CHIMERIX INC
Form 424B4
October 18, 2013

Filed Pursuant to Rule 424(b)(4)
Registration No. 333-191616

PROSPECTUS

2,476,995 Shares

COMMON STOCK

The selling stockholders included in this prospectus are selling 2,476,995 shares of common stock. We will not receive any proceeds from this offering. Our common stock is listed on the Nasdaq Global Market under the symbol CMRX. On October 17, 2013, the last reported sale price of our common stock on the Nasdaq Global Market was $17.00 per share.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves risks. See Risk Factors beginning on page 9.

PRICE $16.50 A SHARE

	Price to Public	***Underwriting Discounts and Commissions(1)***	***Proceeds to Selling Stockholders***
Per Share	*$16.50*	*$0.99*	*$15.51*
Total	*$40,870,417*	*$2,452,225*	*$38,418,192*

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See Underwriters .

Certain of the selling stockholders have granted the underwriters the right to purchase up to an additional 371,549 shares of common stock to cover over-allotments.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on October 23, 2013.

MORGAN STANLEY ***COWEN AND COMPANY***

WILLIAM BLAIR ***CANACCORD GENUITY***

October 18, 2013

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Neither we, the selling stockholders, nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we, the selling stockholders nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing

prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

For investors outside the United States: neither we, the selling stockholders nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially Risk Factors and our financial statements and the related notes, before deciding to buy shares of our common stock. Unless the context requires otherwise, references in this prospectus to Chimerix , the Company , we , us and our refer to Chimerix, Inc.

Overview

Chimerix is a biopharmaceutical company committed to the discovery, development and commercialization of novel, oral antiviral therapeutics that are designed to transform patient care in areas of high unmet medical need. Our proprietary lipid technology has given rise to two clinical-stage compounds, brincidofovir (CMX001) and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety in convenient, orally administered dosing regimens. We have worldwide rights to our lead product candidate, brincidofovir, and initiated the Phase 3 SUPPRESS trial for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients in the third quarter of 2013. We intend to develop brincidofovir as the first broad-spectrum antiviral for double-stranded DNA (dsDNA) viral infections. Our second clinical-stage compound, CMX157, is a Phase 1 product candidate for the treatment of HIV and was licensed to Merck, Sharp & Dohme Corp. (Merck) in 2012.

Brincidofovir is an orally administered nucleotide drug that utilizes our proprietary lipid technology to deliver high intracellular concentrations of a potent antiviral compound, cidofovir-diphosphate (CDV-PP). Following oral dosing, brincidofovir is absorbed through the gut, remains intact in the plasma, and is passively delivered into cells. Once inside cells, brincidofovir is converted into CDV-PP, which acts as an alternative substrate that interferes with viral replication. When CDV-PP is selected by critical enzymes as a substrate over the normal cellular substrate (i.e., nucleotides), the result is diminished viral replication.

Although brincidofovir and intravenous cidofovir (Vistide®) are both converted into CDV-PP once inside cells, Vistide requires high plasma concentrations to deliver a therapeutic level of cidofovir into cells, and has limited utility due to the risk of kidney damage.

The herpesvirus family includes CMV, Epstein-Barr virus (EBV), HHV-6 and other viruses commonly transmitted in childhood and early adulthood, and which establish latency, generally remaining dormant in individuals with a functioning immune system. However, in immunocompromised patients, such as HCT or solid organ transplant (SOT) recipients, CMV and other latent viral infections may reactivate, causing significant morbidity, mortality, graft rejection and facilitating co-infection with other opportunistic pathogens. CMV is the most common infectious pathogen in HCT, and can result in life-threatening pneumonia or other organ involvement, particularly in the first 100 days following transplant when the immune system is most vulnerable. In addition to potent activity against CMV and other herpesviruses, brincidofovir has shown broad-spectrum *in vitro* antiviral activity against all five families of dsDNA viruses that cause human disease: adenoviruses (AdV), polyomaviruses such as BK virus (BKV), papillomaviruses, orthopoxviruses, and herpesviruses.

In the post-transplant setting, there are three paradigms for addressing viral infections: prevention or universal prophylaxis, preemptive therapy, and treatment of disease. Prevention is the administration of an antiviral to at-risk

patients to avoid reactivation of a latent virus or primary infection with a new virus. Preemptive therapy is the initiation of antiviral(s) only after detection of a specific virus in the blood (viremia) in an asymptomatic patient, or other evidence of early infection. Treatment is the watch-and-wait approach of initiating antiviral therapy after the virus is detected in an organ system where clinical signs or symptoms are present.

No drugs are approved for prevention of CMV in HCT recipients, primarily due to the high threshold for safety and tolerability for a compound intended for use as universal prophylaxis across a broader population of at-risk patients. Currently available antivirals with anti-CMV activity are limited by significant renal and hematological side effects. We believe that a safe and well-tolerated antiviral with demonstrated efficacy in

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prevention settings would provide a new standard of care for immunocompromised patients. In HCT, a safe and effective therapy for CMV prevention could potentially replace the current practice of intensive monitoring for CMV viremia with initiation of anti-CMV preemptive therapy following detection. In addition, we believe that an antiviral with broad-spectrum activity could reduce the frequency of other dsDNA viral infections commonly encountered in these patients, and could provide measureable clinical and pharmacoeconomic benefits for patients and the health care system.

We demonstrated the potential clinical utility of brincidofovir in a 230-patient Phase 2 dose-escalation study for the prevention of CMV reactivation in HCT recipients. The results of this study were published in an article, entitled CMX001 to Prevent Cytomegalovirus Disease in Hematopoietic-Cell Transplantation, in the September 26, 2013 issue of the *New England Journal of Medicine* (N Engl J Med 369:1227-36). In this study, brincidofovir or placebo was administered to HCT recipients from stem cell engraftment through Week 13 post-transplant. A reduction of more than 50% in risk of CMV infection was observed for the subjects who received brincidofovir 100 mg twice weekly (BIW). Ten percent of subjects (five of 50 subjects) in the brincidofovir 100 mg BIW cohort met the primary endpoint, CMV disease or a positive quantitative blood test for CMV at the end of the dosing period, versus 37% of subjects (22 of 59 subjects) in the placebo cohort (p=0.002, where the p-value is the statistical probability of a result not due to chance alone). The dose-limiting toxicity of diarrhea was observed in a high proportion of subjects at the highest dose tested, brincidofovir 200 mg BIW, and was subsequently addressed with the addition of a Safety Monitoring and Management Plan (SMMP) incorporated in the final Phase 2 cohort and in subsequent studies. The SMMP has been included in the ongoing Phase 3 study of brincidofovir in CMV prevention in HCT recipients, SUPPRESS. There was no evidence of kidney, hematologic or bone marrow toxicity in the Phase 2 study at any dose tested.

The results of this Phase 2 study, together with brincidofovir s overall preclinical and clinical profile, which includes a safety database of more than 800 subjects exposed to brincidofovir in controlled and uncontrolled clinical studies, supported the progression to the Phase 3 SUPPRESS study of brincidofovir for the prevention of CMV infection in high-risk HCT recipients. The primary endpoint is a composite endpoint of either (i) CMV disease, or (ii) initiation of anti-CMV preemptive therapy triggered by a positive test for CMV in the blood (viremia), assessed through Week 24 post-transplant. We intend to enroll 450 high-risk (i.e., with latent CMV infection) HCT recipients who will be randomized to receive brincidofovir 100 mg BIW or placebo from the early post-transplant period until Week 14 post-transplant. Secondary endpoints include pharmacoeconomic data and the incidence of disease and reactivation of other herpesviruses such as HHV-6, as well as other dsDNA viruses such as AdV, and BKV.

We intend to submit a new drug application (NDA) under an accelerated approval pathway seeking regulatory approval to market brincidofovir in the United States and equivalent applications outside the United States. We have received Fast Track designation from the FDA for the CMV, AdV and smallpox indications for brincidofovir.

We believe that there is a significant commercial opportunity for an antiviral such as brincidofovir with broad-spectrum activity against dsDNA viruses. According to the Center for International Blood and Marrow Transplant Research and the Organ Procurement and Transplantation Network, more than 20,000 HCTs and 28,000 SOTs are performed annually in the United States, with similar numbers of transplants performed annually in Europe according to the European Group for Blood and Marrow Transplantation and the World Health Organization. More than 65% of stem cell transplant patients are at increased risk of CMV infection due to prior exposure to CMV defined by evidence of antibodies to CMV in the blood (i.e., CMV seropositivity). In individuals outside the transplant population, many factors are influencing the epidemiology of dsDNA viral infections, including the use of potent immunosuppressive therapies in autoimmune and other diseases. Since 2009, Chimerix has made brincidofovir available under expanded access regulations to over 80 transplant centers worldwide for the treatment of over 430 patients with life-threatening dsDNA viral infections and no satisfactory alternative treatment options, reflecting the

high unmet medical need in this therapeutic area. Our brincidofovir Compassionate Use Program refers to the emergency investigational new drug (EIND) program which provided treatment to 230 individuals and Study 350, the expanded access study which enrolled 215 patients meeting similar inclusion criteria as the EINDs.

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If brincidofovir obtains regulatory approval, we intend to build our own sales force and to commercialize brincidofovir. In the United States, approximately 200 institutions perform transplants, of which approximately 75% perform HCT and 75% perform SOT. As a result, we believe we can commercialize brincidofovir for prevention of CMV in HCT recipients in the United States and Canada with a relatively small marketing and specialty sales force infrastructure of approximately 50 employees.

We are also evaluating the potential for brincidofovir for AdV infection, an often-fatal viral infection in immunocompromised patients. In September 2013, we presented encouraging results from a Phase 2 study of brincidofovir in the setting of preemptive therapy for AdV at the annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). With little known about the epidemiology of AdV infections, this first interventional trial in AdV infection was designed to mirror the current standard in CMV of initiation of therapy at the time of first detection of replicating virus in the blood. Allogeneic HCT recipients who received brincidofovir 100 mg BIW demonstrated decreased levels of AdV in the blood and a potential benefit in reduced disease progression and all-cause mortality, compared to subjects who received placebo or brincidofovir once weekly (QW). Intent-to-treat analyses as well as exploratory analyses in specific patient groups were consistent in trends favoring the brincidofovir BIW regimen over placebo, although statistical significance was not established in this small study. There were no new safety concerns identified in this trial, and very few temporary or permanent discontinuations of study drug for GI related adverse events were reported, demonstrating the successful implementation of the SMMP. As multiple dsDNA viral infections were noted in these pediatric and high-risk adult HCT recipients, future clinical development may include a study of brincidofovir for prevention of AdV and other dsDNA viral infections. Development of brincidofovir for dsDNA viral infections in SOT recipients and other immunocompromised patients is also under discussion.

CMX157, our second clinical stage compound, is an oral nucleotide compound in Phase 1 development for the treatment of HIV infection. In July 2012, we granted Merck an exclusive worldwide license to develop and commercialize CMX157 for HIV or other indications. Merck is responsible for all development and marketing activities for CMX157 on a worldwide basis.

Our Strategy

Our strategy is to discover, develop, and commercialize novel oral antiviral therapeutics in areas of significant unmet medical need. Key elements of our strategy include:

advancing brincidofovir through Phase 3 clinical development for the prevention of CMV infection in high-risk patients following HCT;

expanding brincidofovir s ability to address the unmet medical need in pediatric HCT recipients;

leveraging the broad-spectrum profile of brincidofovir in other indications including AdV and/or BKV, and in other patient populations, such as SOT recipients and patients receiving therapies which result in compromised immune systems;

obtaining Accelerated Approval and Traditional Approval for marketing of brincidofovir for the prevention of CMV in the United States, and equivalent health authority approvals in Canada and key European markets;

commercializing brincidofovir with a targeted marketing and specialty sales force;

continuing development of brincidofovir as a potential medical countermeasure against smallpox, subject to continuing government support, including from the Biomedical Advanced Research and Development Authority (BARDA); and

advancing compounds from the Chimerix Chemical Library through IND-enabling studies and potential clinical development and/or partnerships.

We may enter into additional collaborations to implement our strategy.

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Our Product Candidates

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

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section entitled Risk Factors immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, risks associated with our business include:

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 have never generated any revenue from sales of products and may never be profitable. We may need to raise additional capital in connection with our continuing operations, which may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.

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

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.

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

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

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Corporate Information

We were incorporated in Delaware in April 2000. Our principal executive offices are located at 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713, and our telephone number is (919) 806-1074. Our corporate website address is *www.chimerix.com*. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We have obtained a registered trademark for Chimerix® in the United States. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of (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. We refer to the Jumpstart Our Business Startups Act of 2012 in this prospectus as the JOBS Act, and references in this prospectus to emerging growth company shall have the meaning associated with it in the JOBS Act.

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THE OFFERING

Common stock offered by the selling stockholders	2,476,995 shares
Common stock to be outstanding after this offering	26,402,092 shares

Over-allotment option

Certain of the selling stockholders have granted to the underwriters the option, exercisable for 30 days from the date of this prospectus, to purchase up to 371,549 additional shares of common stock.

Use of proceeds

The selling stockholders will receive all of the net proceeds from the offering and we will not receive any proceeds from the sale of shares in this offering. See Use of Proceeds.

Risk factors

You should read the Risk Factors section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.

Nasdaq Global Market symbol

CMRX

The number of shares of our common stock to be outstanding after this offering is based on 25,974,809 shares of common stock outstanding as of September 30, 2013, and excludes:

- 2,065,657 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2013, at a weighted-average exercise price of $3.32 per share;
- 102,547 shares of common stock issuable pursuant to outstanding restricted stock units as of September 30, 2013;
- 1,343,760 shares of common stock issuable upon the exercise of outstanding warrants as of September 30, 2013, at a weighted-average exercise price of $7.25 per share;
- 704,225 shares of common stock reserved for future issuance under our 2013 employee stock purchase plan (the ESPP); and
- 1,719,525 shares of common stock reserved for future issuance under our 2013 equity incentive plan (the 2013 plan).

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise by the underwriters of their over-allotment option to purchase up to an additional 371,549 shares of our common stock from certain of the selling stockholders; and
- the issuance of 427,283 shares of our common stock to a selling stockholder upon the exercise of stock options subsequent to September 30, 2013 that will be sold in this offering.

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SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and related notes, Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of the results for the entire year.

We derived the following summary statement of operations data for the years ended December 31, 2010, 2011 and 2012 and balance sheet data as of December 31, 2011 and 2012 from our audited financial statements and related notes appearing elsewhere in this prospectus. We derived the summary statement of operations data for the six months ended June 30, 2012 and 2013 and balance sheet data as of June 30, 2013 from our unaudited financial statements also appearing elsewhere in this prospectus, which have been prepared on the same basis as our audited financial statements and include all adjustments, consisting of normal recurring adjustments necessary for the fair presentation of the financial position and results of operations for these periods.

	Year Ended December 31,			Six Months Ended June 30,	
Statement of Operations Data:	2010	2011	2012	2012	2013
	(in thousands, except share and per share data)				
				(unaudited)	
Revenues:					
Collaboration and licensing	$	$55	$17,445	$	$
Contract and grant	1,715	12,046	16,275	9,283	2,579
Total revenue	1,715	12,101	33,720	9,283	2,579
Operating expenses:					
Research and development	21,074	30,108	30,106	16,075	13,059
General and administrative	5,945	6,985	6,397	3,120	3,725
Total operating expenses	27,019	37,093	36,503	19,195	16,784
Loss from operations	(25,304)	(24,992)	(2,783)	(9,912)	(14,205)
Interest expense, net	(154)	(212)	(776)	(237)	(771)
Fair value adjustment to warrant liability		(385)	(847)	(1,073)	(6,590)
Other income	1				
Net loss	$(25,457)	$(25,589)	$(4,406)	$(11,222)	$(21,566)
Accretion of redeemable convertible preferred stock		(9,565)	(4,357)	(1,800)	(34,108)
Net loss attributable to common stockholders	$(25,457)	$(35,154)	$(8,763)	$(13,022)	$(55,674)
Basic and diluted net loss per common share[(1)]	$(17.52)	$(23.49)	$(5.75)	$(8.58)	$(4.50)
Shares used to calculate net loss per common share[(1)]	1,452,877	1,496,262	1,524,628	1,518,112	12,360,125

(1) See Note 2 of our Notes to Financial Statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common share and the number of shares used in the computation of the per share amounts.

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	As of December 31, 2011	December 31, 2012	June 30, 2013 (unaudited)
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 13,607	$ 19,906	$ 115,438
Short-term investments, available-for-sale	5,918	9,849	7,595
Working capital	18,010	23,931	118,120
Total assets	25,432	32,031	126,554
Loan payable(2)	2,601	14,620	12,703
Redeemable convertible preferred stock warrant liability	6,491	7,512	
Redeemable convertible preferred stock	103,366	107,723	
Total stockholders equity (deficit)	(93,680)	(101,031)	111,044

(2) Loan payable includes the current and long-term portion of our debt, net of debt discount.

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RISK FACTORS

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 prospectus, 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 approximately $11.2 million and $21.6 million for the six months ended June 30, 2012 and 2013, respectively, and net losses of $25.5 million, $25.6 million and $4.4 million for the fiscal years ended 2010, 2011 and 2012, respectively. As of June 30, 2013, we had an accumulated deficit of approximately $147.9 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;

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.

We have incurred significant losses since our inception. We anticipate that wewill continue to incur significant losse

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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, including building a sales force and collaborating with third parties;
achieving broad market acceptance of brincidofovir in the medical community and with 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.

Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully

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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.

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

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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 June 30, 2013, we had $12.7 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;

We depend on the success of our lead product candidate, brincidofovir, whichis still under clinical development, and

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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.

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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 recently announced initiation of 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.

We are developing brincidofovir to treat patients who are extremely ill, and patient deaths that occur in our clinical tr

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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, subjects enrolled in our Phase 2 clinical trials for brincidofovir have 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

Our product candidates may cause adverse effects or have other propertiesthat could delay or prevent their regulat

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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

Even if we obtain regulatory approval for brincidofovir and our other productcandidates, we will still face extensive r

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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.

Even if we obtain FDA approval for brincidofovir or any of our other products in the United States, we may never ob

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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

Our relationships with investigators, health care professionals, consultants, third-party payors, and customers are s

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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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of a

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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.

We are currently transferring the drug substance manufacturing process to our selected contractor that will produce the commercial supply of drug substance and are currently evaluating manufacturers to optimize tablet and suspension formulation production to meet forecasted commercial demand. It is our expectation that only one supplier of drug substance and one supplier of drug product will be qualified as vendors with the FDA. If supply from an approved vendor 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.

We rely on limited sources of supply for the drug component for our leadproduct candidate, brincidofovir, and any d

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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 and 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.

As a result, the development and commercialization of CMX157 would be delayed, 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.

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.

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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 our regulatory 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 of our 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, 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;
pricing and cost-effectiveness;
effectiveness of our or any future collaborators sales and marketing strategies;
ability to obtain hospital formulary approval; and

The commercial success of brincidofovir and our other product candidateswill depend upon the acceptance of these

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

If any of our product candidates, including brincidofovir, is approved but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue and we may not become or remain profitable.

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 an 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 adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market a

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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 approved 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 CMV prevention or treatment, 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

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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, is 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 competitive pricing 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 price competition 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 invest heavily 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.

Hospital formulary approval 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.

Obtaining hospital formulary approval can be an expensive and time consuming process. We cannot be certain if and when we will obtain formulary approval to allow us to sell our product candidates, including brincidofovir, into our target markets. Failure to obtain timely formulary approval will limit our commercial success.

Furthermore, 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. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered

Hospital formulary approval and reimbursement may not be available for brincidofovir and our other product candida

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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.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on

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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.

If we are unable to obtain or protect intellectual property rights related to ourproducts and product candidates, we m

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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

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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

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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 support 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 support 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 the first option segment of the contract. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at Chimerix s 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;

Unfavorable provisions in government contracts, including our contract withBARDA, may harm our business, financ

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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.

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

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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 or fraudulent claim for payment or approval or knowingly makes, uses, or causes to be made or used, 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

Our future success depends on our ability to retain key executives and toattract, retain and motivate qualified perso

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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 September 30, 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 $5.0 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.

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Risks 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;
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.

As of September 30, 2013, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 56.4% 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

Our principal stockholders and management own a significant percentage ofour stock and will be able to exert signi

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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 auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in this prospectus 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.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can 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.

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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 31st 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 31st 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.

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. We believe that with our IPO, our most recent private placement and other transactions that have occurred since 2007, we may have triggered an ownership change limitation. We may also experience ownership changes in the future as a result of this offering and 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.

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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.

Future sales of our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of September 30, 2013, after giving effect to the issuance of 427,283 shares of our common stock upon the exercise of stock options, which shares will be sold by a selling stockholder in this offering, approximately 26,402,092 shares of our common stock were outstanding, and after giving effect to the sale of the shares by the selling stockholders, approximately 12,449,849 of such shares are currently restricted as a result of securities laws or lock-up agreements, but will be available for resale in the public market as described below. As a result of the 90-day lock-up agreements between the underwriters for this offering and the selling stockholders and the

provisions of Rule 144 under the Securities Act, or Rule 144, and Rule 701 under the Securities Act of 1933, as amended, or the Securities

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Act, or Rule 701, the shares of our common stock that will be available for sale in the public market are as follows:

772,825 shares will be eligible for sale under Rule 144 or Rule 701 upon the expiration of the lock-up agreements without regard to volume limitations, manner of sale requirements or other restrictions, unless extended for up to a specified number of additional days as required under the lock-up agreements;
11,677,024 shares will be eligible for sale under Rule 144 upon the expiration of the lock-up agreements, subject to volume limitations, manner of sale requirements and other restrictions, unless extended for up to a specified number of additional days as required under the lock-up agreements; and
1,990,795 shares will be eligible for sale, upon the exercise of vested options, restricted stock units and warrants (based on the number of shares subject to options and warrants outstanding as of September 30, 2013), upon the expiration of the various lock-up agreements, unless extended for up to a specified number of additional days as required under the lock-up agreements.

Moreover, after giving effect to the sale of the shares by the selling stockholders in this offering, the holders of up to approximately 15,199,074 shares of common stock (including shares of our common stock issuable upon the exercise of outstanding warrants) will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to the lock-up agreements between the underwriters for this offering and certain of our security holders and our window period and insider trading policies, if applicable.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements. We may, in some cases, use word such as anticipate, believe, could, estimate, expects, intend, may, plan, predict, project, should, will, would or the negative of those terms, and similar expressions that convey uncertai future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

the success, cost and timing of our product development activities and clinical trials;
our ability to obtain and maintain regulatory approval of our 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, including funding necessary to complete the Phase 3 clinical trials required to file our NDA for brincidofovir;
our plans to research, develop and commercialize our product candidates;
our ability to attract collaborators with development, regulatory and commercialization expertise;
the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
our ability to successfully commercialize our product candidates;
the rate and degree of market acceptance of our 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 may become available;
the loss of key scientific or management personnel;
our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

These forward-looking statements reflect our management s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail under Risk Factors. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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MARKET, INDUSTRY AND OTHER DATA

This prospectus 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.

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USE OF PROCEEDS

The selling stockholders are selling all of the shares of common stock being sold in the offering, including any shares sold by certain of the selling stockholders upon exercise of the underwriters over-allotment option to purchase additional shares. Accordingly, we will not receive any proceeds from the sale of shares of our common stock by the selling stockholders in the offering. The principal purposes of this offering are to facilitate an orderly distribution of shares and to increase our public float.

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PRICE RANGE OF OUR COMMON STOCK

Our common stock has been listed on the Nasdaq Global Market since April 11, 2013 under the symbol CMRX. Prior to that date, there was no public market for our common stock. Shares sold in our IPO on April 11, 2013 were priced at $14.00 per share.

On October 17, 2013, the closing price for our common stock as reported on the Nasdaq Global Market was $17.00 per share. The following table sets forth the ranges of high and low sales prices per share of our common stock as reported on the Nasdaq Global Market for the periods 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 (through October 17, 2013)	$ 22.50	$ 15.48

As of September 30, 2013, there were 83 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.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital 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.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents, and our capitalization as of June 30, 2013:

	As of June 30, 2013 (in thousands, except per share amounts) (unaudited)
Cash and cash equivalents	$ 115,438
Short-term investments, available for sale	$ 7,595
Loan payable	$ 12,703
Shareholders equity:	
Common stock, $0.001 par value, 200,000,000 shares authorized, 25,779,445 shares issued and outstanding	26
Additional paid-in capital	258,870
Accumulated other comprehensive loss	(1)
Accumulated deficit	(147,851)
Total shareholders equity	111,044
Total capitalization	$ 123,747

The table above is based on the number of shares of our common stock outstanding as of June 30, 2013, and excludes:

2,674,920 shares of common stock issuable upon the exercise of outstanding stock options as of June 30, 2013, at a weighted-average exercise price of $2.71 per share (including 427,283 shares issued upon the exercise of outstanding stock options subsequent to June 30, 2013 that will be sold in this offering by a selling stockholder);

102,547 shares of common stock issuable pursuant to outstanding restricted stock units as of June 30, 2013;

1,343,760 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2013, at a weighted-average exercise price of $7.25 per share;

704,225 shares of common stock reserved for future issuance under our 2013 employee stock purchase plan; and

1,732,911 shares of common stock reserved for future issuance under our 2013 equity incentive plan.

You should read this table together with Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes appearing elsewhere in this prospectus.

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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 prospectus. 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 and results of interim periods are not necessarily indicative of the results for the entire year.

We derived the following selected statement of operations data for the years ended December 31, 2010, 2011 and 2012 and the selected balance sheet data as of December 31, 2011 and 2012 from our audited financial statements and related notes appearing elsewhere in this prospectus. We derived the selected statement of operations data for the three and six months ended June 30, 2012 and 2013 and balance sheet data as of June 30, 2013 from our unaudited financial statements appearing elsewhere in this prospectus, which have been prepared on the same basis as our audited financial statements and include all adjustments, consisting of normal recurring adjustments necessary for the fair presentation of the financial position and results of operations for these periods.

	Years Ended December 31,			Six Months Ended June 30,	
	2010	2011	2012	2012	2013
	(in thousands, except share and per share data)				
Statement of Operations:					
Revenues					
Collaboration and licensing revenues	$	$55	$17,445	$	$
Contract and grant revenues	1,715	12,046	16,275	9,283	2,579
Total revenues	1,715	12,101	33,720	9,283	2,579
Operating expenses:					
Research and development	21,074	30,108	30,106	16,075	13,059
General and administrative	5,945	6,985	6,397	3,120	3,725
Total operating expenses	27,019	37,093	36,503	19,195	16,784
Loss from operations	(25,304)	(24,992)	(2,783)	(9,912)	(14,205)
Other income (expense):					
Interest expense, net	(154)	(212)	(776)	(237)	(771)
Fair value adjustments to warrant liability		(385)	(847)	(1,073)	(6,590)
Other income	1				
Net loss	(25,457)	(25,589)	(4,406)	(11,222)	(21,566)
Accretion of redeemable convertible preferred stock		(9,565)	(4,357)	(1,800)	(34,108)
Net loss attributable to common shareholders	(25,457)	(35,154)	(8,763)	(13,022)	(55,674