
10.26(29)	Stock Purchase Agreement dated August 1, 2016, between the Company and AnGes MG, Inc.
10.27(30)	At-the-Market Issuance Sales Agreement, dated October 13, 2016, by and between the Company and IFS Securities, Inc. (doing business as BP, a division of IFS Securities, Inc.).
23.1	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of Vijay B. Samant, Chief Executive Officer and acting Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Vijay B. Samant, Chief Executive Officer and acting Chief Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
(1)	Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.
(2)	Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
(3)	Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 (No. 333-135398) filed on June 23, 2006.
(4)	Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 25, 2016.
(5)	Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

- (6) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
- (7) Incorporated by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
- (8) Incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
- (9) Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on January 15, 2009.
- (10) Incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
- (11) Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014.
- (12) Incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
- (13) Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014.
- (14) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
- (15) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
- (16) Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
- (17) Incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K filed on January 5, 2012.
- (18) Incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
- (19) Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
- (20) Incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
- (21) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015.
- (22) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.
- (23) Incorporated by reference to Exhibit 99 to CytRx Corporation's Current Report on Form 8-K filed on December 21, 2001.
- (24) Incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed on January 5, 2012.
- (25) Incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
- (26) Incorporated by reference to the Exhibit 99.3 to the Company's Current Report on Form 8-K filed on January 5, 2012.
- (27) Incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K for the year ended December 31, 2001.
- (28) Incorporated by reference to the Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.
- (29) Incorporated by reference to the Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.
- (30) Incorporated by reference to the Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.
- a Indicates management contract or compensatory plan or arrangement.
- b Confidential treatment of certain portions of this agreement has been requested and/or received and such portions have been omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 10, 2017

VICAL INCORPORATED

By: /s/ ANTHONY A. RAMOS
Anthony A. Ramos
VP Finance, Chief Accounting Officer (on behalf of the registrant and as the registrant's Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>/s/ VIJAY B. SAMANT</u> Vijay B. Samant	President, Chief Executive Officer and Director (Principal Executive and Financial Officer)	March 10, 2017
<u>/s/ ANTHONY A. RAMOS</u> Anthony A. Ramos	Vice President Finance, Chief Accounting Officer (Principal Accounting Officer)	March 10, 2017
<u>/s/ R. GORDON DOUGLAS, M.D.</u> R. Gordon Douglas, M.D.	Chairman of the Board of Directors	March 10, 2017
<u>/s/ RICHARD M. BELESON</u> Richard M. Beleson	Director	March 10, 2017
<u>/s/ GARY A. LYONS</u> Gary A. Lyons	Director	March 10, 2017
<u>/s/ ROBERT C. MERTON, PH.D.</u> Robert C. Merton, Ph.D.	Director	March 10, 2017
<u>/s/ GEORGE J. MORROW</u> George J. Morrow	Director	March 10, 2017
<u>/s/ THOMAS E. SHENK, PH.D.</u> Thomas E. Shenk, Ph.D.	Director	March 10, 2017

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- 1) Registration Statement (Form S-8 No. 333-30181) pertaining to the 1992 Stock Plan of Vical Incorporated,
- 2) Registration Statement (Form S-8 No. 333-80681) pertaining to the Stock Incentive Plan of Vical Incorporated,
- 3) Registration Statement (Form S-8 No. 333-60293) pertaining to the Stock Incentive Plan of Vical Incorporated,
- 4) Registration Statement (Form S-8 No. 333-66254) pertaining to the Stock Incentive Plan of Vical Incorporated,
- 5) Registration Statement (Form S-8 No. 333-97019) pertaining to the Stock Incentive Plan of Vical Incorporated,
- 6) Registration Statement (Form S-8 No. 333-107581) pertaining to the Stock Incentive Plan of Vical Incorporated,
- 7) Registration Statement (Form S-8 No. 333-116951) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 8) Registration Statement (Form S-8 No. 333-135266) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 9) Registration Statement (Form S-8 No. 333-143885) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 10) Registration Statement (Form S-8 No. 333-169344) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 11) Registration Statement (Form S-8 No. 333-183215) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 12) Registration Statement (Form S-8 No. 333-190343) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- 13) Registration Statement, as amended (Form S-3 No. 333-204462) of Vical Incorporated, and
- 14) Registration Statement (Form S-8 No. 333-213034) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated;

of our report dated March 10, 2017, with respect to the financial statements of Vical Incorporated included in this Annual Report (Form 10-K) of Vical Incorporated for the year ended December 31, 2016.

/s/ Ernst & Young LLP

San Diego, California

March 10, 2017

CERTIFICATION

I, Vijay B. Samant, certify that:

1. I have reviewed this Annual Report on Form 10-K of Vical Incorporated;
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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2017

By:

/s/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer and
Acting Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Vijay B. Samant, the Chief Executive Officer and Acting Chief Financial Officer of Vical Incorporated (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2016, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Annual Report and results of operations of the Company for the period covered by the Annual Report.

Dated: March 10, 2017

/S/ VIJAY B. SAMANT

Vijay B. Samant
Chief Executive Officer and
Acting Chief Financial Officer

THIS CERTIFICATION "ACCOMPANIES" THE ANNUAL REPORT, IS NOT DEEMED FILED WITH THE SEC AND IS NOT TO BE INCORPORATED BY REFERENCE INTO ANY FILING OF THE COMPANY UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (WHETHER MADE BEFORE OR AFTER THE DATE OF THE ANNUAL REPORT), IRRESPECTIVE OF ANY GENERAL INCORPORATION LANGUAGE CONTAINED IN SUCH FILING. A SIGNED ORIGINAL OF THIS CERTIFICATION HAS BEEN PROVIDED TO THE COMPANY AND WILL BE RETAINED BY THE COMPANY AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.