

CHIMERIX INC  
Form 10-K  
March 07, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 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, 2013**

**or**

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

**For the transition period from                      to**

**Commission file number: 001-35867**

**Chimerix, Inc.**

**(Exact Name of Registrant as Specified in its Charter)**

**Delaware**     **33-0903395**  
**(State or Other Jurisdiction of**                         **(I.R.S. Employer**  
**Incorporation or Organization)**                         **Identification No.)**

**2505 Meridian Parkway, Suite 340**

**Durham, North Carolina**                                 **27713**  
**(Address of Principal Executive Offices)**     **(Zip Code)**

**(919) 806-1074**

**(Registrant's Telephone Number, Including Area Code)**

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

<u><b>Title of Each Class</b></u>	<u><b>Name of Each Exchange on Which Registered</b></u>
<b>Common Stock, par value \$0.001 per share</b>	<b>The NASDAQ Stock Market LLC</b>

**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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Market on June 28, 2013 was \$295,687,107.\*

The number of outstanding shares of the registrant's common stock, par value \$0.001 per share, as of February 26, 2014 was 26,762,934.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2014 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will

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be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2013.

\* Based on a closing price of \$24.24 per share on June 28, 2013. Excludes 13,581,132 shares of the registrant's Common Stock held by executive officers, directors and any stockholders whose ownership exceeds 5% of registrant's Common Stock outstanding at June 28, 2013. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

**Chimerix, Inc.**

**FORM 10-K**

**For the Fiscal Year Ended December 31, 2013**

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## PART I

### Forward-Looking Statements

This Annual Report on Form 10-K (Annual Report), may contain “forward-looking statements” within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A, “Risk Factors” in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events that are subject to risks and uncertainties, may contain words such as “may,” “will,” “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate” or other words indicating future results. Such statements may include, but are not limited to, statements concerning the following:

- the initiation, cost, timing, progress and results of our research and development activities, preclinical studies and future clinical trials;
- our ability to obtain and maintain regulatory approval of our future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
  - our plans to research, develop and commercialize our future product candidates;
- our strategic alliance partners’ election to pursue development and commercialization;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our future product candidates;
- the size and growth potential of the markets for our future product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our future product candidates;
- the rate and degree of market acceptance of our future product candidates;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act (JOBS Act);
- our use of the proceeds from our recently completed initial public offering; and
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and need for additional financing.

### Market, Industry and Other Data

This Annual Report contains estimates, projections and other information concerning our industry, our business and relevant antiviral markets, including data regarding the estimated size of relevant antiviral markets, patient populations, projected diagnosis rates and the perceptions and preferences of patients and physicians regarding certain therapies, as well as data regarding market research and estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

## **ITEM 1. BUSINESS**

### *Chimerix Overview*

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals to address unmet medical needs. We were founded in 2000 based on the promise of our proprietary lipid technology to unlock the potential of some of the most broad-spectrum antivirals by enhancing their antiviral activity and safety profiles in convenient, orally administered dosing regimens. We currently have two nucleotide compounds in clinical development that utilize our proprietary lipid technology. Our lead compound, brincidofovir (CMX001), is in Phase 3 clinical development; our second compound, CMX157, was licensed to Merck Sharp & Dohme Corp. (Merck) after completing a Phase 1 study. In addition, we have an active discovery program leveraging our lipid technology and the Chimerix Chemical Library, both focusing on viral targets in areas of high unmet medical need.

### *Brincidofovir*

#### *Phase 3 SUPPRESS Trial*

Brincidofovir is an investigational oral nucleotide analog that has shown broad-spectrum antiviral activity against all five families of DNA viruses that affect humans. We initiated the Phase 3 SUPPRESS trial of brincidofovir in the third quarter of 2013. The trial is designed to demonstrate the safety and efficacy of brincidofovir in the prevention of cytomegalovirus (CMV) infection through the first 24 weeks following a hematopoietic cell transplant (HCT) and, if successful, will serve as the basis for Accelerated Approval for brincidofovir.

SUPPRESS is enrolling 450 allogeneic (non-self) HCT recipients who are at high risk of CMV infection in the post-transplant period based on antibody evidence of a prior infection with CMV, referred to as “CMV seropositive” or “recipient (R+) seropositive.” Because there is no approved CMV prevention available for these patients, the control or “placebo” arm of the study is intensive monitoring for evidence of CMV reactivation in the blood and initiation of early or “preemptive” antiviral therapy. Subjects are randomized 2-to-1 to the active brincidofovir arm (n=300) or the standard-of-care/placebo arm (n=150). Dosing of brincidofovir or placebo begins as soon after the transplant as the patient can swallow a tablet, generally within the first two weeks, and continues through Week 14, the period of greatest risk for viral infections. Subjects will be followed in the trial for an additional 10 weeks after the last dose of study drug, for a total of 24 weeks after transplant.



Brincidofovir has shown activity both *in vitro* and *in vivo* against all five families of DNA viruses that cause disease in humans. Because HCT recipients are also at increased risk for other DNA viral infections including HHV-6, Epstein-Barr Virus (EBV), adenovirus (AdV) and BK virus (BKV), key secondary endpoints in SUPPRESS include clinical events associated with viruses such as encephalitis, respiratory infections, graft failure and measures of kidney function.

During the first year following allogeneic HCT, the rate of non-relapse mortality (mortality not related to recurrence of the underlying malignancy) is approximately 20%, with perhaps one-third of these deaths attributable to the direct and indirect effects of CMV and other DNA viruses. We hope to show that by preventing the significant morbidity related to DNA viruses, we can positively impact the overall success of allogeneic transplantation in the patients who are undergoing this potentially life-saving procedure.

Through decreasing the proportion of subjects with CMV reactivation, brincidofovir may impact both direct effects of CMV such as CMV pneumonitis or hepatitis, and may also reduce the indirect effects of CMV reactivation including inflammation and immune suppression which lead to bacterial, fungal, protozoal and other viral opportunistic infections. It may also be possible to decrease the use of currently available anti-CMV drugs known to have specific toxicities such as neutropenia that increase the risk of bacterial and fungal infections. Another key set of data being collected in SUPPRESS are healthcare utilization costs, including the costs of the toxicities associated with the currently available antivirals, which we believe will be instrumental in future formulary and pricing discussions.

We anticipate data from the SUPPRESS trial in mid-2015.

#### *Successful Identification of Brincidofovir Dose in Study 201*

The SUPPRESS study design and patient population substantially mirrors that of our Phase 2 dose-escalation study, Study 201, the results of which were published in September 2013 in the New England Journal of Medicine (N Engl J Med 2013;369:1227-36). In Study 201, a statistically significant decrease in CMV reactivation (CMV PCR > 200 c/mL at the time of the last dose of study drug) was demonstrated for brincidofovir 100 mg BIW versus placebo (p = 0.002).

A significant change in design from Study 201 to SUPPRESS is the initiation of dosing prior to engraftment (evidence of a functioning bone marrow), a change that could positively impact the probability of success of SUPPRESS. In Study 201, as in studies in CMV prevention using other antiviral agents, dosing began only after there was evidence of engraftment in order to avoid known hematologic toxicities and to avoid exposing patients to unknown toxicities of investigational agents. Review of the hematologic safety data from brincidofovir's safety database of over 900 individuals exposed to date provided evidence of a the lack of hematologic toxicity, and resulted in the ability to begin

dosing of brincidofovir in SUPPRESS in the first days following HCT, prior to engraftment. The ability to dose in the very early post-transplant period may further decrease rates of CMV infection, and increase the likelihood that brincidofovir may prevent reactivation of other DNA viruses such as BKV and HHV-6 which can reactivate in the first weeks after transplant.

The risk:benefit ratio for medications intended for prevention of infection requires a higher standard of safety and tolerability than medications intended for the treatment of established infection, based on the expectation that a larger patient number of individuals will receive the medication for prevention in order to avoid clinically significant disease. With respect to brincidofovir, the safety and tolerability that has been established to date support its continued development as an effective prevention of CMV and other DNA viruses. With regards to the safety and tolerability concerns specific to the HCT population, the lack of observed hematological or bone marrow toxicity is a critical determinant of brincidofovir's use in this population.

Brincidofovir has also not demonstrated any toxicity for the kidney or liver. In Study 201, monitoring for potential renal toxicity included regular serum creatinine levels, calculation of glomerular filtration rate (GFR), and monitoring for the presence of blood in the urine. Subjects receiving one of the effective doses of brincidofovir had a dose-related improvement in kidney function which was consistent and statistically significant across all three measures, while patients who received placebo had a decline through the duration of dosing and the first week of follow-up. In preclinical assessments, brincidofovir has been shown to not be a substrate for hOAT-1, the transporter associated with renal dysfunction and renal failure following the intravenous administration of cidofovir (Vistide®).

The most significant baseline predictor that correlated with these improvements in kidney function was whether or not the patients had evidence of infection with BK virus, a DNA virus which is a member of the polyomavirus family. This is the first evidence of a potential clinical effect of brincidofovir against BKV in HCT recipients. While this potential positive effect may be significant for HCT recipients, it would be even more important in kidney transplant recipients, where BKV has been associated with loss of function and loss of the kidney graft. The evaluation of brincidofovir in kidney transplant recipients is currently being considered in our clinical development plans.

In Study 201, gastrointestinal adverse events and diarrhea in particular were confirmed as the dose-limiting toxicity of brincidofovir. A Safety Monitoring and Management Plan (SMMP) was implemented to identify potentially drug-related diarrhea and other gastrointestinal events and to allow a temporary dose interruption. Earlier identification of potentially drug-related gastrointestinal symptoms and temporary dose interruptions has allowed study subjects to restart brincidofovir successfully in a majority of cases. The SMMP was included in the Phase 2 study in patients with AdV infection (Study 202), with one of 30 patients in the brincidofovir cohorts permanently discontinuing brincidofovir due to diarrhea. The SMMP has been included in the ongoing Phase 3 study of brincidofovir for the prevention of CMV in HCT recipients, SUPPRESS. The SMMP also includes early identification and dose-interruption for potentially drug-related elevations in the liver enzyme ALT, which are reversible upon dosing cessation and typically not accompanied by increases in bilirubin. In our preclinical and early clinical studies, a proportion of individuals had evidence of low-grade ALT increases. In preclinical studies these ALT elevations were not accompanied by any evidence of histopathology and were considered non-adverse.



## *CMX157*

CMX157, our second clinical stage nucleotide analog, uses the same proprietary lipid technology as brincidofovir to deliver high intracellular concentrations of the potent antiviral drug, tenofovir. Tenofovir, marketed under the brand name Viread® and in multiple fixed-dose combinations, is widely used for the treatment of HIV and HBV infection. CMX157 is currently being developed for the treatment of HIV infection following conduct of a Phase 1 clinical study prior to licensing it to Merck in July 2012. We granted Merck an exclusive worldwide license to develop and commercialize CMX157 for HIV or other indications. Merck is now responsible for all development and marketing activities for CMX157 on a worldwide basis.

## *Our Chemical Library and Lipid Technology*

### *Lipid-Antiviral-Conjugate Technology*

Our proprietary technology, which we refer to as lipid-antiviral-conjugate technology, is used to covalently modify a drug molecule with a lipid-side chain that it mimics a naturally occurring phospholipid component of cellular membranes. The lipid mimic can then utilize natural uptake pathways to achieve oral bioavailability, enhance uptake into cells, avoid many toxicities, and yield higher intracellular concentrations of drug.

We believe that our lipid-antiviral-conjugate technology can be used to develop new drugs from parent molecules having a known mechanism of action but with an improved safety and efficacy profile relative to the parent. Preclinical studies and in vitro experiments on a number of drugs have shown specific improvements in biological activity compared with the parent drug.

The primary example of our proprietary lipid technology is brincidofovir, which was developed to deliver a potent but relatively toxic drug, cidofovir, into cells. Use of cidofovir, has been limited by significant toxicities, particularly kidney toxicity. The lipid-bearing brincidofovir molecule allows delivery of a potent, but less toxic molecule than the unmodified cidofovir parent molecule. Thus brincidofovir has a higher benefit:risk ratio that allows its use in the setting of prevention of CMV disease and potentially other DNA viruses.

### *Chimerix Chemical Library*

The Chimerix Chemical Library contains over 10,000 heterocyclic ring systems and nucleosides, the majority of which were originally synthesized in the laboratory of Dr. Leroy Townsend at the University of Michigan. This library includes approximately 3,500 nucleoside analog compounds that are candidates for lipid conjugation. We have an active discovery program focusing on viral diseases where there is significant unmet medical need. We are currently

screening the library for activity against more than thirty viruses including flaviviruses, influenza, herpesviruses and polyomaviruses. Lead chemical series have been identified for CMV and BK viruses and novel compounds with promising activity are being evaluated in various pre-clinical testing models. We believe that several compounds active against key pathogens are amenable to enhancement using our proprietary lipid technology.

## **Our Strategy**

Our strategy is to discover, develop and commercialize novel oral antiviral therapeutics in areas of significant unmet medical need. Our primary initial focus is leveraging the broad-spectrum profile of brincidofovir to address the multiple DNA viral infections common in transplant recipients. We are also weighing the potential of developing brincidofovir for use in non-transplant settings, in light of the broad-spectrum anti-viral activity against numerous DNA viruses.

The key components of our strategy are:

***·Complete Development and Successfully Commercialize Brincidofovir for the Prevention of CMV.***

During 2013, we began enrollment of SUPPRESS, our Phase 3 clinical trial of brincidofovir for the prevention of CMV. If successful, the data from SUPPRESS will be used to support our application for Accelerated Approval of brincidofovir for the prevention of CMV in HCT. We anticipate data from the SUPPRESS trial in mid-2015. If approved, we believe that we are well positioned to maximize the commercial potential of brincidofovir as there are currently no approved therapies for prevention of CMV in HCT. We are in discussions with the FDA regarding the study design for our confirmatory Phase 3 study for Traditional Approval of brincidofovir for the prevention of CMV. We believe the confirmatory study will likely be conducted in kidney transplant recipients.

During 2014, we will be expanding our activities to Europe. We anticipate adding several sites to the SUPPRESS trial. We are also in the process of obtaining scientific advice from the European Medicines Authority on our brincidofovir development plan.

***Evaluate Additional Patient Populations and Applications for Use of Brincidofovir.*** In addition to our initial development program focusing on CMV in transplant recipients, we are evaluating other patient populations and applications for potential future treatment opportunities with brincidofovir.

*Additional patient populations.* We intend to evaluate brincidofovir in other immunocompromised patient populations. Beyond the transplant population, patients are susceptible to multiple DNA viral diseases due to congenital or induced immune deficiencies secondary to biologics therapy for autoimmune and other disorders. Through our Expanded Access Program, hundreds of patients have received brincidofovir for the treatment of a variety of viral diseases.

*Additional viral indications.* Brincidofovir has shown activity in vitro against the five families of DNA viruses that cause disease in humans. In addition to the development progression for the prevention of CMV, we have also evaluated brincidofovir for use in patients with adenovirus (AdV). In an exploratory Phase 2 study in patients with AdV infection, brincidofovir consistently suppressed AdV viremia and showed a favorable numeric difference for progression to AdV disease and non-relapse mortality. We also continue to work with BARDA to develop brincidofovir as a medical countermeasure for the treatment of variola virus, the DNA virus responsible for smallpox. We intend to evaluate brincidofovir for the treatment of patients with various other DNA virus induced diseases. This process has begun with the collection of secondary endpoint data in our SUPPRESS trial and may continue with more virus-specific clinical trials in the future.

***Work with Merck and BARDA to Advance Our Development Programs.***

*Support Merck in the development of CMX157 for the treatment of HIV infection.* We entered into a collaboration and licensing arrangement with Merck in July 2012, whereby Merck is responsible for the future development and commercialization of CMX157. Under this arrangement, Merck is responsible for conducting preclinical studies and clinical trials and obtaining required regulatory approvals for CMX157 and manufacturing and commercializing CMX157.

*Continue our collaboration with BARDA for the development of brincidofovir as a potential medical countermeasure for smallpox, subject to continuing government support.* We have begun pharmacokinetic studies in healthy and infected animals which will support the design of first pivotal efficacy study that is planned to be initiated in 2014.

***Discover and Develop Additional Product Candidates to Strengthen our Antiviral Product Portfolio.*** We have an active discovery and pre-clinical development program focused on identifying and developing new compounds that can be used to treat viral diseases for which no current therapeutic option exists or in areas of high unmet medical need. We intend to leverage our knowledge and experience of nucleosides to advance compounds in the Chimerix Chemical Library through Investigational New Drug (IND)-enabling studies and potential clinical development and/or partnerships. In addition, we are exploring other potential product opportunities based on the ability of our proprietary lipid technology to significantly improve the drug profile of molecules with limitations in safety or delivery.

## **Our Product Candidates**

The following chart depicts our product candidates, their indications, and their current stage of development:



## Commercial Agreements

### *Merck*

In July 2012, we entered into a collaboration and license agreement granting Merck exclusive worldwide rights to CMX157, our novel nucleoside phosphonate being developed for the treatment of HIV infection. Under the terms of the agreement, Merck received an exclusive worldwide license for any human use of CMX157 and agreed to use commercially reasonable efforts to develop and commercialize CMX157 in the United States and at least three major European markets. Following execution of the agreement, we received a \$17.5 million upfront payment from Merck. As additional consideration, we are eligible to receive up to a total of \$151.0 million in milestone payments if certain development and regulatory milestones are achieved by Merck for products utilizing CMX157, as well as tiered royalties on net sales ranging from high single digits to low double digits, if CMX157 is successfully commercialized.

Milestone payments are triggered upon the completion of various stages of the regulatory approval process for each of the first two indications for CMX157, with the final milestones reached upon approval in the United States and three major European markets. Royalties for any given product will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to such product or ten years from the first commercial sale of such product. As of December 31, 2013, other than the upfront payment received upon execution of the agreement, we have not received any payments from Merck pursuant to the agreement.

Unless earlier terminated, the agreement continues in effect until the termination of Merck's royalty payment obligations. The agreement allows for termination by Merck in its entirety, or on a region-by-region basis, upon 90 days advance written notice, or, with respect to a particular product, immediately upon written notice if Merck has a safety concern regarding such product. In addition, either party may terminate for the other party's material breach of the agreement which remains uncured for 90 days. In the event of termination by us for material breach by Merck or termination by Merck upon written notice to us (other than termination due to safety concerns with respect to a particular product), Merck would be required to assign to us certain clinical data and regulatory materials related to CMX157 and, upon written request, grant to us a limited, non-exclusive license to Merck's patent rights covering CMX157. In such event, we would be required to pay to Merck a tiered, low single digit royalty on net sales depending on any such product's development stage at the time of such termination.

### *BARDA*

In February 2011, we entered into a contract with BARDA for the advanced development of CMX001 as a medical countermeasure in the event of a smallpox release (Contract Number HHSO100201100013C). BARDA is a division of the U.S. Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Preparedness and Response that supports the advanced research and development, manufacturing, acquisition and stockpiling of medical countermeasures. The scope of work for the contract includes preclinical, clinical and manufacturing



development activities that fall into the following areas: non-clinical animal efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities.

Under the contract, BARDA will reimburse our costs, plus pay us a fixed fee, for the research and development of CMX001 as a treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment which ended on May 31, 2013, plus up to four extension periods of around one year each, referred to as option segments, each of which may be exercised at BARDA's sole discretion. We must complete agreed upon milestones and deliverables in each discrete work segment before the next option segment is eligible to be exercised. Under the contract as currently in effect, if each follow-on option segment is exercised by BARDA, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees.

We completed the base performance segment of the contract on May 31, 2013 and currently working on under the first option segment of the contract which is planned to end May 31, 2014. BARDA must notify us at least 30 days before the end of the first option segment if it intends to exercise the second option segment of the contract. If all option segments are exercised by BARDA, the term of the contract would be extended to February 15, 2016. As of December 31, 2013, we had recognized revenue in aggregate of \$32.7 million with respect to the base performance segment and the first extension period.

Pursuant to the contract, Chimerix and the U.S. government share the rights to any inventions made in the performance of our work under the contract. Specifically, the U.S. government retains a nonexclusive, nontransferable, irrevocable, paid up license to any invention made in the performance of our work under the contract; provided, however, that the U.S. government may, under certain circumstances, including circumstances involving public health and safety, license such inventions to third parties without our consent. There have been no inventions made to date under the BARDA contract.

The contract may be terminated by BARDA ten days after giving us notice of a material default which remains uncured for ten days. In addition, BARDA is also permitted under applicable law to terminate the contract if it is in the U.S. government's best interest.

We anticipate renegotiating certain aspects of the smallpox animal plan to take into account recent guidance from the FDA for development of CMX001 under the Animal Efficacy Rule. The results of this negotiation are uncertain and we do not anticipate continuing this program without ongoing support from BARDA.

### *The Regents of the University of California*

In May 2002, we entered into a license agreement with The Regents of the University of California (UC) under which we obtained an exclusive, worldwide license to UC's patent rights in certain inventions (the UC Patent Rights) related

to lipid-conjugated antiviral compounds and their use, including certain patents relating to brincidofovir and CMX157. Under the license agreement, we are permitted to research, develop, manufacture and commercialize products utilizing the UC Patent Rights for all human and veterinary uses, and to sublicense such rights subject to certain sublicensing fees and royalty payments.

In consideration for the rights granted to us under the license agreement, we issued UC an aggregate of 64,788 shares of our common stock. In connection to the development and commercialization of brincidofovir and CMX157, we could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement. In addition, upon commercialization of any product utilizing the UC Patent Rights, which would include brincidofovir or CMX157, we will be required to pay low single digit royalties on net sales of such product.

The license agreement requires that we diligently develop, manufacture and commercialize compounds that are covered by the UC Patent Rights, and we have agreed to meet certain development and commercialization milestones. UC may, at its option, either terminate the license agreement or change the license granted from an exclusive license to a non-exclusive license if we fail to meet such development and commercialization milestones. We are currently in compliance with these milestone requirements. Specifically, the license agreement contains a due diligence requirement stating that we must commence a Phase III clinical trial for the first Licensed Product within 9 years of the Effective Date (as those terms are defined within the license agreement). On January 31, 2011 we received a letter from UC stating that we had satisfied these requirements, thereby waiving compliance with further due diligence obligations.

## **Commercial Operations**

In anticipation of potential regulatory approval and commercial launch of brincidofovir, we are building out select commercial functions in the U.S. tied to key milestones, such as availability of topline data from the SUPRESS trial in mid-2015, and the potential filing of the NDA for brincidofovir.

Patients who receive HCT and solid organ transplants (SOTs) are likely to be treated at a small number of major medical centers by specialized teams of physicians. There are approximately 200 U.S. transplant centers, which overlap in performing HCT and SOT. The management of therapies for transplant patients is largely the responsibility of transplant physicians and infectious disease specialists who oversee post-transplant therapies. Overall, transplant and transplant infectious disease treatment is a small clinical discipline with a clearly identified group of key opinion leaders (KOLs). While the standard of care for post-transplant therapies may vary by institution and country, it is often driven by research activities or publications of these KOLs from academic transplant research centers. Many of these key opinion leaders have participated in our clinical trials and/or have experience using brincidofovir through our Compassionate Use Program. We believe we can access these KOLs to help inform future commercialization plans for brincidofovir, including the prioritization and probability of success in evaluating additional study populations involving DNA viruses.

If approved for the prevention of CMV in patients who have received a HCT, we believe it is possible for us to commercialize brincidofovir for this indication in the United States and Canada with a relatively small commercial infrastructure, which may include a contract sales force, partner sales force, or internal team. While our commercialization efforts would initially be focused on physicians who are responsible for HCT recipients, this commercial infrastructure would serve as the foundation for an expanded focus on physicians who are responsible for SOT recipients, subject to market approval in this patient population.

Outside of the United States and Canada, subject to obtaining necessary marketing approvals, we likely will seek to commercialize brincidofovir through distribution or other collaboration arrangements. If we elect to develop brincidofovir for other DNA viral indications, we would plan to do so selectively either on our own or by establishing alliances with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs and our available resources.

### **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our experience and scientific and commercial knowledge provide us with competitive advantages, we may face competition from large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical and generic drug companies, academic institutions, government agencies, research institutions and others.

We believe that the key competitive factors that will affect the commercial success of brincidofovir and our other product candidates are the efficacy, safety and tolerability profile and the risk-benefit trade-off compared to alternative therapies or procedures. Securing market access and reimbursement will be an important element of product uptake and market penetration. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel technologies that are more effective, safer or have greater market access than brincidofovir, or obtain regulatory approval for their products more rapidly than we do. In addition, our ability to compete may be affected by the availability of generic products.

We expect that, if approved, brincidofovir would compete with a number of existing products and other product candidates that target serious viral infections, including drugs and vaccines which demonstrate efficacy against viruses that affect our target patient populations. We believe brincidofovir has potential benefits over the competitive products, including the potential to be the first antiviral indicated for the prevention of CMV in allogeneic stem cell transplant patients. Potentially competing products that are currently marketed include:

- oral and intravenous ganciclovir, a drug that is sold by generic manufacturers;
- Valcyte® (valganciclovir), a prodrug of ganciclovir that is marketed by Hoffmann-La Roche Inc.;
- Cytogam®, a pooled CMV hyperimmunoglobulin, marketed by CSL Limited;
- Vistide® (cidofovir for injection), marketed by Gilead Sciences, Inc.; and
- Foscavir® (foscarnet sodium for injection), marketed by Clinigen Group plc and generic manufacturers.

We are aware of several product candidates currently in development that may compete against brincidofovir for the prevention or mitigation of CMV infection in a variety of settings, including:

· Ietermovir, an anti-CMV drug being developed pursuant to an exclusive worldwide license agreement between AiCuris GmbH & Co. KG and Merck; and

· ASP0113 (TransVax), a CMV prevention vaccine, licensed to Astellas Pharma Inc. from Vical Incorporated and in development by Astellas and Vical.

Other vaccine products are being developed by GlaxoSmithKline plc (GlaxoSmithKline), Novartis International AG, sanofi-aventis U.S. (Sanofi), and a variety of university and governmental organizations. Other products used against the same viruses targeted by brincidofovir include valacyclovir, an antiviral drug marketed by GlaxoSmithKline and a number of generic manufacturers; leflunomide, a drug approved for rheumatoid arthritis and sold in the United States by Sanofi under the brand name Arava®; and quinolone antibiotics, which are manufactured by a variety of branded pharmaceutical companies and generic manufacturers. Furthermore, we anticipate that we will face intense and increasing competition as new products enter the market, as advanced technologies become available and as generic forms of currently branded products become available.

Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete. Changes in the health care system may limit our ability to price brincidofovir or our other product candidates at a level that would allow recovery of our research and development costs and may impede our ability to generate or maintain a profit.

We believe that brincidofovir has potential benefits over existing and potential competitive products as described in more detail under “Business — Brincidofovir.” As a result, we believe that brincidofovir should be well placed to establish market share if we obtain the required regulatory approvals for brincidofovir. However, even with those benefits, we may not be able to make promotional claims that brincidofovir is superior to these competing products, and brincidofovir may be unable to compete successfully against these products. See “Risk Factors — Risks Related to Commercialization of Our Product Candidates.”

## **Our Intellectual Property**

We strive to protect and enhance the proprietary technologies we believe are important to our business, including by seeking and maintaining patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain licenses to our intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

We believe that we have a strong intellectual property position and substantial know-how relating to the development and commercialization of our lipid technology platform and the Chimerix Chemical Library.

At February 14, 2014, our worldwide patent portfolio included:

- over 105 patents or patent applications that we own or have in-licensed from academic institutions, related to brincidofovir and CMX157, which represented a slight increase over the number of patents and patent applications in our patent portfolio at the end of fiscal 2013;
- 21 patents and patent applications related to our agreement with the University of Michigan regarding our proprietary Chemical Library; and
- 45 US and foreign exclusively and jointly owned patents, and 77 U.S., PCT, and foreign applications.

Patents generally have a term of twenty years from the date they are filed. As our patent portfolio has been built over time, the remaining terms of the individual patents across our patent portfolio vary. We believe that our patents and patent applications are important for maintaining the competitive differentiation of our lipid-antiviral-conjugate technology platform and the Chimerix Chemical Library, enhancing our freedom of action to sell our antivirals, upon appropriate regulatory approvals, in markets in which we choose to participate, and maximizing our return on research and development investments. No single patent is in itself essential to the conduct of our business as a whole.

We are also open to expanding our intellectual property portfolio through licensing intellectual property from third parties as we deem appropriate. We have granted and will continue to grant to others licenses under our patents when we consider these arrangements to be in our interest.

## **Manufacturing**

We do not own or operate and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. In the past, we have relied on third-party manufacturers for supply of our lead product candidate, brincidofovir, as well as our other product candidates. We expect that in the future we will rely on such manufacturers for supply of drug substance and product that will be used in clinical trials of brincidofovir. When produced on a commercial scale, we expect that cost-of-goods-sold relating to brincidofovir will generally be in-line with that of other small-molecule pharmaceutical compounds.

The manufacturing process for brincidofovir is relatively straight-forward and generally in-line with other small molecule pharmaceutical compounds in terms of cost and complexity. The process is robust and reproducible, does not require dedicated reactors or specialized equipment, uses common synthetic chemistry and readily available materials, including off-the-shelf and made-to-order starting materials, and is readily transferable.

Our current drug substance supply chain for brincidofovir involves various contractors that supply the raw materials for the drug substance process and a contract manufacturer for the drug substance. We have validated the drug substance production process for brincidofovir at a scale of up to 100 kilograms, which is an amount that safely

exceeds our currently projected commercial requirements. We have completed transferring the drug substance manufacturing process to our selected contractor that will produce the commercial supply of drug substance and drug product. Manufacturers of drug components must meet certain FDA qualifications with respect to manufacturing standards. At present, we have qualified only one firm as a supplier of drug substance and a separate firm as the supplier of drug product. We continually assess our manufacturing needs and may seek to engage additional qualified vendors as circumstances dictate. Changes in our requirements may require revalidation of the manufacturing process at a different scale and potentially at a different contractor depending on the necessary scale, infrastructure and technical capabilities. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative suppliers for certain portions of our supply chain, as appropriate.

Our drug products (tablets and suspension) are also manufactured under contract. We have validated manufacturing of brincidofovir tablets at a 165 kg commercial scale. In addition, stability data are available to support sufficient commercial shelf life. We have also developed a suspension formulation for brincidofovir and have manufactured that formulation at pilot scale. We are currently evaluating manufacturers to optimize tablet and suspension formulation production to meet forecasted commercial demand.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our systems and contractors are required to be in compliance with these regulations, and this is assessed regularly through monitoring of performance and a formal audit program. We have personnel with extensive technical, manufacturing, analytical and quality experience and strong project management discipline to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Pursuant to our license agreement with Merck, the manufacture of CMX157 is under the control and direction of Merck.

## **Government Regulation and Product Approval**

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any product candidate that we develop must be approved by the FDA before it may be legally marketed in the United States and by the appropriate foreign regulatory agency before it may be legally marketed in foreign countries.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA), and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial civil or criminal sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, debarment, restitution, disgorgement or civil or criminal penalties.

Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies according to good laboratory practices (GLP), or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as current good clinical practices (GCPs), to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice standards (cGMP), to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and FDA review of the NDA.



The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA's regulations comprising the good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board (IRB), at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### ***U.S. Review and Approval Processes***

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, under the Pediatric Research Equity Act (PREA), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The

FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted (discussed below).

The FDA reviews all NDAs submitted to determine if they are substantially complete before it accepts them for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA), the FDA has 10 months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the drug approval process, the FDA also will determine whether a risk evaluation and mitigation strategy (REMS), is necessary to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without a REMS, if required.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable it will outline the deficiencies in the submission and often will request additional testing or information.

The NDA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials testing, which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

#### *Orphan Drug Designation*

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 product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product 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 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. Orphan product exclusivity also could block the approval of a product for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if a drug candidate is determined to be contained within the competitor's product for the same indication or disease. 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. Orphan drug status in the European Union has similar but not identical benefits to those provided in the United States.

#### *Expedited Development and Review Programs*

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for marketing approval, including a Fast Track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to establish safety and efficacy for the approved indication. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

### *Post-Approval Requirements*

Any drug products for which we or our strategic alliance partners receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. These promotion and advertising agreements include, among others, standards for direct-to-consumer advertising, promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Our strategic alliance partners may also utilize third parties for some or all of a product we are developing with such strategic alliance partner. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

### *U.S. Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specifics of the FDA approval of the use of our drug candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman

Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application (ANDA), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

### *Reimbursement*

Sales of pharmaceutical products depend in significant part on the availability of third-party reimbursement. Third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services, including prescription drugs. In addition, significant uncertainty exists as to the reimbursement status of newly approved prescription drugs and other healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of any of our products that is successfully developed and approved. Our product candidates may not be considered cost-effective. It is time consuming and expensive to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow the sale of any of our products that is successfully developed and approved on a competitive and profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities to provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each Part D prescription drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all of the drugs within each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

It is not clear what long-term effect the MMA will have on the prices paid for currently approved drugs and the pricing options for newly approved drugs. Government payment for some of the costs of prescription drugs may increase demand for any of our products that is successfully developed and approved. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, although the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Accordingly, any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.



The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research would be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes of Health, and periodic reports on the status of the research and related expenditures would be made to the U.S. Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear whether research would have any effect on the sales of any of our products that is successfully developed and approved, if the product or the condition that it is intended to treat becomes the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits of a competitor's product could adversely affect the sales of any of our products that is successfully developed and approved. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act (ACA), as amended by the Health Care and Education Affordability Reconciliation Act of 2010, is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. We cannot predict the impact of the ACA on pharmaceutical companies because many of the ACA's reforms require the promulgation of detailed regulations to implement the statutory provisions, which has not yet occurred. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, some states have indicated that they intend not to implement certain sections of the ACA and some members of the U.S. Congress are still working to repeal the ACA. These challenges add to the uncertainty of the effects of the ACA.

The Physician Payment Sunshine Act (Sunshine Act), which was enacted as part of ACA, requires covered manufacturers of drugs covered under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third party as directed by that entity, to physicians and teaching hospitals, or to third parties on behalf of physicians or teaching hospitals, during the course of the preceding calendar year. The final rule implementing the Sunshine Act, published on February 8, 2013, requires data collection on payments to begin on August 1, 2013. Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (up to \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

If not preempted by the ACA, several states require pharmaceutical manufacturers to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in the states. Other states prohibit providing various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, some states, such as California, Nevada and Massachusetts, require pharmaceutical manufacturers to implement compliance programs or marketing codes. Currently, several additional states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their respective national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products for which we receive marketing approval. Historically, the price structures for products launched in the European Union do not follow those of the United States and tend to be significantly lower.

#### *Europe / Rest of World Government Regulation*

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

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

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

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we or our strategic alliance partners must submit a marketing authorization application. The application used to file the NDA or a Biologics License Application in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country

to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

### **Environmental, Health and Safety Regulations**

We are subject to various environmental, health and safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous substances. From time to time, and in the future, our operations may involve the use of hazardous materials.

### **Employees**

As of December 31, 2013, we had 52 full-time employees. Of these employees, 39 employees are engaged in research and development activities and 13 employees are engaged in finance, legal, human resources, facilities and general management. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

### **Corporate Information**

We were incorporated in the State of Delaware in April 2000. Our corporate headquarters are located at 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713 in a facility we lease encompassing approximately 14,500 square feet of office space. The leases for this facility expire in February 2015 and 2018. We separately lease an additional 4,600 square feet of laboratory space in Durham, North Carolina. The lease for this facility expires in June 2014.

Our corporate website address is [www.chimerix.com](http://www.chimerix.com). The information contained on, or that can be accessed through, our website is not part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only.

## ITEM 1A. RISK FACTORS.

*Except for the historical information contained herein or incorporated by reference, this Annual Report and the information incorporated by reference contains forward-looking statements that involve risks and uncertainties. These statements include projections about our research, development and commercialization efforts, our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results may differ materially from those discussed here. Factors that could cause or contribute to differences in our actual results include those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference into this Annual Report. You should consider carefully the following risk factors, together with all of the other information included or incorporated in this Annual Report. Each of these risk factors, either alone or taken together, could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock. There may be additional risks that we do not presently know of or that we currently believe are immaterial which could also impair our business and financial position.*

*An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this Annual Report, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.*

### **Risks Related To Our Financial Condition and Need For Additional Capital**

*We have incurred significant losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.*

We are a biopharmaceutical company focused primarily on developing our lead product candidate, brincidofovir (CMX001). We have incurred significant net losses in each year since our inception, including net losses of \$36.4 million, \$4.4 million and \$25.6 million for the fiscal years ended 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of approximately \$162.7 million.

To date, we have financed our operations primarily through the sale of equity securities and, to a lesser extent, through government funding, licensing fees and debt. We have devoted most of our financial resources to research and

development, including our preclinical development activities and clinical trials. We have not completed development of any product candidates. We expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future. The size of our losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. In particular, we expect to incur substantial and increased expenses as we:

- continue the development of our lead product candidate, brincidofovir, for the prevention of cytomegalovirus (CMV) infection in transplant recipients and potentially other DNA viruses;
  - seek to obtain regulatory approvals for brincidofovir;
  - prepare for the potential commercialization of brincidofovir;
- scale up manufacturing capabilities to commercialize brincidofovir for any indications for which we receive regulatory approval;
- begin outsourcing of the commercial manufacturing of brincidofovir for any indications for which we receive regulatory approval;
- establish an infrastructure for the sales, marketing and distribution of brincidofovir for any indications for which we receive regulatory approval;
  - expand our research and development activities and advance our clinical programs;
  - maintain, expand and protect our intellectual property portfolio;
- continue our research and development efforts and seek to discover additional product candidates; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products with significant market potential. This will require us to be successful in a range of challenging activities, including discovering product candidates, completing preclinical testing and clinical trials of our product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We are only in the preliminary stages of some of these activities.

To date, we have not completed Phase 3 clinical trials or obtained regulatory approval for any of our product candidates, and none of our product candidates have been commercialized. We may never succeed in developing or commercializing any of our product candidates. If our product candidates are not successfully developed or commercialized, or if revenues from any products that do receive regulatory approvals are insufficient, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenues are also dependent upon the size of markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success outside of the United States.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

***Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize our product candidates.***

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development, obtain the necessary regulatory approvals and commercialize our product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- obtaining favorable results for and advancing the development of brincidofovir, initially for the prevention of CMV in hematopoietic cell transplant (HCT) recipients, including successfully initiating and completing our Phase 3 clinical development;
- obtaining accelerated approval in the United States for brincidofovir for CMV prevention in HCT recipients and equivalent foreign regulatory approvals for brincidofovir;
  - launching and commercializing brincidofovir through the development of a strong commercial infrastructure;
- achieving acceptance of brincidofovir in the medical community and securing market access and reimbursement and from third-party payors;
  - obtaining traditional approval in the United States for brincidofovir for CMV prevention; and
  - generating a pipeline of product candidates.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data required to obtain regulatory approval and achieve product sales. Our anticipated development costs would likely increase if we do not obtain favorable results or if development of our product candidates is delayed. In particular, we would likely incur higher costs than we currently anticipate if development of our product candidates is delayed because we are required by the U.S. Food and Drug Administration (FDA) to perform studies or trials in addition to those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs in connection with commercialization. As a result, we cannot assure you that we will be able to generate revenues from sales of any approved product candidates, or that we will achieve or maintain profitability even if we do generate sales.

*If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs, seek corporate partners for the development of our product development programs or relinquish or license on unfavorable terms, our rights to technologies or product candidates.*

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs for brincidofovir and potentially other anti-viral drug therapies.

We received net proceeds of \$107.6 million from the sale of shares in our initial public offering (IPO), including the full exercise of the over-allotment option, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Based upon our current operating plan, we believe that the net proceeds from our IPO, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital requirements at least through mid-2015. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expected, or because the FDA requires us to perform studies or trials in addition to those that we currently anticipate. We may need to raise additional funds if we choose to initiate clinical trials for our product candidates other than brincidofovir. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates, including brincidofovir. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

• significantly delay, scale back or discontinue the development or commercialization of our product candidates, including brincidofovir;

• seek corporate partners for brincidofovir or any of our other product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or

relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects and on our ability to develop our product candidates.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. We do not have any committed external source of funds. Under our collaboration and license agreement with Merck, Sharpe & Dohme Corp. (Merck), we are entitled to receive milestone and royalty payments if specified events occur, but that agreement is terminable by Merck at any time upon 90 days written notice or, in certain circumstances, immediately upon written notice.

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and will impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our debt service obligations. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts, or grant others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We may be required to repay the outstanding indebtedness under our loan agreement if a material adverse change occurs with respect to us, which could have a materially adverse effect on our business.***



As of December 31, 2013, we had \$10.1 million of indebtedness outstanding under our loan and security agreement with Silicon Valley Bank (SVB) and Midcap Financial SBIC, LP (MidCap). Under the loan agreement, an event of default will occur if, among other things, a material adverse change in our business, operations or condition occurs, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the loan agreement occurs. An event of default would allow the lenders to, among other things, accelerate the loan and take certain action with respect to the collateral securing our obligations under the loan agreement. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time any such event of default occurs. In this case, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others, rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

### **Risks Related To Clinical Development and Regulatory Approval**

*We depend on the success of our lead product candidate, brincidofovir, which is still under clinical development, and may not obtain regulatory approval or be successfully commercialized.*

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our lead product candidate, brincidofovir, which has completed a Phase 2 clinical trial for the prevention of CMV infection in adult HCT recipients. In the third quarter of 2013, we initiated our Phase 3 clinical trial, known as SUPPRESS, for brincidofovir for the prevention of CMV infection in adult HCT recipients. We intend to use this trial as a basis to submit a new drug application (NDA) to the FDA under the Accelerated Approval pathway seeking regulatory approval to market brincidofovir in the United States and equivalent applications outside the United States. We also intend to conduct a confirmatory, second Phase 3 trial for the prevention of CMV infection in at-risk transplant recipients. This confirmatory, second trial should have a higher likelihood of clinical events in order to establish a correlation of CMV viremia (a “surrogate” endpoint) with the risk of CMV disease, and thus fulfill the requirements for traditional approval for prevention of CMV infection. Per FDA regulations, the confirmatory second trial would usually be in progress at the time of NDA submission for accelerated approval. Potential study design and patient populations for a confirmatory, second trial are under discussion with the FDA. There is no guarantee that our Phase 3 clinical trials will be completed or, if completed, will be successful. The success of brincidofovir will depend on several factors, including the following:

- successful completion of nonclinical studies and successful enrollment and completion of clinical trials;

receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates;

establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;

- launching commercial sales of the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
  - effectively competing with other therapies;
- a continued acceptable safety profile of the product following approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize brincidofovir, which would materially harm our business.

***We have never obtained regulatory approval for a drug and we may be unable to obtain, or may be delayed in obtaining, regulatory approval for brincidofovir.***

We have never obtained regulatory approval for a drug. It is possible that the FDA may refuse to accept our NDA for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval of brincidofovir. If the FDA does not accept or approve our NDA, it may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will reconsider our application. Depending on the extent of these or any other FDA required studies, approval of any NDA or application that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDA.

Any delay in obtaining, or an inability to obtain, regulatory approvals would prevent us from commercializing brincidofovir, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for brincidofovir, which would have a material adverse effect on our business and could potentially cause us to cease operations.

***We depend on the successful completion of clinical trials for our product candidates, including brincidofovir. The positive clinical results obtained for our product candidates in prior clinical studies may not be repeated in future clinical studies.***

Before obtaining regulatory approval for the sale of our product candidates, including brincidofovir, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A

failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

We have completed a Phase 2 clinical study of brincidofovir for the prevention of CMV infection in HCT patients and recently completed an exploratory Phase 2 study of brincidofovir as preemptive therapy for adenovirus (AdV) infection in HCT recipients. In addition, we have completed an initial Phase 1 study with CMX157. However, we have never conducted a pivotal Phase 3 clinical trial. The positive results we have seen to date in our Phase 2 clinical trial of brincidofovir for the prevention of CMV in HCT patients do not ensure that later clinical trials, such as our currently enrolling Phase 3 SUPPRESS trial and any additional Phase 3 clinical trials, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through preclinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during, or as a result of, clinical trials for our product candidates, including brincidofovir, that could adversely affect the completion of our clinical trials, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- the cost of clinical trials of our product candidates may be greater than we anticipate; the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Negative or inconclusive results of our Phase 3 clinical trial of brincidofovir, which we refer to as SUPPRESS, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for brincidofovir, we do not know whether SUPPRESS or any other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates, including brincidofovir. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates, including brincidofovir, may be adversely impacted.

***We are developing brincidofovir to treat patients who are extremely ill, and patient deaths that occur in our clinical trials could negatively impact our business even if they are not shown to be related to brincidofovir.***

We are developing our lead product candidate, brincidofovir, for the prevention of CMV infection in HCT recipients and have initiated dosing in the Phase 3 SUPPRESS for the prevention of CMV in high-risk HCT patients. These patients receive HCT as a potential cure or remission for many cancers and genetic disorders.

To prepare for their transplant, such patients receive a pre-transplant conditioning regimen, which involves high-dose chemotherapy and may also include radiation therapy. The conditioning regimen suppresses the patient's immune system and/or own bone marrow in order to prevent it from attacking the newly transplanted cells. Generally, patients remain at high risk during the first 100 days following their transplant and can readily acquire infections during that period, which can be serious and even life threatening due to their weakened immune systems. As a result, it is likely that we will observe severe adverse outcomes during our Phase 3 trial for brincidofovir, including patient death. If a significant number of study subject deaths were to occur, regardless of whether such deaths are attributable to brincidofovir, our ability to obtain regulatory approval for brincidofovir may be adversely impacted and our business could be materially harmed.

***Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.***

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all.

Events which may result in a delay or unsuccessful completion of clinical trials, including our Phase 3 clinical trial for brincidofovir, include:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (CROs) and clinical trial sites;
  - delays in obtaining required institutional review board approval at each site;
  - delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
  - delays caused by subjects dropping out of a trial due to side effects or otherwise;
    - clinical sites dropping out of a trial to the detriment of enrollment;
    - time required to add new clinical sites; and
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

For example, due to the specialized indication and patient population being studied in our Phase 3 clinical trial of brincidofovir, the number of study sites available to us is relatively limited, and therefore enrollment of suitable patients to participate in the trial may take longer than is typical for studies involving other indications. This may result in a delay or unsuccessful completion of our Phase 3 clinical trial of brincidofovir. If initiation or completion of any of our clinical trials for our product candidates, including our Phase 3 clinical trial of brincidofovir, are delayed for any of the above reasons, our development costs may increase, our approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

***Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.***

Adverse events (AEs) caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. For example, some subjects enrolled in our Phase 2 clinical trials for brincidofovir reported gastrointestinal and liver-related AEs and safety laboratory value changes. Furthermore, brincidofovir is related to the approved drug cidofovir (CDV), a compound which has been shown to result in significant renal toxicity and impairment following use. There is also a risk that our other product candidates may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in our clinical trials for our product candidates, our ability to obtain regulatory approval for product candidates, including brincidofovir, may be negatively impacted.

Furthermore, if any of our approved products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified risk evaluation and mitigation strategy (REMS);

- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
  - we could be sued and held liable for harm caused to patients; and
  - our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

***After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize brincidofovir and we cannot, therefore, predict the timing of any future revenue from brincidofovir.***

We cannot commercialize our product candidates, including brincidofovir, until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for brincidofovir. Additional delays may result if brincidofovir is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates, including brincidofovir.

*Even if we obtain regulatory approval for brincidofovir and our other product candidates, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.*

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, including brincidofovir, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the labeling ultimately approved for our product candidates, including brincidofovir, will likely include restrictions on use due to the specific patient population and manner of use in which the drug was evaluated and the safety and efficacy data obtained in those evaluations. In addition, the label for brincidofovir may be required to include a boxed warning, or “black box,” regarding brincidofovir being carcinogenic, teratogenic and impairing fertility in animal studies, as well as a contraindication in patients who have had a demonstrated clinically significant hypersensitivity reaction to brincidofovir or CDV or any component of the formulation. The brincidofovir labeling may also include warnings or black boxes pertaining to gastrointestinal or liver-related AEs or safety laboratory value changes.

Brincidofovir and our other product candidates will also be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval, the pathway we are pursuing for an initial marketing approval of brincidofovir in the United States. In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP), and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of our product candidate, a regulatory agency may:

- issue an untitled or warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
  - suspend or withdraw regulatory approval;
  - suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
  - recall and/or seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize brincidofovir and our other product candidates and inhibit our ability to generate revenues.

***Even if we obtain FDA approval for brincidofovir or any of our other products in the United States, we may never obtain approval for or commercialize brincidofovir or any of our other products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

***Our relationships with investigators, health care professionals, consultants, third-party payors, and customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***



Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any products for which we may obtain marketing approval. Our current business operations 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 research, market, sell and distribute our products that we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, but are not limited to, the following:

the federal healthcare anti-kickback statute which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

the federal civil and criminal false claims laws and civil monetary penalties, including civil whistleblower or qui tam actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, clearinghouses and healthcare providers;

the federal Food, Drug and Cosmetic Act (FDCA) which prohibits, among other things, the adulteration or misbranding of drugs and devices;

the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (collectively, the Health Care Reform Law), and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental 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; and state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities.

Efforts to ensure that our 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 may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they also may be subject to criminal, civil or administrative sanctions, including, but not limited to, exclusions from government funded healthcare programs, which could also materially affect our business.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for

limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, the Health Care Reform Law was enacted to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. New provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law.

Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

#### **Risks Related to Our Reliance on Third Parties**

*We rely on third-party manufacturers to produce our preclinical and clinical drug supplies, and we intend to rely on third parties to produce commercial supplies of any approved product candidates.*

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. In the past, we have relied on third-party manufacturers for supply of our preclinical and clinical drug supplies. We expect that in the future we will continue to rely on such manufacturers for drug supply that will be used in clinical trials of our product candidates, including brincidofovir, and for commercialization of any of our product candidates that receive regulatory approval.

Our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured our product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- failure to comply with cGMP and similar foreign standards;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
  - carrier disruptions or increased costs that are beyond our control; and
- failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays, failure to obtain regulatory approval or impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production.

***We rely on limited sources of supply for the drug component for our lead product candidate, brincidofovir, and any disruption in the chain of supply may cause delay in developing and commercializing brincidofovir.***

Manufacturers of drug components must meet certain FDA qualifications with respect to manufacturing standards. We have completed transferring the drug substance manufacturing process to our selected contractor that will produce the commercial supply of drug substance and drug product. At present, we have qualified only one firm as a supplier of drug substance and a separate firm as the supplier of drug product. If supply from either of our approved vendors is interrupted, there could be a significant disruption in commercial supply of brincidofovir. An alternative vendor would

need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of brincidofovir, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials for brincidofovir may be delayed, which could inhibit our ability to generate revenues.

***Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization of brincidofovir.***

We have validated the drug substance production process for brincidofovir at a manufacturer at a scale of 100 kg, and have validated the tablet manufacturing process at a 165 kg commercial scale.

However, we are currently conducting stability studies and analyses that may reveal previously unknown impurities which could require resolution in order to proceed with our planned clinical trials and obtain regulatory approval for the commercial marketing of brincidofovir. In the future, we may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical program and regulatory approval for brincidofovir, increases in our operating expenses, or failure to obtain or maintain approval for brincidofovir.

***We depend on the continuation of our current collaboration with Merck, who is currently responsible for developing and commercializing CMX157.***

In July 2012, we entered into a collaboration and licensing arrangement with Merck, whereby Merck is responsible for the future development and commercialization of CMX157. Under this arrangement, Merck is responsible for conducting preclinical studies and clinical trials, obtaining required regulatory approvals for CMX157, and manufacturing and commercializing CMX157. Our right to receive milestone and royalty payments under the licensing agreement depends on the achievement of certain development, regulatory and commercial milestones by Merck.

The development and commercialization of CMX157 and our ability to receive potential milestone and royalty payments under the license agreement with Merck, would be adversely affected if Merck:

- does not devote sufficient time and resources to the development and commercialization of CMX157;
    - develops, either alone or with others, products that compete with CMX157;
    - fails to gain the requisite regulatory approvals for CMX157;
    - does not successfully commercialize CMX157;
    - does not conduct its activities in a timely manner;
- terminates its collaboration with us (which it is entitled to do at any time on 90 days written notice or, in certain circumstances, immediately upon written notice);
- disputes our respective allocations of rights to CMX157 or technology developed during our collaboration;
    - does not effectively pursue and enforce intellectual property rights relating to CMX157; or
    - merges with a third-party that wants to terminate the collaboration.

We have limited or no control over the occurrence of any of the foregoing. Furthermore, disagreements with Merck could lead to litigation or arbitration, which would be time-consuming and expensive. If any of these issues arise, it may delay the development and commercialization of CMX157 and, ultimately, impair our ability to generate revenues from regulatory and commercialization milestones and royalties based on further development and sales of CMX157.

***We rely on third parties to conduct, supervise and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.***

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical programs for brincidofovir and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of these responsibilities.

We and our CROs are required to comply with the FDA's guidance, which follows the International Conference on Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. For example, upon inspection, the FDA may determine that our Phase 3 clinical trial for brincidofovir, SUPPRESS, does not comply with the ICH GCP. In addition, our Phase 3 clinical trials for brincidofovir will require a sufficiently large number of test subjects to

evaluate the safety and effectiveness of brincidofovir. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat these Phase 3 clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize brincidofovir or our other product candidates. As a result, our financial results and the commercial prospects for brincidofovir and any other product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

#### **Risks Related to Commercialization of Our Product Candidates**

*The commercial success of brincidofovir and our other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients and health care payors.*

If any of our product candidates, including brincidofovir, receive marketing approval, they may nonetheless not gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, product uptake and/or market penetration, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates, including brincidofovir, will depend on a number of factors, including:

- demonstration of clinical safety and efficacy in our clinical trials;
- relative convenience, ease of administration and acceptance by physicians, patients and health care payors;

- prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved label for the relevant product candidate;
- availability of alternative treatments;
- market access and reimbursement levels;
- sufficient financial and human resources to effectively commercialize the product;
- effectiveness of our or any future collaborators' sales and marketing strategies; and

• ability to obtain and maintain sufficient third-party coverage or reimbursement, which may vary from country to country.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.***

We currently do not have a fully developed organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, including brincidofovir, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We may enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States, including for brincidofovir. We intend to build our own sales force and to commercialize brincidofovir, but we will also consider the option to enter into strategic partnerships for our product candidates in the United States.

Our strategy for brincidofovir is to develop a hospital-directed sales force and/or collaborate with third parties to promote the product to healthcare professionals and third-party payors in the United States. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates to healthcare professionals and in geographical regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales, including sales of brincidofovir, will be adversely affected.

Building an internal sales force involves many challenges, including:

- recruiting and retaining talented people;
- training employees that we recruit;
- setting the appropriate system of incentives;
- managing additional headcount; and
- integrating a new business unit into an existing corporate architecture.



If we are unable to build our own sales force or negotiate a strategic partnership for the commercialization of brincidofovir in the United States, we may be forced to delay the potential commercialization of brincidofovir, reduce the scope of our sales or marketing activities for brincidofovir or undertake the commercialization activities for brincidofovir at our own expense. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring brincidofovir to market or generate product revenue.

If we are unable to establish a commercial infrastructure or develop appropriate strategic partnerships,, we may be forced to delay the potential commercialization of brincidofovir. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring brincidofovir to market or generate product revenue.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

***If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market those product candidates outside the United States, including for brincidofovir. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
  - compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
  - foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we will need to comply. Many U.S.-based biopharmaceutical companies have found the process of marketing their own products in Europe to be very challenging.

***We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.***

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions.

Currently the only indicated antiviral treatment for CMV in HCT patients is Cytovene® (ganciclovir), although other antivirals, such as Valcyte® (valganciclovir), Foscavir® (foscarnet), Zovirax® (acyclovir) and Vistide® (cidofovir) are used. Ganciclovir, foscarnet and cidofovir are currently generically available and we expect Valcyte to become generically available in the near-term. We are aware of several companies that are working specifically to develop drugs that would compete against brincidofovir for the prevention or treatment of CMV, including Merck's development of letermovir, ViroPharma Incorporated's development of maribavir and Vical Incorporated's and Astellas Pharma US, Inc.'s development of ASP0113 (TransVax). Many of our competitors have substantially greater financial, technical, commercial and other resources, such as larger research and development staff, stronger intellectual property portfolios and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, drug products that are more effective or less costly than brincidofovir or any other drug candidate that we are currently developing or that we may develop.

We will face competition from other drugs currently approved or that will be approved in the future for the same indications. Therefore, our ability to compete successfully will depend largely on our ability to:

- discover and develop medicines that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates, including brincidofovir, are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
  - obtain required regulatory approvals;
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines; and
- negotiate market access and reimbursement with third-party payors.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for brincidofovir and any other product candidate we develop. We will not achieve our business plan if the acceptance of brincidofovir is inhibited by reimbursement or access issues, or the reluctance of physicians to switch from existing drug products to brincidofovir, or if physicians switch to other new drug products or choose to reserve brincidofovir for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may take steps to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates, including brincidofovir, less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business.

***Market access and reimbursement may not be available for brincidofovir and our other product candidates, which could make it difficult for us to sell our products profitably.***

Market acceptance and sales of brincidofovir, or any other product candidates that we develop, will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. We cannot be sure that reimbursement will be available for brincidofovir, or any other product candidates.

Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize brincidofovir, or any other product candidates that we develop.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell any future products profitably. These legislative and regulatory changes may negatively impact the reimbursement for any future products, following approval. The availability of generic treatments may also substantially reduce the likelihood of reimbursement for any future products, including brincidofovir. The application of user fees to generic drug products will likely expedite the approval of additional generic drug treatments. We expect to experience pricing pressures in connection with the sale of brincidofovir and any other product candidate that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes.

In addition, there may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often

rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for any of our product candidates, including brincidofovir, could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or other indications that later prove to have greater commercial potential.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology or that of our collaboration partners may be unsuccessful in identifying potential product candidates;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- our collaboration partners may change their development profiles for potential product candidates or abandon a therapeutic area.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our research efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights.

## **Risks Related to Our Intellectual Property**

*If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.*

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products in the United States or in other countries. If this were to occur, early generic competition could be expected against brincidofovir, CMX157 and other product candidates in development. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability, scope or ownership, which may result in such patents, or our rights to such patents, being narrowed or invalidated.

Furthermore, even if they are unchallenged, our patents and patent applications, may not adequately protect our intellectual property or prevent others from designing around our claims. If the patent applications we hold or license with respect to brincidofovir and CMX157 fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found not invalid and not unenforceable, will go unthreatened by third parties or will adequately protect our products and product candidates. Further, if we encounter delays in regulatory approvals, the period of time during which we could market brincidofovir and CMX157 under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to brincidofovir, CMX157 or our other product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be possible.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will

not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Further, the laws of some foreign countries do not protect patents and other proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad. We may also fail to pursue or obtain patents and other intellectual property protection relating to our products and product candidates in all foreign countries.

Finally, certain of our activities and our licensors' activities have been funded, and may in the future be funded, by the U.S. federal government. When new technologies are developed with U.S. federal government funding, the government obtains certain rights in any resulting patents, including a nonexclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications, and our rights in such inventions may be subject to certain requirements to manufacture products in the United States.

***Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts or otherwise affect our business.***

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of brincidofovir and CMX157 and/or our other product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. In addition, we may be subject to claims that we are infringing other intellectual property rights, such as trademarks or copyrights, or misappropriating the trade secrets of others, and to the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

***We license certain key intellectual property from third parties, and the loss of our license rights could have a materially adverse effect on our business.***



We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents, proprietary technology and know-how from The Regents of the University of California (UC), which we believe cover brincidofovir and CMX157. If we fail to comply with our obligations under our agreement with UC or our other license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the UC license, brincidofovir and CMX157, which would have a materially adverse effect on our business.

***We may be involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter-claims against us.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in a litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process.

While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors that control the prosecution and maintenance of our licensed patents fail to maintain the patents and patent applications covering our product candidates, we may lose our rights and our competitors might be able to enter the market, which would have a material adverse effect on our business.

#### **Risks Related to Our United States Government Contracts and Grants**

***All of our immediately foreseeable future revenues to fund the development of brincidofovir for the treatment of smallpox are dependent upon our contract with the Biomedical Advanced Research and Development Authority (BARDA), and if we do not receive all of the funds under the BARDA contract, we anticipate that we will suspend or terminate our smallpox program.***

Substantially all of our revenues that fund the development of brincidofovir for the treatment of smallpox have been derived from prior government grants and our current contract with BARDA. Our contract with BARDA is for the development of brincidofovir for the treatment of smallpox. It is divided into a base segment and four option segments. We completed performance under the base segment of the contract in May 2013 and are currently performing under the first option segment of the contract. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at our discretion. There can be no assurance that we will reach agreement with BARDA on the most appropriate development pathway or that the FDA will ultimately agree with the experiments which we perform or the appropriateness of the results of these experiments for approval of brincidofovir for smallpox. In addition, there can be no assurance that any of the subsequent option segments will be exercised or that we will continue to receive revenues under this contract once the current option segment is completed. We do not anticipate continuing this program without ongoing support from BARDA.

Additionally, the contract provides for reimbursement of the costs of the development of brincidofovir for the treatment of smallpox that are allowable under the Federal Acquisition Regulation (FAR), plus the payment of a fixed fee. It does not include the manufacture of brincidofovir for the Strategic National Stockpile. There can be no assurances that this contract will continue, that BARDA will extend the contract for additional option segments, that any such extension would be on favorable terms, or that we will be able to enter into new contracts with the United States government to support our smallpox program. Changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the discovery and development of brincidofovir for the treatment of smallpox. In such event, BARDA is not required to continue funding our existing contract. Any such reduction in our revenues from BARDA or any other government contract could materially adversely affect our financial condition and results of operations. In addition, if we do not receive all of the funds under the BARDA contract, we anticipate that we will suspend or terminate our program for the development of brincidofovir for the treatment of smallpox.

***Unfavorable provisions in government contracts, including our contract with BARDA, may harm our business, financial condition and operating results.***

United States government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our contract with BARDA, the U.S. government has the power to unilaterally:

- audit and object to any BARDA contract-related costs and fees on grounds that they are not allowable under the FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or extending our existing contract based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA contract and may, under certain circumstances, such as circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA contract based on violations or suspected violations of laws or regulations;
- terminate our BARDA contract in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the applicable governmental agency;
  - reduce the scope and value of our BARDA contract;
  - decline to exercise an option to continue the BARDA contract;
- direct the course of a development program in a manner not chosen by the government contractor;

require us to perform the option segments even if doing so may cause us to forego or delay the pursuit of other opportunities with greater commercial potential;

- take actions that result in a longer development timeline than expected; and
- change certain terms and conditions in our BARDA contract.

The U.S. government also has the right to terminate the BARDA contract if termination is in the government's interest, or if we default by failing to perform in accordance with the milestones set forth in the contract.

Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed (plus a portion of the agreed fee) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees.

In addition, we must comply with numerous laws and regulations that affect how we conduct business with the United States government. Among the most significant government contracting regulations that affect our business are:

FAR, and agency-specific regulations supplements to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts and implement federal procurement policy in numerous areas, such as employment practices, protection of the environment, accuracy and retention periods of records, recording and charging of costs, treatment of laboratory animals and human subject research; business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act;

- export and import control laws and regulations; and

laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Furthermore, we may be required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors, in order to satisfy our contractual obligations pursuant to our agreements with the U.S. government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our government contract. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our contract.

As a result of these unfavorable provisions, we must undertake significant compliance activities. The diversion of resources from commercial programs to these compliance activities, as well as the exercise by the U.S. government of any rights under these provisions, could materially harm our business.

***Our business is subject to audit by the U.S. government, including under our contract with BARDA, and a negative audit could adversely affect our business.***

United States government agencies, such as the Department of Health and Human Services (DHHS), routinely audit and investigate government contractors and recipients of federal grants, including our contract with BARDA. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DHHS can also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded. If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us by the U.S. government, which could adversely affect our business.

*Agreements with government agencies may lead to claims against us under the Federal False Claims Act, and these claims could result in substantial fines and other penalties.*

The biopharmaceutical industry is, and in recent years has been, under heightened scrutiny as the subject of government investigations and enforcement actions. Our BARDA contract is subject to substantial financial penalties under the Federal Civil Monetary Penalties Act and the Federal Civil False Claims Act (False Claims Act). The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false record or statement material to a false or fraudulent claim paid or approved by the government. Under the False Claims Act's "whistleblower" provisions, private enforcement of fraud claims against businesses on behalf of the U.S. government has increased due in part to amendments to the False Claims Act that encourage private individuals to sue on behalf of the government. These whistleblower suits, known as qui tam actions, may be filed by private individuals, including present and former employees. The False Claims Act provides for treble damages and up to \$11,000 per false claim. If our operations are found to be in violation of any of these laws, or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment, or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

## **Risks Related to Our Business Operations and Industry**

*Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.*

We are highly dependent on the principal members of our executive team. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. We do not maintain "key person" insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. In addition, failure of any of our clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee may adversely affect the progress of our research, development and commercialization objectives.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by

employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

***We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.\****

As of December 31, 2013, we had 52 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize brincidofovir and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

***Potential product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.***

The use of our product candidates, including brincidofovir, in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- withdrawal of participants from our clinical studies;
- significant costs to defend the related litigation and related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize our product candidates, including brincidofovir; and
- decreased demand for our product candidates, if approved for commercial sale.

We currently carry \$10.0 million in product liability insurance covering our clinical trials. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.



## Risk Related To Our Common Stock

*The market price of our common stock is likely to be volatile, and you may not be able to resell your shares at or above your purchase price.*

Prior to our recently completed IPO, there was no public market for our common stock. The trading price of our common stock is likely to be volatile for the foreseeable future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- results of clinical trials of our product candidates or those of our competitors;
- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA’s review of that NDA;
- failure to successfully develop and commercialize our product candidates, including brincidofovir;
  - termination of any of our license or collaboration agreements;
  - inability to obtain additional funding;
- regulatory or legal developments in the United States and other countries applicable to our product candidates;
  - adverse regulatory decisions;
  - changes in the structure of healthcare payment systems;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
  - introduction of new products, services or technologies by our competitors;
  - failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
  - changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts’ reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- significant lawsuits (including patent or stockholder litigation), and disputes or other developments relating to proprietary rights (including patents, litigation matters and our ability to obtain patent protection for our technologies);
  - additions or departures of key scientific or management personnel;
  - sales of our common stock by us or our stockholders in the future;
    - trading volume of our common stock;
  - general economic, industry and market conditions; and
  - the other factors described in this “Risk Factors” section.

In addition, the stock market in general, and The Nasdaq Global Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Based upon shares of common stock outstanding as of December 31, 2013, and after giving effect to the sale of shares by certain of our stockholders in our recently completed secondary public offering, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 43.7% of our voting stock. Therefore, these stockholders have the ability to substantially influence us through this ownership position. For example, these stockholders, if they choose to act together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

***We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including exemption from compliance with the management report on internal control and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in the Company’s final prospectus filed with the Securities and Exchange Commission on April 10, 2013 and our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (a) December 31, 2018, (b) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (d) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

***The requirements of being a public company may strain our resources and divert management's attention.***

As a public company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and The Nasdaq Global Market have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits smaller “emerging growth companies” to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our 2013 Equity Incentive Plan (the 2013 Plan), our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2013 Plan will automatically increase on January 1st each year, from January 1, 2014 through January 1, 2023, by an amount equal to 2.5% of all shares of our capital stock outstanding as of December 31<sup>st</sup> of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. In addition, our board of directors may grant or provide for the grant of rights to purchase shares of our common stock pursuant to the terms of our 2013 Employee Stock Purchase Plan (ESPP). The number of shares of our common stock reserved for issuance under our ESPP will automatically increase on January 1st each year, from January 1, 2014 through January 1, 2023, by an amount equal to the lesser of 422,535 shares or one percent of all shares of our capital stock outstanding as of December 31<sup>st</sup> of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our 2013 Plan and ESPP each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

***We have broad discretion in the use of the net proceeds from our IPO and may not use them effectively.***

Our management has broad discretion in the application of the net proceeds from our IPO. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we have invested the net proceeds from our IPO in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

***Volatility in our stock price could subject us to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.***

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. We have determined that a Section 382 ownership change occurred in 2002 and 2007 resulting in limitations of at least \$64,000 and \$762,000, respectively, of losses incurred prior to the respective ownership change dates. In addition, we have determined that another Section 382 ownership change occurred in 2013 with our initial public offering, our most recent private placement and other transactions that have occurred since 2007, resulting in a limitation of at least \$6.7 million of losses incurred prior to the ownership change date. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.***

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

***Provisions in our corporate charter documents and under Delaware law could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders and may prevent attempts by our stockholders to replace or remove our current management.***

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;

- allowing the authorized number of our directors to be changed only by resolution of our board of directors;

- limiting the removal of directors;
  - creating a staggered board of directors;
- requiring that stockholder actions must be effected at a duly called stockholder meeting and prohibiting stockholder actions by written consent;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at duly called stockholder meetings.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock.

These provisions may frustrate 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 are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our corporate headquarters are located at 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713 in a facility we lease encompassing approximately 14,500 square feet of office space. The leases for this facility expire in February 2015 and 2018. We separately lease an additional 4,600 square feet of laboratory space in Durham, North Carolina. The lease for this facility expires in June 2014.

**ITEM 3. LEGAL PROCEEDINGS.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

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**PART II**

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

**Market Information**

Our common stock began trading on The NASDAQ Global Market on April 11, 2013 under the symbol “CMRX.” Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the period indicated. Such quotations represent inter-dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions.

Year Ended December 31, 2013	High	Low
Second Quarter (beginning April 11, 2013)	\$25.10	\$15.11
Third Quarter	\$27.00	\$15.31
Fourth Quarter	\$22.50	\$12.96

**Comparative Stock Performance Graph**

The following graph shows a comparison from April 11, 2013 through December 31, 2013 of the cumulative total return for our common stock, the NASDAQ Biotechnology Index (NBI) and the NASDAQ Composite Index (CCMP). The graph assumes an initial investment of \$100 on April 11, 2013. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.

**Comparison of Cumulative Total Return\* Among Chimerix, Inc.,  
the NASDAQ Biotechnology Index and the NASDAQ Composite Index**

(1) This section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

(2) \* \$100 invested on 4/11/2013 in stock or index.



### **Stockholders**

As of December 31, 2013, there were 59 stockholders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

### **Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

The following table provides certain information with respect to all of our equity compensation plans in effect as of December 31, 2013.

### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	* Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)	
Equity compensation plans approved by security holders	1,946,823	\$3.54	2,386,157	(1)
Equity compensation plans not approved by security holders	n/a	n/a	n/a	
Total	1,946,823	\$3.54	2,386,157	(1)

(1) Of the 2,386,157 shares available for issuance, 704,225 were reserved for issuance under our 2013 Employee Stock Purchase Plan.

### Recent Sales of Unregistered Securities

None.

### Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

### Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered securities during the period covered by this Annual Report.

### ITEM 6. SELECTED FINANCIAL DATA.

The following selected financial data should be read together with our financial statements and related notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the related notes. Our historical results are not necessarily indicative of the results that may be expected in the future.

We derived the following selected statement of operations data for the years ended December 31, 2013, 2012, 2011, and 2010 and the selected balance sheet data as of December 31, 2013 and 2012 from our audited financial statements and related notes appearing elsewhere in this Form 10-K.

	Year ended December 31,			
	2013	2012	2011	2010
<b>Statement of Operations:</b>				
<b>Revenues:</b>				
Contract revenue	\$4,370	\$16,275	\$12,046	\$1,715
Collaboration and licensing revenues	—	17,445	55	—
<b>Total revenues</b>	<b>4,370</b>	<b>33,720</b>	<b>12,101</b>	<b>1,715</b>
<b>Operating expenses:</b>				
Research and development	24,662	30,106	30,108	21,074
General and administrative	8,327	6,397	6,985	5,945
<b>Total operating expenses</b>	<b>32,989</b>	<b>36,503</b>	<b>37,093</b>	<b>27,019</b>
Loss from operations	(28,619 )	(2,783 )	(24,992 )	(25,304 )
<b>Other income (expense):</b>				
Interest expense, net	(1,232 )	(776 )	(212 )	(154 )
Fair value adjustments to warrant liability	(6,590 )	(847 )	(385 )	—
Loss on disposal	(4 )	—	—	1
<b>Net loss</b>	<b>(36,445 )</b>	<b>(4,406 )</b>	<b>(25,589 )</b>	<b>(25,457 )</b>
Accretion of redeemable convertible preferred stock	(34,108 )	(4,357 )	(9,565 )	—
<b>Net loss attributable to common shareholders</b>	<b>\$(70,553 )</b>	<b>(8,763 )</b>	<b>(35,154 )</b>	<b>(25,457 )</b>
<b>Net loss per share, basic and diluted</b>	<b>\$(3.65 )</b>	<b>\$(5.75 )</b>	<b>\$(23.49 )</b>	<b>\$(17.52 )</b>
<b>Weighted average shares outstanding, basic and diluted</b>	<b>19,307,422</b>	<b>1,524,628</b>	<b>1,496,262</b>	<b>1,452,877</b>
<b>Balance Sheet Data</b>				
Cash and cash equivalents	\$109,976	\$19,906	\$13,607	\$3,306
Short-term investments, available-for-sale	—	9,849	5,918	—
Working capital	102,802	23,931	18,010	(2,460 )
Total assets	113,387	32,031	25,432	5,018
Loan payable-short-term <sup>(1)</sup>	5,573	4,753	160	1,965

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Loan payable-long-term <sup>(1)</sup>	4,294	9,867	2,441	2,601
Redeemable convertible preferred stock warrant liability	—	7,512	6,491	—
Redeemable convertible preferred stock	—	107,723	103,366	55,132
Accumulated deficit	(162,730)	(101,032)	(93,678 )	(61,504)
Total stockholders' equity (deficit)	98,539	(101,031)	(93,680 )	(59,607)

(1) Loan payable is net of debt discount.

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

*The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this Annual Report. You should carefully read the "Risk Factors" section of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Forward-Looking Statements."*

### **Overview**

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals to address unmet medical needs. We were founded in 2000 based on the promise of our proprietary lipid technology to unlock the potential of some of the most potent antivirals by enhancing their antiviral activity and safety profiles in convenient, orally administered dosing regimens. Based on our lipid technology, our lead compound, brincidofovir (CMX001) is in Phase 3 clinical development, our second compound, CMX157, was licensed to Merck after completing a Phase 1 study and we have an active discovery program focusing on viral targets for which no therapies are currently available.

To date, we have devoted substantially all of our resources to our research and development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through December 31, 2013, we have funded our operations primarily through:

- our IPO generating net proceeds of approximately \$107.6 million after deducting underwriting discounts, commissions and offering expenses;
- the private placement of preferred stock, common stock, and warrants to purchase preferred stock totaling \$100.4 million;
- the receipt of government grants and contracts totaling approximately \$70.2 million;
- the receipt of \$21.0 million in loan proceeds from financial institutions; and
- the receipt of \$17.5 million of up-front proceeds under our collaboration and license agreement with Merck.

We have incurred net losses in each year since our inception in 2000. Our net losses were approximately \$36.4 million, \$4.4 million, and \$25.6 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of approximately \$162.7 million. Substantially all our net losses

resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

• continue the development of our lead product candidate, brincidofovir, for the prevention of CMV infection in transplant recipients;

- seek to obtain regulatory approvals for brincidofovir;
- prepare for the potential commercialization of brincidofovir;

• scale up manufacturing capabilities to commercialize brincidofovir for any indications for which we receive regulatory approval;

• begin outsourcing of the commercial manufacturing of brincidofovir for any indications for which we receive regulatory approval;

• establish an infrastructure for the sales, marketing and distribution of brincidofovir for any indications for which we receive regulatory approval;

- expand our research and development activities and advance our clinical programs;
- maintain, expand and protect our intellectual property portfolio;
- continue our research and development efforts and seek to discover additional product candidates; and

• add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital prior to the commercialization of brincidofovir or any of our other product candidates. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. Failure to receive additional funding could cause us to cease operations, in part or in full.

## **Financial Overview**

### ***Revenues***

To date, we have not generated any revenue from product sales. All of our revenue to date has been derived from government grants and contracts and the receipt of up-front proceeds under our collaboration and license agreement with Merck.

In February 2011, we entered into a contract with BARDA, a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods of approximately one year each, referred to as option segments. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at Chimerix's discretion. The contract is a cost plus fixed fee development contract. Under the contract as currently in effect, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees. In June 2013, we began performing under the first option segment of the contract during which we may receive up to a total of \$5.3 million in expense reimbursement and fees, which is planned to end on May 31, 2014. As of December 31, 2013, we had recognized revenue in aggregate of \$32.7 million with respect to the base performance segment and first extension period.

In July 2012, we entered into a collaboration and license agreement granting Merck exclusive worldwide rights to CMX157, our oral nucleotide compound currently being evaluated to treat HIV infection. Under the terms of the agreement, Merck receives an exclusive worldwide license for any human use of CMX157 and is responsible for future development and commercialization of CMX157. Following execution of the agreement, we received a \$17.5 million upfront payment. In addition, we are eligible to receive payments up to \$151.0 million upon the achievement of certain development and regulatory milestones, as well as tiered royalties on net sales escalating from high single digit to low double digits based on the volume of sales. Such royalties continue through the later of expiration of our patent rights or ten years from the first commercial sale on a country-by-country basis.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and royalties from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestone and other payments, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

### ***Research and Development Expenses***

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses, which include stock option compensation and benefits, for personnel in research and development functions;
- fees paid to consultants and contract research organizations (CROs), including in connection with our preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- payments to third-party manufacturers, which produce, test and package our drug substance and drug product (including continued testing of process validation and stability);
- costs related to legal and compliance with regulatory requirements; and
- license fees for and milestone payments related to licensed products and technologies.

From our inception through December 31, 2013, we have incurred approximately \$153.6 million in research and development expenses, of which \$121.9 million relates to our development of brincidofovir. We plan to increase our research and development expenses for the foreseeable future as we continue development of brincidofovir for the prevention of CMV infection in HCT recipients and other indications and to advance further the development of our other product candidates, subject to the availability of additional funding.

The table below summarizes our research and development expenses for the periods indicated. Our direct research and development expenses consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, preclinical development, and payments to third-party manufacturers of drug substance and drug product. We typically use our employee and infrastructure resources across multiple research and development programs.



	Years Ended December 31,		
	2013	2012	2011
	(in thousands)		
Direct research and development expense	\$13,185	\$22,013	\$21,794
Personnel costs	9,344	5,914	5,480
Indirect research and development expense	2,133	2,179	2,834
	\$24,662	\$30,106	\$30,108

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with the development of our product candidates, including:

- the uncertainty of the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- the potential benefits of our candidates over other therapies;
- the ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;
- the results of future clinical trials;
- the timing and receipt of any regulatory approvals; and
- the filing, prosecuting, defending and enforcing of patent claims and other intellectual property rights, and the expense of doing so.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate in the United States, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that product candidate.

#### *Brincidofovir*

The majority of our research and development resources are currently focused on our brincidofovir Phase 3 clinical trial, SUPPRESS, and our other planned clinical and preclinical studies and other work needed to provide sufficient data supporting the safety, tolerability and efficacy of brincidofovir for accelerated approval in the United States and equivalent health authority approval in Canada and key European countries. We have incurred significant expense in connection with these efforts, including expenses related to:

- Phase 2 clinical testing of brincidofovir, our compassionate use and early-IND programs,

- manufacturing to produce, test and package our drug substance and drug product for brincidofovir; and
  - initiation, enrollment, and conduct of our Phase 3 clinical trial, SUPPRESS.

We expect to incur significant expenses related to:

- manufacturing to produce, test and package our drug substance and drug product for brincidofovir; and
  - initiation, enrollment, and conduct of our Phase 3 clinical trial, SUPPRESS.

In addition, pursuant to our contract with BARDA, we are evaluating brincidofovir for the treatment of smallpox. During the base performance segment of the contract, we incurred significant expense in connection with the development of orthopox virus animal models, the demonstration of efficacy and pharmacokinetics of brincidofovir in the animal models, the conduct of an open label clinical safety study for subjects with DNA viral infections, and the manufacture and process validation of bulk drug substance and brincidofovir 100 mg tablets.

#### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, corporate development, human resources, information technology, legal and administrative support functions, including stock-based compensation expenses and benefits. Other significant general and administrative expenses include accounting and legal services, expenses associated with obtaining and maintaining patents, cost of various consultants, occupancy costs and information systems.

We expect that our general and administrative expenses will continue to increase as we operate as a public company and due to the potential commercialization of our product candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur increased costs to comply with corporate governance, internal controls, investor relations and disclosures, and similar requirements applicable to public companies.

#### ***Interest Income (Expense), Net***

Interest income consists of interest earned on our cash, cash equivalents and short-term investments.

Interest expense consists primarily of interest accrued or paid on amounts outstanding under our Loan and Security Agreement (LSA) with Silicon Valley Bank (SVB) and MidCap Financial SBIC, LP (MidCap).

### ***Revaluation of Warrants***

In conjunction with various financing transactions, we issued warrants to purchase shares of our preferred and common stock. The underlying security of the warrants related to the Series F financing and to our term loan was redeemable at the option of the security holder. As a result, these warrants were classified as a liability and were marked-to-market at each reporting date. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and are based, in part, on subjective assumptions. Non-cash changes in the fair value of the warrant liability were recorded as fair value adjustments to warrant liability. The final revaluation of the warrants occurred immediately prior to the IPO. Upon the IPO these warrants converted into warrants for common stock and therefore no longer require revaluation.

### ***Stock-based Compensation***

The Financial Accounting Standards Board (FASB) authoritative guidance requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Total consolidated stock-based compensation expense of \$3.1 million, \$1.4 million and \$966,000 was recognized in the years ended December 31, 2013, 2012 and 2011, respectively. The stock-based compensation expense recognized included expense from performance-based stock options and restricted stock units (RSUs).

Stock-based compensation expense is estimated, as of the grant date, based on the fair value of the award and is recognized as an expense over the requisite service period, which generally represents the vesting period. We estimate the fair value of our stock options using the Black-Scholes option-pricing model and the fair value of our stock awards based on the quoted market price of our common stock.

For performance-based stock options and performance-based RSUs, we begin to recognize the expense when it is deemed probable that the performance-based goal will be met. We evaluate the probability of achieving performance-based goals on a quarterly basis.

Equity instruments issued to non-employees are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our audited financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate these estimates and judgments. We base our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates. In addition, our reported financial condition and results of operations could vary if new accounting standards are enacted that are applicable to our business.

Our significant accounting policies are described in Note 1 to our audited financial statements for the year ended December 31, 2013 included in this Annual Report. We believe that our accounting policies relating to revenue recognition, accrued expenses and stock-based compensation are the most critical to understanding and evaluating our reported financial results. We have identified these policies as critical because they both are important to the presentation of our financial condition and results of operations and require us to make judgments and estimates on matters that are inherently uncertain and may change in future periods. For more information regarding these policies, you should refer to Note 1 to our audited financial statements included in this Annual Report.

### ***Revenue Recognition***

We derive our revenues from two sources: contracts and grants, and collaborations and licensing. Contract and grant revenues are revenues generated pursuant to federal contracts and other awarded grants. Collaboration and licensing revenues are revenues related to license and collaboration agreements. We recognize revenue in accordance with the criteria outlined in the SEC's Topic 13 and Accounting Standards Codification (ASC) 605-25 and by the FASB. Following these accounting pronouncements, revenue is recognized when all four of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery of the products and/or services has occurred and risk of loss has passed; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has "stand-alone value" to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered. Revisions to the estimated period of recognition are reflected in revenue prospectively.

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied. 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.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive, (ii) there is no ongoing performance obligation related to the achievement of the milestone earned, and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with the achievement of the milestone. Contingent based event payments we may receive under a license or collaboration agreement will be recognized when received.

From our inception through December 31, 2013, we have not generated any revenue from product sales. For the same period, we have generated \$70.2 million in grant and contract revenue. We recognize revenue under government grants and contracts as qualifying research activities are conducted based on invoices received from company vendors. Any amounts received in advance of performance are recorded as deferred revenue until earned.

We entered into a collaboration and licensing agreement with Merck in July 2012. The agreement provides for various types of payments, including a \$17.5 million non-refundable upfront license fee, contingent event-based milestone payments and future royalties on net product sales. We recognized the upfront license fee payment from Merck as revenue for the year ended December 31, 2012, as our remaining performance obligations under the contract are not considered substantive. The contingent event-based payments pursuant to our agreement with Merck do not meet the definition of a milestone as achievement of the triggering event for such payments is based on the performance of Merck and not our performance. Therefore the milestone method will not be applied to any such payments. We did not recognize any revenue under this agreement for the year ended December 31, 2013.

### ***Clinical Trial Accruals***

As part of the process of preparing financial statements, we are required to estimate our expenses resulting from our obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical trial expense recognition if actual results differ from the estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. Through December 31, 2013, there had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

### *Valuation of Stock-Based Compensation*

We record the fair value of stock options issued to employees as of the grant date as compensation expense. We recognize compensation expense over the requisite service period, which is equal to the vesting period. For non-employees, we also record the fair value of stock options as of the grant date as compensation expense. We then periodically re-measure the awards to reflect the current fair value at each reporting period until the non-employee completes the performance obligation or the date on which a performance commitment is reached. Expense is recognized over the related service period.

Stock-based compensation expense includes stock options and RSUs granted to employees and stock options granted to non-employees and has been reported in our statements of operations as follows:

	Years Ended December 31,		
	2013	2012	2011
	(in thousands)		
Research and development			
Employee	\$ 1,905	\$ 336	\$ 315
Non-employee	67	80	—
General and administrative			
Employee	1,017	921	651
Non-employee	82	59	—
Total	\$ 3,071	\$ 1,396	\$ 966

We calculate the fair value of RSU based compensation based on the closing price of our Company's common stock on the date the RSU vests.

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and the fair value of the underlying common stock on the date of grant. In applying these assumptions, we considered the following factors:

We have limited operating history to estimate the volatility of our common stock price. We calculate expected volatility based on a blend of company specific historical data and a group of similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants.

- The assumed dividend yield is based on our expectation of not paying dividends for the foreseeable future. Prior to our IPO, we determined the average expected life of stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. We expect to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. We determine the risk-free interest rate by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant.

- We estimate forfeitures based on our historical analysis of actual stock option forfeitures.

The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2013, 2012, and 2011 are set forth below:

*Employee Stock Options*

	Years Ended December 31,		
	2013	2012	2011
Volatility	76.40%	80.55%	82.00%
Expected term (in years)	6.1	6.0	7.0
Risk-free interest rate	1.49 %	0.86 %	2.85 %
Expected dividend yield	0 %	0 %	0 %
Weighted average option value per share	\$2.52	\$1.93	\$1.74

*Non-employee Stock Options*

Years Ended  
December 31,

	2013	2012	2011
Volatility	79.69%	81.77%	77.80%
Expected term (in years)	4.2	5.8	2.7
Risk-free interest rate	1.30 %	0.78 %	0.40 %
Expected dividend yield	0 %	0 %	0 %
Weighted average option value per share	\$5.01	\$3.48	\$3.38

### *Common Stock Fair Value*

Prior to our IPO, the fair value of our common stock for purposes of determining the exercise price for stock option grants was determined on each grant date by our board of directors, or by a committee of our board of directors acting under delegated authority, with input from management. All options to purchase shares of our common stock were intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, determined in good faith and based on the information known to us on the date of grant. In the absence of a public trading market for our common stock prior to our IPO, on each grant date, our board of directors, or a committee of our board of directors acting under delegated authority, considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:



- external market conditions affecting the biotechnology industry;
- trends within the biotechnology industry;
- the prices at which we sold shares of preferred stock to third-party investors;
- the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- our results of operations, financial position, status of our research and development efforts, stage of development and business strategy;
- the lack of an active public market for our common and our preferred stock; and
- the likelihood of achieving a liquidity event in light of prevailing market conditions, such as an initial public offering or sale of our company.

Our board of directors, or a committee of our board of directors acting under delegated authority, also considered and relied upon appraisals of the value of our stock from an independent third-party valuation specialist who conducted a thorough analysis using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants (AICPA) Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation (AICPA Practice Guide). The independent third-party valuation specialist provided appraisals containing the valuation analyses to the fair value of our common stock.

For all grants of stock options made following the completion of our IPO in April 2013, we have determined, and will determine in the future, fair value based on the closing price of our common stock on the Nasdaq Global Market on the date of determination.

#### ***Fair Value Adjustments to Warrant Liability***

We issued warrants to purchase shares of our Series F preferred stock in connection with (i) a loan and security agreement entered into with SVB and MidCap in January 2012, and (ii) an equity financing agreement with certain investors for the sale of Series F preferred stock, which occurred in February 2011. As discussed in Note 2 to our audited financial statements for the year ending December 31, 2013 included in this Annual Report, the warrants to purchase shares of our Series F preferred stock were classified as a liability and are required to be measured at fair value for the year ending December 31, 2012. Upon completion of our IPO, these warrants were adjusted to a fair value of \$14.1 million. The warrant liability was reclassified as common stock warrants and therefore no longer requires revaluation for the year ending December 31, 2013.

The adjustment to the fair valuation of the warrants resulted in other expense of \$6.6 million, \$847,000 and \$385,000 for the year ended December 31, 2013, 2012 and 2011, respectively. The warrants were valued using a two stage process. Using a contingent claims model, the fair value of total equity and all components of our capital structure, including the warrants, was determined as of the time of our sale of Series F preferred stock. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporated both Monte Carlo and risk neutral frameworks. Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure including the warrants. Each warrant value was weighted by its respective probability to determine the final fair value of the warrants as of

December 31, 2012 and 2011. Upon completion of our IPO, all outstanding warrants to purchase redeemable convertible preferred stock were converted into common stock warrants and no longer required to be remeasured.

### **Utilization of Net Operating Loss Carryforwards**

At December 31, 2013, we had net operating loss carryforwards for federal and state tax purposes of approximately \$117.5 million and \$106 million, respectively. At December 31, 2012, we had net operating loss carryforwards for federal and state tax purposes of approximately \$83.6 million and \$65.8 million, respectively. In addition, we had tax credit carryforwards for federal tax purposes of approximately \$3.5 million as of December 31, 2013, which begin to expire in 2022. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. In general, if we experience a greater than 50% aggregate change in ownership of certain significant stockholders or groups over a three-year period (a Section 382 ownership change), utilization of our pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Code (and similar state laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the pre-change net operating loss carryforwards before utilization and may be substantial. We have determined that a Section 382 ownership change occurred in 2002 and 2007 resulting in limitations of at least \$64,000 and \$762,000, respectively, of losses incurred prior to the respective ownership change dates. In addition, we have determined that another Section 382 ownership change occurred in 2013 with our initial public offering, our most recent private placement and other transactions that have occurred since 2007, resulting in a limitation of at least \$6.7 million of losses incurred prior to the ownership change date. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

### **JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups (JOBS) Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an “emerging growth company,” we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier of (a) December 31, 2018, (b) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30<sup>th</sup>, and (d) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

## RESULTS OF OPERATIONS

### *Comparison of the Years Ended December 31, 2013 and December 31, 2012*

The following table summarizes our results of operations for the years ended December 31, 2013 and December 31, 2012, together with the changes in those items in dollars and percentage:

	Years ended December		Dollar Change	% Change	
	2013	2012	Increase/(Decrease)		
	(in thousands, except percentages)				
Revenues:					
Contract revenue	\$4,370	\$16,275	\$(11,905 )	(73.1 )	%
Collaboration and licensing revenue	-	17,445	(17,445 )	*	
Total revenues	4,370	33,720	(29,350 )	(87.0 )	%
Operating expenses:					
Research and development	24,662	30,106	(5,444 )	(18.1 )	%
General and administrative	8,327	6,397	1,930	30.2	%
Loss from operations	(28,619)	(2,783 )	25,836	928.4	%
Interest expense, net	(1,232 )	(776 )	456	58.8	%
Fair Value of warrant adjustment	(6,590 )	(847 )	5,743	678.0	%
Loss on disposal	(4 )	-	4	*	
Net loss	\$(36,445)	\$(4,406 )	\$ 32,039	727.2	%

\*Not meaningful or not calculable.

### ***Contract Revenue***

For the year ended December 31, 2013, contract revenue decreased to \$4.4 million compared to \$16.3 million for the year ended December 31, 2012. The decrease of \$11.9 million, or 73.1% was related to a decline in reimbursable expenses related to our contract with BARDA. During the year ended December 31, 2012, in connection with our performance under the base segment of the BARDA contract, we were fully engaged in clinical trials, drug product manufacturing and animal studies. For the year ended December 31, 2013, we completed performance of the base segment of the BARDA contract in May and commenced performance under the first option segment in June.

### ***Collaboration and Licensing Revenue***

For the year ended December 31, 2013, collaboration and licensing revenue decreased to zero compared to \$17.4 million for the year ended December 31, 2012. Collaboration and license fee revenue for the year ended December 31, 2012 consisted of revenue from an upfront license payment related to our collaboration and license arrangement with Merck for the exclusive rights to CMX157. The upfront license payment was fully recognized in the quarter in which execution of the definitive agreement took place. We did not have collaboration and license revenue during the year ended December 31, 2013.

### ***Research and Development Expenses***

For the year ended December 31, 2013, our research and development expenses decreased to \$24.7 million compared to \$30.1 million for the year ended December 31, 2012. The decrease of \$5.4 million, or 18.1%, was primarily related to the following:

- a decrease in clinical trial expenses of \$5.1 million related to the completion of multiple Phase 1 and Phase 2 clinical studies in the year ended December 31, 2012, combined with the fact that our activities associated with our Phase 3 SUPRESS trial were in start-up mode in 2013;
  - a decrease in consulting fees of \$1.4 million as we hired 4 additional employees in 2013;
  - a decrease in BARDA contracted work of \$1.3 million related to CMC validation and animal studies;
- a decrease in license fee expenses of \$875,000 due to the payment of fees to UCSD associated with the exclusive license of CMX157 to Merck in July 2012; and

offset by an increase in compensation expense of \$2.0 million due to the addition of 4 employees in 2013 and a full year of compensation for 7 employees who joined in the second half of 2012 and the one-time, non-cash stock compensation expense of \$1.4 million related to the vesting of RSUs upon completion of our IPO.

***General and Administrative Expenses***

For the year ended December 31, 2013, our general and administrative costs increased to \$8.3 million compared to \$6.4 million for the year ended December 31, 2012. The increase of \$1.9 million, or 30.2%, was related to the following:

- an increase in non-cash stock compensation for the one-time expense of \$560,000 related to the vesting of RSUs upon the completion of our IPO;
- an increase of \$489,000 for professional fees associated with the registration and sale of share of our common stock by existing shareholders in October 2013; and
- an increase in legal and external service costs attributable to the growth of business and preparations associated with operating as a public company.

***Interest Expense, Net***

For the year ended December 31, 2013, our net interest expense increased to \$1.2 million compared to \$776,000 for the year ended December 31, 2012. The increase of \$456,000, or 58.8%, was attributable to the increased interest expense associated with the larger outstanding loan balance for the year ended December 31, 2013 compared to the year ended December 31, 2012 as we drew upon the second tranche of our loan late in the third quarter of 2012.

***Fair Value of Warrant Adjustment***

Our outstanding Series F preferred warrants were deemed to be derivative instruments that required liability classification and mark-to-market accounting. As such, the applicable fair value of the warrants was determined using a two-stage, contingent claims model, resulting in the recognition of additional expenses of \$6.6 million and \$847,000 for the years ended December 31, 2013 and 2012, respectively. These expenses are primarily due to the increased likelihood of the occurrence of a liquidity event as well as the underlying stock price. Upon the completion of our IPO, these warrants converted to common stock warrants and are no longer considered to be a derivative instrument. Consequently, these common stock warrants will not be valued at each reporting period.

**Comparison of the years ended December 31, 2012 and 2011**

The following table summarizes the results of our operations for the years ended December 31, 2012 and 2011, together with the year-over-year changes in those items in dollars (in thousands):

Years Ended		Dollar	% Change
December 31,		Change	
2012	2011	Increase/(Decrease)	
(in thousands, expect for percentages)			

Revenues:

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Contract revenue	\$16,275	\$12,046	\$4,229	35.1	%
Collaboration and licensing revenue	17,445	55	17,390	*	
Total revenues	33,720	12,101	21,619	56	%
Operating expenses:					
Research and development	30,106	30,108	(2 )	*	
General and administrative	6,397	6,985	(588 )	(8.4 )	%
(Loss) income from operations	(2,783 )	(24,992)	(22,209 )	(88.9 )	%
Interest expense, net	(776 )	(212 )	564	266.0	%
Fair value of warrant adjustment	(847 )	(385 )	472	120.0	%
Net (loss) income	\$(4,406 )	\$(25,589)	\$(21,183 )	(82.8 )	%

\* Not meaningful or not calculable

*Contract Revenue*

Contract revenues for the years ended December 31, 2012 and 2011, were \$16.3 million and \$12.0 million, respectively, and consisted of revenue related to our BARDA contract. Revenue increased \$4.2 million, or 35.1%, during 2012 due to the timing of our research activities and the level of services required to be performed under our BARDA contract. In the year ended December 31, 2012, we were fully engaged in conducting CMC validation, animal studies, and program management in connection with our BARDA contract; whereas in the year ended December 31, 2011, our revenues were lower as the work performed under our BARDA contract was more “start-up” in nature and for a smaller reimbursable amount.

*Collaboration and Licensing Revenue*

Collaboration and license fee revenue for the year ended December 31, 2012, consisted of revenue from an upfront license payment related to our exclusive collaboration and license arrangement with Merck for the rights to CMX157. The upfront license payment was fully recognized in the quarter in which execution of a definitive agreement took place. We did not have significant collaboration and license revenue for the year ended December 31, 2011.

*Research and Development Expenses*

During the years ended December 31, 2012 and 2011, our research and development expenses were primarily unchanged at \$30.1 million.

*General and Administrative Expenses*

During the years ended December 31, 2012 and 2011, our general and administrative expenses were \$6.4 million and \$7.0 million, respectively, representing a decrease of \$588,000, or 8.4%. This decrease in general and administrative expenses was due primarily to decreased spending in consulting expenses of \$470,000 for the initial set-up of the systems required to manage and report under the BARDA contract.

*Interest Expense, Net*

During the years ended December 31, 2012 and 2011, our interest expense, net was \$776,000 and \$212,000, respectively, representing an increase of \$564,000. During the year ended December 31, 2012, as compared to the year ended December 31, 2011, the net interest expense increased primarily due to the addition of non-cash amortization of finance charges associated with entering into a loan and security agreement in January 2012.

*Fair Value of Warrant Adjustment*

Some of our outstanding warrants during the years ended December 31, 2012 and 2011 were deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, we determined the fair value of the warrants using a two-stage, contingent claims model, resulting in the recognition of additional losses of \$847,000 and \$385,000 for the years ended December 31, 2012 and 2011, respectively. These losses were primarily due to the increased value of the warrants due to increased likelihood of the occurrence of a liquidity event.

**LIQUIDITY AND CAPITAL RESOURCES**

We have incurred losses since our inception in 2000 and, as of December 31, 2013, we had an accumulated deficit of \$162.7 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more of equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements.

Since our inception through December 31, 2013, we have funded our operations principally with \$209.5 million (net of issuance costs of \$10.3 million) from the sale of common stock and preferred stock and the exercise of common stock warrants, including \$107.6 million in net proceeds from our IPO in April 2013, approximately \$37.4 million of research funding from our various National Institute of Allergy and Infectious Diseases awards and approximately \$32.7 million in revenue from our BARDA contract, debt financings totaling \$21.0 million, and \$17.5 million of licensing revenue under our collaboration agreement with Merck. As of December 31, 2013, we had cash, cash equivalents and short-term investments of approximately \$110.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

During 2012, we entered into a loan and security agreement with SVB and MidCap allowing for borrowings up to \$15.0 million. In January 2012, we borrowed \$3.0 million under this agreement which had an interest only period for twelve months, followed by a thirty month principal and interest period at a rate of 8.25%. In September 2012, we borrowed an additional \$12.0 million under this agreement which had an interest only period of six months, followed with a thirty-two month principal interest period at a rate of 8.25%. As of December 31, 2013, the balance of the loan was \$10.1 million.

### *Cash Flows*

The following table sets forth the significant sources and uses of cash for the periods set forth below:

	Years Ended December 31,		
	2013	2012	2011
Net cash used in operating activities	\$(25,559 )	\$(1,876 )	\$(26,279 )
Net cash provided by (used in) investing activities	9,462	(4,139 )	(6,236 )
Net cash provided by financing activities	106,167	12,314	42,816
Net increase in cash and cash equivalents	90,070	6,299	10,301

### *Operating Activities*

Net cash used in operating activities of \$25.6 million for the year ended December 31, 2013 was primarily the result of our \$36.4 million net loss, offset by the add-back of non-cash expenses of \$6.6 million related to the revaluation of our warrant liability and \$3.1 million for stock based compensation. The change in operating assets and liabilities includes an increase in prepaid expenses and other current assets and deposits of \$1.8 million primarily related to start-up activities of our Phase 3 SUPPRESS clinical trial, offset by a decrease of \$535,000 in accounts receivable due to a decrease in reimbursable expenses related to our contract with BARDA and an increase in accounts payable and accrued liabilities of \$1.7 million.



Net cash used in operating activities of \$1.9 million during the year ended December 31, 2012 was primarily the result of our \$4.4 million net loss, offset by the add-back of non-cash expenses of \$847,000 related to the revaluation of our warrant liability and \$1.4 million for stock based compensation.

Net cash used in operating activities of \$26.3 million during the year ended December 31, 2011 was primarily the result of our \$25.6 million net loss offset by the add-back of non-cash expenses of \$385,000 related to the revaluation of our warrant liability and \$1.1 million for stock based compensation. The change in operating assets and liabilities included an increase in accounts receivable of \$4.2 million related to outstanding BARDA contract receivables.

#### *Investing Activities*

Net cash provided by investing activities of \$9.5 million during the year ended December 31, 2013 was primarily the result of maturity of certain short-term investments. Net cash used in investing activities of \$4.1 million and \$6.2 million during the years ended December 31, 2012 and 2011, respectively, were primarily the result of the purchases offset by maturities of short-term investments.

#### *Financing Activities*

Net cash provided by financing activities of \$106.2 million for the year ended December 31, 2013 was primarily the result of approximately \$107.6 million in net proceeds from the completion of our IPO and \$3.5 million from the exercise of stock options and a warrant offset by \$5.0 million in debt repayment. Net cash provided by financing activities of \$12.3 million during the year ended December 31, 2012 was primarily the result of loan proceeds from the first and second tranche of our loan offset by the repayment of our previous loan. Net cash provided by financing activities for the year ended December 31, 2011 primarily consisted of approximately \$45.0 million of proceeds from the sale of our Series F preferred stock, offset by an approximately \$2.0 million repayment of indebtedness.

On April 16, 2013, we completed our IPO of common stock pursuant to a registration statement that was declared effective on April 10, 2013. We sold 7,320,000 shares of our common stock at a price of \$14.00 per share. The underwriters exercised their over-allotment option on April 16, 2013, selling an additional 1,098,000 shares at \$14.00 per share. As a result of the IPO, we raised a total of \$107.6 million in net proceeds after deducting underwriting discounts and commissions of \$8.2 million and offering expenses of \$2.1 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital. Upon completion of the IPO, all outstanding shares of our preferred stock were converted into 14,480,088 shares of common stock. In addition, we issued 1,076,002 shares of common stock related to the accrued accumulated Series F dividends.

On October 23, 2013, we completed an underwritten offering of shares of our common stock held by existing shareholders. In connection with the offering, existing stockholders sold 2,476,995 shares of our common stock at \$16.50 per share; the offering did not result in proceeds to the company.

### *Future Funding Requirements*

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize brincidofovir or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Additionally, we expect to continue to incur additional costs associated with operating as a public company. Furthermore, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital requirements through at least mid-2015. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

- the progress, costs, results and timing of SUPPRESS, and the clinical development of brincidofovir for other potential indications;
- the willingness of the FDA to accept SUPPRESS, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of brincidofovir for the prevention of CMV and for other potential indications;
  - the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
  - the ability to continue to receive government funding;
  - the achievement of milestones under our agreement with Merck;
- the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;
  - the ability of our product candidates to progress through clinical development successfully;

- our need to expand our research and development activities;
- the costs associated with securing, establishing and maintaining commercialization and manufacturing capabilities;
  - the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
  - our need and ability to hire additional management and scientific and medical personnel;
  - the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements, or other collaborations, strategic alliances or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

## CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table summarizes our contractual obligations at December 31, 2013:

	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
	(In thousands)				
Operating leases <sup>(1)</sup>	\$1,135	\$ 331	\$ 763	\$ 41	\$ —
Loan payable and interest <sup>(2)</sup>	10,050	5,700	4,350	—	—
Minimum royalties <sup>(3)</sup>	\$1,550	—	150	600	800
<b>Total</b>	<b>\$12,735</b>	<b>\$ 6,031</b>	<b>\$ 5,263</b>	<b>\$ 641</b>	<b>\$ 800</b>

(1) Consists of our corporate headquarters leases encompassing 14,500 square feet of office space that expire in February 2018, and our laboratory lease encompassing 4,600 square feet that expires in June 2014, both of which

are located in Durham, North Carolina.

- (2) Consists of our loan and security agreement with SVB and MidCap, pursuant to which we have borrowed \$15.0 million in principal which bears interest at a rate of 8.25% and is repayable through 2015.
- (3) Consists of amounts payable under a license agreement with the University of Michigan for certain intellectual property related to the Chimerix Chemical Library.

In addition to the amounts set forth in the table above, we have payment obligations under license agreements that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones. Under our license agreement with UC, we made milestone and sublicense payments totaling approximately \$1.2 million through December 31, 2013. We will be required to make additional payments when certain milestones are achieved and we are obligated to pay royalties based on future product sales. As of December 31, 2013, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. In connection with the development and commercialization of brincidofovir and CMX157, in addition to royalties on product sales, we could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement. Under our license agreement with the University of Michigan, we are required to pay minimum royalties from 2016 through the expiration of the last licensed patent (which we estimate will occur in 2024) which are included in the table above, but any additional royalties that may be payable under the University of Michigan agreement are not estimable and therefore not included in the table above.

Additionally, we enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination or cancellation within 30 days of notice, and therefore are not included in the table above. We also have agreements with our executive officers that require the funding of specific payments, if certain events occur, such as a change in control or the termination of employment without cause. These potential payment obligations are not included in the table above.

### *Off-Balance Sheet Arrangements*

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

### **JOBS Act**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other companies.

### **ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

We do not believe that our cash, cash equivalents and available-for-sale investments have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the years ended December 31, 2013 or 2012.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Chimerix, Inc.

We have audited the accompanying balance sheets of Chimerix, Inc. as of December 31, 2013 and 2012, and the related statements of operations and comprehensive loss, statements of redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2013. 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 Chimerix, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Raleigh, North Carolina

March 7, 2014

**Chimerix, Inc.****BALANCE SHEETS****(in thousands, except share and per share data)**

	December 31,	
	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	\$109,976	\$19,906
Short-term investments, available-for-sale	—	9,849
Accounts receivable	248	783
Prepaid and other current assets	2,765	983
Deferred financing costs, current portion	20	33
Total current assets	113,009	31,554
Property and equipment, net of accumulated depreciation	338	407
Deposits and prepaid assets, less current portion	30	22
Deferred financing costs, less current portion	10	48
Total assets	\$113,387	\$32,031
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$2,214	\$1,964
Accrued liabilities	2,420	906
Loan payable, current portion	5,573	4,753
Total current liabilities	10,207	7,623
Other long-term liabilities	347	337
Loan payable, less current portion	4,294	9,867
Redeemable convertible preferred stock warrant liability	—	7,512
Total liabilities	14,848	25,339
Redeemable convertible preferred stock	—	107,723
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 and 89,700,000 shares authorized at December 31, 2013 and 2012, respectively; 26,664,972 and 1,533,996 shares issued and outstanding at December 31, 2013 and 2012, respectively	26	3
Additional paid-in capital	261,243	—
Accumulated other comprehensive loss	—	(2 )
Accumulated deficit	(162,730)	(101,032)



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Total stockholders' equity (deficit)	98,539	(101,031)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 113,387	\$ 32,031

See accompanying notes to these financial statements.

**Chimerix, Inc.****STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

(in thousands, except share and per share data)

	Year ended December 31,		
	2013	2012	2011
Revenues:			
Contract revenue	\$4,370	\$16,275	\$12,046
Collaboration and licensing revenue	—	17,445	55
Total revenues	4,370	33,720	12,101
Operating expenses:			
Research and development	24,662	30,106	30,108
General and administrative	8,327	6,397	6,985
	32,989	36,503	37,093
Loss from operations	(28,619 )	(2,783 )	(24,992 )
Other expense:			
Interest expense, net	(1,232 )	(776 )	(212 )
Fair value adjustments to warrant liability	(6,590 )	(847 )	(385 )
Loss on asset disposal	(4 )	—	—
Net loss	(36,445 )	(4,406 )	(25,589 )
Other comprehensive loss:			
Unrealized gain (loss) on securities available-for-sale	2	2	(4 )
Comprehensive loss	\$(36,443 )	\$(4,404 )	\$(25,593 )
Net loss	\$(36,445 )	\$(4,406 )	\$(25,589 )
Accretion of redeemable convertible preferred stock	(34,108 )	(4,357 )	(9,565 )
Net loss attributable to common stockholders	\$(70,553 )	\$(8,763 )	\$(35,154 )
Per share information:			
Net loss, basic and diluted	\$(3.65 )	\$(5.75 )	\$(23.49 )
Weighted-average shares outstanding, basic and diluted	19,307,422	1,524,628	1,496,262

See accompanying notes to these financial statements.

## Chimerix, Inc.

## Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands)

	Redeemable Convertible Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Comprehensive Loss	Other Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2010	\$ 55,131	\$ 2	\$ 1,895	\$ —	\$ (61,504 )	\$ (59,607 )
Share-based compensation	—	—	966	—	—	966
Issuance of redeemable convertible preferred stock	38,670	—	—	—	—	—
Issuance of common stock	—	—	89	—	—	89
Exercise of stock options	—	—	30	—	—	30
Dividends on redeemable preferred stock	3,235	—	(2,980 )	—	(255 )	(3,235 )
Adjustment of redeemable preferred stock to redemption value	6,330	—	—	—	(6,330 )	(6,330 )
Comprehensive loss:						
Unrealized loss on investments, net	—	—	—	(4 )	—	(4 )
Net loss	—	—	—	—	(25,589 )	(25,589 )
Total comprehensive loss						(25,593 )
Balance, December 31, 2011	103,366	2	—	(4 )	(93,678 )	(93,680 )
Share-based compensation	—	—	1,396	—	—	1,396
Exercise of stock options	—	1	13	—	—	14
Dividends on redeemable preferred stock	3,600	—	(1,409 )	—	(2,191 )	(3,600 )
Adjustment of redeemable preferred stock to redemption value	757	—	—	—	(757 )	(757 )
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	2	—	2
Net loss	—	—	—	—	(4,406 )	(4,406 )
Total comprehensive loss						(4,404 )
Balance, December 31, 2012	107,723	3	—	(2 )	(101,032 )	(101,031 )
Share-based compensation	—	—	3,071	—	—	3,071
Exercise of stock options	—	—	1,946	—	—	1,946
Dividends on redeemable preferred stock	976	—	(349 )	—	(627 )	(976 )
Adjustment of redeemable preferred stock to redemption value	33,132	—	(8,506 )	—	(24,626 )	(33,132 )
Exercise of warrants	—	—	1,537	—	—	1,537
Issuance of 8,418,000 shares of common stock at \$14.00 per share,	—	23	107,611	—	—	107,634

net of issuance costs of \$10,217,696						
Conversion of redeemable preferred stock into common stock	(141,831 )	—	141,831	—	—	141,831
Reclassification of redeemable preferred stock warrant liability to additional paid in capital	—	—	14,102	—	—	14,102
Comprehensive loss:						
Unrealized gain on investments, net	—	—	—	2	—	2
Net loss	—	—	—	—	(36,445 )	(36,445 )
Total comprehensive loss						(36,443 )
Balance, December 31, 2013	\$ —	\$ 26	\$ 261,243	\$ —	\$(162,730 )	\$ 98,539

See accompanying notes to these financial statements.

**Chimerix, Inc.****STATEMENTS OF CASH FLOWS****(in thousands)**

	Year ended December 31,		
	2013	2012	2011
Operating activities			
Net loss	\$(36,445 )	\$(4,406 )	\$(25,589 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	258	280	270
Non-cash interest expense	248	238	50
Amortization/accretion of premium/discount on investments	196	84	118
Loss on disposal of equipment	4	—	—
Share-based compensation costs	3,071	1,396	1,055
Deferred lease obligation	10	—	(4 )
Fair value measurement of redeemable convertible preferred stock warrant liability	6,590	847	385
Net change in:			
Accounts receivable	535	3,404	(4,187 )
Prepaid and other current assets and deposits	(1,790 )	65	(442 )
Accounts payable and accrued liabilities	1,764	(3,784 )	2,065
Net cash used in operating activities	(25,559 )	(1,876 )	(26,279 )
Investing activities			
Purchase of property and equipment	(193 )	(126 )	(321 )
Purchase of short-term investments	(1,852 )	(9,907 )	(13,640 )
Sales of short-term investments	750	—	500
Maturities of short-term investments	10,757	5,894	7,100
Repayment of loan to officer	—	—	125
Net cash provided by (used in) investing activities	9,462	(4,139 )	(6,236 )
Financing activities			
Proceeds from issuance of redeemable convertible preferred stock and warrants	—	—	45,000
Proceeds from exercise of stock options	1,946	14	30
Proceeds from exercise of warrant	1,537	—	—
Proceeds from loan payable	—	15,000	—
Proceeds from initial public offering, net of offering costs	107,634	—	—
Debt discount	—	(75 )	—
Repayment of loan payable	(4,950 )	(2,601 )	(1,965 )
Stock offering and deferred financing costs	—	(24 )	(249 )
Net cash provided by financing activities	106,167	12,314	42,816
Increase in cash and cash equivalents	90,070	6,299	10,301
Cash and cash equivalents:			

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Beginning of period	19,906	13,607	3,306
End of period	\$109,976	\$19,906	\$13,607
Supplemental schedule of cash flow information			
Interest payments	\$1,092	\$448	\$186

See accompanying notes to these financial statements.

**Chimerix, Inc.**

**Notes to Financial Statements**

**1. The Business and Summary of Significant Accounting Policies**

*Description of Business*

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel, oral antivirals to address unmet medical needs. The Company was founded in 2000 based on the promise of its proprietary lipid technology to unlock the potential of some of the most potent antivirals by enhancing their antiviral activity and safety profiles in convenient, orally administered dosing regimens. Based on the Company's lipid technology, its lead compound, brincidofovir (CMX001) is in Phase 3 clinical development, its second compound, CMX157, was licensed to Merck after completing a Phase 1 study and the Company has an active discovery program focusing on viral targets for which no therapies are currently available.

On March 25, 2013, the Company's board of directors approved and implemented a 3.55-for-1 reverse stock split of the Company's outstanding common stock. The reverse stock split resulted in an adjustment to the preferred stock conversion price to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

On April 10, 2013, the Company completed the initial public offering (IPO) of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 7,320,000 shares of common stock under the registration statement at a public offering price of \$14.00 per share. Net proceeds were approximately \$93.3 million, after deducting underwriting discounts and commissions of \$7.1 million and offering expenses of \$2.1 million. Upon the completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock and dividends accrued on Series F redeemable convertible preferred stock were converted into 15,556,091 shares of common stock and all outstanding warrants to purchase redeemable convertible preferred stock were converted into warrants to purchase 1,613,395 shares of common stock. On April 16, 2013, the underwriters exercised the full over-allotment option pursuant to which the Company sold an additional 1,098,000 shares at \$14.00 per share. Net proceeds from the over-allotment shares were approximately \$14.3 million after deducting underwriting discounts and commissions of \$1.1 million.

On October 23, 2013, the Company completed an underwritten secondary public offering of 2,476,995 shares of common stock held by certain of the Company's existing stockholders. The Company did not issue any shares of

common stock and received no proceeds in connection with such offering. The principal purposes of the offering were to facilitate an orderly distribution of shares and to increase the Company's public float.

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the Company's financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Although these estimates are based on knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

### ***Cash and Cash Equivalents***

The Company considers any highly liquid instrument with an original maturity of three months or less at acquisition to be a cash equivalent. Cash equivalents consist of money market accounts.

### ***Investments***

Investments consist primarily of corporate bonds and commercial paper. The Company invests in high-credit quality investments in accordance with its investment policy which minimizes the probability of loss.

Available-for-sale securities are carried at fair value as determined by quoted market prices, with the unrealized gains and losses, net of tax, reported as a separate component of stockholders deficit. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis in interest income or expense, net. Investments with original maturities beyond three months at the date of purchase and which mature on, or less than twelve months from, the balance sheet date are classified as long-term. The Company periodically reviews available-for-sale securities for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Any such declines in value judged to be other-than-temporary on available-for-sale securities are reported in interest income or expense, net. There were no such declines in value for the years ended December 31, 2013 and 2012.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, short-term investments and accounts receivable. The Company is exposed to credit risk, subject to federal deposit insurance, in the event of default by the financial institutions holding its cash and cash equivalents to the extent of amounts recorded on the balance sheets. Accounts receivable represent amounts due from an agency of the federal government.





### ***Accounts Receivable***

Accounts receivable at December 31, 2013 and December 31, 2012 consisted of amounts billed and unbilled under the Company's contract with the Biomedical Advanced Research and Development Authority (BARDA). Receivables under the BARDA contract are recorded as qualifying research activities as conducted and invoices from the Company's vendors are received. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded a charge to allowance for doubtful accounts as management believes all receivables are fully collectible.

### ***Fair Value of Financial Instruments***

The carrying amounts of certain financial instruments, including accounts receivable, notes receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of such instruments. The carrying amount of borrowings under loans payable approximates its fair value based on the determination that the stated rate on such loans payable is consistent with current interest rates for similar borrowing arrangements available to the Company.

For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with the fair value hierarchy. Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates and are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, fair value measurements cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the calculated current or future fair values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. These levels are:

*Level 1* — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

*Level 2* — Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and models for which all significant inputs are observable, either directly or indirectly.

*Level 3* — Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The determination of where an asset or liability falls in the hierarchy requires significant judgment. The Company evaluates hierarchy disclosures and, based on various factors, it is possible that an asset or liability may be classified differently from period to period. However, the Company expects that changes in classification between levels will be rare.

The Company has cash equivalents, consisting of money market accounts and commercial paper, whose value is based on using quoted market prices. Accordingly, these securities are classified as Level 1.

At December 31, 2012, the Company had short-term investments, comprised of corporate bonds and commercial paper, for which quoted prices were not available that were valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

The warrants issued for Series F redeemable convertible preferred stock included in the Company's 2012 financial statements are categorized as Level 3 as there are significant unobservable inputs. The valuation of the warrants at December 31, 2012 reflected a two stage process. Using a contingent claims model in combination with the Company's Series F financing, which occurred in February 2011, the fair value of total equity and all components of the Company's capital structure, including the warrants, was determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities consistent with market practice, a distribution of equity values was produced which covered the range of values that an informed market participant might expect. These outcomes were organized into ranges and a probability calculated based on the percent of the total falling into each range. This process created a range of equity values. Using a contingent claims framework, each equity value was allocated to the various components of the capital structure including the warrants. Each warrant value was weighted by its respective probability to determine the final fair value of the warrants as of December 31, 2012. The key unobservable inputs used in the determination of the fair value were (i) volatility – 79%, (ii) range of implied fair value of the Series F redeemable convertible preferred stock – \$2.19 to \$2.85, (iii) time to liquidity – 8 months to 5 years, and (iv) range of probabilities of liquidity event outcomes – 2% to 31%. The warrants were valued again at April 10, 2013, just prior to the Company's IPO, using a Black-Scholes valuation model. The key unobservable inputs used in determination of the fair value at that time were (i) volatility – 79%, (ii) fair value of the Series F redeemable convertible preferred stock – \$3.94, (iii) expected life – 2.5 years, (iv) risk-free interest rate – 0.24%, and (v) dividend yield – 0%. As the warrants for Series F redeemable convertible preferred stock converted to warrants for common stock upon the IPO, no future valuations are necessary.



There was no material re-measurement to fair value of financial assets and liabilities that are not measured at fair value on a recurring basis.

Below is a table that presents information about certain assets and liabilities measured at fair value on a recurring basis:

	Fair Value Measurements at December 31, 2013			
	December 31, 2013 (in thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 107,349	\$ 107,349	\$ —	\$ —

	Fair Value Measurements at December 31, 2012			
	December 31, 2012 (in thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 17,687	\$ 16,381	\$ 1,306	\$ —
Short-term investments	9,849	—	9,849	—
Redeemable convertible preferred stock warrant liability	7,512	—	—	7,512

Below is a table that presents a reconciliation of the beginning and ending balances of liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Fair Value Measurements (Level 3) (in thousands)
Redeemable Convertible Preferred Stock Warrant Liability	
Balance at January 1, 2012	\$ 6,491
Issuance	174
Fair value increase recorded in other expense	847
Fair value at December 31, 2012	7,512

Fair value increase recorded in other expense	6,590
Reclassification of warrant liability to additional paid-in capital	(14,102 )
Fair value at December 31, 2013	\$ —

### ***Prepaid and Other Current Assets***

Prepaid and other current assets consist of the following:

	December 31, 2013	December 31, 2012
	(in thousands)	
Prepaid development expenses	\$ 2,433	\$ 486
Deferred public offering costs	—	273
Other prepaid and other current assets	332	224
	\$ 2,765	\$ 983

### ***Property and Equipment***

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to five years. Leasehold improvements are amortized over the shorter of the useful life of the asset or the term of the related lease. Maintenance and repairs are charged against expense as incurred.

***Impairment of Long-Lived Assets***

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If the estimated future cash flows (undiscounted and without interest charges) from the use of an asset are less than the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. To date, no such write-downs have occurred.

***Deferred Public Offering Costs***

Deferred public offering costs totaling \$0.3 million at December 31, 2012 are included in prepaid and other current assets. These costs represent legal and accounting costs related to the Company's efforts to raise capital through an IPO. At the completion of the IPO in April 2013, these costs were reclassified to additional paid-in capital as a reduction of the IPO proceeds.

***Deferred Rent***

The Company recognizes rent expense on a straight-line basis over the non-cancelable term of its operating lease and records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability. The Company also records landlord-funded lease incentives, such as reimbursable leasehold improvements, as a deferred rent liability, which is amortized as a reduction of rent expense over the non-cancelable term of its operating lease.

***Accrued Liabilities***

Accrued liabilities consist of the following:

	December 31, 2013	December 31, 2012
	(in thousands)	
Accrued compensation	\$ 1,779	\$ 560
Accrued development expenses	350	98
Other accrued liabilities	291	248
	\$ 2,420	\$ 906

***Redeemable Convertible Preferred Stock Warrant Liability***

Freestanding warrants for shares that are either putable or redeemable are classified as liabilities on the balance sheet at fair value. As further discussed in Note 6, the preferred stock underlying certain warrants was redeemable in certain circumstances, and as such the freestanding warrants that are related to the purchase of the Company's Series F preferred stock were liabilities that should be recorded at the estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded in other income.

### ***Redeemable Convertible Preferred Stock***

The Company classified its redeemable convertible preferred stock, for which the Company did not control the redemption, outside of permanent equity. The Company recorded redeemable convertible preferred stock at fair value upon issuance, net of any offering costs, and the carrying value was adjusted to the redemption value at the end of each reporting period. These adjustments were effected through charges against additional paid-in capital and accumulated deficit.

### ***Revenue Recognition***

The Company's revenues generally consist of (i) contract and grant revenues – revenues generated under federal contracts and other awarded grants, and (ii) collaboration and licensing revenues – revenues related to non-refundable upfront fees, royalties and milestone payments earned under license agreements. Revenues are recognized when the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products and/or services has occurred; (3) the selling price is fixed or determinable; and (4) collectability is reasonably assured.

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has “stand-alone value” to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered. Revisions to the estimated period of recognition are reflected in revenue prospectively.

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, the Company recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied. 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.

Milestone payments are recognized when earned, provided that (i) the milestone event is substantive; (ii) there is no ongoing performance obligation related to the achievement of the milestone earned; and (iii) it would result in additional payments. Milestone payments are considered substantive if all of the following conditions are met: the milestone payment is non-refundable; achievement of the milestone was not reasonably assured at the inception of the arrangement; substantive effort is involved to achieve the milestone; and the amount of the milestone appears reasonable in relation to the effort expended, the other milestones in the arrangement; and the related risk associated with the achievement of the milestone. Contingent based event payments the Company may receive under a license or collaboration agreement will be recognized when received.





For the years ended December 31, 2013, 2012 and 2011, contract and grant revenue consisted only of revenue from the BARDA contract as there was no grant revenue. The Company recognizes contract and grant revenue as qualifying research activities are conducted based on invoices received from the Company's vendors. Changes in fringe and indirect rates are recognized as a change in estimate in the period such rate changes are approved by BARDA.

### ***Clinical Trial Accruals***

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of trials, or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through December 31, 2013, there had been no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company's clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

### ***Research and Development***

Major components of research and development costs include cash compensation, stock based compensation, pre-clinical studies, clinical trial and related clinical manufacturing, drug development, materials and supplies, legal, regulatory compliance, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Research and development costs, including upfront fees and milestones paid to contract research organizations, are expensed as goods as received or services rendered. Costs incurred in connection with clinical trial activities for which the underlying nature of the activities themselves do not directly relate to active research and development, such as costs incurred for market research and focus groups linked to clinical strategy as well as costs to build the Company's brand, are not included in research and development costs but are reflected as general and administrative costs.

### ***Interest Expense, Net***

Interest expense, net includes interest earned on short-term investments, interest incurred on loans payable, the amortization of deferred financing costs related to fees paid to attorneys and other non-lender entities in order to acquire debt, and the amortization of debt discount related to fees paid to the lender in order to acquire debt.

### ***Income Taxes***

Deferred tax assets and liabilities are determined based on differences between the financial and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when the Company determines that it is more likely than not that some portion of a deferred tax asset will not be realized. The Company has incurred operating losses from April 7, 2000 (inception) through December 31, 2013, and therefore has not recorded any current provision for income taxes.

Additionally, the Company recognizes the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities based on the technical merits of the position. The tax benefit recognized in the financial statements for a particular tax position is based on the largest benefit that is more likely than not to be realized upon settlement. Accordingly, the Company establishes reserves for uncertain tax positions.

### ***Share-Based Compensation***

The Company measures and recognizes compensation expense for all share-based payment awards made to employees and directors, including employee stock options, based on estimated fair values. The fair value of share-based awards is estimated on the grant date using the Black-Scholes valuation model. The value of the portion of the award that is ultimately expected to vest is recorded as expense over the requisite service periods.

The Company also accounts for equity instruments issued to non-employees using a fair value approach. The Company values equity instruments, stock options and warrants granted to lenders and consultants using the Black-Scholes valuation model. The measurement of non-employee share-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the term of the related financing or the period over which services are received.

### ***Basic and Dilutive Net Loss Per Share of Common Stock***

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of converting redeemable convertible preferred stock, warrants to purchase redeemable convertible preferred stock and common stock, restricted stock and options. Diluted net loss per share of common stock is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock, and options outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock at December 31, 2013, 2012 and 2011.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of converting redeemable convertible preferred stock, warrants to purchase convertible preferred stock and options to purchase common stock, as the impact of such items are anti-dilutive during periods of net loss. Shares excluded from the calculations were 4,773,213, 11,259,579 and 11,034,134 for the years ended December 31, 2013, 2012 and 2011, respectively.

### ***Segments***

The Company operates in only one segment. The chief operating decision-maker, who is the Company's Chief Executive Officer, and management use cash flows as the primary measure to manage the business and do not segment the business for internal reporting or decision making.

### ***Impact of Recently Issued Accounting Standards***

In July of 2013, the Financial Accounting Standards Board issued ASU 2013-11, "Income Taxes, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Taskforce)" ("ASU 2013-11"). Beginning January 1, 2014, the effective date of this regulation, the Company will adopt the provisions of ASU 2013-11 related to presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. Adoption of ASU 2013-11 is not expected to have a material impact to the financial statements.

## **2. Investments**

The Company had no short or long-term investments at December 31, 2013.

The following table summarizes available-for-sale securities as of December 31, 2012:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Corporate bonds	\$8,353	\$	— \$ (2	) \$ 8,351
Commercial paper	1,498		—	1,498
Total	\$9,851	\$	— \$ (2	) \$ 9,849

All of the Company's investments as of December 31, 2012 had maturities of one year or less.

### 3. Property and Equipment

Property and equipment consist of the following:

	December 31, 2013	December 31, 2012
	(in thousands)	
Lab equipment	\$ 873	\$ 958
Leasehold improvements	78	78
Computer equipment	324	393
Office furniture and equipment	222	212
	1,497	1,641
Less accumulated depreciation	(1,159 )	(1,234 )
	\$ 338	\$ 407

### 4. Loan Payable

On January 27, 2012, the Company entered into a Loan and Security Agreement (LSA) with Silicon Valley Bank (SVB) and MidCap Financial SBIC, LP (MidCap) allowing for borrowings up to \$15.0 million, split between a first tranche of \$3.0 million borrowed at the time of the agreement, and a second tranche of up to \$12.0 million that would be available to be drawn by December 31, 2012 upon meeting one of three stated financial and/or operational goals.

The first tranche was used to repay the remaining principal balance outstanding of \$2.6 million under a previous loan. This repayment was deemed a modification of debt and therefore the remaining related deferred financing costs totaling \$0.1 million remained in deferred financing costs and are being amortized over the term of the LSA through interest expense. The first tranche has an interest-only period of twelve months followed by a 30-month principal and interest amortization period with interest being charged at 8.25% per year for the full period of the LSA.

The Company met one of the financial and/or operational goals mentioned above and, in September 2012, the remaining \$12.0 million was borrowed in the second tranche. The second tranche has a six-month interest-only period followed by a 32 month principal and interest amortization period with interest being charged at the same rate as the first tranche. There are certain fees in accordance with the LSA which are being recorded as discounts or other long and short-term liabilities depending on the nature of the fees. The fees are being accreted through interest expense. Approximately \$0.1 million and \$0.1 million was included in interest expense for the years ended December 31, 2013 and 2012, respectively.

Concurrently with entering into the LSA, the Company also granted SVB a warrant to purchase shares of Series F preferred stock at a price of \$2.045 per share equal to 2% of the aggregate amount of the advances made to the Company pursuant to the LSA, divided by the exercise price. In relation to the first tranche, the warrant became exercisable to purchase an aggregate of 29,340 shares of Series F preferred stock, and in relation to the second tranche, the warrant became exercisable to purchase an additional 117,360 shares of Series F preferred stock. As discussed in Note 1, the warrant is classified as a liability and is required to be measured at fair value. Therefore, the warrant was recorded as a debt discount at its fair value at the time of grant and accreted over the life of the LSA using the effective interest method. Upon the completion of the Company's IPO, this warrant was converted into a warrant to purchase 41,323 shares of common stock at an exercise price equal to \$7.26. In May 2013, SVB exercised the warrant in full and it is no longer outstanding.

The future payments under the LSA are as follows (in thousands):

Years ending December 31,	
2014	\$6,322
2015	4,508
	10,830
Less: amount representing interest	(780 )
Total payments under LSA	\$10,050

## 5. Commitments and Contingencies

### *Leases*

The Company leases its facilities and certain office equipment under long-term non-cancelable operating leases that expire at various dates through 2018. The Company has the following minimum payments under noncancelable operating lease obligations that existed at December 31, 2013 (in thousands):

Years ending December 31,	
2014	\$331
2015	275
2016	245
2017	243
2018	41
	\$1,135

Rent expense under non-cancelable operating leases and other month-to-month equipment rental agreements, including common area maintenance fees, totaled approximately \$0.5 million and \$0.4 million for the years ended December 31, 2013 and 2012, respectively.

***Significance of Revenue Source***

The Company is the recipient of federal research contract funds from BARDA. Periodic audits are required under the grant and contract agreements and certain costs may be questioned as appropriate under the agreements. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the agreements has been made as of December 31, 2013 and 2012.

## 6. Redeemable Convertible Preferred Stock

In February 2011, the Company issued 22,004,895 shares of \$0.001 par value Series F redeemable convertible preferred stock at \$2.045 per share and warrants to purchase an aggregate of 5,501,215 shares of Series F redeemable convertible preferred stock at an exercise price of \$2.045 per share for proceeds of \$45.0 million, less issuance costs of \$0.2 million. Upon the completion of the Company's IPO, these warrants were converted into warrants to purchase an aggregate of 1,549,628 shares of common stock at an exercise price of \$7.26 per share. The warrants are exercisable at any time and expire on February 4, 2018.

In January 2012, the Company issued a warrant to SVB to purchase a number of shares of Series F redeemable convertible preferred stock at an exercise price of \$2.045 per share equal to 2% of the aggregate amount of the advances made to the Company pursuant to the LSA, divided by the exercise price. Following the first and second tranches of the LSA, the warrant was exercisable to purchase an aggregate of 146,700 shares of Series F redeemable convertible preferred stock. Upon the completion of the Company's IPO, this warrant was converted into a warrant to purchase 41,323 shares of common stock at an exercise price of \$7.26 per share. In May 2013, SVB exercised the warrant in full and it is no longer outstanding.

The following table summarizes the authorized, issued and outstanding shares of redeemable convertible preferred stock as of December 31, 2012:

	Authorized Shares	Issued and Outstanding Shares
Series A	800,000	800,000
Series B	2,233,879	2,233,879
Series B-1	2,054,333	2,033,333
Series C	5,141,690	5,141,690
Series D	11,354,526	11,295,846
Series E	7,894,871	7,894,871
Series F	40,200,000	22,004,895
Total Shares	69,679,299	51,404,514

Upon the completion of the Company's IPO in April 2013, the Company's outstanding shares of redeemable convertible preferred stock and dividends accrued on Series F redeemable convertible preferred stock were automatically converted into an aggregate of 15,556,091 shares of common stock.

### *Warrants*

The following warrants for the purchase of preferred stock were issued, outstanding and exercisable at December 31, 2012:



Class	Date	Shares	Price Per Share	Expiration
Series B-1	November 5, 2003	21,000	\$ 1.500	November 2013
Series D	November 24, 2008	58,680	\$ 2.045	November 2018
Series F	February 7, 2011	5,501,215	\$ 2.045	February 2018
Series F	January 27, 2012	146,700	\$ 2.045	January 2022

As discussed in Note 1, the warrants exercisable for the Company's Series F preferred stock were classified as a liability and were required to be measured at fair value. Therefore, such warrants were recorded at the full fair value with the Company's Series F preferred stock being recorded at the residual value at the time of issuance. At each reporting date prior to the Company's IPO, the warrants exercisable for the Company's Series F preferred stock were recorded to fair value which was charged to other income. For the years ended December 31, 2013 and 2012, the Company recorded expense of \$6.4 million and \$0.8 million, respectively, related to the valuation of the warrants. These amounts, coupled with the fair valuation of the warrants issued in relation to the Company's LSA (see note 4), total to the fair value adjustments to warrant liability amount per the statements of operations and comprehensive loss.

Upon the completion of the Company's IPO, all outstanding warrants to purchase redeemable convertible preferred stock were converted into warrants to purchase 1,613,395 shares of common stock and are no longer required to be measured at fair value. On April 16, 2013, a warrant was exercised to purchase 211,783 shares of the Company's common stock. The Company received proceeds of \$1.5 million in connection with such exercise. On May 24, 2013, a warrant was net exercised which resulted in the issuance of 37,600 shares of the Company's common stock. On November 5, 2013, a warrant was net exercised which resulted in the issuance of 3,906 shares of the Company's common stock.

The following warrants for the purchase of common stock were issued, outstanding and exercisable at December 31, 2013:

Class	Date	Shares	Price Per Share	Expiration
Common	February 7, 2011	1,337,845	\$ 7.26	February 2018

## 7. Stockholders' Equity (Deficit)

### *Common Stock*

The Company's common stock consists of 200.0 million and 89.7 million authorized shares at December 31, 2013 and December 31, 2012, respectively, and 26.7 million and 1.5 million shares issued and outstanding at December 31, 2013 and December 31, 2012, respectively.

### *Shares Reserved for Future Issuance*

The following shares of common stock reserved for future issuances:

	December 31, 2013	December 31, 2012
Conversion of preferred stock and preferred stock warrants	—	16,093,483
Exercise of common stock warrants	1,337,845	—
Stock options issued and outstanding	1,946,823	2,593,423
Restricted Stock units outstanding	-	43,199
Authorized for future purchases under the 2013 Employee Stock Purchase Plan	704,225	—
Authorized for future grants under the 2013 Equity Incentive Plan	1,681,932	—
Authorized for future grants under the 2012 Equity Incentive Plan	—	427,933
	5,670,825	19,158,038

### *Stock Options*

In connection with the Company's IPO, the Company adopted the 2013 Equity Incentive Plan (the 2013 Plan). The 2013 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Additionally, the 2013 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants. Initially, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2013 Plan is the sum of (i) 1,408,450 shares, plus (ii) 244,717 shares, which was the number of shares reserved for issuance under the Company's 2012 Equity Incentive Plan (the 2012 Plan) at the time the 2013 Plan became effective, plus (iii) any shares subject to

outstanding stock options or other stock awards that would have otherwise returned to the 2012 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of each year, beginning on January 1, 2014 and continuing through and including January 1, 2023, by 2.5% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2013 Plan is 2,816,901 shares. Following the effectiveness of the 2013 Plan in April 2013, no further grants were made under the 2012 Plan.

The 2013 Plan has an "early exercise" provision under which options to purchase common stock may be exercised prior to being fully vested; however, the shares issued for options exercised under the "early exercise" provision continue to vest under the same terms as the underlying exercised option. Upon termination of an employee prior to the vesting of such shares, the Company can either repurchase the unvested shares or let the repurchase right expire.

The Company estimates the fair value of its share-based awards to employees, directors and consultants using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of highly complex and subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the Company's limited operating history and historical and implied volatility data, the Company has based its estimates of expected volatility on a blend of Company specific historical data and a group of similar public traded companies. When selecting these public companies on which it has based its expected stock price volatility, the Company selected companies with comparable characteristics to it, including enterprise value, risk profiles, positions within the industry, and with historical share price information sufficient to meet the expected life of its stock options. For employee stock options the Company uses the "simplified" method for estimating expected life, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. The expected term for share-based compensation granted to non-employees is the contractual life. The risk-free interest rates for the periods within the expected life of the option are based on the U.S. Treasury instrument with a life that is similar to the expected life of the option grant. The Company has never paid, and does not expect to pay, dividends in the foreseeable future. The following table illustrates the assumptions for the Black-Scholes model used in determining the fair value of the options granted.

	Employees					
	Year Ended December 31,					
	2013		2012		2011	
Dividend yield	0.00	%	0.00	%	0.00	%
Weighted-average risk-free interest rate	1.49	%	0.86	%	2.85	%
Volatility	76.40	%	80.55	%	82.00	%
Expected term (in years)	6.1		6.0		7.0	
Weighted-average fair value per option	\$2.52		\$1.93		\$1.74	

	Non-Employees					
	Year Ended December 31,					
	2013		2012		2011	
Dividend yield	0.00	%	0.00	%	0.00	%
Weighted-average risk-free interest rate	1.30	%	0.78	%	0.40	%
Volatility	79.69	%	81.77	%	77.80	%
Expected term (in years)	6.2		5.8		2.7	
Weighted-average fair value per option	\$5.01		\$3.48		\$3.38	

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. For the years ended December 31, 2013, 2012 and 2011, the Company applied a forfeiture rate based on the Company's historical forfeitures.

In February 2013, the Company's board of directors adopted the 2013 Employee Stock Purchase Plan (ESPP), which was subsequently ratified by stockholders and became effective in April 2013. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward the Company's success and that of its affiliates. The ESPP initially authorized the issuance of 704,225 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2014 through January 1, 2023 by the least of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986. As of the date hereof, no shares of common stock have been purchased under the ESPP.

A summary of activity related to the Company's stock options is as follows:

Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual
-------------------------------	---------------------------------	--

			Life (in Years)
Balance, January 1, 2012	2,631,415	\$ 2.24	7.69
Granted	382,167	3.24	—
Exercised	(16,530)	) 0.82	—
Expired or Canceled	(102,228)	) 2.63	—
Forfeited	(301,401)	) 1.69	—
Balance, December 31, 2012	2,593,423	\$ 2.45	7.36
Granted	292,906	10.62	—
Exercised	(801,049)	) 2.43	—
Expired or Canceled	(2,816)	) 1.57	—
Forfeited	(135,641)	) 4.55	—
Balance, December 31, 2013	1,946,823	\$ 3.54	7.03
Exercisable at December 31, 2013	1,266,070	\$ 2.32	6.21
Vested or expected to vest at December 31, 2013	1,952,222	\$ 3.50	7.02

At December 31, 2013, the aggregate intrinsic value of options outstanding and exercisable was \$16.2 million. The total intrinsic value of options exercised was \$12.4 million, \$18,000 and \$16,000 for the years ended December 31, 2013, 2012 and 2011, respectively.

In 2012, the Company modified option grants for four individuals. Three of the modifications extended the term to exercise the option resulting in \$30,000 in additional compensation expense. One option was modified to continue vesting after the participant's termination and to extend the time to exercise such option resulting in additional compensation expense of \$0.3 million.

For awards with only service conditions and graded-vesting features, the Company recognizes compensation expense on a straight-line basis over the requisite service period. The fair value of options vested and share-based compensation expense recognized are as follows:

	Year Ended December 31,		
	2013	2012	2011
	(in thousands)		
Research and development:			
Employee	\$ 537	\$ 336	\$ 315
Non-employee	67	80	—
General and administrative:			
Employee	458	921	651
Non-employee	82	59	—
	\$ 1,144	\$ 1,396	\$ 966

Cash received from option exercises under all share-based payment arrangements for 2013 and 2012 was \$1.9 million and \$14,000, respectively. There was no actual tax benefit realized for the tax deductions from option exercises of the share-based payment arrangements during 2013 or 2012.

As of December 31, 2013, there was approximately \$2.5 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the 2013 Plan. That compensation cost is expected to be recognized over a weighted-average period of approximately 2.54 years.

The Company continues to account for stock options issued to non-employees using a fair value approach. The compensation costs of these arrangements are subject to re-measurement over the vesting terms as earned. Compensation cost for performance-based awards is recognized when it is probable that the performance criteria will be met.

### ***Restricted Stock Units***

In 2013 and 2012, the Company issued RSUs to certain employees which vest based on specific performance criteria. By their terms, the RSUs became immediately vested upon the effective date of the registration statement for the Company's common stock in connection with the IPO, subject to the continuous service with the Company at the vesting event. When vested, the RSU represented the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted.

A summary of activity related to the Company's RSUs is as follows:

	Number of Restricted Stock Units Outstanding
Balance, December 31, 2012	43,199
Granted	59,348
Share issuance	(102,547 )
Balance, December 31, 2013	—

In April 2013, \$1.9 million in compensation expense had been recorded in connection with the RSUs as the performance criterion was met upon the completion of the Company's IPO. In November 2013, the requisite number of shares of common stock were issued in relation to the RSUs.

### *Fair Value Estimate*

Prior to the Company's IPO, the Company was required to estimate the fair value of the common stock underlying stock-based awards when performing the fair value calculations with the Black-Scholes option-pricing model. The fair value of the common stock underlying stock-based awards was determined on each grant date by the Company's board of directors, with input from management. All options to purchase shares of common stock were intended to be granted with an exercise price per share no less than the fair value per share of common stock underlying those options on the date of grant, based on the information known on the date of grant.

The Company was privately held with no active public market for its common stock. Therefore, management had for financial reporting purposes periodically determined the estimated per share fair value of the Company's common stock and redeemable convertible preferred stock at various dates using contemporaneous valuations consistent with the American Institute of Certified Public Accountants Practice Aid, "Valuation of Privately-Held Company Equity Securities Issued as Compensation," also known as the Practice Aid. These valuations were performed with the assistance of a third-party valuation specialist. The Company performed these contemporaneous valuations as of February 15, 2011, December 31, 2011, and September 30, 2012 and December 31, 2012. In conducting these contemporaneous valuations, management considered all objective and subjective factors that it believed to be relevant in each valuation conducted, including management's best estimate of the Company's business condition, prospects and operating performance at each valuation date. Within the contemporaneous valuations performed, a range of factors, assumptions and methodologies were used. The significant factors included external market conditions affecting the biotechnology industry, trends within the biotechnology industry, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of the preferred stock relative to common stock at the time of each grant, the results of operations, financial position, status of research and development efforts, stage of development and business strategy, the lack of an active public market for the common and preferred stock, and the likelihood of achieving a liquidity event such as an IPO or sale of the Company in light of prevailing market conditions.

The dates of the Company's contemporaneous valuations had not always coincided with the dates of its stock-based compensation grants. In such instances, management's estimates had been based on the most recent contemporaneous valuation of the Company's shares of common stock and its assessment of additional objective and subjective factors management believed were relevant and which may have changed from the date of the most recent contemporaneous valuation through the date of the grant. In addition, the Company performed retrospective valuations as of certain key option grant dates using similar methodologies as were used in the contemporaneous valuations. As a result, the Company concluded certain options granted in 2012 had reassessed values different from the grant date. The reassessed values were used to determine stock compensation expense for the year ended December 31, 2012.

## 8. Income Taxes

No income tax expense or benefit has been recorded for the years ended December 31, 2013 or December 31, 2012. This is due to the establishment of a valuation allowance against the deferred tax assets generated during those periods. At December 31, 2013, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved.

A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2013, 2012, and 2011:

	2013		2012		2011				
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings			
	(in thousands)								
Income tax benefit at statutory rate	\$(12,392)	34.0	%	\$(1,499)	34.0	%	\$(8,700)	34.0	%
State income taxes	(852 )	2.3	%	(100 )	2.3	%	(1,164)	4.6	%
Research and development credits	(2,265 )	6.2	%	—	0.0	%	(1,171)	4.6	%
Permanent items	3,060	(8.4	)%	868	(19.7	)%	964	(3.8	)%
Provision to return adjustments	320	(0.9	)%	2	0.0	%	12	0.0	%
Effect of change in state tax rate	(1 )	0.0	%	609	(13.9	)%	630	(2.5	)%
Increase in unrecognized tax benefits	566	(1.5	)%	—	0.0	%	314	(1.2	)%
Valuation allowance	11,564	(31.7	)%	120	(2.7	)%	9,115	(35.7	)%
Net benefit	\$—	0.0	%	\$—	0.0	%	\$—	0.0	%

The components of deferred tax assets and liabilities at December 31, 2013 and 2012 are as follows:

December 31,



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	2013	2012
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$40,721	\$31,431
Research and development expenses	127	34
Capitalized Section 174 expenses	69	80
Research and development credits	2,640	941
Accrued bonuses	405	54
Other	497	445
Total gross deferred tax assets	44,459	32,985
Valuation allowance	(44,405)	(32,841)
	54	144
Deferred tax liabilities:		
Other	(54 )	(144 )
Total deferred tax liabilities	(54 )	(144 )
Net deferred tax assets	\$—	\$—

At December 31, 2013, the Company has net operating loss carryforwards for federal and state tax purposes of approximately \$117.5 million and \$106 million, respectively. At December 31, 2012, the Company has net operating loss carryforwards for federal and state purposes of approximately \$83.6 million and \$65.8 million, respectively. The federal losses begin to expire in 2020 and the state losses begin to expire in 2023. The Company's federal and state net operating loss carryforwards include approximately \$7.3 million of excess tax benefits related to deductions from the exercise of stock options. The tax benefit of these deductions has not been recognized in deferred tax assets. If utilized, the benefits from these deductions will be recorded as adjustments to additional paid-in capital. In addition, the Company has tax credit carryforwards for federal tax purposes of approximately \$3.5 million as of December 31, 2013, which begin to expire in 2022. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. Management has recorded a valuation allowance for all of the deferred tax assets due to the uncertainty of future taxable income.

The research and development credit, which had previously expired on December 31, 2011, was reinstated as part of the American Taxpayer Relief Act of 2012 enacted on January 2, 2013. This legislation retroactively reinstated and extended the credit from the previous expiration date through December 31, 2013. As a result, the Company adjusted its deferred tax assets in 2013 for the 2013 and 2012 research and development credits, which resulted in an increase to the deferred tax assets and a corresponding increase to the valuation allowance of \$1.2 million and \$1.1 million, respectively.

In general, if the Company experiences a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period (a Section 382 ownership change), utilization of its pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Internal Revenue Code (and similar state laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the net operating loss carryforwards before utilization and may be substantial. The ability of the Company to use its net operating loss carryforwards may be limited or lost if the Company experienced one or more Section 382 ownership changes in connection with past offerings of its stock or as a result of future changes in its stock ownership. Losses from a specific period may be subject to multiple limitations, and would generally be limited by the lowest of those limitations.

The Company has determined that a Section 382 ownership change occurred in 2002, and as such, losses incurred prior to that date are subject to an annual limitation of at least \$64,000. Additionally, the Company has determined that a Section 382 ownership change occurred in 2007, and as such, losses incurred prior to that date are subject to an annual limitation of at least \$762,000. The Company evaluated Section 382 ownership changes subsequent to 2007 through 2013 and concluded that a Section 382 ownership change occurred in 2013 as a result of the initial public offering, The Company's most recent private placement and other transactions that have occurred since 2007. As such, losses incurred prior to that date are subject to an annual limitation of at least \$6.7 million.

The Company had gross unrecognized tax benefits of approximately \$0.3 million as of January 1, 2013. As the 2012 R&D tax credit was not yet enacted into current law, no R&D credit was reflected on the 2012 provision. As a result,

the Company recognized an increase in the unrecognized tax benefit associated with the federal R&D credit carryover in the current year related to the periods ending December 31, 2012 and 2013. As of December 31, 2013, the total gross unrecognized tax benefits were approximately \$0.9 million and of this total, none would reduce the Company's effective tax rate if recognized. The Company does not anticipate a significant change in total unrecognized tax benefits or the Company's effective tax rate due to the settlement of audits or the expiration of statutes of limitations within the next twelve months. Furthermore, the Company does not expect any cash settlement with the taxing authorities as a result of these unrecognized tax benefits as the Company has sufficient unutilized carryforward attributes to offset the tax impact of these adjustments.

The Company has determined that there may be a future limitation on the Company's ability to utilize its entire federal R&D credit carryover. Therefore, the Company recognized an uncertain tax benefit associated with the federal R&D credit carryover during the year ended December 31, 2013, as follows (in thousands):

Balance at December 31, 2011	\$314
Increases related to 2012	—
Balance at December 31, 2012	314
Increase related to 2013	297
Increase related to prior periods	269
Balance at December 31, 2013	\$880

The Company has determined that it had no other material uncertain tax benefits for the year ended December 31, 2013. As of January 1, 2014, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal and state income tax examinations for the tax years 2000 through 2013. The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties at January 1, 2014.

## 9. Significant Agreements

### *The Regents of the University of California*

In May 2002, the Company entered into a license agreement with The Regents of the University of California (UC) under which the Company obtained an exclusive, worldwide license to UC's patent rights in certain inventions (the UC Patent Rights) related to lipid-conjugated antiviral compounds and their use, including certain patents relating to brincidofovir and CMX157. The license agreement was amended in September 2002 in order to expand the scope of the license and again in December 2010 in order to modify certain financial terms. The agreement was amended a third time in September 2011 to add additional patents related to certain metabolically stable lipid-conjugate compounds. A fourth amendment was executed in July 2012 to alter the rights and obligations of the parties in light of the Company's current business plans. As partial consideration for the rights granted to the Company under the license agreement, the Company is required to pay certain cash milestone payments in connection with the development and commercialization of compounds that are covered by the UC Patent Rights. In connection with the development and commercialization of brincidofovir and CMX157, the Company could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement.

Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UC Patent Rights for all human and veterinary uses, and to sublicense such rights. UC retained the right, on behalf of itself and other non-profit institutions, to use the UC Patent Rights for educational and research purposes and to publish information about the UC Patent Rights.

In consideration for the rights granted under the license agreement, the Company has issued UC an aggregate of 64,788 shares of common stock. As additional consideration, the Company is required to pay certain cash milestone payments in connection with the development and commercialization of compounds that are covered by the UC Patent Rights, plus certain annual fees to maintain such patents until the Company commercializes a product utilizing UC Patent Rights. In addition, upon commercialization of any product utilizing the UC Patent Rights (which would include the commercialization of brincidofovir or CMX157), the Company will be required to pay low single digit royalties on net sales of such product.

In the event the Company sublicenses a UC Patent Right (including UC Patent Rights relating to brincidofovir or CMX157) the Company is obligated to pay to UC a fee, which amount will vary depending upon the size of any upfront payment the Company receives and the clinical development stage of the compound being sublicensed, but which could be up to approximately 50% of the sublicense fee in certain circumstances. In addition, the Company will also be required to pay to UC a low single digit sublicense royalty on net sales of products that use the sublicensed UC Patent Rights, but in no event will the Company be required to pay more than 50% of the royalties it receives in connection with the relevant sublicense. Any such royalty payment will be reduced by other payments the Company is

required to make to third parties until a minimum royalty has been reached.

As a result of meeting certain milestones and sublicense fees related to this license agreement, the Company recognized expenses of \$0.9 million for the year ended December 31, 2012. The Company did not recognize expenses under this license agreement for the year ended December 31, 2013.

***Biomedical Advanced Research and Development Authority (BARDA)***

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. The contract has been amended several times; most recently on December 10, 2013 to increase the option segment award to \$5.3 million.

Under the contract, BARDA will reimburse the Company, plus pay a fixed fee, for the research and development of brincidofovir as a broad-spectrum therapeutic antiviral for the treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods of approximately one year each, referred to as option segments, each of which may be exercised at BARDA's sole discretion. The Company must complete the agreed upon milestones and deliverables in each discrete work segment before the next option segment is eligible to be exercised. Under the contract as currently in effect, the Company may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees.

The Company is currently performing under the first option segment of the contract during which the Company may receive up to a total of \$5.3 million in expense reimbursement and fees. The term of the first option segment is 12 months and is scheduled to end on May 30, 2014.

***Merck, Sharp & Dohme Corp.***

In July 2012, the Company entered into a collaboration and license agreement granting Merck exclusive worldwide rights to CMX157, the Company's lipid acyclic nucleoside phosphonate currently being evaluated to treat HIV infection. Under the terms of the agreement, Merck received an exclusive worldwide license for any human use of CMX157 and has agreed to use commercially reasonable efforts to develop and commercialize CMX157 in the United States and at least three major European markets. Following execution of the agreement, the Company received a \$17.5 million upfront payment from Merck.

As additional consideration, the Company is eligible to receive up to a total of \$151.0 million in milestone payments if certain development and regulatory milestones are achieved by Merck for products utilizing CMX157, as well as tiered royalties on net sales ranging from high single digits to low double digits, depending upon the volume of sales of each applicable product, if CMX157 is successfully commercialized. Milestone payments are triggered upon the completion of various stages of the regulatory approval process for each of the first two indications for CMX157, with the final milestones reached upon approval in the United States and three major European markets. Royalties for any given product will continue on a country-by-country basis through the later of the expiration of the Company's patent rights applicable to such product or ten years from the first commercial sale of such product.

The Company's participation in the collaboration with Merck, including its involvement in the joint steering committee to monitor the development of CMX157, represents a right and an observation role only, rather than a substantive performance obligation. As such, the Company's performance in this collaboration relates to the specific transfers in connection with the license which was completed during the same quarter the agreement was entered into. Therefore, the Company recognized the upfront payment during the year ended December 31, 2012.

The contingent event-based payments that the Company may receive pursuant to the agreement do not meet the definition of a milestone as achievement of the triggering event for such payments is based on the performance of Merck and not the Company. Therefore, the milestone method will not be applied to those payments.

#### 10. Selected Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for 2013 and 2012 are as follows (in thousands, except per share data):

	2013 Quarter			
	Fourth	Third	Second	First
Total revenues	\$879	\$912	\$808	\$1,771
Operating loss	(7,979 )	(6,436 )	(7,656 )	(6,548 )
Net loss	(8,174 )	(6,706 )	(12,459 )	(9,107 )
Net loss per common share, basic and diluted	\$(0.31 )	\$(0.26 )	\$(0.91 )	\$(22.58 )
Weighted average shares outstanding, basic and diluted	26,416,787	25,866,109	23,067,201	1,534,016

2012 Quarter

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	Fourth	Third	Second	First
Total revenues	\$3,581	\$20,856	\$6,205	\$3,078
Operating (loss) income	(4,143 )	11,272	(4,422 )	(5,490 )
Net (loss) income	(4,326 )	11,142	(4,324 )	(6,898 )
Net (loss) income per common share, basic	\$(3.90 )	\$6.70	\$(3.44 )	\$(5.14 )
Net (loss) income per common share, diluted	\$(3.90 )	\$0.11	\$(3.44 )	\$(5.14 )
Weighted average shares outstanding, basic	1,532,633	1,529,442	1,518,753	1,517,465
Weighted average shares outstanding, diluted	1,532,633	52,933,956	1,518,753	1,517,465

Net income (loss) per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation. Diluted weighted average shares outstanding are identical to basic weighted average shares outstanding and diluted net loss per common share is identical to basic net loss per common share for all quarters of 2013 and for the first, second and fourth quarters of 2013 because common share equivalents are excluded from the calculations of diluted weighted average shares outstanding for those quarters, as their effect is antidilutive.

## 11. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these financial statements to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2013, and events which occurred subsequently but were not recognized in the financial statements.

In February 2014, the Company entered into an extension of a current facility lease for the period beginning March 2014 and ending June 2014. Future minimum payments under this extension total \$0.1 million.

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

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

**Evaluation of Disclosure Controls and Procedures**

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of December 31, 2013, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

**Management's Report on Internal Control Over Financial Reporting**

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

**Changes in Internal Control Over Financial Reporting**

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**



Not applicable.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this item and not set forth below will be set forth in the section headed “Election of Directors” and “Executive Officers” in our Proxy Statement for our 2014 Annual Meeting of Stockholders (Proxy Statement), to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2013, and is incorporated herein by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.chimerix.com> under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this item will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Transactions With Related Persons” in our Proxy Statement and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this item will be set forth in the section headed “Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

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**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

1. *Financial Statements.* We have filed the following documents as part of this Annual Report:

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	54
<u>Balance Sheets</u>	55
<u>Statements of Operations and Comprehensive Loss</u>	56
<u>Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</u>	57
<u>Statements of Cash Flows</u>	58
<u>Notes to Financial Statements</u>	59

2. *Financial Statement Schedules.* None.

3. *Exhibits.*

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Document</b>
3.1 <sup>(1)</sup>	Amended and Restated Certificate of Incorporation of the Registrant.
3.2 <sup>(1)</sup>	Amended and Restated Bylaws of the Registrant.
4.1 <sup>(1)</sup>	Form of Common Stock Certificate of the Registrant.
4.2 <sup>(1)</sup>	Form of Warrant to Purchase Stock issued to participants in the Registrant's Series F Preferred Stock financing dated February 7, 2011.
4.3 <sup>(1)</sup>	Amended and Restated Investor Rights Agreement dated February 7, 2011 by and among the Registrant and certain of its stockholders.
10.1+ <sup>(1)</sup>	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+ <sup>(1)</sup>	Chimerix, Inc. 2002 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice thereunder.
10.3+ <sup>(1)</sup>	Chimerix, Inc. 2012 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice and Form of Restricted Stock Unit Award Agreement and Form of Restricted Stock Unit Award Grant Notice thereunder.

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- 10.4+ (1) Chimerix, Inc. 2013 Equity Incentive Plan and Form of Stock Option Agreement, Notice of Exercise and Form of Stock Option Grant Notice thereunder.
- 10.5+ (1) Chimerix, Inc. 2013 Employee Stock Purchase Plan.
- 10.6+ Chimerix, Inc. Non-Employee Director Compensation Policy.
- 10.7+ Chimerix, Inc. Officer Change in Control Severance Benefit Plan, as amended.
- 10.8+ (1) Employment Offer Letter to Timothy W. Trost dated March 16, 2011.
- 10.9+ (1) Employment Offer Letter to M. Michelle Berrey, M.D., M.P.H. dated November 7, 2012.
- 10.10+ (1) Employment Offer Letter to Michael D. Rogers, Ph.D. dated March 4, 2013.
- 10.11+ (2) Employment Offer Letter to Linda M. Richardson dated December 13, 2013
- 10.12+ (1) Directorship Offer Letter to Ernest Mario, Ph.D. dated January 31, 2013.
- 10.13 (1) Office Lease by and between the Registrant and ACP 2505 Meridian LLC dated September 1, 2007, as amended.
- 10.14 (1) Lease Agreement by and between the Registrant and Biopharm Properties, LLC dated September 1, 2008, as amended.
- 10.15 (1) Deed of Sublease Agreement by and between the Registrant and MDxHealth, Inc. dated March 7, 2011, as amended.
- 10.16 Sixth Amendment to the Lease Agreement between the Registrant and Biopharm Properties, LLC dated March 6, 2014.
- 10.17\* (1) Collaboration and Exclusive License Agreement by and between the Registrant and Merck Sharp & Dohme Corp. dated July 23, 2012.
- 10.18\* (1) Contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.

- 10.19\* (3) Contract modification No. 14, dated May 30, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
- 10.20\*\* Contract modification No. 15, dated August 28, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
- 10.21\*\* Contract modification No. 16, dated December 10, 2013, to the contract by and between the Registrant and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services dated February 16, 2011, as amended.
- 10.22\* (1) License Agreement by and between the Registrant and The Regents of the University of California dated May 13, 2002, as amended.
- 10.23(1) Loan and Security Agreement by and among the Registrant, Midcap Financial SBIC, LP and Silicon Valley Bank dated January 27, 2012, as amended.
- 10.24 First Loan Modification Agreement, dated December 18, 2013, to the Loan and Security Agreement by and among the Registrant, Midcap Financial SBIC, LP and Silicon Valley Bank dated January 27, 2012, as amended.
- 23.1 Consent of Ernst & Young LLP, an Independent Registered Public Accounting Firm.
- 24.1 Power of Attorney. Reference is made to the signature page hereto.
- 31.1 Certification of Principal Executive Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Financial Officer, pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS\*\*\* XBRL Instance Document.
- 101.SCH\*\*\* XBRL Taxonomy Extension Schema 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.

+ Indicates management contract or compensatory plan.

\* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

\*\* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of the section, and shall not be part of any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

- (1) Incorporated by reference to Chimerix, Inc.'s Registration Statement on Form S-1 (No. 333-187145), as amended.
- (2) Incorporated by reference to Chimerix, Inc.'s Current Report on Form 8-K (No. 001-35867) filed with the SEC on December 18, 2013.
- (3) Incorporated by reference to Chimerix, Inc.'s Quarterly Report on Form 10-Q (No. 001-35867) filed with the SEC on August 14, 2013.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Chimerix, Inc.

Date: March 7, 2014 By: /s/ Kenneth I. Moch  
 Kenneth I. Moch  
 President & Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth I. Moch and Timothy W. Trost, and each of them, his true and lawful attorneys-in-fact, each with full power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Kenneth I. Moch Kenneth I. Moch	President, Chief Executive Officer and Director (Principal Executive Officer)	March 7, 2014
/s/ Timothy W. Trost Timothy W. Trost	Senior Vice President, Chief Financial Officer and Corporate Secretary (Principal Financial and Accounting Officer)	March 7, 2014
/s/ Ernest Mario Ernest Mario, Ph.D.	Chairman of the Board of Directors	March 7, 2014
/s/ Farah Champsi Farah Champsi	Director	March 7, 2014



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/s/ Martha J. Demski Martha J. Demski	Director	March 7, 2014
/s/ Rodman L. Drake Rodman L. Drake	Director	March 7, 2014
/s/ Wende Hutton Wende Hutton	Director	March 7, 2014
/s/ James Nidel James Nidel, M.D., Ph.D.	Director	March 7, 2014
/s/ Arthur M. Pappas Arthur M. Pappas	Director	March 7, 2014
/s/ Timothy J. Wollaeger Timothy J. Wollaeger	Director	March 7, 2014