

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***

	<b><i>Price to Public</i></b>	<b><i>Underwriting Discounts and Commissions<sup>(1)</sup></i></b>	<b><i>Proceeds to Selling Stockholders</i></b>
<b><i>Per Share</i></b>	\$16.50	\$0.99	\$15.51
<b><i>Total</i></b>	\$40,870,417	\$2,452,225	\$38,418,192

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

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*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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TABLE OF CONTENTS**TABLE OF CONTENTS**

	Page
<u>Prospectus Summary</u>	<u>1</u>
<u>Risk Factors</u>	<u>9</u>
<u>Special Note Regarding Forward-Looking Statements</u>	<u>39</u>
<u>Market, Industry and Other Data</u>	<u>41</u>
<u>Use of Proceeds</u>	<u>42</u>
<u>Price Range of Our Common Stock</u>	<u>43</u>
<u>Dividend Policy</u>	<u>44</u>
<u>Capitalization</u>	<u>45</u>
<u>Selected Financial Data</u>	<u>46</u>
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>47</u>
<u>Business</u>	<u>72</u>
<u>Management</u>	<u>117</u>
	Page
<u>Executive and Director Compensation</u>	<u>126</u>
<u>Certain Relationships and Related Party Transactions</u>	<u>144</u>
<u>Principal and Selling Stockholders</u>	<u>148</u>
<u>Description of Capital Stock</u>	<u>151</u>
<u>Shares Eligible for Future Sale</u>	<u>156</u>
<u>Material U.S. Federal Income Tax Consequences to Non-U.S. Holders of our Common Stock</u>	<u>158</u>
<u>Underwriters</u>	<u>161</u>
<u>Legal Matters</u>	<u>166</u>
<u>Experts</u>	<u>166</u>
<u>Where You Can Find Additional Information</u>	<u>166</u>
<u>Index to Financial Statements</u>	<u>F-1</u>

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.

TABLE OF CONTENTS

## 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

## TABLE OF CONTENTS

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.



## TABLE OF CONTENTS

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.

3

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TABLE OF CONTENTS

## **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.

4

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TABLE OF CONTENTS

## 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 30<sup>th</sup>, and (d) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. 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.

TABLE OF CONTENTS

## 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.

6

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TABLE OF CONTENTS**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.

Statement of Operations Data:	Year Ended December 31,			Six Months Ended June 30,	
	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 <sup>(1)</sup>	\$(17.52 )	\$(23.49 )	\$(5.75 )	\$(8.58 )	\$(4.50 )
Shares used to calculate net loss per common share <sup>(1)</sup>	1,452,877	1,496,262	1,524,628	1,518,112	12,360,125

See Note 2 of our Notes to Financial Statements appearing elsewhere in this prospectus for an explanation of the (1) 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.



TABLE OF CONTENTS

	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 <sup>(2)</sup>	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.

8

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TABLE OF CONTENTS

## 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.

TABLE OF CONTENTS

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



TABLE OF CONTENTS

**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

If we fail to obtain additional financing, we could be forced to delay, reduce or eliminate our product development programs

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

## TABLE OF CONTENTS

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;

12

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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.

TABLE OF CONTENTS

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 trials



TABLE OF CONTENTS

**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

TABLE OF CONTENTS

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

After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize our product candidates, including brincidofovir.

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



TABLE OF CONTENTS

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

TABLE OF CONTENTS

**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

18

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TABLE OF CONTENTS

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

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

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.

TABLE OF CONTENTS

## **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.



TABLE OF CONTENTS

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.

## TABLE OF CONTENTS

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

TABLE OF CONTENTS

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.

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

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

TABLE OF CONTENTS

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

If we obtain approval to commercialize any products outside of the United States, a variety of risks associated with

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



TABLE OF CONTENTS

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

TABLE OF CONTENTS

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

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

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.

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

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



TABLE OF CONTENTS

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

TABLE OF CONTENTS

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;

30

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TABLE OF CONTENTS

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



## TABLE OF CONTENTS

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



TABLE OF CONTENTS

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

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

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.

TABLE OF CONTENTS

## **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



TABLE OF CONTENTS

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 30<sup>th</sup>, and (d) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable

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.

TABLE OF CONTENTS

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

**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.



TABLE OF CONTENTS

**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

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital app

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

TABLE OF CONTENTS

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.

TABLE OF CONTENTS

## **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 uncertainty about 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.

TABLE OF CONTENTS

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.

40

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TABLE OF CONTENTS

## **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.

41

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TABLE OF CONTENTS

## **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.

42

---

TABLE OF CONTENTS

## 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.



TABLE OF CONTENTS

## **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.

44

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TABLE OF CONTENTS**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.

TABLE OF CONTENTS**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 )
Net loss per share, basic and diluted	\$(17.52 )	\$(23.49 )	\$(5.75 )	\$(8.58 )	\$(4.50 )
Weighted average shares outstanding:					
Basic and diluted	1,452,877	1,496,262	1,524,628	1,518,112	12,360,125

	As of December 31,	As of June
	2011	30,
	2012	2013

	(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 <sup>(1)</sup>	2,601	14,620	12,703
Redeemable convertible preferred stock warrant liability	6,491	7,512	
Redeemable convertible preferred stock	103,366	107,723	
Accumulated deficit	(93,678 )	(101,032 )	(147,851 )
Total stockholders' equity (deficit)	(93,680 )	(101,031 )	111,044

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

TABLE OF CONTENTS

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

## 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 in September 2013 we announced the initiation of patient dosing in the Phase 3 SUPPRESS study for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients. We intend to develop brincidofovir as the first broad-spectrum antiviral against double-stranded DNA (dsDNA) viruses. 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.

To date, we have devoted substantially all of our resources to our research and development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through June 30, 2013, we have funded our operations primarily through:

the IPO generating net proceeds of approximately \$107.6 million after deducting underwriting discounts, commissions and offering expenses;

the private placement of preferred stock, common stock, and warrants to purchase preferred stock totaling \$100.4 million;

the receipt of government grants and contracts totaling approximately \$68.4 million;

the receipt of \$21.0 million in loan proceeds from financial institutions; and

the receipt of \$17.5 million of up-front proceeds under our collaboration and license agreement with Merck.

We have incurred net losses in each year since our inception in 2000. Our net losses were approximately \$25.5 million, \$25.6 million, and \$4.4 million for the years ended December 31, 2010, 2011 and 2012, respectively, and \$11.2 million and \$21.6 million for the six months ended June 30, 2012 and 2013, respectively. As of June 30, 2013, we had an accumulated deficit of approximately \$147.9 million. Substantially all our net losses resulted from costs

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

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We anticipate that our expenses will increase substantially as we:

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

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

47

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## TABLE OF CONTENTS

scale up manufacturing capabilities to commercialize brincidofovir for any indications for which we receive regulatory approval;  
begin outsourcing of the commercial manufacturing of brincidofovir for any indications for which we receive regulatory approval;  
establish an infrastructure for the sales, marketing and distribution of brincidofovir for any indications for which we receive regulatory approval;

expand our research and development activities and advance our clinical programs;  
maintain, expand and protect our intellectual property portfolio;

continue our research and development efforts and seek to discover additional product candidates; and  
add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts and operations as a public company.

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

## **Financial Overview**

### **Revenue**

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

In September 2003, we were awarded a \$36.3 million grant from the National Institute of Allergy and Infectious Diseases (NIAID) to support our development of an oral drug for the treatment of smallpox. The work performed under this grant resulted in our selection of brincidofovir as a lead product candidate for development. The grant, and our activities conducted in connection therewith, were substantially complete in early 2010. However, the grant was not formally terminated until February 2011.

In February 2011, we entered into a contract with Biomedical Advanced Research and Development Authority (BARDA), a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods of approximately one year each, referred to as option segments. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at Chimerix's discretion. The contract is a cost plus fixed fee development contract. Under the contract currently in effect, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees. We are currently performing under the first option segment of the contract during which we may receive up to \$5.0 million in expense reimbursement and fees. As of June 30, 2013, we had recognized revenue in aggregate of \$30.9 million with respect to the base performance segment and the first extension

period.

In July 2012, we entered into a collaboration and license agreement granting Merck exclusive worldwide rights to CMX157, our oral nucleotide compound currently being evaluated to treat HIV infection. Under the

48

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## TABLE OF CONTENTS

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

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

### **Research and Development Expenses**

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

salaries and related overhead expenses, which include stock option compensation and benefits, for personnel in research and development functions;

fees paid to consultants and CROs, including in connection with our preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;

payments to third-party manufacturers, which produce, test and package our drug substance and drug product (including continued testing of process validation and stability);

costs related to compliance with regulatory requirements; and

license fees for and milestone payments related to licensed products and technologies.

From our inception through June 30, 2013, we have incurred approximately \$142.0 million in research and development expenses, of which we estimate \$110.3 million relates to our development of brincidofovir. In the years ended December 31, 2010, 2011 and 2012, we spent \$21.1 million, \$30.1 million, and \$30.1 million, respectively and \$16.1 million and \$13.1 million for the six months ended June 30, 2012 and 2013, respectively, on research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of brincidofovir for the prevention of CMV infection in HCT and other indications and to further advance the development of our other product candidates, subject to the availability of additional funding.

Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. We typically use our employee and infrastructure resources across multiple research and development programs.

The table below summarizes our research and development expenses for the periods indicated. Our direct research and development expenses consist primarily of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, preclinical development, and payments to third-party

manufacturers of drug substance and drug product. We typically use our employee and infrastructure resources across multiple research and development programs.

TABLE OF CONTENTS

	Years Ended			Six Months Ended	
	December 31, 2010	2011	2012	June 30, 2012	2013
	(unaudited)				
	(in thousands)				
Direct research and development expense	\$ 14,803	\$ 21,794	\$ 22,013	\$ 11,990	\$ 7,053
Personnel costs	3,874	5,480	5,914	2,907	5,029
Indirect research and development expense	2,397	2,834	2,179	1,178	977
	\$ 21,074	\$ 30,108	\$ 30,106	\$ 16,075	\$ 13,059

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

the uncertainty of the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;

the potential benefits of our candidates over other therapies;

the ability to market, commercialize and achieve market acceptance for any of our product candidates that we are developing or may develop in the future;

the results of future clinical trials;

the timing and receipt of any regulatory approvals; and

the filing, prosecuting, defending and enforcing of patent claims and other intellectual property rights, and the expense of doing so.

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

**Brincidofovir**

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

data analysis of our Phase 2 clinical trial in patients with AdV, Study 202;

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

In addition, pursuant to our contract with BARDA, we are evaluating brincidofovir for the treatment of smallpox.

During the base performance segment of the contract, we incurred significant expense in connection with the development of orthopox virus animal models, the demonstration of efficacy and pharmacokinetics of brincidofovir in the animal models, the conduct of an open label clinical safety study for subjects with dsDNA viral infections, and the manufacture and process validation of bulk drug substance and brincidofovir 100 mg



## TABLE OF CONTENTS

tablets. As of June 30, 2013, we initiated performance under the first option segment of the contract with BARDA, however, we have not yet incurred significant expenses related to this performance as the activities were minimal and start-up in nature.

### **General and Administrative Expenses**

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

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

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

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

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

### **Revaluation of Warrants**

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

### **Stock-based Compensation**

The Financial Accounting Standards Board (FASB) authoritative guidance requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Total consolidated stock-based compensation expense of \$753,000, \$966,000 and \$1.4 million was recognized in the years ended December 31, 2010, 2011 and 2012, respectively, and \$539,000 and \$2.6 million was recognized in the six months ended June 30, 2012 and 2013, respectively. The stock-based compensation expense recognized included expense from performance-based stock options and restricted stock units (RSUs).

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

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

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

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

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles

## TABLE OF CONTENTS

in the United States (GAAP). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies related to revenue recognition, clinical trial expenses, valuation of stock-based compensation and restricted stock units are the most critical for fully understanding and evaluating our financial condition and results of operations.

### **Revenue Recognition**

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

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

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

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

collaboration agreement will be recognized when received.

From our inception through June 30, 2013, we have not generated any revenue from product sales. For the same period, we have generated \$68.4 million in grant and contract revenue. We recognize revenue under government grants and contracts as qualifying research activities are conducted based on invoices received from company vendors.

Any amounts received in advance of performance are recorded as deferred revenue until earned.



## TABLE OF CONTENTS

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

### **Clinical Trial Accruals**

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

Our objective is to reflect the appropriate clinical trial expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of trials, or the services completed. During the course of a clinical trial, we adjust the rate of clinical trial expense recognition if actual results differ from the estimates. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. Although we do not expect that our estimates will be materially different from amounts actually incurred, our understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period. Through June 30, 2013, there had been no material adjustments to our prior period estimates of accrued expenses for clinical trials. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

### **Valuation of Stock-Based Compensation**

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

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

Years Ended		Six Months Ended	
December 31,		June 30,	
2010	2011	2012	2013

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	(in thousands)			(unaudited)	
Research and development					
Employee	\$ 299	\$ 315	\$ 336	\$ 166	\$ 313
Non-employee			80	31	21
General and administrative					
Employee	454	651	921	322	250
Non-employee			59	20	77
Total	\$ 753	\$ 966	\$ 1,396	\$ 539	\$ 661

53

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TABLE OF CONTENTS

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

We do not have sufficient history to estimate the volatility of our common stock price. We calculate expected volatility based on reported data for selected reasonably similar publicly traded companies for which the historical information is available. For the purpose of identifying peer companies, we consider characteristics such as industry, length of trading history, similar vesting terms and in-the-money option status. We plan to continue to use the guideline peer group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future option grants.

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

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

The assumptions used in the Black-Scholes option-pricing model for the years ended December 31, 2010, 2011, and 2012 and the six months ended June 30, 2012 and 2013 are set forth below:

**Employee Stock Options**

	Years Ended December 31,			Six Months Ended June 30,	
	2010	2011	2012	2012	2013
Volatility	91.00 %	82.00 %	80.55 %	79.91 %	81.65 %
Expected term (in years)	7.0	7.0	6.0	6.0	6.1
Risk-free interest rate	2.69 %	2.85 %	0.86 %	0.91 %	1.18 %
Expected dividend yield	0 %	0 %	0 %	0 %	0 %
Weighted average option value per share	\$ 1.75	\$ 1.74	\$ 1.93	\$ 1.75	\$ 2.07

**Non-employee Stock Options**

	Years Ended December 31,		Six Months Ended June 30,	
	2010	2011	2012	2013
Volatility	77.80 %	81.77 %	83.15 %	73.44 %
Expected term (in years)	2.7	5.8	5.5	3.9
Risk-free interest rate	0.40 %	0.78 %	0.83 %	0.53 %
Expected dividend yield	0 %	0 %	0 %	0 %
Weighted average option value per share	\$ 3.38	\$ 3.48	\$ 2.49	\$ 5.92

### **Common Stock Fair Value**

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

TABLE OF CONTENTS

our common stock prior to our IPO, on each grant date, our board of directors, or a committee of our board of directors acting under delegated authority, considered various objective and subjective factors, along with input from management, to determine the fair value of our common stock, including:

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

Our board of directors, or a committee of our board of directors acting under delegated authority, also considered and relied upon appraisals of the value of our stock from an independent third-party valuation specialist who conducted a thorough analysis using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants (AICPA) Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation (AICPA Practice Guide). The independent third-party valuation specialist provided appraisals containing the valuation analyses described below as to the fair value of our common stock as of June 1, 2009, February 15, 2011, December 31, 2011, September 30, 2012, December 31, 2012 and March 1, 2013.

The June 1, 2009 Valuation

The valuation analysis as of June 1, 2009, identified three primary components of our business: brincidofovir for the smallpox indication, brincidofovir for commercial indications, and CMX157 for HIV and other assets.

The valuation of brincidofovir for the smallpox indication involved combining a Monte Carlo simulation with an income approach that reflected the significant business risk associated with procuring government contracts and receiving the expected base revenue going forward. Separately, as part of our long-range planning, we developed expense and potential sales projections that indicated the expected growth path of research and development expenditures. This data was used as input to a compound option-pricing model which was then used to estimate values of brincidofovir for commercial indications and CMX157 for HIV and other assets.

In addition, the AICPA guidelines require the examination of the implied value of our equity when a financing occurs on or very close to the valuation date. Since our Series E preferred stock financing was expected to occur shortly following the valuation date, this was used as a basis for determining the total value of our equity following the financing event. The valuation analysis yielded a fair value of our common stock of \$3.16 per share as of June 1, 2009.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options on the dates set forth in the table below in reliance on the valuation analysis as of June 1, 2009, and the other objective and subjective factors described above:

Grant Dates	Number of Common Shares	Exercise Price per Common	Fair Value per Common Share	Intrinsic Value per Grant
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	Underlying Options Granted	Share	
January 15, 2010	41,547	\$ 3.16	\$ 3.16
February 5, 2010	1,492	\$ 3.16	\$ 3.16
April 14, 2010	234,771	\$ 3.16	\$ 3.16
April 20, 2010	56,338	\$ 3.16	\$ 3.16

55

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TABLE OF CONTENTS

Grant Dates	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Fair Value per Common Share	Intrinsic Value per Grant
May 11, 2010	7,125	\$ 3.16	\$ 3.16	
May 24, 2010	39,436	\$ 3.16	\$ 3.16	
July 6, 2010	39,436	\$ 3.16	\$ 3.16	
July 20, 2010	52,672	\$ 3.16	\$ 3.16	
August 12, 2010	14,084	\$ 3.16	\$ 3.16	

The February 15, 2011 Valuation

AICPA guidelines require that when a financing event takes place close to the valuation date, the implied value of equity within that financing must be considered in the valuation analysis. Since our Series F preferred stock financing closed in early February 2011, this event was used as a basis for this valuation. Our value of equity was calculated by back-solving for the overall equity value implied in the financing. Our Series F preferred stock financing resulted in gross proceeds of \$45.0 million, approximately 62% of which was raised from new outside investors. Because this investment was a significant amount, where a portion was made by informed investors that had no prior investment in us, we determined that this investment represented the fair value of our Series F preferred stock and the related warrants to purchase Series F preferred stock issued in connection therewith. After setting up the contingent claims allocation model to be representative of the total interests of each class of equity security then-outstanding, the model was back-solved, holding the claims of each equity security constant relative to one another, in order to determine the fair value of our equity. The valuation analysis yielded a fair value of our common stock of \$2.35 per share as of February 15, 2011.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options to purchase our common stock on the dates set forth in the table below in reliance on the valuation analysis as of February 15, 2011, and the other objective and subjective factors described above:

Grant Dates	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Fair Value per Common Share	Intrinsic Value per Grant
April 7, 2011	721,530	\$ 2.35	\$ 2.35	
April 8, 2011	12,674	\$ 2.35	\$ 2.35	
May 10, 2011	39,716	\$ 2.35	\$ 2.35	
June 20, 2011	14,084	\$ 2.35	\$ 2.35	
August 15, 2011	14,084	\$ 2.35	\$ 2.35	
September 6, 2011	3,380	\$ 2.35	\$ 2.35	
September 30, 2011	15,774	\$ 2.35	\$ 2.35	
November 17, 2011	70,422	\$ 2.35	\$ 2.35	
February 22, 2012 <sup>(1)</sup>	1,690	\$ 2.35	\$ 2.49	\$ 240
February 28, 2012 <sup>(1)</sup>	4,225	\$ 2.35	\$ 2.49	\$ 600

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March 29, 2012 <sup>(1)</sup>	14,084	\$ 2.35	\$ 2.49	\$ 2,000
April 18, 2012 <sup>(1)</sup>	14,084	\$ 2.35	\$ 2.49	\$ 2,000

The December 31, 2011, valuation analysis described below was not completed until late April 2012, and therefore was not available at the time the February 22 and 28, March 29 and April 18, 2012 stock option grants were made.

(1) The board of directors or a committee of the board of directors, as applicable, determined the exercise price of these option grants in good faith based on all of the information known to them at the time of such grants.

The December 31, 2011 Valuation

The valuation analysis at December 31, 2011, was completed in two stages. Using a contingent claims model in combination with our sale of Series F preferred stock, which occurred in February 2011, the fair value of total equity and all components of our capital structure, including our common stock, was determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporated both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities that are consistent with the expectations of market participants, a distribution of equity values was produced which covered the range of events that an informed market participant might expect. These outcomes were organized into ranges and a



TABLE OF CONTENTS

probability was calculated based on the percent of the total falling into each range. This process created a range of equity values. Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure, including our common stock. The value of our common stock was weighted by its respective probability to determine the final fair value of our common stock as of December 31, 2011. The valuation analysis yielded a fair value of our common stock of \$2.38 per share as of December 31, 2011.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options on the dates set forth in the table below in reliance on the valuation analysis as of December 31, 2011, and the other objective and subjective factors described above.

Grant Dates	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Fair Value per Common Share	Intrinsic Value per Grant
May 16, 2012	1,408	\$ 2.38	\$ 3.38	\$ 1,400
June 1, 2012	14,084	\$ 2.38	\$ 3.38	\$ 14,100
June 13, 2012	123,019	\$ 2.38	\$ 3.38	\$ 123,000
June 27, 2012	845	\$ 2.38	\$ 3.38	\$ 840
July 16, 2012	14,084	\$ 2.38	\$ 3.38	\$ 14,000
August 17, 2012	7,041	\$ 2.38	\$ 4.26	\$ 13,250
September 17, 2012	2,816	\$ 2.38	\$ 4.26	\$ 5,300
October 8, 2012 <sup>(1)</sup>	4,224	\$ 2.38	\$ 4.26	\$ 7,950
October 25, 2012 <sup>(1)</sup>	4,507	\$ 2.38	\$ 4.26	\$ 8,480

The September 30, 2012 valuation analysis described below was not completed until January 2013, and therefore was not available at the time the October 8, 2012 and October 25, 2012 stock option grants were made. The board of directors or a committee of the board of directors, as applicable, determined the exercise price of these option grants in good faith based on all of the information known to them at the time of such grants.

The September 30, 2012 Valuation

The valuation analysis at September 30, 2012, was completed in two stages. Using a contingent claims model in combination with our sale of Series F preferred stock, which occurred in February 2011, the fair value of total equity and all components of our capital structure, including our common stock, was determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities that are consistent with the expectations of market participants, a distribution of equity values was produced which covered the range of events that an informed market participant might expect. These outcomes were organized into ranges and a probability was calculated based on the percent of the total falling into each range. This process created a range of equity values.

In addition to the range of simulation outcomes associated with the firm as a going concern, an additional outcome was assigned to reflect the increased likelihood of the occurrence of an initial public offering. As a result of an in-depth management assessment regarding developments in our business, a 20% probability of an initial public offering was assigned. In particular, during the period from December 31, 2011, through September 30, 2012, the following events occurred which increased the likelihood of the occurrence of an initial public offering:

in February 2012, we announced positive results from Study 201, our brincidofovir Phase 2 study in CMV;  
in May 2012, a positive End-of-Phase 2 meeting was held with the FDA with respect to brincidofovir for the prevention of CMV infection in HCT recipients; and  
in July 2012, we announced the execution of an exclusive license and collaboration agreement with Merck for the out-license of CMX157, pursuant to which we received \$17.5 million in upfront fees.

Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure, including our common stock. The value of our common stock was

57

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TABLE OF CONTENTS

weighted by its respective probability to determine the final fair value of our common stock as of September 30, 2012. The valuation analysis yielded a fair value of our common stock of \$4.26 per share as of September 30, 2012.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options on the date set forth in the table below in reliance upon the valuation analysis as of September 30, 2012, and the other objective and subjective factors described above:

Grant Date	Number of Common Shares Underlying Options Granted	Exercise Price per Common Stock	Fair Value per Common Share	Intrinsic Value per Grant
November 18, 2012	176,056	\$ 4.26	\$ 4.26	

The December 31, 2012 Valuation

The valuation analysis at December 31, 2012, was completed in two stages. Using a contingent claims model in combination with our sale of Series F preferred stock, which occurred in February 2011, the fair value of total equity and all components of our capital structure, including our common stock was determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities that are consistent with the expectations of market participants, a distribution of equity values was produced which covered the range of events that an informed market participant might expect. These outcomes were organized into ranges and a probability was calculated based on the percent of the total falling into each range. This process created a range of equity values.

In addition to the range of simulation outcomes associated with the firm as a going concern, an additional outcome was assigned to reflect the increased likelihood of the occurrence of an initial public offering. As a result of an in-depth management assessment regarding the developments in our business, a 30% probability of an initial public offering was assigned. In particular, during the period from September 30, 2012, through December 31, 2012, the following events occurred which increased the likelihood of the occurrence of an initial public offering:

in November 2012, we appointed M. Michelle Berrey, M.D., M.P.H. as our Chief Medical Officer;  
in December 2012, we completed the enrollment of our brincidofovir Phase 2 study in AdV;  
in December 2012, agreement was reached with the FDA for timing and primary endpoints for our Phase 3 study with respect to brincidofovir for the prevention of CMV infection in HCT recipients; and  
in December 2012, we made significant progress with respect to our development of brincidofovir for the treatment of smallpox.

Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure, including our common stock. The value of our common stock was weighted by its respective probability to determine the final fair value of our common stock as of December 31, 2012. The valuation analysis yielded a fair value of our common stock of \$5.05 per share as of December 31, 2012.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options on the dates set forth in the table below in reliance upon the valuation analysis as of December 31, 2012, and the other objective and subjective factors described above:

Grant Date	Number of Common Shares Underlying Options Granted	Exercise Price per Common Stock	Fair Value per Common Share	Intrinsic Value per Grant
February 4, 2013	84,507	\$ 5.05	\$ 5.05	
February 21, 2013	1,408	\$ 5.05	\$ 5.05	

58

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TABLE OF CONTENTSThe March 1, 2013 Valuation

The valuation analysis at March 1, 2013, was completed in two stages. Using a contingent claims model in combination with our sale of Series F preferred stock, which occurred in February 2011, the fair value of total equity and all components of our capital structure, including our common stock was determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities that are consistent with the expectations of market participants, a distribution of equity values was produced which covered the range of events that an informed market participant might expect. These outcomes were organized into ranges and a probability was calculated based on the percent of the total falling into each range. This process created a range of equity values.

In addition to the range of simulation outcomes associated with the firm as a going concern, an additional outcome was assigned to reflect the increased likelihood of the occurrence of an initial public offering. As a result of an in-depth management assessment regarding the developments in our business, a 45% probability of an initial public offering was assigned. In particular, during the period from December 31, 2012, through March 1, 2013, the following events occurred which increased the likelihood of the occurrence of an initial public offering:

in February 2013, we appointed Ernest Mario, Ph.D. as the Chairman of our Board of Directors; in February 2013, our discussions with the FDA with respect to our Phase 3 study for brincidofovir for the prevention of CMV infection in HCT recipients resulted in an agreed population, endpoint and study design for which we received a Study May Proceed letter; and in February 2013, the FDA granted Fast Track designation for brincidofovir for the prevention of CMV infection. Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure, including our common stock. The value of our common stock was weighted by its respective probability to determine the final fair value of our common stock as of March 1, 2013. The valuation analysis yielded a fair value of our common stock of \$7.57 per share as of March 1, 2013.

Our board of directors, or a committee of our board of directors acting under delegated authority, granted stock options on the date set forth in the table below in reliance upon the valuation analysis as of March 1, 2013, and the other objective and subjective factors described above:

Grant Date	Number of Common Shares Underlying Options Granted	Exercise Price per Common Share	Fair Value per Common Share	Intrinsic Value per Grant
March 13, 2013	98,591	\$ 7.57	\$ 7.57	

In connection with the preparation of the financial statements included in the registration statement related to our IPO, we reassessed the estimated fair value of our common stock on a retrospective basis for financial reporting purposes. Based on the September 30, 2012, and December 31, 2012, valuation reports, we concluded that certain stock options granted during 2012 had an exercise price (which was determined in good faith based on all available information as of the date of grant, rather than based on retrospective analysis) that was different than the reassessed fair value of the common stock at the date of grant. We used these fair value reassessments to determine stock-based compensation expense which is recorded in our financial statements. The difference between the reassessed fair value of the common stock versus the exercise price of the stock options is reflected as intrinsic value in the applicable tables

above.

Post-IPO Valuation of Common Stock

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

59

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TABLE OF CONTENTS

The intrinsic value of all outstanding vested and unvested options as of June 30, 2013, was as follows:

	Number of Options	Aggregate Intrinsic Value (in thousands)
Unvested	823,221	\$ 16,926
Vested	1,851,699	\$ 40,657

**Restricted Stock Units (RSUs)**

In 2012 and 2013, we issued RSUs to certain employees which vest based on specific performance criteria. By their terms, the RSUs became immediately vested upon the effective date of our registration statement for our common stock in connection with the IPO, subject to the RSU holder's continuous service with the Company at the vesting event. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. We recorded compensation expense attributable to the RSUs. As of June 30, 2013, \$1.9 million in compensation expense had been recorded as the performance criterion was met.

**Fair Value Adjustments to Warrant Liability**

We issued warrants to purchase shares of our Series F preferred stock in connection with (i) a loan and security agreement entered into with SVB and MidCap in January 2012, and (ii) an equity financing agreement with certain investors for the sale of Series F preferred stock, which occurred in February 2011. As discussed in Note 2 to our financial statements appearing elsewhere in this prospectus, the warrants to purchase shares of our Series F preferred stock are classified as a liability and are required to be measured at fair value. The adjustment to the fair valuation of the warrants resulted in other expense of \$385,000 and \$847,000 for the year ended December 31, 2011 and 2012, respectively, and \$1.1 million and \$6.6 million for the six months ended June 30, 2012 and 2013, respectively. The warrants were valued using a two stage process. Using a contingent claims model, the fair value of total equity and all components of our capital structure, including the warrants, was determined as of the time of our sale of Series F preferred stock. Using this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporated both Monte Carlo and risk neutral frameworks. Using a contingent claims framework, each equity value in the array was allocated to the various components of the capital structure including the warrants. Each warrant value was weighted by its respective probability to determine the final fair value of the warrants as of December 31, 2011 and 2012. The key unobservable inputs used in the determination of the December 31, 2012 fair value are (i) volatility 79%, (ii) range of implied fair value of the Series F redeemable convertible preferred stock \$2.19 to \$2.85, (iii) time to liquidity 8 months to 5 years, and (iv) range of probabilities of liquidity event outcomes 2% to 31%.

Upon completion of our IPO, these warrants were adjusted to a fair value of \$14.1 million. The non-cash transaction was recorded in other income (expense). The warrant liability was reclassified as common stock warrants and therefore no longer requires revaluation.

**Utilization of Net Operating Loss Carryforwards**

At December 31, 2011 and 2012, we had net operating loss carryforwards for federal and state tax purposes of approximately \$80.2 million and \$75.9 million and \$83.4 million and \$65.8 million, respectively, which begin to

expire in 2020 and 2018, respectively. In addition, we had tax credit carryforwards for federal tax purposes of approximately \$0.9 million as of December 31, 2012, which begin to expire in 2022. The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. In general, if we experience a greater than 50% point aggregate change in ownership of certain significant stockholders or groups over a three-year period (a Section 382 ownership change), utilization of our pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Code (and similar state laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the pre-change net operating loss carryforwards before utilization and may be substantial. We have determined that a Section 382 ownership change occurred in 2002 and 2007 resulting in limitations of at least \$64,000 and \$762,000, respectively, of



TABLE OF CONTENTS

losses incurred prior to the respective ownership change dates. We believe that with our initial public offering, our most recent private placement and other transactions that have occurred since 2007, we may have triggered an ownership change limitation and we are in the process of performing the relevant analyses. 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.

**JOBS Act**

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

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

**Results of Operations****Comparison of the Years Ended December 31, 2010 and 2011**

	Years Ended December		Increase	% Increase
	31,	31,	(Decrease)	(Decrease)
	2010	2011		
	(in thousands, except percentages)			
Revenues:				
Collaboration and license revenue	\$	\$ 55	\$ 55	*
Contract and grant revenue	1,715	12,046	10,331	602.4 %
Operating expenses:				
Research and development	21,074	30,108	9,034	42.9 %
General and administrative	5,945	6,985	1,040	17.5 %

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Loss from operations	(25,304 )	(24,992 )	(312 )	(1.2 )%
Interest expense, net	(154 )	(212 )	58	37.7 %
Fair value of warrant adjustment		(385 )	385	*
Other income	1		(1 )	*
Net loss	\$ (25,457 )	\$ (25,589 )	\$ 132	0.5 %

\*

Not meaningful or not calculable

61

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TABLE OF CONTENTS

**Contract and Grant Revenue**

For the year ended December 31, 2011, we recorded \$12.0 million in revenue for services performed pursuant to the BARDA contract that was awarded in February 2011. In the year ended December 31, 2010, our revenue consisted of amounts paid pursuant to our grant from the NIAID and a \$491,000 federal research and development tax credit.

**Research and Development Expenses**

Research and development expenses were \$21.1 million and \$30.1 million for the years ended December 31, 2010 and 2011, respectively. The increase in research and development expenses during this period of \$9.0 million, or 42.9%, was primarily due to:

an increase in clinical trial costs by \$4.3 million due to the initiation of our Phase 2 study for brincidofovir; an increase in compound manufacturing costs by \$2.3 million as we began our efforts to manufacture and process validation of bulk drug substance and 100 mg tablets under the BARDA contract; an increased in compensation costs by \$1.6 million as we added ten additional employees in our clinical, regulatory and program management departments; and

an increase of \$400,000 in regulatory and patent legal fees.

**General and Administrative**

General and administrative expenses were \$5.9 million and \$7.1 million for the years ended December 31, 2010 and 2011, respectively. The increase in general and administrative expenses during this period of \$1.2 million, or 19.6%, was primarily due to:

an increase in business development expenses in the amount of \$446,000; an increase in consultant fees in the amount of \$680,000 primarily due to a reimbursable one-time contract implementation required to support the BARDA contract and general staffing support; and an increase in legal fees in the amount of \$150,000 primarily due to activities related to BARDA.

**Interest Expense, Net**

Interest expense, net was \$154,000 and \$212,000 for the years ended December 31, 2010 and 2011, respectively. The increase of \$58,000, or 37.7%, relates to interest expense attributable to a full year of interest payments made in 2011 in connection of the loan we incurred in March 2010, as compared to eight months of interest payments made in 2010.

**Fair Value of Warrant Adjustment**

Some of our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, the fair value of the warrants were determined by us using a two-stage contingent claims model, resulting in the recognition of additional losses of \$385,000 for the year ended December 31, 2011. The loss is due to the increased value of the warrants due to increased likelihood of the occurrence of a liquidity event. We did not have any warrants outstanding at December 31, 2010 that were deemed to be derivative instruments.

TABLE OF CONTENTS**Comparison of the Years Ended December 31, 2011 and 2012**

	Years Ended December		Increase	% Increase
	31,	31,	(Decrease)	(Decrease)
	2011	2012		
	(in thousands, except percentages)			
Revenues:				
Collaboration and license revenue	\$ 55	\$ 17,445	\$ 17,390	*
Contract and grant revenue	12,046	16,275	4,229	35.1 %
Operating expenses:				
Research and development	30,108	30,106	(2 )	*
General and administrative	6,985	6,397	(588 )	(8.4 )%
Loss from operations	(24,992 )	(2,783 )	(22,209 )	(88.9 )%
Interest expense, net	(212 )	(776 )	564	266.0 %
Fair value of warrant adjustment	(385 )	(847 )	462	120.0 %
Net loss	\$ (25,589 )	\$ (4,406 )	\$ (21,183 )	(82.8 )%

\*not meaningful

**Collaboration and License Revenue**

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

**Contract and Grant Revenue**

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

**Research and Development Expenses**

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

**General and Administrative Expenses**

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

systems required to manage and report under the BARDA contract.

### **Interest Expense, Net**

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

### **Fair Value of Warrant Adjustment**

Some of our outstanding warrants are deemed to be derivative instruments that require liability classification and mark-to-market accounting. As such, at the end of each reporting period, we determined the

TABLE OF CONTENTS

fair value of the warrants were determined using a two-stage, contingent claims model, resulting in the recognition of additional losses of \$385,000 and \$847,000 for the years ended December 31, 2011 and 2012, respectively. These losses are primarily due to the increased value of the warrants due to increased likelihood of the occurrence of a liquidity event.

## Comparison of the Six Months Ended June 30, 2012 and 2013

The following table summarizes our results of operations for the six months ended June 30, 2012 and 2013, together with the changes in those items in dollars and percentage:

	Six Months Ended June		Dollar Change	% Change
	2012	2013		
	(unaudited)			
	(in thousands)			
Revenue				
Contract revenue	\$ 9,283	\$ 2,579	\$ (6,704 )	(72.2 )%
Operating expenses:				
Research and development	16,075	13,059	(3,016 )	(18.8 )%
General and administrative	3,120	3,725	605	19.4 %
Loss from operations	(9,912 )	(14,205 )	4,293	(43.3 )%
Interest expense, net	(237 )	(771 )	534	(225.3 )%
Fair value of warrant adjustments	(1,073 )	(6,590 )	5,517	(514.2 )%
Net loss	\$ (11,222 )	\$ (21,566 )	\$ 10,344	92.2 %

### Contract Revenue

For the six months ended June 30, 2013, total revenue decreased to \$2.6 million compared to \$9.3 million for the six months ended June 30, 2012. The decrease of \$6.7 million, or 72.2%, is related to a decline in reimbursable expenses related to our contract with BARDA, which completed its initial performance segment during the second quarter of 2013. During the six months ended June 30, 2012, in connection with our performance under the BARDA contract, we were fully engaged in clinical trials, drug product manufacturing and animal studies. Activities associated with the second segment of the contract began in June 2013 but were minimal at this early stage of the performance period.

### Research and Development Expenses

For the six months ended June 30, 2013, our research and development expenses decreased to \$13.1 million compared to \$16.1 million for the six months ended June 30, 2012. The decrease of \$3.0 million, or 18.8%, is primarily related to the decreased efforts of BARDA contracted work offset by a one-time non-cash compensation expense of \$1.4 million associated with the vesting of RSU s upon the completion of our IPO.

### General and Administrative Expenses

For the six months ended June 30, 2013, our general and administrative costs increased to \$3.7 million compared to \$3.1 million for the six months ended June 30, 2012. The increase of \$605,000, or 19.4%, is primarily related to a one-time non-cash compensation expense of \$560,000 related to the vesting of RSU s upon the completion of our IPO.

## **Interest Expense, Net**

For the six months ended June 30, 2013, our net interest expense increased to \$771,000 compared to \$237,000 for the six months ended June 30, 2012. The increase of \$534,000 is attributable to the increased interest expense associated with the larger outstanding loan balance we had in the six months ending June 30, 2013 compared to the six months ending June 30, 2012 as we drew upon the second tranche of our loan in the third quarter of 2012.

## **Fair Value of Warrant Adjustment**

Some of our outstanding warrants were deemed to be derivative instruments that required liability classification and mark-to-market accounting. As such, the applicable fair value of the warrants was

TABLE OF CONTENTS

determined using a two-stage, contingent claims model, resulting in the recognition of additional losses of \$6.6 million and \$1.1 million for the six months ended June 30, 2013 and 2012, respectively. These losses are primarily due to the increased likelihood of the occurrence of a liquidity event as well as the underlying stock price. Upon the completion of our IPO, these warrants converted to common stock warrants and are no longer considered to be a derivative instrument. Consequently, these common stock warrants will not be valued at each reporting period.

## **Quarterly Results of Operations Data**

The following table sets forth unaudited quarterly statement of operations data for the four quarters of 2011 and 2012 and the first two quarters of 2013. We have prepared the statement of operations data for each of these quarters on the same basis as the audited financial statements included elsewhere in this prospectus and, in the opinion of the management, the statement of operations data includes all adjustments, consisting solely of normal recurring adjustments necessary for the fair statement of the results of operations for these periods. This information should be read together with the audited financial statements and related notes. These quarterly results of operations are not necessarily indicative of our operating results for any future period.



## TABLE OF CONTENTS

For each quarter presented through the quarter ended June 30, 2013, our total operating revenues relate mainly to the BARDA contract with the exception of the three months ended September 30, 2012, where we received a non-refundable upfront license fee payment of \$17.5 million in connection with entering into a license agreement for our compound, CMX157. Under the BARDA contract, we recognize revenue in connection with the performance of qualifying research activities and upon receipt from invoices from our sub-contractors. Variability from quarter to quarter is attributable to the nature of the work being performed and invoiced during the quarter. The base segment of the BARDA contract began in February 2011 and ended on May 2013; we recognized \$30.8 million in contract revenue during this period. The first option segment of the BARDA contract began in June 2013 and ends on May 31, 2014. We may receive up to a total of \$5.0 million in revenue related to expense reimbursement and a fixed fee for the first option segment of the BARDA contract.

Over the periods presented, we have experienced significant fluctuations in our research and development expenses. Increases in expenses during the quarters ended June 30, 2012 and September 30, 2011, were the result of increased Chemistry, Manufacturing and Control activities for brincidofovir under the BARDA contract. Furthermore, all throughout 2011 and 2012, we conducted several Phase 1 and Phase 2 studies for the development of brincidofovir. In 2013, activities under the base segment of the BARDA contract began to wind down as did our clinical trials in support of brincidofovir. Our general and administrative expenses have remained relatively consistent over the quarters presented. During the second quarter of 2013, we incurred one-time non-cash expense compensation associated with the vesting of RSUs for both the research and development and general and administrative segments of our business in the amounts of \$1.4 million and \$560,000, respectively.

The fair value of our warrants increased over each of the quarters presented as the value of the warrants was adjusted to reflect the increase to our company's valuation.

In the quarter ended September 30, 2012, our net income for the quarter was largely attributable to the fact that we recognized \$17.5 million in connection with entering into a license agreement for our compound, CMX157.

## **Liquidity and Capital Resources**

We have incurred losses since our inception in 2000 and, as of June 30, 2013, we had an accumulated deficit of \$147.9 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more of equity offerings, debt financings, government or other third-party funding, strategic alliances and licensing or collaboration arrangements.

Since our inception through June 30, 2013, we have funded our operations principally with \$209.5 million (net of issuance costs of \$10.3 million) from the sale of common stock and preferred stock and the exercise of common stock warrants, including \$107.6 million in net proceeds from our IPO in April 2013, approximately \$37.4 million of research funding from our various National Institute of Allergy and Infectious Diseases awards and approximately \$30.9 million in revenue from our BARDA contract, debt financings totaling \$21.0 million, and \$17.5 million of licensing revenue under our collaboration agreement with Merck. As of June 30, 2013, we had cash, cash equivalents and short-term investments, available-for-sale of approximately \$123.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

During 2012, we entered into a loan and security agreement with SVB and MidCap allowing for borrowing up to \$15.0 million. In January 2012, we borrowed \$3.0 million under this agreement which had an interest only period for

twelve months followed by a thirty month principal and interest period at a rate of 8.25%. In September 2012, we borrowed an additional \$12.0 million under this agreement that had an interest only period of six months followed with a thirty two month principal interest period at 8.25%. As of June 30, 2013, the outstanding balance of the loan was \$12.7 million.

TABLE OF CONTENTS**Cash Flows**

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

	Years Ended December 31,			Six Months Ended June 30,	
	2010	2011	2012	2012	2013
Net cash (used in) operating activities	\$(21,681)	\$(26,279)	\$(1,876 )	(9,587)	(13,630 )
Net cash provided by (used in) investing activities	(236 )	(6,236 )	(4,139 )	5,853	2,036
Net cash provided by financing activities	4,603	42,816	12,314	363	107,126
Net increase (decrease) in cash and cash equivalents	(17,314)	10,301	6,299	(3,371)	95,532

**Operating Activities**

Net cash used in operating activities of \$21.7 million during the year ended December 31, 2010, was primarily a result of our \$25.5 million net loss, offset by net changes in our operating assets and liabilities of \$2.7 million and the add-back of non-cash expenses of \$753,000 for stock-based compensation, \$213,000 for depreciation, and \$119,000 amortization of investment discount. The net change in our operating assets and liabilities included a decrease of accounts receivable of \$937,000 and \$181,000 of prepaid expenses and an increase in accounts payable and accrued liabilities of \$1.6 million.

Net cash used in operating activities of \$26.3 million during the year ended December 31, 2011, was primarily a result of our \$25.6 million net loss, offset by net changes in our operating assets and liabilities of \$2.6 million and the add-back of non-cash expenses of \$1.1 million for stock-based compensation, \$270,000 for depreciation, \$385,000 increase in assets due to revaluation of our warrant liabilities, and \$117,000 in amortization of investment discount.

The net change in our operating assets and liabilities included increases in accounts receivable of \$4.2 million and prepaid expenses of \$442,000, offset in part by an increase in accounts payable and accrued liabilities of \$2.1 million.

Net cash used in operating activities of \$1.9 million during the year ended December 31, 2012, was primarily the result of our net loss of \$4.4 million, offset by net changes in our operating assets and liabilities of \$315,000 and the add-back non-cash items of \$1.4 million for stock-based compensation, \$847,000 increase in assets due to revaluation of our warrant liabilities, \$280,000 for depreciation, and \$322,000 of amortization for fees paid in connection with our loan. The net change in our operating assets and liabilities include decreases in our accounts receivable of \$3.4 million offset by increases in accounts payable and accrued liabilities of \$3.8 million.

Net cash used in operating activities of \$9.6 million during the six months ended June 30, 2012 was primarily the result of our \$11.2 million net loss, offset by the add-back of non-cash expenses of \$1.1 million related to the revaluation of our warrant liability and \$539,000 for stock based compensation.

Net cash used in operating activities of \$13.6 million for the six months ended June 30, 2013 was primarily the result of our \$21.6 million net loss, offset by the add-back of non-cash expenses of \$6.6 million related to the revaluation of our warrant liability and \$2.6 million for stock based compensation. The change in operating assets and liabilities include an increase in prepaid expenses and other current assets of \$2.1 million primarily related to start-up activities of our Phase 3 SUPRESS study.

### **Investing Activities**

Net cash used in investing activities during the periods presented primarily reflect our use of cash to purchase short-term investments, offset by sales and maturities of short-term investments.

### **Financing Activities**

Net cash provided by financing activities in the year ended December 31, 2010, primarily consisted of approximately \$4.6 million of net loan proceeds, which we received in March 2010. Net cash provided by financing activities for the year ended December 31, 2011 primarily consisted of approximately \$44.8 million

## TABLE OF CONTENTS

of net proceeds from the sale of our Series F preferred stock, offset by an approximately \$2.0 million repayment of indebtedness. Net cash provided by financing activities for the year ended December 31, 2012, primarily consisted of approximately \$12.4 million of net loan proceeds related to a loan agreement we entered into in January 2012.

Net cash provided by financing activities of \$0.4 million during the six months ended June 30, 2012 was primarily the result of loan proceeds from the first tranche of our loan offset by the repayment of our previous loan.

Net cash provided by financing activities of \$107.1 million for the six months ended June 30, 2013 was primarily the result of approximately \$107.6 million in net proceeds from the completion of our IPO and \$1.5 million from the exercise of a warrant offset by \$2.1 million in debt repayment.

On April 16, 2013, we completed our IPO of common stock pursuant to a registration statement that was declared effective on April 10, 2013. We sold 7,320,000 shares of our common stock at a price of \$14.00 per share. The underwriters exercised their over-allotment option on April 16, 2013 selling an additional 1,098,000 shares at \$14.00 per share. As a result of the IPO, we raised a total of \$107.6 million in net proceeds after deducting underwriting discounts and commissions of \$8.2 million and offering expenses of \$2.1 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of the IPO.

## **Future Funding Requirements**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize brincidofovir or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We have incurred and we expect to continue to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and short-term investments (including the net proceeds from our IPO) will enable us to fund our operating expenses and capital requirements through at least mid-2015. We intend to use our current cash, cash equivalents and short-term investments to fund our Phase 3 clinical trial, SUPPRESS. We may require additional capital to fund any additional clinical or preclinical studies necessary to support and to submit an application for brincidofovir for the prevention of CMV infection in HCT patients. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

the progress, costs, results and timing of SUPPRESS, and the clinical development of brincidofovir for other potential indications;

the willingness of the FDA to accept SUPPRESS, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and accelerated approval and traditional approval of brincidofovir for

the prevention of CMV and for other potential indications;  
the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;  
the ability to continue to receive government funding;  
the achievement of milestones under our agreement with Merck;

68

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TABLE OF CONTENTS

the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;

the ability of our product candidates to progress through clinical development successfully;

our need to expand our research and development activities;

the costs associated with securing, establishing and maintaining commercialization and manufacturing capabilities;

the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;

our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

our need and ability to hire additional management and scientific and medical personnel;

the effect of competing technological and market developments;

our need to implement additional internal systems and infrastructure, including financial and reporting systems; and

the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

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

## Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2012:

	Total	Less Than 1 Year	1 3 Years	3 5 Years	More Than 5 Years
	(in thousands)				
Operating leases <sup>(1)</sup>	\$ 187	\$ 169	\$ 18		
Loan payable and interest <sup>(2)</sup>	16,873	6,042	10,831		
Minimum royalties <sup>(3)</sup>	\$ 1,550		50	500	1,000
Total	\$ 18,610	\$ 6,211	\$ 10,899	\$ 500	\$ 1,000

Consists of our corporate headquarters leases encompassing 14,500 square feet of office space that expired in February 2013, and our laboratory lease encompassing 4,600 square feet that expires in February 2014, both of which are located in Durham, North Carolina. In 2013, we extended two facility leases for the period beginning March 2013 and ending February 2015 and 2018. Future minimum payments under these extensions total \$246,000 in less than 1 year, \$804,000 in 1 3 years and \$284,000 in 3 5 years.

(2) Consists of our loan and security agreement with SVB and MidCap, pursuant to which we have borrowed \$15.0 million in principal which bears interest at a rate of 8.25% and is repayable through 2015.

(3)

Consists of amounts payable under a license agreement with the University of Michigan for certain intellectual property related to the Chimerix Chemical Library.

69

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## TABLE OF CONTENTS

In addition to the amounts set forth in the table above, we have payment obligations under license agreements that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones. Under our license agreement with UC, we made milestone and sublicense payments totaling approximately \$1.2 million through December 31, 2012. We will be required to make additional payments when certain milestones are achieved and we are obligated to pay royalties based on future product sales. As of December 31, 2012, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales and, therefore, any related payments are not included in the table above. In connection with the development and commercialization of brincidofovir and CMX157, in addition to royalties on product sales, we could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement. Under our license agreement with the University of Michigan, we are required to pay minimum royalties from 2016 through the expiration of the last licensed patent (which we estimate will occur in 2024) which are included in the table above, but any additional royalties that may be payable under the University of Michigan agreement are not estimable and therefore not included in the table above.

Additionally, we enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination or cancellation within 30 days of notice, and therefore are not included in the table above. We also have an employment agreement with our chief executive officer that requires the funding of specific payments, if certain events occur, such as a change in control or the termination of his employment without cause. These potential payment obligations, which are described in Executive and Director Compensation Potential Payments Upon Termination or Change of Control, are not included in the table above.

### **Off-Balance Sheet Arrangements**

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

### **Recent Accounting Pronouncements**

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurements and Disclosure Requirement in U.S. GAAP and IFRS.

This guidance includes amendments that clarify the intent regarding the application of existing fair value measurements and disclosures, and amendments that change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011. The standard was adopted as of January 1, 2012, and the retrospective application of this standard did not have a material impact on our financial statements.

In June 2011, the FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. This guidance requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance is effective for interim and annual periods beginning after December 15, 2011. This standard was adopted as of January 1, 2012, and the retrospective application of this standard did not have a material impact on our financial statements.

### **Basic and Diluted Net Loss Attributable to Common Stockholders per Common Share**

Our Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock, Series E preferred stock and Series F preferred stock represented participating securities. However, since we operate at a loss, and losses were not allocated to our preferred stock, the two class method does not affect our calculation of earnings per share. We had a net loss for all periods presented. Accordingly, the inclusion of stock options to purchase common stock and warrants exercisable for common stock would be anti-dilutive.

Dilutive common stock equivalents would include the dilutive effect of convertible securities, stock options to purchase common stock and warrants exercisable for common stock. Potentially dilutive common

TABLE OF CONTENTS

stock equivalents totaled approximately 6,781,550 shares, 11,034,134 and 11,259,579 shares for the years ended December 31, 2010, 2011 and 2012, respectively. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect. Therefore, the weighted-average shares used to calculate both basic and diluted earnings per share are the same.

## **Quantitative and Qualitative Disclosure About Market Risk**

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

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during 2011 or 2012 or the six months ended June 30, 2013.

TABLE OF CONTENTS

## **BUSINESS**

### **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 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.

TABLE OF CONTENTS

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.

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.

## TABLE OF CONTENTS

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.



TABLE OF CONTENTS

## **Our Product Candidates**

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

### **Advantages of Brincidofovir**

Our lead product candidate, brincidofovir, is a broad-spectrum antiviral that recently initiated Phase 3 clinical development for CMV prevention in adult HCT recipients. Utilizing our proprietary lipid technology, this nucleotide compound is dosed orally in tablet or liquid form. Brincidofovir's safety and tolerability profile supports its continued investigation as a potential antiviral prevention for multiple dsDNA viruses. The structures of cidofovir and brincidofovir are graphically depicted below.

TABLE OF CONTENTS

We believe brincidofovir has the following advantages that support its rapid development:

*Our proprietary technology results in higher intracellular levels of the active antiviral CDV-PP, while avoiding bone marrow toxicities and cidofovir-related kidney and toxicity.* As a result of its phospholipid structure, brincidofovir remains intact in the plasma, is cleaved to cidofovir only after entering cells, and is then converted to CDV-PP, the active antiviral. By more efficiently delivering drug inside cells, our technology allows for more cidofovir to be delivered to the site of viral replication while minimizing the amount of free cidofovir in the plasma, which in turn decreases the risk of nephrotoxicity. The chart below illustrates the amount of CDV-PP formed after *in vitro* exposure of cells to brincidofovir and cidofovir. Exposure of cells *in vitro* to brincidofovir results in a greater than 100-fold increase in intracellular concentration of CDV-PP relative to the same level of exposure to cidofovir.

Additionally, dosing with brincidofovir results in levels of CDV-PP detectable in the cells for a long period of time. This allows for less frequent dosing and a low pill burden, potentially important benefits for patients.

## TABLE OF CONTENTS

The graphic below demonstrates the relative plasma and the intracellular concentrations for each compound, as well as the intracellular activation and site of action of brincidofovir versus cidofovir.

*We believe brincidofovir is the most potent antiviral compared with those marketed or in development, with the broadest activity against dsDNA viruses.* Through our EIND program and Study 350, pediatric and adult HCT recipients with life-threatening AdV infection who received brincidofovir treatment had improved survival as compared to historical mortality rates. These data supported the initiation of our Phase 2 AdV study in pediatric and adult HCT recipients. Data were recently presented on the positive clinical benefit of this broad-spectrum antiviral from the exploratory Phase 2 study of brincidofovir as preemptive therapy in HCT recipients infected with AdV, a pathogenic dsDNA virus with no available therapy. Evidence of improved kidney function and reduced hematuria (blood in the urine) in brincidofovir-treated subjects with evidence of BKV at enrollment compared to placebo-treated subjects were observed in our Phase 2 study in CMV prevention, Study 201, reflecting potential activity against BKV.

*The clinical development program for brincidofovir is currently supported by a large safety database of over 800 subjects exposed to date, a completed clinical pharmacology program, short and long-term toxicology program, validated commercial-scale manufacturing, and an extensive patent estate.* We have seen no evidence to date of hematologic, bone marrow, or kidney toxicity in our brincidofovir clinical program, and have developed a safety management algorithm to address the brincidofovir-related diarrhea observed in the Phase 2 CMV study. In this same study, we also observed low-level, asymptomatic increases in serum levels of the liver enzyme alanine aminotransferase (ALT), which were reversible after stopping brincidofovir treatment. Similar changes in ALT were observed across all preclinical species and were considered non-adverse based on the absence of any histopathology.

*A concentrated prescriber base should allow us to commercialize brincidofovir independently.* Approximately 200 hospitals in the United States perform HCT and/or SOT. We estimate that a full commercial infrastructure of approximately 50 employees would allow us to efficiently market brincidofovir in both HCT and SOT in the United States and Canada.

## **Development Strategy for Brincidofovir**

In Study 201, a placebo-controlled Phase 2 study in high-risk HCT patients, brincidofovir 100 mg BIW was demonstrated to be superior to placebo for the prevention of CMV infection ( $p < 0.002$ ). There was no evidence of hematologic or bone marrow toxicity. Additionally, consistent with our preclinical data, there was no evidence of on-therapy or follow-up kidney toxicity. The dose-limiting toxicity, diarrhea, was addressed with an SMMP in the final cohort of the Phase 2 study and in subsequent studies, including throughout the duration of our recently completed Phase 2 AdV study.

TABLE OF CONTENTS

We initiated SUPPRESS, our Phase 3 study of brincidofovir for the prevention of CMV infection in CMV seropositive (R+) adults undergoing HCT, in the third quarter of 2013. The primary endpoint is a composite endpoint of (i) CMV disease or (ii) the initiation of preemptive anti-CMV therapy triggered by a positive test for CMV viremia. Subjects are randomized 2:1 to brincidofovir or placebo, will take study drug through Week 14, and will be monitored through Week 24 post-transplant. As part of SUPPRESS, we put in place the SMMP that was developed during the conduct of our Phase 2 CMV study which we believe will reduce the incidence of patient withdrawals due to diarrhea.

The SMMP directs the investigators to interrupt study medication when the study subject presents with gastrointestinal symptoms possibly related to the use of brincidofovir. When incorporated in prior trials, such treatment interruptions allow the symptoms to subside, after which therapy can be resumed. We believe the following factors will also increase SUPPRESS's probability of success:

our Phase 2 brincidofovir study, Study 201, demonstrated clinically and statistically significant evidence for the effectiveness of brincidofovir for the prevention of CMV at relevant doses (dose-response analyses demonstrated a decreased CMV event rate for the twice-weekly dosing regimen compared to once-weekly dosing of the same total weekly dose);

the 100 mg BIW brincidofovir dose and dosing regimen included in SUPPRESS demonstrated clinically relevant decreases in the frequency of multiple viral endpoints versus placebo in Study 201;

brincidofovir's hematology safety data allows for dosing in SUPPRESS shortly after subjects receive their transplant, prior to stem cell engraftment (evidence of production of blood cells by the new transplant), which will allow detection of early CMV events in the first weeks after HCT, and has the potential to increase the difference in event rate for the brincidofovir cohort as compared to placebo;

antivirals have demonstrated a higher rate of clinical success in Phase 3 after success in Phase 2, compared with compounds in most other therapeutic areas;

the SUPPRESS study population is consistent with the subjects enrolled in Study 201: CMV seropositive patients undergoing HCT, including patients at increased risk of CMV reactivation);

brincidofovir's safety profile to date shows no evidence of bone marrow toxicity or renal toxicity, which are primary limitations of currently available anti-CMV therapies;

brincidofovir delivers the same active antiviral, CDV-PP, as intravenous cidofovir which has demonstrated clinical antiviral efficacy; and

CMV viremia is clinically accepted as a trigger for initiation of preemptive therapy in order to avoid progression to CMV disease, as demonstrated in a prospective double-blind study of ganciclovir as preemptive therapy.

We intend to submit an NDA under an accelerated approval pathway seeking regulatory approval to market brincidofovir for the prevention of CMV infection in HCT recipients in the United States. We have received Fast Track designation to support our development and commercialization strategy for the prevention of CMV infection.

As part of our overall development program for brincidofovir, we are pursuing the development of brincidofovir for other dsDNA viral infections:

We recently presented positive data from our Phase 2 study of brincidofovir as a preemptive therapy for AdV disease in 48 pediatric and adult HCT recipients. In this study, brincidofovir 100 mg BIW showed greater antiviral activity and lower all-cause mortality compared with placebo.

We are exploring the use of brincidofovir for BKV and JC virus (JCV) in HCT, SOT and other immunosuppressed patient populations. Through our placebo-controlled clinical studies and compassionate use program, we have early evidence of clinical benefit of brincidofovir for these polyomaviruses. We have undertaken a preclinical program to better understand brincidofovir's mechanism of action in polyomaviruses.

## TABLE OF CONTENTS

Under the financial sponsorship of BARDA, we are developing brincidofovir as a potential medical countermeasure against smallpox, an orthopoxvirus that is considered a Category A bioterror agent by the U.S. Centers for Disease Control and Prevention. Brincidofovir has shown encouraging activity in relevant animal models of smallpox, and we anticipate renegotiating certain aspects of the smallpox animal plan to take into account recent guidance from the FDA for development of brincidofovir under the Animal Efficacy Rule. However, the results of this negotiation are uncertain and we do not anticipate continuing this program without ongoing support from BARDA.

We believe that a well-tolerated antiviral with demonstrated efficacy in prevention would provide a new standard of care for patients with various forms of immune suppression, including HCT and SOT recipients. Additionally, the current and future epidemiology of dsDNA viral infections, influenced by the increasingly widespread use of potent immunosuppressants, the evolution of viral resistance, and the role of childhood and adult vaccines may provide additional lifecycle opportunities for brincidofovir based on its broad-spectrum antiviral activity.

## **Market Overview**

### **Background on dsDNA Viruses**

Viruses are among the simplest infectious agents and can replicate only inside the living cells of a host. Although it is estimated that there are millions of unique virus types, only a few thousand have been well described. Viruses are typically classified into groups based on the nature of their genetic material (e.g., single- or double-stranded DNA, or single- or double-stranded RNA).

Five families of dsDNA viruses are of particular importance as causes of human illness:

Herpesviruses, which include CMV, herpes simplex virus (HSV), Epstein-Barr virus (EBV), HHV-6 and varicella zoster virus (VZV);

Adenoviruses, of which there are over 50 subspecies;

Polyomaviruses, which include BKV and JCV;

Papillomaviruses (HPV); and

Poxviruses, which include vaccinia (VACV), monkeypox (MPXV), and smallpox (variola or VARV).

A large percentage of the world's population has been exposed to one or more dsDNA viruses, usually limited to a mild viral syndrome during childhood or early adulthood. Viruses may remain dormant for the rest of a person's life as long as the immune system is intact. However, clinically significant viral reactivation or primary infection can occur in immunocompromised patient populations, including patients who are being treated with immune-modulating therapies following transplantation, during intensive cancer chemotherapy, or as therapy for autoimmune disorders.

Although our initial regulatory strategies are focused on HCT and SOT, clinical indications for a broad-spectrum antiviral in many other areas of immune suppression may provide additional opportunities.

Viral infections pose a serious threat to the health of patients who have undergone HCT or SOT. In these settings, the patient's immune system is intentionally destroyed or suppressed to prevent stem cell or organ rejection, putting the patient at risk for reactivation of viruses that are dormant within their bodies. This can result in serious or fatal viral-induced disease, co-infection with other opportunistic viral, bacterial or fungal infections, and damage to or loss of the graft. The growing use of potent immunosuppressive drugs has successfully reduced transplant rejection and mortality rates but has also placed patients at greater risk for viral infections and their sequelae.

In the transplant setting and based on data from our Brincidofovir Compassionate Use Program, three dsDNA viruses are responsible for the majority of viral infections of concern: CMV, AdV and BKV. The effect of many other dsDNA

viruses, each independently having a low incidence, can collectively increase morbidity and mortality within HCT, SOT, and other immunocompromised populations.

## TABLE OF CONTENTS

### **Background on the HCT Market and HCT Therapies**

#### **HCT**

Stem cell transplants replace the blood forming (hematopoietic) system in patients who have malignant, damaged or defective bone marrow, offering a potential cure or remission for many cancers and genetic disorders. HCTs are defined by the donor of the stem cells (allogeneic and autologous transplants), the source of the stem cells (bone marrow, peripheral blood or cord blood) and the conditioning regimen used prior to the transplantation (myeloablative, reduced intensity or non-myeloablative).

Allogeneic HCTs use cells from a family member or unrelated donor and can cure or improve outcomes in a wide variety of diseases, including leukemia, lymphoma, myeloproliferative disorders, myelodysplastic syndrome, and congenital immunodeficiencies. However, allogeneic HCT is associated with significant morbidity and mortality due to procedure-related toxicities, infection, and graft versus host disease (GVHD, a process whereby the injected stem cells (the graft) attack the tissues in the body of the transplant patient (the host). In general, the greater the difference in the donor and recipient's genetic make-up, the greater the risk for GVHD and the greater the need to immunosuppress patients after their transplant. Autologous HCTs use the patient's own cells and can improve outcomes in neoplastic diseases and autoimmune conditions. As with allogeneic HCT, autologous HCT therapeutic regimens and infections contribute to morbidity and mortality.

At transplantation, the donor's cells are infused into the body through a vein and form new cells of the bone marrow, where they begin to grow and produce new red blood cells, white blood cells and platelets during a process called engraftment. Engraftment typically occurs within the first month following transplantation. Until engraftment occurs, patients have very few white blood cells to fight infections and can easily acquire serious or life-threatening infections due to their weakened immune systems. Even after engraftment, patients are at high risk for complications during the first 100 days following their transplant, particularly if ongoing immunosuppression is necessary.

#### **Growth of the HCT Market**

HCT remains underutilized, with many patients referred for a transplant only when they reach an advanced stage of disease. In order to increase the number of patients who could potentially benefit from HCT, there has been significant focus on alternative stem cells sources such as unrelated donors and umbilical cord blood stem cells. However, use of unrelated donors for stem cell results in higher risk of reactivation of dsDNA viruses such as CMV.

Overall, the number of stem cell transplants being performed in the United States has grown at approximately 4% annually since 2000. Of the allogeneic transplants, the unrelated donor subset has been growing at a higher rate than other subsets within HCT.

### **Viral Diseases Associated with HCT**

#### **CMV in HCT**

CMV, a human herpesvirus, is the most common infectious threat in HCT, with 80% of CMV-seropositive (R+) allogeneic transplant recipients developing detectable CMV in the blood, which is known to correlate with progression to disease and death, if untreated. Common manifestations of active CMV infection in immunosuppressed patients are pneumonia, gastrointestinal (GI) disease, hepatitis, and retinitis. In addition, because CMV itself is immunosuppressive, reactivation of the virus can predispose a patient to other opportunistic infections.

Rather than waiting for evidence of CMV disease, the most commonly accepted intervention for CMV is frequent monitoring for CMV in the blood and initiation of anti-CMV preemptive therapy with intravenous ganciclovir or valganciclovir, available antivirals with the side-effect of suppression of neutrophils and an associated increased risk for bacterial and fungal infections.



## TABLE OF CONTENTS

The initial indication for which we are seeking regulatory approval for brincidofovir is prevention of CMV infection in recipients of allogeneic HCT who are seropositive for CMV. To the extent that the risk-benefit ratio for brincidofovir is established in SUPPRESS, particularly in prevention of clinical manifestations of other dsDNA viral infections, indications in patient populations with more moderate CMV risk estimates may be pursued. Based on a survey of recent literature, we believe that the following table reflects the risk of CMV reactivation in HCT recipients:

- (1) R+ refers to recipient seropositive for CMV, R- refers to recipient seronegative for CMV, D+ refers to donor seropositive for CMV, and D- refers to donor seronegative for CMV.
- (2) Risk of CMV Infection is defined as the likelihood of detectable CMV in blood.
- (3) Non-Relapse Mortality is defined as death in the first year following HCT that is not due to relapse of the underlying disease.

### **AdV in HCT**

Although AdV infection is much less frequent than CMV in HCT, disseminated AdV has a high mortality rate of 80%, and no approved therapies for prevention, preemptive therapy or treatment. AdV is more frequent in pediatric HCT patients who have not been as widely exposed to the many AdV subspecies as have adults. Manifestations of serious AdV infection besides AdV pneumonitis include acute hemorrhagic cystitis, liver failure, and renal damage such as nephritis or obstructive nephropathy. AdV infection is also associated with graft failure or delayed engraftment in HCT.

Factors associated with an increased risk of rapid progression to AdV infection, such as conditioning regimens and source of hematopoietic cells, have been identified in the scientific literature, but the frequency of detectable AdV in the blood or AdV disease, as well as the predictors of rapid progression of AdV disease, were unknown prior to our Phase 2 trial for the preemption of AdV infection.

### **BKV in HCT**

BKV, a polyomavirus, is a dsDNA virus that can be a significant medical problem in HCT and has no approved therapy. The virus establishes lifelong latency in the kidneys and urinary tract following primary infection. BKV rarely causes disease in healthy adults; however, in HCT recipients with prolonged immunosuppression, BKV reactivation can lead to hemorrhagic cystitis (HC), a painful condition that often requires hospitalization for pain control or bladder irrigation. HC is associated with significant hematuria and clotting, and can result in impairment of kidney and/or bladder function. Little data on epidemiology of BKV exist in the HCT population. Our prospective data from Study 201 found a greater than 50% incidence of BKV in urine in subjects enrolled in that trial and showed evidence of worsening renal function through a decrease in estimated glomerular filtration rate (eGFR) and an increase in serum creatinine for BKV-positive subjects randomized to placebo. These data are presented in the figures below.

TABLE OF CONTENTS

**Background on the SOT Market and SOT Therapies**

SOT of the kidney, liver, pancreas, heart, and lung has become standard therapy for selected end-stage diseases. Although quality of life and survival rates following organ transplantation have improved greatly due to advances in surgical technique, immunosuppressive therapy, and medical management, complications such as infection and graft rejection remain major causes of morbidity and mortality following SOT. Management of viral infections after transplantation involves antiviral therapy and reduction in immunosuppressive therapy, a balancing act between controlling the infection and avoiding rejection of the new organ. More than 28,000 SOTs are performed annually in the United States, and a comparable number of procedures are performed each year in Europe.

**CMV in SOT**

CMV remains the most frequent opportunistic infection affecting the overall outcome of SOT, and typically reactivates during the first six months following transplantation. Furthermore, a recent study has shown that 37% of patients on Valcyte for prevention of CMV in high-risk kidney, kidney-pancreas and heart transplants developed late-onset CMV within 12 months post-transplant. In addition to directly causing morbidity and occasional mortality, CMV also influences short and long term complications that collectively contribute to reduced graft and patient survival. Prevention of CMV infection and disease in SOT is a critical

## TABLE OF CONTENTS

step forward towards improved patient outcomes but is limited by the side effects, need for monitoring and restricted addressable population of current antivirals.

### **BKV in SOT**

BKV infection affects 20–40% of kidney transplant recipients and can lead to BKV-associated nephropathy (BKVAN), a disease resulting in loss of the new kidney in 30–65% of affected patients. The incidence of BKVAN appears to be on the rise, related to the increased use of immunosuppressive drugs. Progression to BKVAN is generally asymptomatic. However, BKV DNA can often be detected in blood or urine for several months prior to the development of renal dysfunction, which may represent an opportunity for earlier intervention with antiviral therapy.

### **Background on Antiviral Therapies in Transplant Patients**

Antiviral therapeutics are differentiated in general based on several characteristics, the most important of which are:

safety and tolerability;  
dosing schedule and duration;  
route of administration;  
potency;  
spectrum of antiviral coverage; and  
viral resistance.

Currently available therapies have significant shortcomings with respect to many of these characteristics. In particular, existing therapies are limited by their lack of broad-spectrum efficacy as well as their major side effects, notably nephrotoxicity and myelosuppression. These limitations can lead to increased hospitalizations, severe and life-threatening neutropenia, renal impairment, use of expensive granulocyte colony-stimulating factor (G-CSF) therapies, platelet and blood transfusions, need for dialysis, and life-threatening secondary bacterial and fungal infections. The prevalence of disease and the limitations of existing therapies contribute to the significant unmet medical need for effective and better tolerated antivirals.

Brincidofovir's differentiated product profile has the potential to address many of these unmet medical needs. See the table titled "Key Characteristics of Brincidofovir and Approved and Investigational Antivirals" below.

### **Unmet Medical Need in HCT Antiviral Therapy**

There are three paradigms commonly used for addressing viral infections in the transplant setting: prevention, preemptive therapy and treatment.

Prevention is the administration of an antiviral to at-risk patients in an effort to avoid reactivation of a latent virus or primary infection with a new virus. The goal of prevention is to eliminate the need for preemptive therapy by suppressing reactivation of a latent virus and avoiding infection with a new virus, with the potential benefit of decreasing the need for frequent monitoring for indicators of early viral infection, such as low levels of virus in the blood.

In order to be approved for prevention, a therapy must be generally safe and well-tolerated without toxicities that overlap with the inherent risks of the patient population. Currently available antivirals cannot be used for prevention of many dsDNA viral diseases in HCT recipients because they have toxicities that risk the function or survival of the new graft.

Preemptive therapy is the initiation of antiviral(s) only after detection of a specific virus in the blood (viremia) or other organ system in an asymptomatic patient. The goal of preemptive therapy is to avoid progression to symptomatic disease.

83

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## TABLE OF CONTENTS

Because preemptive therapy is initiated only after the level of virus in the blood reaches a threshold associated with progression to disease, limited drug toxicities may be more acceptable as disease and mortality risks are more substantial.

Treatment is the watch-and-wait approach of initiating antiviral therapy after the virus is detected in an organ system where symptoms are present. In HCT recipients, treatment after the onset of clinical signs and symptoms has a limited impact on mortality, and is no longer considered the standard of care.

### **Prevention**

Within the field of infectious diseases, prevention of disease with a safe and well-tolerated therapeutic is a preferred paradigm. There are multiple precedents for prevention in other viral indications, including the approval of valacyclovir for the prevention of transmission of herpes simplex infection based on the well-established safety profile of acyclovir and valacyclovir. In children at high risk of disease from respiratory syncytial virus (RSV), the monoclonal antibody palivizumab is approved for prevention.

In spite of trials conducted with ganciclovir for CMV prevention, ganciclovir is approved for use only as a preemptive therapy or treatment for CMV in HCT. Ganciclovir was limited in its ability to be used as a preventive therapy by the risk of significant neutropenia, which has multiple consequences including an increased risk of invasive bacterial and fungal infections, an increased risk of late-onset CMV disease, or even loss of the graft itself. These observations have been confirmed in multiple studies, and highlight the need for a safe and well-tolerated antiviral for use as a prevention in HCT.

### **Preemptive Therapy The Current Standard of Care in HCT**

Rather than waiting for evidence of CMV disease, the most commonly accepted intervention for CMV involves frequent monitoring for CMV viremia and initiation of anti-CMV preemptive therapy upon detection. Approximately 30–40% of HCT recipients require preemptive therapy in response to CMV viremia, making this the most commonly used strategy to prevent the development of CMV disease in HCT recipients. The most commonly utilized preemptive therapy is ganciclovir, which is administered intravenously and requires close monitoring for hematologic and other toxicities. Valganciclovir is an orally administered prodrug of ganciclovir with a similar toxicity profile. Second-line therapies of foscarnet or intravenous cidofovir have recognized renal toxicity. As noted above, ganciclovir initiated as preemptive therapy demonstrated a decrease in CMV disease, but is limited in overall benefit by neutropenia and resulting susceptibility to secondary invasive bacterial and fungal infections, as well as the emergence of CMV resistance.

### **Treatment**

CMV treatment after the onset of clinical signs and symptoms has a limited impact on mortality and is no longer considered the standard of care.

### **The Potential for a Broad-Spectrum Antiviral**

The prevention of CMV with brincidofovir provides us the opportunity to simultaneously explore the prevention and control of other dsDNA viral infections in the transplant setting. Although each of these additional viral infections has a lower incidence than does CMV in HCT or SOT, individually and in aggregate they have a meaningful impact on clinical endpoints and healthcare utilization.

We believe prevention of reactivation of CMV and other dsDNA viruses represents a significant unmet medical need.

In addition to AdV, BKV and CMV, other human herpesviruses such as EBV, HSV-1, HSV-2, VZV, and HHV-6 contribute to the overall morbidity and mortality in HCT. For example, EBV has long been recognized as the most common causative agent of post-transplant lymphoproliferative disorder, a condition which is especially prevalent in the pediatric population and in certain SOT populations. Over the past several years, an increasing number of clinical syndromes, including those with neurological disease and pulmonary involvement, have been attributed to EBV infection. The increase in frequency of EBV infections has been linked to several risk factors, particularly the use of cord blood and T-cell depleted grafts.

The risks and clinical presentation of specific dsDNA viruses have been reviewed for the HCT and SOT patient populations, but for an individual patient, multiple dsDNA viruses contribute to the risk of disease, dependent on prior exposure and current level of immunosuppression. We believe that an ideal antiviral in the

## TABLE OF CONTENTS

transplant setting would have broad-spectrum potential to prevent CMV and other viral infections, particularly AdV and BKV as there are no approved therapies for these two viral infections.

### **The Competitive Landscape**

#### **Currently Available Antiviral Therapies**

We believe that a well-tolerated antiviral with demonstrated efficacy as prevention would provide a new standard of care for immunocompromised patients. In HCT, an effective CMV prevention could potentially replace the current practice of frequent monitoring for CMV viremia and initiation of CMV-specific preemptive therapy. In addition, an antiviral for CMV prevention that could reduce the frequency of other opportunistic viral infections would provide an additional measurable clinical and pharmacoeconomic benefit for patients.

To date, the safety and tolerability limitations of current therapies have precluded their use as prevention in the HCT patient population.

Because of the importance of CMV as a pathogen in HCT recipients, a number of companies have pursued clinical studies to assess the effectiveness of antiviral agents administered as prevention. Randomized clinical studies examining the potential of ganciclovir for CMV prevention demonstrated a significant reduction in early CMV disease, but no survival benefit due to the increased occurrence of invasive fungal and bacterial infections and late onset CMV disease. Twenty-one percent of patients had severe neutropenia with a lowest value of less than 500 cells/ $\mu$ L for at least two consecutive days. In this study, neutropenia was associated with an increase in infections and was a negative predictor of overall and event-free survival. Ganciclovir has also been associated with delayed engraftment and specifically a decrease in lymphocytes which protect against viral infections.

Valganciclovir (marketed as Valcyte®), an oral prodrug for delivery of ganciclovir, is approved for CMV prevention for many high-risk recipients of SOT. Sufficient risk-benefit ratios for use of valganciclovir as prevention have been demonstrated in SOT for high-risk adult and pediatric kidney and heart transplant patients, and for high-risk adult kidney-pancreas transplant patients. However, the known impact of valganciclovir on white blood cells requires frequent monitoring for evidence of asymptomatic neutropenia and related risk of invasive bacterial and fungal infections. Given the need for continued monitoring for adverse effects with current antivirals, a significant need exists for an antiviral for CMV prevention with superior safety, tolerability and resistance profiles.

#### **Second-line Therapies: Cidofovir and Foscarnet**

Administration of intravenous cidofovir (marketed as Vistide®) has become standard in some transplant centers for renal transplant patients with BKVAN, despite the limitations of the efficacy and safety profile. Anecdotal reports have claimed clearance of BKV from both the blood and allograft of renal transplant recipients treated with intravenous cidofovir combined with reduction in immunosuppression. However, other retrospective analyses have failed to demonstrate antiviral benefit from cidofovir therapy for BKV infection. The high potential for cidofovir to cause nephrotoxicity in patients who are already experiencing renal insufficiency remains a serious concern for treating physicians. Foscarnet is associated with significant renal toxicity, which limits its utility to patients who have ganciclovir resistance or treatment failure.

In the Phase 2 study of brincidofovir for CMV prevention, preemptive therapy with ganciclovir or valganciclovir was necessary in 32% of subjects (74 of 230), primarily subjects who received either an inactive dose of brincidofovir or placebo. Data available for 71 subjects demonstrate the clinical limitations and pharmacoeconomic implications of

preemptive therapy:

70% of subjects had moderate to severe decreases of white blood cells;  
41% experienced decreased levels of white blood cells putting them at risk of fungal and bacterial infections;  
25% experienced some decrease in kidney function;  
23% had severe adverse events requiring hospitalization;

85

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## TABLE OF CONTENTS

18% had life-threatening adverse events including bacterial/fungal infections, bone marrow, or kidney toxicity; 15% required injected medications (G-CSF) to increase their white blood cell count; 14% needed to switch to second line therapy (foscarnet or cidofovir) due to the toxicity of the initial regimen; and 7% required red blood cell transfusions, and 3% required platelet transfusions. We believe that there is an unmet medical need for safe and effective antiviral therapies to replace current preemptive therapies in order to improve outcomes and decrease transplant-related costs.

## **Investigational Agents for CMV**

Several companies are pursuing the development of new therapies for CMV disease.

### **Letermovir**

Letermovir is a viral terminase inhibitor with specific activity for CMV that is being developed as an oral antiviral for the prevention and treatment of CMV. AiCuris GmbH & Co. KG (AiCuris), which licensed letermovir to Merck in 2012, completed a Phase 2 study for CMV prevention in 2012 in which letermovir was tested in HCT recipients with a limited number of underlying diseases. Based on publicly available information, mismatched or cord blood transplant recipients, and those with GVHD or with impaired liver or renal function, were excluded from the study.

Publicly presented data from letermovir's Phase 2 study showed a benefit of letermovir versus placebo in preventing CMV reactivation during therapy, but do not address the post-therapy follow-up period. While no clinical data on letermovir resistance have been published or presented to date, resistance to letermovir was generated *in vitro* after a single passage.

### **Maribavir**

Maribavir is an oral antiviral that inhibits CMV protein kinase UL97, thereby preventing viral encapsulation for CMV specifically. ViroPharma Incorporated (ViroPharma) previously discontinued development of maribavir after Phase 3 studies failed to show benefit in HCT and liver transplant recipients for the prevention of CMV infection versus placebo and oral ganciclovir, respectively. ViroPharma is now evaluating maribavir in Phase 2 studies for the treatment of refractory CMV infection in transplant recipients using doses of 400, 800 and 1,200 mg twice daily, doses that are significantly higher than those tested in their previous Phase 3 studies. CMV resistance against maribavir has been described and published.

### **ASP0113**

ASP0113 (TransVax) is being developed by Vical Incorporated (Vical) and Astellas Pharma US, Inc. (Astellas) for the prevention of CMV disease reactivation in transplant recipients. This DNA vaccine is specifically targeted at enhancing immunity against CMV by using CMV antigens. Publicly available data from the Phase 2 trial in HCT recipients indicate that the vaccine prevented CMV infection in 69% of the subjects who received active vaccine versus 38% of the subjects randomized to placebo; however, this positive effect did not reach statistical significance.

Vical and Astellas announced initiation of their Phase 3 study of ASP0113 for the prevention of CMV in mid-2013. They are enrolling 500 CMV seropositive allogeneic HCT recipients and are measuring overall mortality at one year as the primary endpoint. Both companies have also announced their intention to initiate a Phase 2 trial for prevention of CMV in the SOT patient population in 2013.

## **Key Characteristics of Brincidofovir**

Key characteristics of brincidofovir along with comparative data for five approved therapies, two investigational antivirals, and one DNA-based vaccine specific for prevention of CMV in the transplant setting are presented below. Of the five therapies that are currently approved for human use, none is approved for the prevention of CMV infection in HCT recipients.

86

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## TABLE OF CONTENTS

Based on publicly available information, the table below highlights the key differentiating characteristics for brincidofovir, in particular the potent and broad-spectrum activity of brincidofovir compared with the CMV-specific activity of a majority of other antivirals.

- (1) Potency refers to the concentrations of each antiviral required to reduce viral replication by 50% *in vitro* (effective concentration, EC<sub>50</sub>).
- (2) Resistance means the emergence of specific mutations in the virus which decrease the antiviral activity of the drug.
- (3) Valganciclovir is rapidly converted to ganciclovir *in vivo*. Accordingly, ganciclovir is the relevant compound for cell activity studies.
- (4) The selection of resistant virus *in vitro* after a single passage of CMV in the presence of letermovir has been reported.

## **Preclinical and Clinical Development for Brincidofovir**

Building on positive data from our Phase 2 study for the prevention of CMV disease in HCT recipients, we initiated the Phase 3 SUPPRESS trial in the third quarter of 2013.

### **Preclinical Program for Brincidofovir**

#### **In Vitro Efficacy and Resistance Data**

Brincidofovir's broad-spectrum potency against dsDNA viruses has been characterized *in vitro* in cell culture systems and *in vivo* in multiple animal models. In cell culture assays, brincidofovir is typically 50- to 100-fold more potent than cidofovir against dsDNA viruses, including herpesviruses, adenoviruses, polyomaviruses, papillomaviruses, and orthopoxviruses.

The following table shows the concentrations of brincidofovir and each of the approved and investigational antivirals required to reduce viral replication by 50% *in vitro*. Smaller numbers depict a more potent molecule than larger numbers, and results depicted by > in general are above a threshold that would indicate antiviral activity (i.e., adequate *in vitro* data do not exist to support pursuing a clinical indication). Data are compiled from multiple sources and include multiple materials and methodologies; comparisons should be limited to general trends in orders of magnitude differences in *in vitro* potency.

TABLE OF CONTENTS

- (1) Valganciclovir is rapidly converted to ganciclovir in vivo. Accordingly, ganciclovir is the relevant compound for cell activity studies.

Although brincidofovir delivers the same active antiviral, CDV-PP, as intravenous cidofovir, the ability of brincidofovir to deliver CDV intracellularly through the lipid-conjugate technology results in brincidofovir demonstrating approximately 800-fold improvement in vitro in activity against BKV, more than 400-fold more activity against CMV, 65-fold more activity against AdV and 250-fold more activity against variola major, the causative agent of smallpox.

Brincidofovir has a high barrier to CMV resistance, and no mutations shown to have phenotypic resistance to any anti-CMV antiviral were detected in Study 201. *In vitro* brincidofovir-resistant CMV is slow to emerge, involves a unique mutation, and has reduced fitness compared to wild-type CMV. We have completed a 39-week chronic toxicology study in monkeys and 26-additional studies in mice, rabbits, rats, dogs, and monkeys. Based on results from these studies, we do not currently plan to conduct additional toxicology studies. We have also completed 41 Absorption, Distribution, Metabolism and Excretion (ADME) studies which demonstrate that brincidofovir is readily absorbed and widely distributed after oral administration in animals. In vitro cytochrome P450 and drug transporter inhibition studies indicated low-to-moderate potential for drug-drug interactions. In the development of Vistide®, Gilead identified mammary rat tumors that led to the inclusion of potential carcinogenicity in a black box warning. We observed similar findings with brincidofovir and may have a black box warning for brincidofovir with regard to carcinogenic risk.

## **Clinical Development Program for Brincidofovir**

We are developing brincidofovir initially for the prevention and preemptive therapy of clinically significant infection and disease, including as a potential therapy for CMV and AdV infection and as a possible countermeasure for smallpox. To date, over 800 subjects have received brincidofovir in controlled and uncontrolled studies and under EIND regulations in the United States and foreign equivalent regulations outside the United States.

Our planned brincidofovir clinical program to date has been comprised of the following studies:

*Phase 1 and Clinical Pharmacology Studies.* Evaluations of safety, tolerability and pharmacokinetics (PK) in healthy subjects and subjects with hepatic impairment, drug metabolism in healthy subjects, and food effects on PK. In addition, we conducted clinical pharmacology studies to support the Phase 3 program, including a thorough QTc study, a food effect study, and a drug interaction study with midazolam (completed).

*Study 201:* Phase 2 evaluation of QW and BIW dosing regimens of brincidofovir for the prevention of CMV infection in 230 adult HCT recipients (completed).

## TABLE OF CONTENTS

*Study 202:* Phase 2 evaluation of QW or BIW dosing regimens of brincidofovir for the preemptive therapy of AdV infection in 48 pediatric and adult HCT recipients (completed).

*Compassionate Use Program: EINDs and Study 350.* EINDs allowed the treatment of more than 230 patients in over 80 medical centers. Study 350 enrolled 215 subjects with one or more life-threatening dsDNA viral infections (completed).

*Study 301: SUPPRESS.* Phase 3 evaluation of brincidofovir for the prevention of CMV infection in 450 adult HCT recipients (enrollment ongoing).

*Study 333:* Long-term (three-year) follow up study of previously enrolled subjects in a Phase 3 study of brincidofovir (planned).

In the third quarter of 2013, we initiated SUPPRESS, our Phase 3 study evaluating brincidofovir for the prevention of CMV infection in adult HCT recipients. Assuming a positive outcome, the study may be sufficient for accelerated approval of brincidofovir. The protocol for the SUPPRESS trial was submitted to the FDA under a CMV-specific IND held by us. We do not intend to request a Special Protocol Assessment from the FDA prior to commencing the SUPPRESS trial. We have received Fast Track designation for the CMV prevention indication of brincidofovir.

Future clinical development for brincidofovir may include a Phase 3 study in pediatric HCT recipients as well as the possible development of brincidofovir for BKV infection in HCT and SOT recipients. We are also evaluating potential development activities in Europe and other key markets.

We currently hold multiple individual INDs with respect to brincidofovir, including an IND for the treatment of AdV infection (submitted on November 18, 2010) and an IND for the prevention of clinically significant CMV infection in HCT patients (submitted on January 22, 2013).

### **Study 201: Prevention of CMV Infection in HCT Recipients**

The key efficacy findings from our development program to date include the demonstration of superiority of brincidofovir over placebo for the prevention of CMV in HCT recipients in Study 201.

Study 201 was a randomized, placebo-controlled, dose-escalation study in CMV seropositive (R+) allogeneic HCT recipients, evaluating the ability of brincidofovir to prevent CMV infection. Subjects in five dosing groups received either placebo or oral brincidofovir, in doses ranging from 40 mg once weekly to 200 mg BIW. The primary endpoint was defined as (i) the incidence of CMV disease at any time during therapy, or (ii) a CMV polymerase chain reaction (PCR) assay result of greater than 200 copies/mL at the time of the last dose of study drug. All subjects who received at least one dose of drug or placebo and had at least one efficacy evaluation post baseline were included in the primary analysis, regardless of their CMV PCR status (negative or positive) at baseline (modified intent to treat, or mITT, population).

All brincidofovir doses and dose regimens in Study 201 demonstrated antiviral activity when compared to placebo, with the exception of the lowest dose, 40 mg QW. The proportion of subjects who developed CMV disease or a CMV PCR positive result at the end of 100 mg BIW dosing period was 10% (five of 50 subjects) versus 37% (22 of 59 subjects) for placebo-treated subjects ( $p=0.002$ , mITT population).

In a pre-specified subgroup analysis of subjects who were CMV negative at baseline, zero of 41 subjects (0%) in the brincidofovir 100 mg BIW group developed CMV PCR of 1,000 copies/mL or more during the brincidofovir dosing period, compared to 15 of 47 (32%) of subjects in the placebo cohort ( $p<0.001$ ) (see figures below). When individual subject data were examined (CMV PCR copies/mL over time), the brincidofovir 100 mg BIW dose regimen resulted in lower frequency and/or lower overall levels of CMV PCR.



TABLE OF CONTENTS

## **Overall Safety and Tolerability for Brincidofovir**

There was no indication of myelotoxicity or nephrotoxicity associated with brincidofovir at any dose in the Phase 2 Study, nor discontinuations from the study related to these events. Based on the decreased CMV events in both BIW dosing cohorts, and the superior tolerability of the 100 mg BIW dose, results from Study 201, brincidofovir 100 mg BIW demonstrated the most favorable risk benefit ratio to warrant further evaluation. Overall, there was a similar frequency and severity of adverse events seen in this dosing group compared to the placebo group.

90

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## TABLE OF CONTENTS

Because of the severity of their underlying illnesses and the multiple drugs administered to HCT patients both pre- and post-transplant, there is a high background level of AEs in this patient population. Of the AEs reported in Study 201 in 20% or more of subjects, GI-associated events (including diarrhea, nausea, vomiting and abdominal pain) and elevated ALT levels generally increased in frequency with increasing doses of brincidofovir.

In the cohort of subjects receiving the highest dose of brincidofovir explored in Study 201, brincidofovir 200 mg BIW, an increased rate of GI AEs were reported, particularly diarrhea. Diarrhea in the transplant setting has the potential to originate from a variety of sources, including conditioning regimens, concomitant medications, and infections. At this time, the FDA requested that doses of brincidofovir be limited to a total weekly dose of 200 mg or less. As part of the FDA's request, we implemented a program-wide SMMP that included interruption of study drug for subjects who experienced Grade 3 or higher GI AEs. In the final cohort of subjects in our Phase 2 study, 10% of the subjects administered brincidofovir 100 mg BIW discontinued brincidofovir due to GI AEs, compared to 3% in the placebo group. A decrease in serum albumin from baseline provides an additional marker for discriminating drug-related diarrhea from diarrhea of other etiologies. We believe that monitoring of serum albumin concentrations coupled with dose interruption is an appropriate strategy to decrease the severity of GI AEs without loss of antiviral activity and could allow for completion of the intended therapy duration. Following the introduction of the SMMP in Study 202 for AdV, less than 10% of subjects discontinued from brincidofovir BIW or QW due to GI AEs. The SMMP is included in the ongoing Phase 3 SUPPRESS study.

A dose-related, transient increase in ALT was associated with brincidofovir therapy. At a dose of 100 mg BIW, approximately 30% of subjects experienced ALT increases greater than three times the upper limit of normal, compared to 16% in the placebo group. When present, the ALT increases follow a predictable pattern and return to baseline levels following completion of therapy. The brincidofovir-related increases in ALT were not associated with increases in aspartate aminotransferase or bilirubin. Few clinical hepatobiliary AEs were reported in association with brincidofovir therapy and most were mild or moderate in intensity. The ALT increases observed in Study 201 were consistent with ALT elevations observed across all preclinical species exposed to brincidofovir, a finding considered non-adverse as there was no histopathologic evidence of liver injury or hepatic necrosis. In Study 202, there were no Grade 3/4 elevations of ALT in either brincidofovir dosing cohort, and no temporary or permanent discontinuations for ALT elevations.

There has been no evidence of nephrotoxicity with brincidofovir pre-clinically. The mechanism of nephrotoxicity for intravenous cidofovir is directly related to high plasma concentrations of intravenous cidofovir needed to reach therapeutic intracellular levels of CDV-PP. Cidofovir is rapidly taken up by cells in the kidney by a receptor called the human organic anion transporter one (hOAT-1), which leads to high concentrations of cidofovir in the duct system in the kidneys and subsequent renal toxicity. Brincidofovir is not a substrate for hOAT-1.

The lack of nephrotoxicity observed with brincidofovir in preclinical *in vitro* and animal studies is supported by clinical data. Based on the pharmacokinetic and safety data generated in our Compassionate Use Program, the FDA granted a waiver for the conduct of a renal insufficiency clinical pharmacology study. A further indication of brincidofovir's lack of nephrotoxicity was observed in Study 201, where there was a dose-related improvement in estimated GFR in the patients infected with BKV and receiving brincidofovir as compared with subjects on placebo. These data provide a clinical correlate to the *in vitro* activity of brincidofovir against BKV.

## **Study 202: Background and Rationale for Study Design**

In June 2011, we initiated Study 202, a randomized placebo-controlled, multi-site study evaluating brincidofovir as a preemptive therapy for AdV disease in HCT recipients. We announced top-line results from the study in August 2013,



and the results were presented in an oral session at the annual ICAAC meeting in September 2013.

As a broad-spectrum antiviral with activity across all dsDNA viruses that affect humans, brincidofovir demonstrated *in vitro* activity against major species of AdV. Based on this *in vitro* activity, brincidofovir was administered to patients with life-threatening AdV infections and no alternative therapy through our Compassionate Use Program, which included EINDs and Expanded Access Study 350. Anecdotal results from

## TABLE OF CONTENTS

these patients who received brincidofovir showed relative improvements in mortality compared to historical data, in addition, a decrease in all-cause mortality was observed in patients with at least a 1 log<sub>10</sub> decline in AdV levels in the blood (viremia).

Incorporating this experience, Study 202, the first proof-of-concept study in AdV, was designed to evaluate the safety, tolerability and efficacy of two dosing regimens of brincidofovir versus placebo for the preemptive treatment of asymptomatic AdV viremia. A number of factors influenced the design for Study 202, including the limited information available on the natural history of AdV infection in immunocompromised patients, ethical considerations due to the placebo-controlled design of the study and high mortality associated with AdV disease in HCT, and limited epidemiologic data that indicated a low incidence of AdV viremia in subjects post-HCT. Potential risk factors associated with an increased likelihood of rapid progression to AdV infection have been identified in scientific literature, but the frequency of AdV viremia or AdV disease was unknown prior to this trial.

AdV viremia was chosen as a potential early indicator of AdV disease based on the accepted clinical utility of viremia as an early trigger for initiation of antiviral therapy for CMV in this same patient population. Furthermore, the response seen in subjects with AdV viremia who received brincidofovir under EIND or through Study 350 suggested that viremia would be an appropriate trigger for initiation of preemptive therapy.

Subjects enrolled in Study 202 with any detectable AdV viremia at screening, and independent of their potential risk of progression to AdV infection (e.g., time since transplant, type of allogeneic transplant or conditioning regimen). Due to concerns associated with the placebo arm of the trial, the high mortality associated with AdV infection in HCT, and the lack of approved therapy for AdV, subjects in the trial who were considered by their physician to be treatment failures were allowed to switch to open-label brincidofovir if they were considered to have progressed to AdV disease or had increases in AdV viremia.

### **Study 202: Design**

Study 202 was designed to assess brincidofovir as a preemptive therapy for AdV disease in HCT recipients. Study participants were randomized at the time of detection of AdV viremia to receive six to 12 weeks of preemptive therapy with once weekly (QW) or twice weekly (BIW) brincidofovir or placebo, followed by four weeks of follow-up post-therapy. Subjects with increasing AdV viremia or subjects who developed AdV disease while on randomized therapy were offered open-label brincidofovir 100 mg BIW. Adults or children weighing at least 50 kg received brincidofovir or placebo in tablet form at doses of 100 mg BIW or 200 mg QW. Pediatric subjects (i.e., subjects weighing less than 50 kg) received brincidofovir or placebo in liquid form at doses of 2 mg/kg BIW or 4 mg/kg QW. We screened over 700 recipients of allogeneic HCTs for AdV viremia, and completed enrollment of the 48 planned subjects at 29 U.S. transplant centers in December 2012.

The primary endpoint in Study 202 was treatment failure, which was a composite endpoint consisting of (i) progression to probable or definitive AdV disease, or (ii) a confirmed increase in AdV viremia of at least 1 log<sub>10</sub> from Baseline. Subjects who were considered treatment failures at any time during randomized therapy were offered open-label treatment with brincidofovir. Secondary endpoints included the incidence and time to mortality, the percentage of subjects on randomized therapy with undetectable plasma AdV polymerase chain reaction (PCR) measured at various time points, and the percentage of subjects who had emergence or progression of CMV, EBV or BKV viremia or disease during the study.

### Study 202: Results

The brincidofovir BIW dosing regimen showed greater antiviral activity and lower all-cause mortality compared with brincidofovir QW or placebo. Subjects in the BIW dosing group demonstrated a significant rapid decrease in level of AdV viremia compared to the QW and placebo groups. In a post-hoc analysis of subjects who entered the trial with high levels of AdV viremia (viral load greater than  $3.0 \log_{10}$  copies/mL), viral decline on brincidofovir was consistent for seven of eight (7 of 8, 88%) subjects, all suppressing AdV viremia levels to below the assay's limit of detection (LOD =  $2.0 \log_{10}$  copies/mL, or 100 copies/mL), within the first week of dosing, versus only one of eight (1 of 8, 13%) high-level viremic subjects in the placebo cohort ( $p=0.010$ ). The brincidofovir QW dose was effective in suppressing AdV viremia, even with subjects

TABLE OF CONTENTS

presenting with high level AdV viremia at Baseline; however, subjects receiving brincidofovir QW did not suppress AdV viremia below the lower limit of detection of the virus as quickly as the twice-weekly group.

## **Study 202: AdV PCR for Individual Subjects**

Regarding the primary endpoint of treatment failure, three of 14 (3 of 14, 21%) subjects enrolled in the BIW cohort were considered treatment failures with AdV viremia or progression to AdV disease, versus six of 16 (6 of 16, 38%) subjects in the QW cohort and six of 18 (6 of 18, 33%) subjects in the placebo cohort. These data show a favorable numeric difference between the brincidofovir BIW group versus placebo, although these data were not statistically significant for the primary endpoint. The favorable numeric difference for the brincidofovir BIW dosing group is consistent with the results of secondary endpoint analyses that also favor the BIW group.

TABLE OF CONTENTS

Overall mortality was lower for subjects who received brincidofovir 100 mg BIW (two of 14, 14%) versus brincidofovir QW (five of 16, 31%) and placebo (seven of 18, 39%), as presented below.

## **Study 202: All-Cause Mortality through the End of Study**

Study 202 confirmed brincidofovir's safety and tolerability profile, including the lack of hematologic and renal toxicity for both dosing regimens of brincidofovir. In addition, the study showed the successful implementation of the SMMP to address GI side effects reported in earlier trials. Temporary dose interruptions for Grade 3 diarrhea allowed subjects to stay enrolled in the study, with only one permanent discontinuation for diarrhea in the QW cohort. Three additional discontinuations in the trial were reported for abdominal pain (BIW cohort), lower GI hemorrhage (BIW cohort) and severe rash (placebo cohort). There was no difference in ALT elevations between the three dosing groups. No new safety issues were identified, and no changes were necessary in the safety monitoring of the recently initiated Phase 3 SUPPRESS trial for the prevention of CMV infection.

### **Study 202: Overall Conclusions and Future Directions**

The data from Study 202 provide useful information that are important in considering our future plans for development of brincidofovir against AdV. In spite of the limitations of this exploratory study, the results are consistent with the suppression of AdV viremia observed in subjects receiving brincidofovir through the Compassionate Use Program, and suggest that early intervention with brincidofovir BIW has the potential to improve outcomes in subjects with AdV infection.

Unlike CMV infection, viremia does not appear to be an indicator of early AdV disease, and thus not an appropriate trigger for initiation of antiviral therapy in this patient population. For subjects who entered the study with low-level AdV viremia, a significant proportion spontaneously cleared viremia prior to the initiation of therapy or during placebo therapy. These data indicate that low level AdV viremia may be a transient phenomenon in some subjects and that AdV viremia detection may be better interpreted in the context of a subject's baseline risk assessment and underlying level of immunosuppression. In contrast, high level AdV viremia at screening was often associated with rapid development of symptoms and detection of end-organ disease prior to the start of therapy. In addition, the data indicate that a number of subjects had evidence of AdV end-organ disease at the time of first detection of AdV viremia. The fact that AdV viremia may not precede end-organ infection may be related to a different site of latency for AdV, as compared to CMV, or may reflect primary infection with AdV, rather than reactivations of latent virus.

While the interpretation of safety data is limited by the small sample size and the inherent complexity of the subject population, the very low rate of discontinuations due to AEs and lack of myelosuppression or nephrotoxicity in this trial supports a favorable benefit-to-risk ratio for brincidofovir in this population.

## TABLE OF CONTENTS

Evidence of improved mortality rates with brincidofovir in this population overall, in addition to reduced CMV reactivation in Study 201, suggest that future trials should explore a prevention approach in subjects at highest risk of AdV infection.

We intend to meet with the FDA during the fourth quarter of 2013 to discuss the results of Study 202 and future plans for development of brincidofovir in the context of our overall pediatric plan.

## **Open-Label Studies**

Beginning in 2009, Chimerix made brincidofovir available to over 80 transplant centers worldwide through our Compassionate Use Program, including EINDs or foreign equivalents and our formal open-label expanded access study, Study 350. Through these programs, brincidofovir was made available to treat life-threatening dsDNA viral diseases in patients or for whom there were no therapeutic options. While the majority of patients treated were HCT or SOT recipients, we also provided brincidofovir for patients with other diseases, including congenital deficiencies or HIV.

### **EINDs**

Clinical testing of therapeutic agents prior to approval must be performed pursuant to an IND submitted to and approved by the FDA. In addition, the FDA may allow non-approved drugs to be administered to patients in certain situations utilizing a set of regulations known as expanded access. One such type of expanded access is the EIND application. A physician may request use of an investigational antiviral product through a single-patient EIND application if:

the physician considers the product may be urgently needed for the patient's serious or life-threatening condition;  
no satisfactory alternative therapy is available; and  
the patient cannot receive the product through any existing clinical trials or expanded access protocols.

Over 230 patients have been treated with brincidofovir under EINDs or foreign equivalent regulations for severe, life-threatening dsDNA viral infections. Viruses treated with brincidofovir include all major dsDNA viruses, including CMV, AdV, BKV, EBV, JCV, HHV-6, HHV-8, HSV-1, HSV-2, VZV, HPV, molluscum, and vaccinia. The average period of dosing with brincidofovir was approximately 11 weeks. Over 80 international transplant centers have requested brincidofovir. In this EIND population, approximately one-third of patients infected with CMV were infected with at least one other dsDNA virus, the most common being BKV and AdV.

In 2010, we focused our Compassionate Use Program efforts on Study 350 and significantly curtailed the availability of brincidofovir under the EIND program in an effort to standardize the data collected from patients receiving brincidofovir under the expanded access regulations.

### **Study 350**

Study 350, a multicenter, open-label clinical study of brincidofovir, evaluated the safety, tolerability and antiviral activity of brincidofovir in 142 adult and 68 pediatric patients with various severe, life-threatening dsDNA viral infections at 36 transplant centers in the United States. Patients must have failed all other available treatment options in order to qualify for this study. Patient ages ranged from one to 78 years, and were treated for dsDNA viral infections including CMV, HSV, EBV, AdV, BKV, JCV, and HHV6. Approximately 28% of patients were co-infected with two or more dsDNA viruses. The average period of dosing in Study 350 was approximately two months. Review of safety data has not revealed any unexpected safety signals associated with brincidofovir

administration in a complex and highly compromised patient population.

Across our Compassionate Use Program, approximately one-third of patients dosed with brincidofovir were co-infected with two or more dsDNA viruses. Analyses of outcomes and potential indicators of response across the many viral diseases are ongoing.

TABLE OF CONTENTS

**Phase 3 Study: SUPPRESS**

We recently initiated SUPPRESS, our Phase 3 study evaluating the safety and efficacy of brincidofovir for the prevention of CMV in adult HCT recipients. SUPPRESS is expected to enroll approximately 450 CMV seropositive (R+) HCT recipients who are at increased risk of CMV infection, with approximately 300 of the 450 enrolled subjects receiving brincidofovir 100 mg BIW versus placebo (2-to-1 ratio). Dosing will begin shortly after subjects receive their transplant, and will not require evidence of stem cell engraftment (evidence of production of blood cells by the new transplant), a safety precaution in our Phase 2 CMV trial of brincidofovir and in other recent trials of investigational antivirals for CMV prevention. Earlier dosing of study drug will allow subjects to reach effective therapeutic drug concentrations early post-transplant, and will capture the early CMV events for placebo recipients, thereby potentially increasing the difference in event rate for brincidofovir versus the placebo cohort.

Subjects will receive brincidofovir or placebo from the early post-transplant period through Week 14 post-transplant, the period of highest risk for viral reactivation. Subjects will continue to be monitored through Week 24 post-transplant. The primary endpoint for SUPPRESS is the prevention of clinically significant CMV infection through the first 24 weeks post-transplant. The Roche TAQMAN® real-time PCR assay, which was recently approved by the FDA, will be used to monitor levels of CMV in the blood. The trial is powered to detect a relative 50% decrease in clinically significant CMV infection in subjects receiving brincidofovir versus those receiving placebo. Secondary endpoints include evidence of other dsDNA viruses, including AdV, VZV, BKV, and other herpesviruses such as HHV-6, which contribute to morbidity and mortality in the first year following HCT.

Data from SUPPRESS are expected in 2015 and, if positive, may support Accelerated Approval of brincidofovir for the prevention of CMV infection.

**Phase 2 Data Using SUPPRESS Endpoint and Inclusion Criteria**

In order to assure adequate power for the Phase 3 SUPPRESS trial, we calculated the maximum estimated failure rates for subjects enrolled in Study 201 using the primary endpoint and inclusion criteria for SUPPRESS. This analysis includes subjects with negative or positive CMV PCR at baseline (first day of dosing) and excludes subjects who had any samples during screening that were CMV PCR positive. Using a conservative approach, failures included (i) subjects with CMV disease, (ii) subjects with CMV PCR values greater than 1,000 copies/mL, (iii) subjects with CMV PCR values greater than 100 copies/mL and defined as high risk in the SUPPRESS protocol or (iv) subjects that initiated anti-CMV preemptive therapy, independent of CMV PCR. Where insufficient data were available, subjects were considered as having met criteria for a failure.

This analysis demonstrates that a 50% reduction (22% vs. 46%) in clinical risk, which is the assumed clinically relevant difference between brincidofovir and placebo, would be achieved if similar prescriptions of subjects reach the failure endpoint in Study 301 as were observed in Study 201.

Based on completed and planned studies, we anticipate that more than 950 adult subjects will have been exposed to at least one dose of brincidofovir through the end of SUPPRESS in both controlled and uncontrolled studies, including nearly 600 adult subjects enrolled in randomized, placebo-controlled studies. Of these, over 500 subjects will have received doses of at least 150 mg per week for at least 10 weeks in controlled studies upon our anticipated submission for brincidofovir for the prevention of CMV in HCT recipients.





## TABLE OF CONTENTS

Based on our interactions with the FDA, we believe, but cannot guarantee, that with the successful completion of SUPPRESS, we will have completed the preclinical and clinical studies necessary to submit an NDA for the prevention of CMV in HCT recipients. We intend to submit an NDA under an accelerated approval pathway seeking regulatory approval to market brincidofovir in the United States. A confirmatory, second trial of brincidofovir for the prevention of CMV is under discussion with the FDA to support Traditional Approval of brincidofovir for the prevention of CMV. The patient population studied in this second trial must have a higher incidence of clinical events related to CMV reactivation, and may include SOT recipients or pediatric HCT recipients. The confirmatory, second trial is usually in progress at the time of NDA submission under the accelerated approval pathway. Additionally, we plan to seek regulatory approval for marketing of brincidofovir for the prevention of CMV in HCT recipients in Canada and key European markets.

We are actively exploring potential future clinical development opportunities for brincidofovir in other immunocompromised patient populations.

## **Brincidofovir as a Medical Countermeasure Against Smallpox**

Variola virus, the dsDNA virus that causes smallpox, is an orthopoxvirus that infects only humans. The Department of Homeland Security (DHS) has declared smallpox to be a material threat to national security and the U.S. Centers for Disease Control and Prevention classifies smallpox as a Category A bioterror agent. Additionally, smallpox has been identified as a high-priority threat by the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE). An antiviral is needed, in particular, for patients who cannot be vaccinated due to conditions that prevent them from mounting an appropriate immune response to a smallpox vaccine.

We received our initial funding for the development of brincidofovir as a medical countermeasure for the treatment of smallpox from the NIAID. brincidofovir demonstrated high potency in inhibiting variola virus replication in cultured cells as well as related viruses that have been used to create animal models of smallpox including ectromelia in mice, rabbitpox, monkeypox and vaccinia.

In order to supply brincidofovir to the Strategic National Stockpile as a treatment for smallpox infection, FDA approval is ultimately required. We submitted an IND for brincidofovir for the treatment of smallpox to FDA in 2005. The brincidofovir development program for this indication was granted Fast Track Status at that time. Should we be successful with our development efforts, an NDA will be submitted to the FDA in order to obtain an approval for brincidofovir for the treatment of smallpox.

Since smallpox is no longer a communicable disease in humans, the development of brincidofovir for treatment of smallpox is occurring under the Animal Efficacy Rule . Under this Rule, the FDA can rely on the evidence from animal studies to provide substantial evidence of the effectiveness of these products in support of an NDA. Products evaluated for effectiveness under the Animal Efficacy Rule are evaluated for safety in clinical trials using the same regulations as exist for other drugs. Therefore, the safety data generated for brincidofovir in the clinical trials described in the section titled Clinical Development Program for brincidofovir would provide the clinical safety data for the treatment of smallpox indication.

In February 2011, we were awarded a Broad Agency Announcement (BAA) contract by BARDA to fund development of brincidofovir for the treatment of smallpox in the event of a smallpox outbreak. See Commercial Agreements below for more information on this contract.

Under the base performance segment of the BARDA contract described below, we have devoted a substantial amount of effort to develop animal models of smallpox and to explore efficacy in these models. Additionally, as part of progressing the clinical development of brincidofovir for the smallpox indication, the base performance segment of the BARDA contract supported Clinical Study brincidofovir-350. This study provided safety data for brincidofovir relevant to the treatment of smallpox indication.

In December 2011, we presented a summary of studies of brincidofovir conducted in mouse, rabbit and monkey models of smallpox and the current animal efficacy development plan to a Smallpox Advisory Committee convened by FDA to provide guidance on acceptable models of smallpox. Based on the information provided at that meeting, FDA provided specific guidance to Chimerix on the development of brincidofovir for smallpox under the Animal Efficacy Rule. The FDA provided feedback on the animal models

## TABLE OF CONTENTS

that could be used for studies that may lead to approval for a smallpox treatment indication. Specifically, the FDA suggested the mouse ectromelia model and the rabbit rabbitpox model would be appropriate for brincidofovir. In addition, we and the FDA agreed that no additional work would be conducted in the currently available monkey models of smallpox. An updated animal efficacy development plan incorporating this feedback was submitted to the FDA in August 2012 in advance of a Type C meeting in September 2012.

Brincidofovir has shown encouraging activity in relevant animal models of smallpox. *In vivo*, the antiviral activity of brincidofovir has been characterized in the rabbitpox model of smallpox. In this model, we have shown that brincidofovir possesses statistically significant efficacy at a dose we believe has the potential to be equivalent to the human dose being evaluated in the SUPPRESS trial. We are continuing to work with BARDA on additional experiments which have the potential to lead to FDA approval of brincidofovir for the smallpox indication.

## **CMX157**

CMX157, our second oral nucleotide compound, uses the same proprietary lipid technology as brincidofovir to deliver high intracellular concentrations of another potent antiviral drug, tenofovir. CMX157 is being developed for the treatment of HIV infection, and was licensed to Merck in July 2012. We submitted an IND for CMX157 for the treatment of HIV infection on April 30, 2009. We are no longer the sponsor of record for this IND. Merck became the sponsor of this IND upon its licensing of CMX157 from us.

CMX157 is a novel lipid-conjugate of the acyclic nucleoside phosphonate, tenofovir, the active molecule underlying the prodrug Viread®. Viread, which is marketed in the United States by Gilead Sciences, Inc. (Gilead), is the most widely used nucleotide reverse transcriptase inhibitor (NRTI), approved for the treatment of HIV and chronic hepatitis. Based on supportive preclinical data, we believe CMX157 has the potential for higher intracellular concentrations in target tissues of tenofovir-diphosphate (TFV-PP), the active form of both CMX157 and Viread, as well as a decreased frequency of dosing and an improved safety profile over existing NRTIs. CMX157 is more than 200-fold more potent *in vitro* versus tenofovir against all major HIV subtypes resistant to current therapies, which may allow activity against tenofovir-resistant viruses and against Hepatitis B. CMX157's structure results in decreased circulating levels of tenofovir, lowering systemic exposure and thereby reducing the potential for renal side effects.

Prior to the transaction with Merck, we completed a Phase 1 clinical study of CMX157 in healthy subjects, demonstrating a favorable safety, tolerability and drug distribution profile. This study demonstrated plasma concentrations of CMX157 that exceeded target levels at doses of 100 mg and higher after a single dose. TFV-PP was measurable in peripheral blood mononuclear cells in all subjects after a single dose of 400 mg of CMX157, but not so after a standard dose of Viread. TFV-PP remained detectable for up to six days after dosing, suggesting the possibility for infrequent dosing. In the study, CMX157 was well-tolerated and no safety issues were observed. No trends in clinical laboratory results, vital signs or electrocardiogram parameters were noted, and no severe adverse events were reported. The chart below presents peak plasma concentrations after oral administration of CMX157 in the Phase 1 study.

TABLE OF CONTENTS

\*Concentration that equaled TFV-PP level produced by TFV peak concentration *in vitro*.

## **Chimerix Chemical Library**

The Chimerix Chemical Library contains over 10,000 heterocyclic ring systems and nucleosides that were originally synthesized in the laboratory of Dr. Leroy Townsend at the University of Michigan. We are currently screening the library for activity against more than thirty viruses including flaviviruses, influenza, herpesviruses and polyomaviruses. Lead chemical series have been identified for influenza and novel compounds with promising activity are being evaluated. We believe that several compounds active against key pathogens are amenable to enhancement using our proprietary lipid technology.

## **Commercial Agreements**

### **Merck**

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

As additional consideration, we are eligible to receive up to a total of \$151.0 million in milestone payments if certain development and regulatory milestones are achieved by Merck for products utilizing CMX157, as well as tiered royalties on net sales ranging from high single digits to low double digits, depending upon the volume of sales of each applicable product, if CMX157 is successfully commercialized. Milestone payments are triggered upon the completion of various stages of the regulatory approval process for each of the first two indications for CMX157, with the final milestones reached upon approval in the United States and three major European markets. Royalties for any given product will continue on a country-by-country basis through the later of the expiration of our patent rights applicable to such product or ten years from the first commercial sale of such product. As of September 30, 2013, other than the upfront payment received upon execution of the agreement, we have not received any payments from Merck pursuant to the agreement.

Unless earlier terminated, the agreement continues in effect until the termination of Merck's royalty payment obligations. The agreement allows for termination by Merck in its entirety, or on a region-by-region basis, upon 90 days advance written notice, or, with respect to a particular product, immediately upon written

## TABLE OF CONTENTS

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

## **BARDA**

In February 2011, we entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release (Contract Number HHSO100201100013C). BARDA is a division of the U.S. Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Preparedness and Response that supports the advanced research and development, manufacturing, acquisition and stockpiling of medical countermeasures. The scope of work for the contract includes preclinical, clinical and manufacturing development activities that fall into the following areas: non-clinical animal efficacy studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, management, and administrative activities. The contract has been amended several times, most recently on May 30, 2013, pursuant to which BARDA exercised the first option segment.

Under the contract, BARDA will reimburse our costs, plus pay us a fixed fee, for the research and development of brincidofovir as a treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods of around one year each, referred to as option segments, each of which may be exercised at BARDA's sole discretion. We must complete agreed upon milestones and deliverables in each discrete work segment before the next option segment is eligible to be exercised. Under the contract as currently in effect, if each follow-on option segment is exercised by BARDA, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees. On May 30, 2013, we extended our contract with BARDA for the continued development of brincidofovir as a potential medical countermeasure against smallpox. The extension of the contract provides up to \$5 million in funding over 12 months for us to conduct animal studies that are necessary for an approval of brincidofovir for the treatment of smallpox infection under the U.S. Food and Drug Administration's (FDA) Animal Efficacy Rule. If all option segments are exercised by BARDA, the term of the contract would be extended to February 15, 2016.

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

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

## **NIAID**

In September 2003, we were awarded a \$36.3 million grant from the NIAID to support our development of an oral drug for the treatment of smallpox. The work performed under this grant resulted in our selection of brincidofovir as a lead product candidate for commercial development. The grant, and our activities conducted in connection therewith, were concluded in February 2011.

The U.S. government retained march-in and other rights with respect to inventions developed by us under the NIAID contract, and if the U.S. government exercised these rights, we could be obligated, for example, to license intellectual property developed by us on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights.

100

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TABLE OF CONTENTS

## **Commercialization, Marketing and Sales**

Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Due to the complexity of HCT and SOT treatment regimens, treating physicians are readily identifiable and are well informed, which may make it easier to identify potential prescribers after a drug is approved. Patients who receive HCT and SOTs will mostly likely be treated at a small number of major medical centers by specialized teams of physicians. In the United States, there are approximately 200 institutions at which transplants are performed, of which approximately 75% perform HCTs and 75% perform SOTs. Due to the different requirements and treatment regimens for HCT and SOT patients, only approximately one-third of these hospitals perform both HCT and SOTs. Of the approximately 150 hospitals that perform HCTs, approximately 50 perform both pediatric and adult transplants, approximately 60 perform adult transplants only and approximately 40 perform pediatric HCTs only.

The management of therapies for transplant patients is largely the responsibility of the transplant physicians and an even smaller subset of specialists in infectious diseases who oversee post-transplant therapies. In many hospitals, the infectious disease physicians are responsible for only HCT or only SOT patients, and often further sub-specialize to pediatric versus adult transplant patients. Overall, transplant and transplant infectious disease treatment is a small clinical discipline with a clearly identified group of key opinion leaders. While the standard of care for post-transplant therapies varies from institution to institution and from country to country, it is often driven by research activities or publications of these key opinion leaders from academic transplant research centers. Many of these key opinion leaders have participated in our clinical trials and/or have experience using brincidofovir through our Compassionate Use Program.

If approved for the prevention of CMV in patients who have received HCT, we believe that it will be possible for us to commercialize brincidofovir for this indication with a relatively small specialty sales force that calls on a limited and focused group of physicians. For the United States and Canada, we foresee the need for a full commercial infrastructure of approximately 50 people. While our commercialization efforts would initially be focused on physicians who are responsible for HCT patients, this sales and marketing infrastructure would serve as the foundation for an expanded focus on physicians who are responsible for SOT patients, subject to marketing approval in this patient population.

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

## **Competition**

Our industry is highly competitive and subject to rapid and significant technological change. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions. We believe that the key competitive factors that will affect the development and commercial success of brincidofovir and the product candidates that we develop are efficacy, safety and tolerability profile, convenience in dosing, product labeling, value, price and the availability of reimbursement from the government and other third-parties. Our commercial opportunity could be reduced or eliminated if our competitors have products which are better in one or more of these categories.



We expect that, if approved, brincidofovir would compete with a number of existing products and other product candidates that target serious viral infections. Many of our potential competitors have substantially greater financial, technical, commercial and human resources than we do and significantly more experience in the discovery, development and regulatory approvals of product candidates, and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for product candidates and achieving widespread market acceptance. Our competitors' products and product candidates may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize, which could render brincidofovir or any other product candidate that we develop

## TABLE OF CONTENTS

obsolete or non-competitive before we can recover the expenses of developing and commercializing any such product candidate. We anticipate that we will face intense and increasing competition as new products enter the market, as advanced technologies become available and as generic forms of currently branded products become available.

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

We anticipate that, if approved, brincidofovir will compete with other antiviral products, including drugs and vaccines which demonstrate efficacy against viruses that affect our target patient populations. These include both oral and intravenous ganciclovir, a drug that is sold by generic manufacturers; Valcyte® (valganciclovir), a prodrug of ganciclovir that is marketed by Hoffmann-La Roche Inc.; Cytogam®, a pooled CMV hyperimmunoglobulin, marketed by CSL Limited; Vistide® (cidofovir for injection), marketed by Gilead; and Foscavir® (foscarnet sodium for injection), marketed by Clinigen Group plc and generic manufacturers.

We are aware of several product candidates currently in development that may compete against brincidofovir, including letermovir, an anti-CMV drug being developed pursuant to an exclusive worldwide license agreement between AiCuris and Merck.

We are aware of several therapeutic vaccine candidates that are being studied for the prevention or mitigation of CMV infection in a variety of settings. One such vaccine, ASP0113 (TransVax), was licensed to Astellas from Vical and is being developed by Astellas and Vical. Other vaccine products are being developed by GlaxoSmithKline plc (GlaxoSmithKline), Novartis International AG, sanofi-aventis Group (Aventis), and a variety of university and governmental organizations.

Other products used against the same viruses targeted by brincidofovir include valacyclovir, an antiviral drug marketed by GlaxoSmithKline and a number of generic manufacturers; leflunomide, a drug approved for rheumatoid arthritis and sold in the United States by Aventis under the brand name Arava®; and quinolone antibiotics, which are manufactured by a variety of branded pharmaceutical companies and generic manufacturers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than brincidofovir or any other product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. In addition, our ability to compete may be affected because in many cases insurers or other third-party payers seek to encourage the use of generic products.

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

## **Intellectual Property**

We strive to protect and enhance the proprietary technologies that we believe are important to our business, and seek to obtain and maintain patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We are not currently aware of any third-party patents (other than patents we have licensed) encompassing our proprietary compounds brincidofovir and CMX157.

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

## TABLE OF CONTENTS

proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of nucleoside phosphonates.

We believe that we have a strong intellectual property position and substantial know-how relating to the development and commercialization of our lipid-antiviral conjugates, including brincidofovir, CMX157, and derivatives of brincidofovir or CMX157, consisting of patents or patent applications that we own or have in-licensed from third parties. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our technology.

Our objective is to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment, and identification of additional nucleoside phosphonate compounds and their derivatives, in order to protect our lipid-antiviral conjugate therapeutics and to maintain our position in the antiviral field. Specifically, we seek patent protection in the United States and in certain other jurisdictions for novel compositions of matter covering brincidofovir and CMX157, and chemistries which facilitate the synthesis of nucleoside phosphonate compounds, including brincidofovir and CMX157, as well as uses of these compounds in a variety of anti-viral therapies, where available and when appropriate. Our policy is to pursue, maintain, and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions, and improvements that are commercially important to the development of our business. We are also expanding our intellectual property estate into the area of novel anti-fungal nucleoside phosphonates.

### **Brincidofovir**

The patent portfolio for brincidofovir is directed to cover compositions of matter, formulation, manufacturing methods, and methods of use. This patent portfolio includes issued U.S. patents, pending U.S. patent applications, and corresponding foreign national and regional counterpart patents and patent applications. The patents and patent applications relating to brincidofovir include patent applications owned by us, as well as patents and patent applications in-licensed (exclusive license) from The Regents of the University of California. The issued composition of matter patents (U.S. Patent Nos. 6,716,825; 7,034,014; 7,094,772; and 7,790,703), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire in 2020. The issued methods of use patents (U.S. Patent Nos. 6,716,825; 7,452,898; and 7,790,703), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire in 2020. Based on our current development plan, we believe that an additional term of up to five years for one of the brincidofovir U.S. patents may result from the patent term extension provision of the Hatch-Waxman Amendments of 1984 (the Hatch-Waxman Act). We expect that the patent applications in this portfolio, if issued, and if appropriate maintenance, renewal, annuity, and other governmental fees are paid, would expire between 2020 and 2031, excluding any additional term from patent term adjustment or patent term extension. Assuming one of the U.S. composition of matter or method of use patents covering brincidofovir were awarded the maximum patent term extension, the term of that patent could extend to December 2025. The patent term calculation method and the provisions under the Hatch-Waxman Act are described under **Patent Term** below.

The term of issued brincidofovir composition of matter patents in other jurisdictions (Australia, Canada, Europe, Hong Kong, India, Japan, Mexico, Russia, and South Africa) and methods of use patents and patent applications (if applicable) relating to brincidofovir (in Australia, Canada, China, Europe, Hong Kong, India, Japan, Mexico, Russia, and South Africa), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire between 2020 and 2031. These patents and patent applications (if applicable), depending on the national laws, may benefit from extension of patent term in individual countries. In the European Union member countries, for example, a supplementary protection certificate (SPC), if obtained, provides a maximum five years of market

exclusivity. The duration of the SPC can be extended to five and a half years when the SPC relates to a human medicinal product for which data from clinical trials conducted in accordance with an agreed Pediatric Investigation Plan (PIP) have been submitted. Likewise, in Japan, the term of a patent may be extended by a maximum of five years in certain circumstances.

## TABLE OF CONTENTS

### **CMX157**

The patent portfolio for CMX157 is directed to cover compositions of matter, formulation, and methods of use. This patent portfolio includes issued U.S. patents, pending U.S. patent applications, and corresponding foreign national and regional counterpart patents and patent applications. The patents and patent applications relating to CMX157 include patent applications owned by us, as well as patents and patent applications in-licensed (exclusive license) from The Regents of the University of California. The issued composition of matter patents (U.S. Patent Nos. 6,716,825; 7,034,014; 7,094,772; 7,790,703; and 7,687,480), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire in 2020. The issued methods of use patents (U.S. Patent Nos. 6,716,825; 7,790,703; and 7,687,480), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire in 2020. We believe that an additional term of up to five years for one of the CMX157 U.S. patents may result from the patent term extension provision of the Hatch-Waxman Act. We expect that the patent applications in this portfolio, if issued, and if appropriate maintenance, renewal, annuity, and other governmental fees are paid, would expire between 2020 and 2031, excluding any additional term from patent term adjustment or patent term extension. The patent term calculation method and the provisions under the Hatch-Waxman Act are described in the Patent Term section below.

The term of issued CMX157 composition of matter patents in other jurisdictions (Australia, Canada, Europe, Hong Kong, India, Japan, Mexico, Russia, and South Africa) and methods of use patents and patent applications (if applicable) relating to CMX157 (in Australia, Canada, China, Europe, Hong Kong, India, Japan, Mexico, Russia, and South Africa), if the appropriate maintenance, renewal, annuity, and other government fees are paid, are expected to expire between 2020 and 2031. Like the patents relating to brincidofovir, the patents and patent applications (if applicable), covering CMX157, depending on the national laws, may also benefit from extension of patent term in individual countries.

### **Other Product Candidates**

In addition to brincidofovir and CMX157, we have a chemical library of more than 10,000 heterocyclic compounds purchased from the University of Michigan which includes approximately 3,500 nucleoside analog candidates for lipid conjugation. We also license certain intellectual property rights relating to these compounds from the University of Michigan, in exchange for which we agree, among other things, to use commercially reasonable efforts to develop and commercialize products utilizing the licensed intellectual property, and to pay certain royalties and other fees to the University of Michigan. Focused screening of the library has identified viable hits against multiple pathogens including compounds with activity against influenza and compounds with activity against both CMV and BKV. Lead selection is in progress for a dual active CMV/BKV programs. We believe additional nucleoside phosphonate antiviral compounds, unrelated to brincidofovir and CMX157, are protected under U.S. Patents 7,994,143 and 7,749,983, which are expected to expire between 2027 and 2028, if the appropriate maintenance, renewal, annuity, and other government fees are paid.

### **Patent Term**

The term of individual patents and patent applications listed in previous sections will depend upon the legal term of the patents in the countries in which they are obtained. In most countries, the patent term is 20 years from the date of filing of the patent application (or parent application, if applicable). For example, if an international (PCT) application is filed, any patent issuing from the PCT application in a specific country expires 20 years from the filing date of the PCT application. In the United States, however, if a patent was in force on June 8, 1995, or issued on an application that was filed before June 8, 1995, that patent will have a term that is the greater of twenty years from the filing date

or seventeen years from the date of issue.

Under the Hatch-Waxman Act, the term of a patent that covers an FDA-approved drug may also be eligible for patent term extension (PTE). PTE permits patent term restoration of a U.S. patent as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended.

Similar provisions may be available in Europe and certain

## TABLE OF CONTENTS

other foreign jurisdictions to extend the term of a patent that covers an approved drug. When possible, depending upon the length of clinical trials and other factors involved in the filing of a new drug application (NDA) we expect to apply for patent term extensions for patents covering nucleoside phosphonates and their derivatives, and their use in treating various diseases. As a specific example, if we are awarded the maximum length of PTE, our U.S. granted composition of matter patents relating to brincidofovir would have an expected expiration date of December 20, 2025.

However, depending on any changes in our clinical path, the PTE may not be granted, or may be less than the maximum.

For additional information on patent term extension and the BPCA, see [Business Government Regulation and Product Approval](#).

## **Proprietary Rights and Processes**

We may rely, in some circumstances, on proprietary technology and processes (including trade secrets) to protect our technology. However, these can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, contractors, and collaborators. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our proprietary technology and processes may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors, contractors, or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology and processes, please see the section on [Risk Factors Risks Related to Our Intellectual Property](#).

## **Technology Licenses**

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

In May 2002, we entered into a license agreement with The Regents of the University of California (UC) under which we obtained an exclusive, worldwide license to UC's patent rights in certain inventions (the UC Patent Rights) related to lipid-conjugated antiviral compounds and their use, including certain patents relating to brincidofovir and CMX157. The agreement was amended in September 2002 in order to expand the scope of the license and again in December 2010 in order to modify certain financial terms. The agreement was amended a third time in September 2011 to add additional patents related to certain metabolically stable lipid-conjugate compounds. A fourth amendment was executed in July 2012 to alter the rights and obligations of the parties in light of our current business plans.

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

In consideration for the rights granted to us under the license agreement, we have issued UC an aggregate of 64,788 shares of our common stock. As additional consideration, we are required to pay certain cash milestone payments in connection with the development and commercialization of compounds that are covered by the UC Patent Rights, plus certain annual fees to maintain such patents until we commercialize a product utilizing UC Patent Rights. In



connection with the development and commercialization of brincidofovir and CMX157, we could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement. In addition, upon commercialization of any product utilizing the UC Patent Rights (which would include the commercialization of brincidofovir or CMX157), we will be required to pay low single digit royalties on net sales of such product.

In the event we sublicense a UC Patent Right (including UC Patent Rights relating to brincidofovir or CMX157), we are obligated to pay to UC a fee, which amount will vary depending upon the size of any

105

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## TABLE OF CONTENTS

upfront payment we receive and the clinical development stage of the compound being sublicensed, but which could be up to approximately 50% of the sublicense fee in certain circumstances. In addition, we will also be required to pay to UC a low single digit sublicense royalty on net sales of products that use the sublicensed UC Patent Rights, but in no event will we be required to pay more than 50% of the royalties we receive in connection with the relevant sublicense. Any such royalty payment will be reduced by other payments we are required to make to third parties until a minimum royalty has been reached. As of September 30, 2013, we had paid an aggregate of approximately \$1.2 million to UC pursuant to the license agreement.

The license agreement requires that we diligently develop, manufacture and commercialize compounds that are covered by the UC Patent Rights, and we have agreed to meet certain development and commercialization milestones. UC may, at its option, either terminate the license agreement or change the license granted from an exclusive license to a non-exclusive license if we fail to meet such development and commercialization milestones. We are currently in compliance with these milestone requirements. Specifically, Section 3.3(a)(5) of the license agreement contains a due diligence requirement stating that we must commence a Phase III clinical trial for the first Licensed Product within 9 years of the Effective Date (as those terms are defined within the license agreement). On January 31, 2011 we received a letter from UC stating that we had satisfied the requirements of Section 3.3(a)(5), thereby waiving compliance with further due diligence obligations under Section 3.3(a)(5).

We may terminate the license agreement upon 90 days notice to UC. UC may terminate the license agreement in the event of our nonperformance or breach of the license agreement which remains uncured after 60 days of receiving written notice of such nonperformance or breach. Absent early termination, the license agreement will automatically terminate upon the later of the expiration date of the longest-lived patent right included in the UC Patent Rights, which is currently expected to be in October 2028, or the 21<sup>st</sup> anniversary of the effective date of the agreement, which would be May 2023.

## **Other**

We also license intellectual property from certain other parties that we believe to be necessary or useful for the conduct of our business, including from the University of Michigan, and may enter into additional license agreements in the future.

## **Manufacturing**

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

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

Our current drug substance supply chain for brincidofovir involves various contractors that supply the raw materials for the drug substance process and a contract manufacturer for the drug substance. We have validated the drug

substance production process for brincidofovir at a scale of 100 kilograms, which is an amount that far exceeds our anticipated commercial requirements. We are currently transferring the drug substance manufacturing process to our selected contractor that will produce the commercial supply of drug substance. Changes in our requirements may require revalidation of the manufacturing process at a different scale and potentially at a different contractor depending on the necessary scale, infrastructure and technical capabilities. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative suppliers for certain portions of our supply chain, as appropriate.

Our drug products (tablets and suspension) are also manufactured under contract. We have validated manufacturing of brincidofovir tablets at a 165 kg commercial scale. In addition, stability data are available to

106

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## TABLE OF CONTENTS

support sufficient commercial shelf life. We have also developed a suspension formulation for brincidofovir and have manufactured that formulation at pilot scale. We are currently evaluating manufacturers to optimize tablet and suspension formulation production to meet forecasted commercial demand.

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

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

## **Government Regulation and Product Approval**

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

## **United States Drug Development Process**

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA) and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;

submission to the FDA of an IND, which must become effective before human clinical trials may begin; approval by an independent institutional review board (IRB) at each clinical site before each trial may be initiated; performance of adequate and well-controlled human clinical trials according to the FDA's guidance which follows the International Conference on Harmonization Good Clinical Practice (ICH GCP), to establish the safety and efficacy of the proposed drug for its intended use;

submission to the FDA of an NDA for a new drug;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice standards (cGMP), to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

107

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TABLE OF CONTENTS

potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

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

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

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

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

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

*Phase 3.* The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. In some cases, the FDA has approved a drug based on the results of a single adequate and well-controlled



## TABLE OF CONTENTS

study of excellent design and which provided highly reliable and statistically strong evidence of important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

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

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product.

Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### **The Animal Efficacy Rule**

The FDA amended its regulations, effective June 30, 2002, to include what is frequently referred to as the Animal Efficacy Rule whereby the FDA may approve for marketing certain new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear agents not otherwise naturally present in circumstances that would permit the typical clinical testing regime, based on evidence of safety in healthy subjects and evidence of effectiveness derived only from appropriate animal studies and any additional supporting data. In addition to seeking approval for the prevention of CMV infection after the conduct of clinical studies, we anticipate that we will seek approval for therapeutic use of brincidofovir in the treatment of smallpox using the animal efficacy rule.

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

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

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



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

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (PDUFA) the

FDA has 12 months after submission of an NDA in which to complete its initial review of a standard NDA and respond to the applicant, and eight months for a priority review NDA. The FDA does not always meet its PDUFA goal dates for review of standard and priority review

## TABLE OF CONTENTS

NDA. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission at any time during the review cycle.

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

Before approving an NDA, the FDA will inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with FDA regulations regarding conduct of clinical trials for the product's trials. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

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

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

### **Expedited Development and Review Programs**

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drug products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for

which it is being studied. Unique to a Fast Track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept those sections and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

## TABLE OF CONTENTS

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

### **Post-Approval Requirements**

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

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products as discussed under Manufacturing above. Manufacturers of our products are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are also required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws.

Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA. These restrictions may include suspension of a product until the FDA is assured that quality standards can be met, continuing oversight of manufacturing by the FDA under a consent decree, which frequently includes the imposition of costs and continuing inspections over a period of many years, as well as possible withdrawal of the product from the market. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented. Other types of changes to the approved

product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

## TABLE OF CONTENTS

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

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

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

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

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

To obtain regulatory approval of an investigational drug or biological product under European Union regulatory systems, we must submit a marketing authorization application to the European Medicines Agency. The application used to submit the NDA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with applicable regulatory requirements, ICH GCP and the ethical principles that have their origin in the Declaration of Helsinki.

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

### ***Pharmaceutical Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any drug candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drug products for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our drug candidates may not be considered medically necessary or cost-effective. A payor's

decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In 2003, the United States government enacted legislation providing a partial prescription drug benefit for Medicare recipients, which became effective at the beginning of 2006. Government payment for some of the costs of prescription drugs may increase demand for any products for which we receive marketing approval.

112

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## TABLE OF CONTENTS

However, to obtain payments under this program, we would be required to sell products to Medicare recipients through prescription drug plans operating pursuant to this legislation. These plans will likely negotiate discounted prices for our products. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the drug candidates that we are developing and could adversely affect our net revenue and results.

Different pricing and reimbursement schemes exist in other countries. In the European Community, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any drug candidate for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### **Third-Party Reimbursement and Pricing**

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on product availability,



or formulary access, and reimbursement from payors, such as government and private insurance plans. To allow access to brincidofovir, we will work with payors and reimbursement bodies to demonstrate the potential benefits of brincidofovir (including improved, cost-effective patient care and comparative effectiveness of brincidofovir), which we believe will differentiate brincidofovir from competitive therapies. We intend to price brincidofovir in the United States on a course of therapy basis consistent with other branded antiviral products.

## TABLE OF CONTENTS

In markets outside the United States, including the countries in the EU, pricing of pharmaceutical products may be subject to governmental control. Evaluation criteria used by many EU government agencies for the purposes of pricing and reimbursement typically focus on a product's degree of innovation and its ability to meet a clinical need unfulfilled by currently available therapies. We believe that, if approved, the clinical profile and patient friendly dosing of brincidofovir will enable us to negotiate a competitive price for brincidofovir in countries where pricing is set by a government agency, and to obtain reimbursement for brincidofovir from the responsible agencies in each market. As in the United States, we intend to price brincidofovir in the EU on a course of therapy basis consistent with other branded antiviral products.

### **Project BioShield**

The Project BioShield Act of 2004 and related 2006 federal legislation (Project BioShield) provides expedited procedures for bioterrorism related procurement and awarding of research grants, making it easier for the HHS to quickly commit funds to countermeasure projects. Project BioShield initially provided appropriations of \$5.6 billion to be expended over ten years into a special reserve fund for procurement of countermeasures for the Strategic National Stockpile (SNS). BARDA is one of the U.S. government agencies responsible for awarding procurement contracts for biomedical countermeasures under Project BioShield.

Project BioShield relaxes procedures under the Federal Acquisition Regulation (FAR) for procuring property or services used in performing, administering or supporting biomedical countermeasure research and development. In addition, if the Secretary of HHS deems that there is a pressing need, Project BioShield authorizes the Secretary to use an expedited award process, rather than the normal peer review process, for grants, contracts and cooperative agreements related to biomedical countermeasure research and development activity.

Under Project BioShield, the Secretary of HHS, with the concurrence of DHS and upon the approval of the President, can contract to purchase unapproved countermeasures for the SNS in specified circumstances. The U.S. Congress is notified of a recommendation for a stockpile purchase after Presidential approval. Project BioShield specifies that a company supplying the countermeasure to the SNS is paid on delivery of a substantial portion of the countermeasure. To be eligible for purchase under these provisions, the Secretary of HHS must determine that there are sufficient and satisfactory clinical results or research data, including data, if available, from preclinical and clinical trials, to support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years. Project BioShield also allows the Secretary of HHS to authorize the emergency use of medical products that have not yet been approved by the FDA. To exercise this authority, the Secretary of HHS must conclude that:

- the agent for which the countermeasure is designed can cause serious or life-threatening disease;
- the product may reasonably be believed to be effective in detecting, diagnosing, treating or preventing the disease;
- the known and potential benefits of the product outweigh its known and potential risks; and
- there is no adequate alternative to the product that is approved and available.

Although this provision permits the Secretary of HHS to circumvent the FDA approval process, we believe its use would be limited to rare circumstances.

### **Other U.S. Healthcare Laws and Compliance Requirements**

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local

governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992 (VHCA), each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General

## TABLE OF CONTENTS

Services Administration, additional laws and requirements apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes purport to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

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

## **U.S. Marketing Exclusivity**

### **Hatch-Waxman Exclusivity**

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

clinical trials necessary to demonstrate safety and effectiveness.

### **Pediatric Exclusivity**

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued Written Request for such a trial.

115

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## TABLE OF CONTENTS

### **Orphan Drug Designation and Exclusivity**

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological product intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 people in the United States, or more than 200,000 individuals in the United States, but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven year exclusive marketing period in the United States for that product, for that indication. During the seven year exclusivity period, the FDA may not approve any other applications to market the same drug or biological product for the same indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. A designated orphan drug may not receive orphan product exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the drug to meet the needs of patients with the rare disease or condition. Orphan drug status in the European Union has similar but not identical benefits as those in the United States.

### **Employees**

As of September 30, 2013, we had 52 full-time employees, consisting of research, process development, manufacturing, regulatory affairs, program management, finance, human resources, administration and business development personnel. We also regularly use independent contractors and other temporary employees across the organization to augment our regular staff. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel.

### **Legal Proceedings**

From time to time, we are involved in various legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results or financial condition.

### **Incorporation/Facilities**

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



TABLE OF CONTENTS**MANAGEMENT****Executive Officers, Key Employees and Directors**

The following table sets forth certain information regarding our executive officers, key employees and directors as of the date of this prospectus:

Name	Age	Position(s)
Executive Officers and Key Employees		
Kenneth I. Moch	59	President, Chief Executive Officer and Director
Timothy W. Trost	55	Senior Vice President, Chief Financial Officer and Corporate Secretary
M. Michelle Berrey, M.D., M.P.H.	47	Chief Medical Officer
Michael D. Rogers, Ph.D.	59	Chief Development Officer
Hervé Momméja-Marin, M.D.	42	Vice President, Clinical Research
Non-Employee Directors		
Ernest Mario, Ph.D. <sup>(1)</sup>	75	Chairman of the Board of Directors
Farah Champsi <sup>(1)(2)</sup>	52	Director
Martha J. Demski <sup>(2)</sup>	61	Director
Rodman L. Drake <sup>(3)</sup>	70	Director
Wende Hutton <sup>(3)</sup>	53	Director
James Niedel, M.D., Ph.D. <sup>(1)(3)</sup>	70	Director
Arthur M. Pappas <sup>(2)</sup>	66	Director
Timothy J. Wollaeger <sup>(3)</sup>	70	Director

(1) Member of the nominating and corporate governance committee.

(2) Member of the audit committee.

(3) Member of the compensation committee.

**Executive Officers and Key Employees**

*Kenneth I. Moch.* Mr. Moch joined us in June 2009 as Chief Operating Officer and has served as our President and Chief Executive officer since April 2010. Mr. Moch has served as one of our directors since May 2010. From January 2008 to June 2009, Mr. Moch served as President at Euclidean Life Science Advisors, a provider of strategic advisory services to life sciences companies, and concurrently served as President and Chief Executive Officer of BioMedical Enterprises, Inc., a medical device manufacturer, from January 2009 to June 2009. From October 2006 to January 2008, Mr. Moch served as Managing Director, Healthcare Investment Banking at ThinkEquity Partners, an investment banking firm. From 1998 to 2006, Mr. Moch served as President and Chief Executive Officer at Alteon Inc., a biotechnology company specializing in small molecule therapeutics for cardiovascular aging and diabetic complications, having joined in 1995 as SVP, Finance and Business Development and Chief Financial Officer. Mr. Moch served as Chairman of the Board of Directors of Alteon, Inc. from 2001 to 2006. Mr. Moch also served as a member of the board of directors of Emisphere Technologies, Inc., a drug development company, from December 2008 to November 2009. Mr. Moch earned an A.B. in biochemistry from Princeton University and an M.B.A. from the Stanford University Graduate School of Business. Our board of directors believes that Mr. Moch's more than 30 years of experience in managing and financing biomedical technologies and having played a key role in building



several life science companies qualifies him to serve on our board of directors.

*Timothy W. Trost.* Mr. Trost joined us in March 2011 as our Senior Vice President, Chief Financial Officer, and has also served as our Corporate Secretary since February 2012. Prior to serving as an employee, since July 2010 Mr. Trost served as a consultant in connection with our Series F preferred stock financing and our contract with BARDA.

From July 2002 to February 2010, Mr. Trost served as Vice President and Chief Financial Officer at Argos Therapeutics, Inc., a venture-backed immunotherapy company. From March 1997 to June 2002, Mr. Trost served as Senior Vice President and Chief Financial Officer at InteCardia, Inc., a venture-backed cardiac imaging company that was acquired by Syncor International Corporation in September 2001. From March 1994 to March 1997, Mr. Trost served as Executive Vice President and Chief

## TABLE OF CONTENTS

Financial Officer of Coastal Physician Group, Inc. (NYSE: DR), a contract provider of emergency room physicians, having joined as Vice President of Corporate Development. From October 1992 to March 1994, Mr. Trost served as Vice President of Finance at Morganite North America, Inc. From July 1980 through September 1992, Mr. Trost was with PricewaterhouseCoopers LLP, last serving as a Senior Manager in the Research Triangle practice. Mr. Trost holds a B.S. in accounting from the University of Illinois at Urbana-Champaign and is a Certified Public Accountant.

*M. Michelle Berrey, M.D., M.P.H.* Dr. Berrey has served as our Chief Medical Officer since November 2012. From January 2007 to January 2012, Dr. Berrey served as Chief Medical Officer at Pharmasset, Inc., a company that focused on the development of nucleotide analogs for the treatment of hepatitis C. From January 2004 to January 2007, Dr. Berrey served as Vice President, Viral Diseases, Clinical Pharmacology & Discovery Medicine at GlaxoSmithKline, where she was responsible for the early development of compounds for the treatment of HIV, hepatitis viruses and hepatic fibrosis. Dr. Berrey earned a B.A. in English from Emory University, an M.D. from the Medical College of Georgia and an M.P.H. from Emory University. Dr. Berrey completed her internship and residency in Internal Medicine at the University of North Carolina, Chapel Hill, and was a Senior Fellow in Infectious Diseases at the University of Washington, Seattle, where she conducted research in HIV transmission and acute HIV infection. Dr. Berrey is board certified in internal medicine and infectious diseases.

*Michael D. Rogers, Ph.D.* Dr. Rogers has served as our Chief Development Officer since March 2013. From 2007 to 2012, Dr. Rogers served as Chief Development Officer at Pharmasset, Inc., where his primary responsibility was to facilitate the design and implementation of development programs for HCV antiviral compounds. From 2004 to 2007, Dr. Rogers served as Vice President, Division of Viral Diseases at GlaxoSmithKline, where he was responsible for antiviral discovery activities directed toward HIV and hepatitis C virus indications. From 2001 to 2004, Dr. Rogers served as Vice President, Antiviral Discovery Medicine at GlaxoSmithKline. Dr. Rogers has over 29 years of industry experience and has participated in all phases of antiviral and anti-infective drug development, including discovery, preclinical development, and phase 1, 2, 3, and 3b/4 clinical development programs. Dr. Rogers received his doctorate in medical parasitology and a Master of Public Health degree in medical microbiology from the University of North Carolina, Chapel Hill. He completed a postdoctoral fellowship in clinical microbiology at St. Jude Children's Research Hospital in Memphis, Tennessee.

*Hervé Momméja-Marin, M.D.* Dr. Momméja-Marin has served as our Vice President, Clinical Research since July 2010. From September 2006 to June 2010, Dr. Momméja-Marin served as Senior Medical Director, Infectious Diseases, for i3 Research Limited, a contract research organization, where he was the lead therapeutic expert in infectious diseases. From June 2005 to September 2006, Dr. Momméja-Marin served in various roles, most recently as Director of Clinical Research at Gilead Sciences, Inc., where he was responsible for the global development of hepatitis B and hepatitis C programs. Dr. Momméja-Marin received a medical degree from Paris VII University, France. Dr. Momméja-Marin received his French certifications in internal medicine and multiple subspecialties.

## **Non-Employee Directors**

*Ernest Mario, Ph.D.* Dr. Mario has served as one of our directors and as Chairman of our board of directors since February 2013. Since August 2007, Dr. Mario has served as Chief Executive Officer of Capnia, Inc., a privately held pharmaceutical company. From April 2003 to August 2007, Dr. Mario served as Chief Executive Officer and Chairman of the board of directors of Reliant Pharmaceuticals, Inc., a privately held pharmaceutical company. From November 1997 to December 2001, Dr. Mario served as Chairman and Chief Executive Officer of ALZA Corporation, a research-based pharmaceutical company, and as Co-Chairman and Chief Executive Officer from August 1993 to November 1997. From January 1992 until March 1993, Dr. Mario served as Deputy Chairman of Glaxo Holdings plc., a pharmaceutical company, and as Chief Executive from May 1989 to March 1993. Dr. Mario

has served as a director of XenoPort Inc., a biopharmaceutical company, since June 2012, TONIX Pharmaceuticals Holdings Corp., a specialty pharmaceutical company, since October 2011, Celgene Corporation, a biopharmaceutical company, since August 2007, and Boston Scientific Corporation, a medical devices company, since October 2001. Dr.

Mario also served as a director of Vivus, Inc., a biopharmaceutical company, from April 2012 to July 2013, and Maxygen, Inc., a biotechnology company, from July 2001 to August 2013. Dr. Mario is the recipient of the

TABLE OF CONTENTS

2007 Remington Medal, the American Pharmacists Association's highest honor. Dr. Mario earned a B.S. in Pharmacy from Rutgers University, and a M.S. and a Ph.D. in Physical Sciences from the University of Rhode Island. Our board of directors believes that Dr. Mario's expertise and experience in the pharmaceutical industry qualifies him to serve on our board of directors.

*Farah Champsi.* Ms. Champsi has served as one of our directors since July 2010. Ms. Champsi joined Alta Partners, a venture capital firm, in 2000 and serves as Managing Director where she focuses her efforts on biopharmaceutical and medical technology companies. Ms. Champsi also serves on the board of directors of Portola Pharmaceuticals, Inc. and Trevena, Inc., both biopharmaceutical companies. Prior to Alta Partners, Ms. Champsi served as an investment banker at Robertson Stephens & Company from 1987 to 1999 and was elected a general partner in 1992 and head of the global life sciences investment banking group in 1995, where she focused on biotechnology and other life sciences companies. Ms. Champsi earned a B.A. in Economics from Smith College and an M.B.A. from the Stanford University Graduate School of Business. Our board of directors believes that Ms. Champsi's experience and expertise in investment banking in biopharmaceutical companies, as well as being responsible for building a successful life sciences investment banking franchises, qualifies her to serve on our board of directors.

*Martha J. Demski.* Ms. Demski has served as one of our directors since 2005. Since August 2011, Ms. Demski has served as Senior Vice President and Chief Financial Officer of Althea Technologies, Inc., a fully-integrated contract development and manufacturing organization. From July 2008 to December 2010, Ms. Demski served as the Interim Chief Operating Officer and Chief Financial Officer of the Sidney Kimmel Cancer Center (SKCC), a non-profit corporation engaged in biomedical research, which voluntarily filed for Chapter 11 bankruptcy in 2009. From April 2006 to May 2008, Ms. Demski served as Senior Vice President of U.S. Trust. From 2005 to July 2008, Ms. Demski served on the Board of Trustees at SKCC, as well as Chair of the Audit Committee and Chair of the Governance and Nominating Committee. From December 1988 to June 2004, Ms. Demski served as Vice President, Chief Financial Officer, Treasurer and Secretary of Vical Incorporated, a biopharmaceutical company. Ms. Demski earned a B.A. from Michigan State University and M.B.A. from The University of Chicago Booth School of Business. Our board of directors believes that Ms. Demski's more than 30 years' experience in the fields of finance and biotechnology as well her experience in conducting financing transactions qualifies her to serve on our board of directors.

*Rodman L. Drake.* Mr. Drake has served as one of our directors since August 2013. From January 2002 to December 2012, Mr. Drake was Managing Director of Baringo Capital, LLC, a private equity group he co-founded. From November 1997 to January 2002, Mr. Drake was president of Continuation Investments Group Inc., a private equity firm. Prior to that, Mr. Drake was co-chairman of the KMR Power Company and Chief Executive Officer and Managing Director of Cresap McCormick & Paget, a leading management consulting firm, and served as President of the Mandrake Group, a consulting firm specializing in strategy and organizational design. Mr. Drake is a member of the Board of Directors of Celgene Corporation, a global biopharmaceutical company, The Animal Medical Center of New York and is also the Chairman of the Brookfield Investment Management Funds and the Columbia Atlantic Funds. Mr. Drake served as a member of the Board of Directors of Jackson Hewitt Tax Service, Inc. from 2004 to 2011. From 2007 to 2009, Mr. Drake served as a member of the Board of Directors of Apex Silver Mines Limited, from 2005 to 2010, he served as a member of the Board of Directors of Student Loan Corporation, and from 2005 to 2010, he served as a member of the Board of Directors of Crystal River Capital, a NYSE listed company which was sold in 2010, where he also served as Chairman, President and Chief Executive Officer from 2009 through 2010. Mr. Drake received an M.B.A. from Harvard Business School and a B.A. from Yale University. Our board of directors believes that Mr. Drake's breadth of experience in corporate governance, finance, strategy and organizational design as a senior executive of investment and management consulting firms, as well as his extensive experience as a member of various boards of directors, qualifies him to serve on our board of directors.

*Wende Hutton.* Ms. Hutton has served as one of our directors since February 2012. Since 2004, Ms. Hutton has served as General Partner at Canaan Partners, a global venture capital firm. Ms. Hutton earned an A.B. in human biology from Stanford University and an M.B.A. from Harvard Business School, where she was a Baker Scholar. Our board of directors believes that Ms. Hutton's experience in finance and diverse

TABLE OF CONTENTS

expertise from across the entire medical spectrum, as well as facilitating the market entrance of more than 12 novel and lifesaving medical devices, new drugs and diagnostics, qualifies her to serve on our board of directors.

*James Niedel, M.D., Ph.D.* Dr. Niedel has served as one of our directors since February 2011. Since 2005, Dr. Niedel has served as Managing Director at New Leaf Venture Partners, a healthcare technology fund focused on biopharmaceutical investments. From 2002 to 2005, Dr. Niedel was a venture partner at Sprout Group, a healthcare and information technology fund. During 2001, Dr. Niedel was Chief Science and Technology Officer for GlaxoSmithKline, a global healthcare company. From 1995 to 2001, Dr. Niedel was a member of the board of directors of Glaxo Wellcome plc with responsibility for Global Research and Development, Information Technology and Product Strategy. From 1988 to 1995, Dr. Niedel was V.P. Research and S.V.P. R&D for the U.S. subsidiary of GlaxoSmithKline. Before joining the pharmaceutical industry, Dr. Niedel was employed by the Duke University Medical Center from 1973 to 1989 as Professor of Medicine and Chief of the Division of Clinical Pharmacology, in which time he had completed an Internal Medicine residency and a Hematology-Oncology fellowship. Dr. Niedel received M.D. and Ph.D. (Biochemistry) degrees from the University of Miami and is a fellow of the Royal College of Physicians (London). Our board of directors believes that Dr. Niedel's expertise and experience in the biopharmaceutical industry qualifies him to serve on our board of directors.

*Arthur M. Pappas.* Mr. Pappas has served as one of our directors since February 2011. Since 1994, Mr. Pappas has served as a managing partner of Pappas Ventures, a company investing in the life sciences, biotechnology, specialty pharmaceuticals, medical devices and related ventures. From 1989 to 1994, Mr. Pappas served as the Chief Executive Officer of Glaxo Far East (Pte) Ltd., Glaxo Latin America, Inc. and various other subsidiaries of Glaxo Holdings, plc, a global pharmaceutical company. From 1982 to 1987, Mr. Pappas served as Chief Executive Officer of Merrell Dow Brazil and Merrell Dow Pharmaceuticals Pacific, Ltd., which were subsidiaries of Merrell Dow Pharmaceuticals, Inc., a pharmaceutical company. Mr. Pappas has previously served on numerous boards of directors, including those of Glaxo Holdings, plc, and Quintiles Transnational Corp., a global provider of biopharmaceutical outsourcing services. Mr. Pappas is a decorated Vietnam veteran, having served as an officer in the 101st Airborne Division. Mr. Pappas earned a B.S. in Biology from Ohio State University and an M.B.A. in Finance from Xavier University. Our board of directors believes that Mr. Pappas' more than 30 years of operating experience as a pharmaceutical and biotechnology industry executive and venture capital investor in life science companies, as well as being responsible for the development, licensing, and launch of a number of key global products, qualifies him to serve on our board of directors.

*Timothy J. Wollaeger.* Mr. Wollaeger has served as one of our directors since 2002. Since 2002, Mr. Wollaeger has served as a Managing Director of Sanderling Ventures, an investment firm dedicated to building new biomedical companies. From 1993 to 2006, Mr. Wollaeger was the General Partner of Kingsbury Capital Partners, L.P., a healthcare-oriented venture capital firm. From 1990 to 1993, Mr. Wollaeger was Senior Vice President of Columbia Hospital Corporation, a hospital management company that merged into Hospital Corporation of America in 1993. From 1987 to 1993, Mr. Wollaeger was a General Partner and co-founder of Biovest Partners, L.P., an investment fund. From 1983 to 1986, Mr. Wollaeger served as Senior Vice President and Chief Financial Officer of Hybritech, Inc., a biotechnology company that was acquired by Eli Lilly & Co. in 1986. From 1972 to 1980, Mr. Wollaeger was employed by Baxter Healthcare Corporation, a global healthcare company, where he most recently served as Vice President and General Manager of Baxter's operations in Mexico. Mr. Wollaeger is Chairman of the Board of Sotera Wireless, Inc., a medical device company, and a director of Asteres, Inc., a creator of business and technology solutions, and CalciMedica, Inc., a drug development company, and is Chairman of Naviscan, Inc., a medical imaging company. Investment funds affiliated with Mr. Wollaeger were early stage investors in Pyxis Corporation, a technology developer for hospitals that was acquired by Cardinal Health, Inc. in 1996, Biosite, Inc., a medical diagnostic company that was acquired by Inverness Medical Innovations, Inc. in 2007, Amylin Pharmaceuticals, Inc., a biopharmaceutical company that was acquired by Bristol-Myers Squibb Company in 2012, and Vical Incorporated.

Mr. Wollaeger earned a B.A. in Economics from Yale University and earned an M.B.A. from the Stanford University Graduate School of Business. Our board of directors believes that

120

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## TABLE OF CONTENTS

Mr. Wollaeger's nearly 40 years of experience in the biotechnology and medical products fields in both corporate management and venture capital qualifies him to serve on our board of directors.

### **Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors is to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that eight of our nine directors, Ms. Champsi, Ms. Demski, Mr. Drake, Ms. Hutton, Dr. Mario, Dr. Niedel, Mr. Pappas and Mr. Wollaeger, are independent directors, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

In accordance with the terms of our amended and restated certificate of incorporation and bylaws, our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms.

Our board of directors is comprised of the following classes:

Class I, which consists of Ms. Champsi, Ms. Hutton and Mr. Pappas, whose terms will expire at our annual meeting of stockholders to be held in 2014;

Class II, which consists of Ms. Demski, Mr. Drake and Dr. Niedel, and whose terms will expire at our annual meeting of stockholders to be held in 2015; and

Class III, which consists of Dr. Mario, Mr. Moch and Mr. Wollaeger, and whose terms will expire at our annual meeting of stockholders to be held in 2016.

At each annual meeting of stockholders, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members. The authorized number of directors may be changed only by resolution by a majority of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66 2/3% of our voting stock.

### **Board Leadership Structure**

Our board of directors is currently chaired by Dr. Mario. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Moch serves as our President and Chief Executive Officer while Dr. Mario serves as our Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.



## Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in

121

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## TABLE OF CONTENTS

preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

## **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

### **Audit Committee**

Our audit committee consists of Ms. Demski, Ms. Champai and Mr. Pappas. Our board of directors has determined that each of the members of our audit committee satisfies the Nasdaq Global Market and SEC independence requirements.

Ms. Demski serves as the chair of our audit committee. Our board of directors has determined that Ms. Demski qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Ms. Demski's formal education and previous and current experience in financial roles. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law; prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions in accordance with our related person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;
- reviewing on a periodic basis our investment policy; and

reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

122

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TABLE OF CONTENTS

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

## **Compensation Committee**

Our compensation committee consists of Mr. Drake, Dr. Niedel, Ms. Hutton and Mr. Wollaeger. Mr. Drake serves as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act), is an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code), and satisfies the Nasdaq Global Market independence requirements. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and making recommendations to the full board of directors regarding performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
  - reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
  - establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act, and to the extent applicable, determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act, as well as applicable Nasdaq rules and regulations;
- reviewing any conflicts of interest raised by the work of any compensation consultant that had any role in determining or recommending the amount or form of executive or director compensation and how such conflict is being addressed for disclosure in our proxy statements to be filed with the SEC;
  - administering our equity incentive plans;
  - establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
  - reviewing the adequacy of its charter on a periodic basis;
- reviewing with management and approving our disclosures under the caption Compensation Discussion and Analysis in our periodic reports or proxy statements to be filed with the SEC;



## TABLE OF CONTENTS

preparing the report that the SEC requires in our annual proxy statement; and reviewing and assessing on an annual basis the performance of the compensation committee.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### **Nominating and Corporate Governance Committee**

Our nominating and corporate governance committee consists of Ms. Champsi, Dr. Mario and Dr. Nidel. Our board of directors has determined that each of the members of this committee satisfies the Nasdaq Global Market independence requirements. Ms. Champsi serves as the chair of our nominating and corporate governance committee.

The functions of this committee include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

determining the minimum qualifications for service on our board of directors;

evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;

evaluating, nominating and recommending individuals for membership on our board of directors;

evaluating nominations by stockholders of candidates for election to our board of directors;

considering and assessing the independence of members of our board of directors;

developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;

considering questions of possible conflicts of interest of directors as such questions arise;

reviewing the adequacy of its charter on an annual basis; and

annually evaluating the performance of the nominating and corporate governance committee.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act of 2002, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### **Compensation Committee Interlocks and Insider Participation**

Our compensation committee consists of Mr. Drake, Dr. Nidel, Ms. Hutton and Mr. Wollaeger. None of these individuals has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

### **Limitation on Liability and Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation and bylaws limit our directors and officers liability to the fullest extent permitted under Delaware corporate law. Delaware corporate law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

for any transaction from which the director derives an improper personal benefit;  
for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;  
under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of  
shares); or  
124

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TABLE OF CONTENTS

for any breach of a director's duty of loyalty to the corporation or its stockholders.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors or officers, then the liability of our directors or officers shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Delaware law and our amended and restated bylaws provide that we will, in certain situations, indemnify any person made or threatened to be made a party to a proceeding by reason of that person's former or present official capacity with us against judgments, penalties, fines, settlements and reasonable expenses. Any person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our amended and restated certificate of incorporation and amended bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.



TABLE OF CONTENTS**EXECUTIVE AND DIRECTOR COMPENSATION**

Our named executive officers for the year ended December 31, 2012, which consist of our principal executive officer, our two other most highly compensated executive officers and two former executive officers who would have been included among our highest compensated executive officers but for the fact that they were not serving as officers as of December 31, 2012, are:

Kenneth I. Moch, our President and Chief Executive Officer;  
 Timothy W. Trost, our Senior Vice President, Chief Financial Officer and Corporate Secretary;  
 M. Michelle Berrey, M.D., M.P.H., our current Chief Medical Officer;  
 Dorothy Margolskee, M.D., our former interim Chief Medical Officer; and  
 J. Michael Grindel, Ph.D., our former Head of Development and Program Management.

**Summary Compensation Table**

Name and principal position	Year	Salary (\$)	Option awards (\$) <sup>(1)</sup>	Non-equity incentive plan compensation (\$) <sup>(2)</sup>	All other compensation (\$) <sup>(3)</sup>	Total (\$)
Kenneth I. Moch <i>President and Chief Executive Officer</i>	2012	427,450	283,091 <sup>(4)</sup>	85,490	1,318	797,349
Timothy W. Trost <i>Senior Vice President, Chief Financial Officer and Corporate Secretary</i>	2012	275,000		34,375	1,318	310,693
M. Michelle Berrey, M.D., M.P.H. <i>Chief Medical Officer</i>	2012	47,731 <sup>(5)</sup>	499,129		110	546,970
Dorothy J. Margolskee, M.D. <i>Former Interim Chief Medical Officer</i>	2012	816,848 <sup>(6)</sup>	37,176			854,024
J. Michael Grindel, Ph.D. <i>Former Head of Development and Program Management</i>	2012	384,375 <sup>(7)</sup>				384,375

- In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2012 computed in accordance with Financial Accounting Standard Board Accounting Standards Codification Topic 718 for stock-based compensation transactions (ASC 718). Assumptions used in the calculation
- (1) of these amounts are included in Note 8 to our financial statements appearing elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.
- (2) Amount represents annual performance-based bonuses earned for 2012. 50% of the amount of each performance-based bonus shown above was paid in cash in March 2013 and 50% of the amount shown above was

paid in the form of restricted stock units. Drs. Margolskee, Grindel and Berrey are not eligible to receive a performance-based bonus for 2012. For more information, see below under Annual Performance-Based Bonus Opportunity.

(3) Amounts shown represent term life insurance, long-term disability insurance, short-term disability insurance and accidental death and dismemberment insurance paid by us on behalf of the named executive officers. All of these benefits are provided to the named executive officers on the same terms as provided to all of our regular full-time employees in the United States. For more information regarding these benefits, see below under Perquisites, Health, Welfare and Retirement Benefits.

(4) On June 13, 2012, an outstanding and unvested option held by Mr. Moch to purchase 83,009 shares that was granted on April 14, 2010 and subject to vesting upon the occurrence of certain performance goals was cancelled.

(5) Dr. Berrey became our Chief Medical Officer on November 12, 2012 at an annual salary of \$340,000. The amount above reflects the pro-rated portion earned from Dr. Berrey's hire date through December 31, 2012.

(6) Dr. Margolskee served as our interim Chief Medical Officer from March 30, 2012 until a successor was hired on November 12, 2012. The amount above represents the total amount paid by us to Synergee LLC for Dr. Margolskee's consulting services to us during 2012, as described further below under Agreements with our Named Executive Officers.

(7) Dr. Grindel served as our Head of Development and Program Management until December 31, 2012, however his service as an executive officer terminated on November 30, 2012. The amount above represents the total amount paid by us to EPD Pharma Solutions, LLC for Dr. Grindel's consulting services to us during 2012, as described further below under Agreements with our Named Executive Officers.

126

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TABLE OF CONTENTS**Annual Base Salary**

The compensation of our named executive officers is generally determined and approved by our board of directors, based on the recommendation of the compensation committee of our board of directors (the Committee). Our board of directors approved the following 2012 base salaries for our named executive officers, which became effective on January 1, 2012, with the exception of Dr. Berrey. Our board of directors approved the following 2012 base salary for Dr. Berrey in connection with her commencement of employment, which became effective on November 12, 2012.

Name	2012 Base Salary (\$)
Kenneth I. Moch	427,450
Timothy W. Trost	275,000
M. Michelle Berrey	340,000

Synergiee LLC and EPD Pharma Solutions, LLC are paid consulting fees pursuant to the terms of consulting agreements with the Company for Drs. Margolskees and Grindel's services, respectively, described below under Agreements with our Named Executive Officers. The company paid an hourly rate of \$400 for Dr. Margolskees services as interim Chief Medical Officer and a weekly rate ranging from \$8,000 to \$10,000 for Dr. Grindel's services relating to BARDA and non-BARDA activities, which was reduced to an hourly rate of \$250 in December 2012 in connection with Dr. Grindel's cessation of services relating to BARDA.

**Annual Performance-Based Bonus Opportunity**

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve defined annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is based on the individual's target bonus, as a percentage of base salary, or target bonus percentage, and the extent to which we achieve the corporate goals that our board of directors establishes each year.

The actual performance-based bonus paid, if any, is calculated by multiplying the executive's annual base salary, target bonus percentage, and the percentage attainment of the corporate goals established by the board of directors for such year with respect to the executive. Our board of directors will generally consider each named executive officer's individual contributions towards reaching our annual corporate goals but does not typically establish specific individual goals for our named executive officers. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and individual performance.

At the end of the year, the board of directors reviews our performance against predetermined goal weightings assigned to each corporate goal and approves the extent to which we achieved each of our corporate goals. The board of directors may award a bonus in an amount above or below the amount resulting from the calculation described above, based on other factors that the board determines, in its sole discretion following recommendation by the Committee, are material to our corporate performance and provide appropriate incentives to our executives, for example based on events or circumstances that arise after the original corporate goals are set. The board of directors may also determine that the bonus will be paid in the form of cash, equity awards such as options or restricted stock unit awards, or a combination of cash and equity awards.



TABLE OF CONTENTS

The board of directors sets the target bonus for each of the named executive officers at the beginning of each year for which the bonus will apply, or in connection with the hiring of a new named executive officer, as applicable. Each of the following named executive officers' 2012 target bonus percentage is set forth below:

Name	Target bonus
Kenneth I. Moch	40 %
Timothy W. Trost	25 %

Drs. Margolskee and Grindel were not eligible to receive performance-based bonuses for 2012. Because Dr. Berrey commenced employment with us in November 2012, she did not earn a performance-based bonus in 2012. However, her target bonus percentage beginning in 2013 is 25%. The corporate goals and relative overall weighting towards corporate goal achievement established by the board of directors, upon recommendation by the Committee, for 2012 were for progress with respect to: brincidofovir business development (50%); CMX157 business development (20%); FDA interactions regarding brincidofovir development (10%); the conduct of our Phase 2 AdV study (10%); and our contract with BARDA (10%).

No specific individual goals were established for any of our named executive officers for 2012. Rather, the board of directors assigned a specific weighting to each corporate goal on which the executive's performance bonus was based. Messrs. Moch's and Trost's performance bonuses were dependent on all of the corporate goals based on the overall weightings listed above. For 2012, there was no minimum percentage of corporate goals that must be achieved in order to earn a bonus.

In early 2013, the board of directors considered each corporate goal in detail and determined that we had achieved 50% of the 2012 corporate goals. Specifically, the Committee determined that we, as a company, had not achieved our goal with respect to brincidofovir business development, which constituted 50% of the overall corporate goals. The remaining award of 50% was based, in part, upon progress with respect to: CMX157 business development, FDA interactions regarding brincidofovir, conduct of our brincidofovir Study 202 (a Phase 2 clinical trial in patients with AdV), and our contract with BARDA. Accordingly, we paid Messrs. Moch and Trost a bonus calculated based on 50% of overall corporate goal achievement. Upon recommendation from the Committee, the board of directors determined that 50% of the performance bonus would be awarded to the executives in the form of a cash payment and 50% would be awarded in the form of restricted stock units under our 2012 plan, the terms of which are further described below under Equity Benefit Plans. We paid the cash portion of the performance bonuses to our executives in March 2013. In February 2013, we granted to Messrs. Moch and Trost a restricted stock unit award covering 8,479 and 3,409 shares of our common stock, respectively, which represented 50% of the performance bonus award to which they were entitled. The restricted stock unit awards vest according to the standard restricted stock unit vesting schedule described in the section below entitled Equity-Based Incentive Awards.

## Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests with those of our employees and consultants, including our named executive officers. The board of directors or the Committee is responsible for approving equity grants. As of December 31, 2012, the only form of equity award to our named executive officers has been stock option grants. As discussed above, in January 2013, our board of directors determined to pay 50% of the performance bonus for 2012 in the form of restricted stock units. Restricted stock units represent the right to be issued our common stock upon the occurrence of future dates or events. Vesting of the stock option and restricted stock units is tied to continuous service with us and serves as an additional retention measure. Although we may grant equity awards to our employees and consultants from time to time, we do not have a current practice of making annual equity grants to our

executives. In addition, our executives generally are awarded an initial grant upon commencement of employment. Additional grants may occur periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

Prior to our IPO in April 2013, we granted all equity awards pursuant to the 2012 plan and the 2002 plan, the terms of which are described below under Equity Benefit Plans. Following our IPO, we have granted all equity awards pursuant to the 2013 plan, the terms of which are described below under Equity

128

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## TABLE OF CONTENTS

**Benefit Plans.** All options are granted with a per share exercise price equal to no less than the fair market value of a share of our common stock on the date of grant of each award.

Generally our stock option awards vest over a four-year period and may be granted with an early exercise feature allowing the holder to exercise and receive unvested shares of our stock, so that the holder may have a greater opportunity for gains on the shares to be taxed at long-term capital gains rates rather than ordinary income rates. Our restricted stock units (including the units that were granted to Messrs. Moch and Trost in February 2013 in respect of their 2012 performance bonuses) vested upon the effective date of our registration statement filed in connection with our IPO.

Effective June 13, 2012, the board of directors granted Mr. Moch an option to purchase 117,386 shares of common stock with an exercise price of \$2.38 per share in connection with the cancellation of Mr. Moch's performance-based stock option granted in 2010 that never vested. On March 30, 2012, the board of directors granted an option to purchase 14,084 shares of common stock to Dr. Margolskee in connection with her appointment as interim Chief Medical Officer, with an exercise price of \$2.35 per share. On November 18, 2012, the board of directors granted an option to purchase 176,056 shares of common stock to Dr. Berrey in connection with her commencement of employment with us on November 12, 2012, with an exercise price of \$4.26 per share. We did not grant Mr. Trost or Dr. Grindel stock options or other equity awards in 2012. As discussed in the section above entitled "Annual Performance-Based Bonus Opportunity", we granted restricted stock units to Messrs. Moch and Trost in February 2013 in an amount equivalent to 50% of the performance bonuses earned for 2012.

The vesting terms of the 2012 option grants are described in the footnotes to the "Outstanding Equity Awards at Fiscal Year-End" table below.

## **Agreements with our Named Executive Officers**

Below are written descriptions of our employment or consulting agreements or offer letters with our named executive officers.

*Agreement with Mr. Moch.* We entered into an employment agreement with Mr. Moch in October 2009 setting forth the terms of his employment, that was subsequently amended in April 2010 in connection with Mr. Moch's assuming the office of President and Chief Executive Officer and in December 2012 to make certain clarifications for purposes of Section 409A of the Code. Pursuant to the agreement, Mr. Moch is entitled to an initial annual base salary of \$395,000, subject to increase by the board of directors, and is eligible to receive an annual cash performance bonus based on a target amount that would be between the 50<sup>th</sup> and 75<sup>th</sup> percentile for total cash compensation for chief executive officers of similarly situated companies. The performance bonus is subject to the Company's good faith assessment of Mr. Moch's achievement of individual goals and the achievement of the Company's goals. Pursuant to the agreement, Mr. Moch was granted several options to purchase shares of our common stock, including a 2010 option award covering 83,009 shares of stock that vested upon achievement of certain corporate performance goals that never occurred and was cancelled in June 2012 in connection with Mr. Moch's 2012 stock option grant described above under "Equity-Based Incentive Awards". The corporate performance goals that never occurred and resulted in the cancellation of the 2010 option award related to the execution of a qualified definitive agreement for a collaboration transaction that resulted in gross cash proceeds of at least \$30,000,000 and our award of a grant from BARDA for the procurement of smallpox antiviral drug that resulted in gross cash proceeds of at least \$100,000,000. Mr. Moch was eligible for a one-time cash bonus of \$250,000 under his employment agreement in the event we executed a qualified definitive agreement for a collaboration transaction on or before September 30, 2010 that was never awarded. Mr. Moch is additionally entitled to certain severance and change of control benefits pursuant to his agreement, the terms

of which are described below under Termination-Based Compensation. Mr. Moch's agreement had an initial term of one year and is subject to automatic renewal of successive one-year periods unless either Mr. Moch or the Company give 30 days' notice of their intent not to renew.

*Agreement with Mr. Trost.* In March 2011, we entered into an offer letter agreement with Mr. Trost setting forth the terms of his employment. Pursuant to the agreement, Mr. Trost is entitled to an initial annual base salary of \$250,000, subject to adjustment by the board of directors, and was granted an option to purchase 169,014 shares of our common stock.



## TABLE OF CONTENTS

*Agreement with Dr. Berrey.* In November 2012, we entered into an offer letter agreement with Dr. Berrey setting forth the terms of her employment. Pursuant to the agreement, Dr. Berrey is entitled to an initial annual base annual salary of \$340,000, subject to adjustment by the board of directors, and was granted an option to purchase 176,056 shares of our common stock.

*Agreement with Dr. Margolskee.* In February 2012, we entered into a consulting agreement with Synergee LLC relating to certain medical and strategic support services performed by Dr. Margolskee in connection with development of brincidofovir. In March of 2012, the agreement was amended to provide that Dr. Margolskee would serve as interim Chief Medical Officer (CMO), until such time as a replacement CMO was identified and hired. Under the terms of the agreement, Synergee LLC is paid an hourly rate for Dr. Margolskee's services, which was \$400 per hour for services as CMO, as well as reimbursement of out-of-pocket expenses. In connection with serving as interim CMO, Dr. Margolskee was granted an option to purchase 14,084 shares of our common stock. Dr. Margolskee is not eligible for a performance-based bonus in connection with her services to the Company. The agreement has a term of one year and may be terminated by either party upon 30 days prior written notice. During the term and for a period of two years following termination, Dr. Margolskee is prohibited from recruiting Chimerix employees. Dr. Margolskee ceased serving as our interim CMO on November 12, 2012.

*Agreement with Dr. Grindel.* In August 2011, we entered into a consulting agreement with EPD Pharma Solutions, LLC relating to certain consulting services performed by Dr. Grindel as the Company's Head of Development and Program Management. EPD Pharma Solutions, LLC was paid a weekly rate for Dr. Grindel's services of \$6,000 for work performed under the BARDA contract and \$2,000 for work performed on non-BARDA related activities, in addition to reimbursement of Dr. Grindel's out-of-pocket expenses related to these services. Dr. Grindel is not eligible for a performance-based bonus in connection with his services to the Company. The agreement had an initial term of six months and was amended in February 2012 to extend the term until December 31, 2012. On December 1, 2012, the agreement was amended to reflect Dr. Grindel's discontinuation of his duties with respect to the Company's performance under the BARDA contract. During the term and for a period of two years following termination, Dr. Grindel is prohibited from recruiting Chimerix employees. On January 1, 2013, we entered into a new consulting agreement with EPD Pharma Solutions, LLC for consulting services performed by Dr. Grindel relating to chemistry, manufacturing and control development, non-clinical development and program management for which we pay \$300 per hour, as well as reimbursement of out-of-pocket expenses. The agreement has a term of one year and may be terminated by either party upon 30 days prior written notice.

## **Potential Payments Upon Termination or Change of Control**

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his or her term of service, including salary and unused vacation pay.

Pursuant to his employment agreement, Mr. Moch is entitled to certain severance and change of control payments and benefits. In the event of termination due to disability, Mr. Moch will continue to receive payments at the rate of his then current salary for six months, contingent upon delivery to us of a satisfactory release of claims. In the event that Mr. Moch is terminated without cause, if we do not renew his employment agreement each year, or upon Mr. Moch's resignation for good reason, which is triggered by certain reductions in Mr. Moch's compensation, title, authority or duties or a requirement to relocate, Mr. Moch is eligible to receive payments at the rate of his then current salary for six months and reimbursement of COBRA health and dental premiums for up to six months contingent upon delivery to us of a satisfactory release of claims.

In the event of a change of control, Mr. Moch's employment agreement provides that his outstanding equity awards will accelerate vesting with respect to the number of shares that would have vested during the 12 months immediately following the change of control. In the event that Mr. Moch's employment is terminated without cause or Mr. Moch resigns for good reason following a change of control, Mr. Moch's outstanding equity awards will immediately vest in full.

Each of our named executive officers holds stock options under our equity incentive plans that were granted subject to our form of stock option agreements. A description of the termination and change of control provisions in such equity incentive plans and form of stock option agreements is provided below under

130

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TABLE OF CONTENTS

Equity Benefit Plans. In addition, the restricted stock units granted to Messrs. Moch and Trost in February 2013 that represented 50% of their 2012 performance bonuses vested in full upon the effective date of our registration statement filed in connection with our IPO.

Pursuant to Dr. Grindel's stock option agreement, in the event that Dr. Grindel's continuous service terminates for reasons other than cause or upon his death or disability, Dr. Grindel will be entitled to exercise the vested portion of the option granted to him in 2011 for 14,084 shares for a period of 12 months following the termination of his continuous service.

In February 2013, our board of directors approved an Officer Change in Control Severance Benefit Plan (the severance plan). Under the severance plan, our officers, including Messrs. Moch, Trost and Dr. Berrey, are entitled to receive severance benefits upon a covered termination within the thirty days prior to or thirteen months following a change of control transaction (which generally has the same meaning as set forth in our 2013 plan). A covered termination means the officer's termination without cause or resignation with good reason (including resignation due to any material reduction in duties, authorities or responsibilities, base salary or relocation by more than fifty miles). Upon a covered termination and contingent upon delivery to us of an effective release of claims, Messrs. Moch, Trost and Dr. Berrey are entitled to (i) a payment equal to six months (or twelve months, for Mr. Moch) of base salary; (ii) accelerated vesting of all outstanding stock options and other stock awards; and (iii) payment of COBRA benefits for six months (or twelve months, for Mr. Moch). Payments triggered under the severance benefit plan will not affect the benefits an officer is entitled to under an individually negotiated employment contract or agreement; however, payments under the severance plan will generally be reduced by severance benefits also payable under any individually negotiated employment contract or agreement.

## Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding outstanding equity awards granted to our named executive officers that remain outstanding as of December 31, 2012.

	Grant Date	Option Awards <sup>(1)</sup>			
		Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$) <sup>(2)</sup>	Option expiration date
Kenneth I. Moch	6/20/2009	197,177	28,175 <sup>(3)</sup>	1.57	6/19/2019
	8/12/2009	29,144	17,581 <sup>(4)</sup>	3.16	8/11/2019
	8/12/2009	94,119 <sup>(5)(6)(13)</sup>		3.16	8/11/2019
	4/14/2010	117,386 <sup>(5)(7)(13)</sup>		3.16	4/13/2020
	4/7/2011	211,267 <sup>(5)(8)(13)</sup>		2.35	4/6/2021
	6/13/2012	117,386 <sup>(5)(9)(13)</sup>		2.38	6/12/2022
Timothy W. Trost	4/7/2011	169,014 <sup>(5)(8)</sup>		2.35	4/6/2021
M. Michelle Berrey	11/18/2012		176,056 <sup>(10)</sup>	4.26	11/17/2022
Dorothy J. Margolskee	3/30/2012	14,084 <sup>(11)</sup>		2.35	3/29/2022
J. Michael Grindel	11/17/2011	14,084 <sup>(12)</sup>		2.35	11/16/2021

- All of the option awards granted in 2012 were granted under the 2012 plan and all of the options granted prior to 2012 were granted under the 2002 plan, the terms of which plans are described below under Equity Benefit Plans.
- (1) Except as otherwise indicated, each option award becomes exercisable as it becomes vested and all vesting is subject to the executive's continuous service with the Company through the vesting dates.
  - (2) All of the option awards were granted with a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, as determined in good faith by our board of directors with the assistance of a third-party valuation expert.
  - (3) 64,020 shares were vested on June 8, 2009 and 1,707 shares became vested on August 8, 2010. Thereafter the shares vest in equal monthly installments on the eighth day of each month over the following three years.
  - (4) 21,522 shares were vested on June 8, 2010; 316 shares vest on the eighth day of each month commencing on January 8, 2011 and ending on and including December 8, 2012; and 2,939 shares vest on the eighth day of each month commencing on January 8, 2013 and ending on and including June 8, 2013.
  - (5) The shares underlying the option award are 100% exercisable on the date of grant and prior to vesting.

131

---

## TABLE OF CONTENTS

- 13,689 shares vested on June 8, 2010; 2,933 shares vest and become exercisable on the eighth day of each month commencing on June 8, 2010 and ending on and including December 8, 2010; 2,618 shares vest and become exercisable on the eighth day of each month commencing on January 8, 2011 and ending on and including December 8, 2012.
- (6) The shares vest in forty-eight equal monthly installments on the first day of the month beginning on May 1, 2010.
- (8) 25% of the shares vest on July 26, 2011 and 1/36<sup>th</sup> of the shares vest monthly thereafter.
- (9) 1/48<sup>th</sup> of the shares vest monthly after the grant date.
- (10) 25% of the shares vest on November 12, 2013 and 1/36<sup>th</sup> of the shares vest monthly thereafter.
- 2,816 shares vested immediately on the date of grant. The remainder of the shares vested at a rate of 1,408 per month during the time Dr. Margolskee served as our interim CMO, and at the rate of 704 per month during the time Dr. Margolskee provided continuous services to us but not as our interim CMO. The shares were 100% vested as of December 31, 2012.
- (11) 14,084 shares vested on December 31, 2012. In the event that Dr. Grindel's continuous service terminates for reasons other than cause or upon his death or disability, Dr. Grindel will be entitled to exercise the vested portion of the option for a period of 12 months following the termination of his continuous service. Pursuant to an option transfer agreement dated May, 2012 and amended in November 2012, Mr. Moch transferred vested shares to the 2012 Kenneth Ian Moch Irrevocable GST Trust F/B/O Ellen Gray Stolzman and Descendants with respect to the following options as of December 31, 2012: 94,119 shares subject to the option covering 94,119 shares granted on August 12, 2009; 78,257 shares subject to the option covering 117,386 shares granted on April 14, 2010; 88,028 shares subject to the option covering 211,267 shares granted on April 7, 2011; and 14,673 shares subject to the option covering 117,386 shares granted on June 13, 2012.
- (13)

## **Option Exercises and Stock Vested**

Our named executive officers did not exercise any stock option awards during the fiscal year ended December 31, 2012.

## **Option Repricings**

We did not engage in any repricings or other modifications or cancellations to any of our named executive officers outstanding equity awards during the year ended December 31, 2012, except that in June 2012, we cancelled Mr. Moch's performance-based stock option granted in 2010, as described above under Agreements with our Named Executive Officers .

## **Perquisites, Health, Welfare and Retirement Benefits**

Of our named executive officers, only Messrs. Moch and Trost and Dr. Berrey are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life and accidental death and dismemberment insurance plans, in each case on the same basis as all of our other employees. We provide a 401(k) plan to our employees, including our employee named executive officers, as discussed in the section below entitled 401(k) Plan.

We do not provide perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for term life insurance and long-term disability for all of our employees, including our employee named executive officers. None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

## 401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The plan provides that each participant may contribute up to the lesser of 100% of his or her compensation or the statutory limit, which is \$17,000 for calendar year 2012. Participants that are 50 years or older can also make catch-up contributions, which in calendar year 2012 may be up to an additional \$5,500 above the statutory limit. We do not make contributions into the 401(k) plan on behalf of participants. Participant contributions are held and invested, pursuant to the participant's instructions, by the plan's trustee.

## Nonqualified Deferred Compensation

None of our named executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our board of directors may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

TABLE OF CONTENTS

## Equity Benefit Plans

### *2013 Equity Incentive Plan*

Our board of directors adopted the 2013 plan in February 2013 and our stockholders approved the 2013 plan in March 2013. The 2013 plan became effective in connection with our IPO in April 2013. Following the effectiveness of the 2013 plan, no further grants were made under the 2012 plan.

*Stock Awards.* The 2013 plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2013 plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve.* Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2013 plan is the sum of (i) 1,408,450 shares, plus (ii) 244,717 shares, which was the number of shares reserved for issuance under our 2012 plan at the time our 2013 plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to our 2012 plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of our common stock reserved for issuance under our 2013 plan will automatically increase on January 1 of each year, beginning on January 1, 2014 and continuing through and including January 1, 2023, by 2.5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under our 2013 plan is 2,816,901 shares.

No person may be granted stock awards covering more than 704,225 shares of our common stock under our 2013 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 704,225 shares or a performance cash award having a maximum value in excess of \$5,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

If a stock award granted under the 2013 plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2013 plan. In addition, the following types of shares under the 2013 plan may become available for the grant of new stock awards under the 2013 plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2013 plan may be previously unissued shares or reacquired shares bought by us on the open market. As of the date hereof, no awards have been granted and no shares of our common stock have been issued under the 2013 plan.

*Administration.* Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2013 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares

of common stock to be subject to such stock awards. Subject to the terms of the 2013 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

133

---



TABLE OF CONTENTS

The plan administrator has the authority to modify outstanding awards under our 2013 plan. Subject to the terms of our 2013 plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

*Stock Options.* Incentive and nonstatutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2013 plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2013 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2013 plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

*Tax Limitations On Incentive Stock Options.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options (ISOs) that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as nonstatutory stock options (NSOs). No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

*Restricted Stock Awards.* Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except

as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash,

TABLE OF CONTENTS

delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Stock Appreciation Rights.* Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2013 plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2013 plan, up to a maximum of ten years. Unless the terms of a participant's stock appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

*Performance Awards.* The 2013 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) total stockholder return; (5) return on equity or average stockholder's equity; (6) return on assets, investment, or capital employed; (7) stock price; (8) margin (including gross margin); (9) income (before or after taxes); (10) operating income; (11) operating income after taxes; (12) pre-tax profit; (13) operating cash flow; (14) sales or revenue targets; (15) increases in revenue or product revenue; (16) expenses and cost reduction goals; (17) improvement in or attainment of working capital levels; (18) economic value added (or an equivalent metric); (19) market share; (20) cash flow; (21) cash flow per share; (22) share price performance; (23) debt reduction; (24) implementation or completion of projects or processes; (25) customer satisfaction; (26) stockholders' equity; (27) capital expenditures; (28) debt levels; (29) operating profit or net operating profit; (30) workforce diversity; (31) growth of net income or operating income; (32) billings; and (33) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting

135

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TABLE OF CONTENTS

forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated goals; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any extraordinary items as determined under generally accepted accounting principles. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2013 plan, (b) the class and maximum number of shares by which the share reserve may increase automatically each year, (c) the class and maximum number of shares that may be issued upon the exercise of ISOs, (d) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2013 plan pursuant to Section 162(m) of the Code) and (e) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;

arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;

accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;

arrange for the lapse of any reacquisition or repurchase right held by us;

cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or

make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2013 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change of Control.* The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Under the 2013 plan, a change of control is generally (i) the

acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined

TABLE OF CONTENTS

voting power of the surviving entity; or (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

*Amendment and Termination.* Our board of directors has the authority to amend, suspend, or terminate our 2013 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2013 plan.

## **2012 Equity Incentive Plan**

Our board of directors and our stockholders approved our 2012 plan, which became effective in February 2012. Our 2012 plan was a continuation of and successor to our 2002 plan and after our 2012 plan became effective, no further stock awards were made under our 2002 plan. As of September 30, 2013, there were no shares remaining available for the grant of stock awards under our 2012 plan and there were outstanding stock awards covering a total of 655,136 shares that were granted under our 2012 plan.

The 2012 plan terminated and no further awards were granted upon the effective date of the 2013 plan. All awards granted under the 2012 plan that are repurchased, forfeited, expire or are cancelled will become available for grant under the 2013 plan in accordance with its terms.

*Stock awards.* The 2012 plan provides for the grant of ISO, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of stock awards (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve.* The aggregate number of shares of our common stock originally reserved for issuance pursuant to stock awards under the 2012 plan was the sum of (i) 450,041 shares (which was the number of shares subject to the 2002 plan's available share reserve as of the effective date of the 2012 plan), plus (ii) any shares subject to stock options or other stock awards granted under our 2002 plan that expire or terminate for any reason, are forfeited or repurchased by us or are reacquired, withheld or not issued to satisfy a tax withholding obligation. The maximum number of shares that may be issued upon the exercise of ISOs under our 2012 plan was 6,197,183 shares.

If a stock award granted under the 2012 plan expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2012 plan. In addition, the following types of shares under the 2012 plan may become available for the grant of new stock awards under the 2012 plan: (1) shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) shares withheld to satisfy income or employment withholding taxes; or (3) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2012 plan may be previously unissued shares or reacquired shares bought by us on the open market.

*Administration.* Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2012 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2012 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the

period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2012 plan. Subject to the terms of our 2012 plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.



TABLE OF CONTENTS

*Stock Options.* Incentive and nonstatutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2012 plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2012 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2012 plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

*Tax Limitations On Incentive Stock Options.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the option is not exercisable after the expiration of five years from the date of grant.

*Restricted Stock Unit Awards.* Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2012 plan, (b) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (c) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of certain specified significant corporate transactions, outstanding stock awards shall be assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation. If any surviving or acquiring corporation fails to assume, continue or substitute such stock

## TABLE OF CONTENTS

awards, stock awards held by participants whose continuous service has terminated will accelerate vesting in full prior to the corporate transaction. All stock awards will terminate at or prior to the corporate transaction.

Under the 2012 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

*Change of Control.* The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Our form of option agreement provides for acceleration in full of the stock option if a participant is terminated without cause or resigns for good reason (which includes a resignation due to a material reduction in authority, duties or responsibilities, a material reduction in base salary or a relocation of employment by more than 50 miles) within thirteen months after a change of control. Under the 2012 plan, a change of control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (iii) approval by the stockholders or our board of directors of a plan of complete dissolution or liquidation of us; or (iv) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

*Amendment and Termination.* The 2012 plan will terminate on February 15, 2022. However, our board of directors has the authority to amend, suspend, or terminate our 2012 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent.

## **2002 Equity Incentive Plan**

Our board of directors and our stockholders originally approved our 2002 plan, which became effective in September 2002, and was further amended by our board of directors and stockholders, most recently in February 2011. The 2002 plan terminated and no further awards were granted upon the effective date of the 2012 plan. As of September 30, 2013, there were outstanding stock awards covering a total of 1,883,549 shares that were granted under our 2002 plan.

*Stock Awards.* The 2002 plan provides for the grant of ISO, NSOs, stock bonuses and rights to acquire restricted stock, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

*Share Reserve.* Shares are no longer available for the grant of stock awards under our 2002 plan. However, if a stock award granted under the 2002 plan expires or otherwise terminates without being exercised in full, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2012 plan.

*Administration.* Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2002 plan. Our board of directors may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares

of common stock to be subject to such stock awards. Subject to the terms of the 2002 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award. The plan administrator has the authority to modify outstanding awards under our 2002 plan.

TABLE OF CONTENTS

*Stock Options.* Incentive and nonstatutory stock options are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2002 plan, provided that the exercise price of an incentive stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant and the exercise price of a nonstatutory stock option generally cannot be less than 85% of the fair market value of our common stock on the date of grant. Options granted under the 2002 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2002 plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include cash or, at the discretion of the plan administrator, by (1) the tender of shares of our common stock previously owned by the optionholder, (2) deferred payment and (3) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

*Tax Limitations On Incentive Stock Options.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

*Changes to Capital Structure.* In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (a) the class and maximum number of shares reserved for issuance under the 2002 plan, (b) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (c) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* In the event of certain specified significant corporate transactions, outstanding stock awards shall be assumed, continued or substituted for similar stock awards by the surviving or acquiring corporation. If any surviving or acquiring corporation fails to assume, continue or substitute such stock awards, stock awards held by participants whose continuous service has terminated will accelerate vesting in full prior to the corporate transaction. All stock awards will terminate at or prior to the corporate transaction.

Under the 2002 plan, a corporate transaction is generally (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iii) a reverse merger in which we are the surviving corporate but shares of our common stock outstanding immediately preceding the merger are converted into other property by virtue of the transaction.

140

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## TABLE OF CONTENTS

*Change of Control.* In addition, the plan administrator may provide for special vesting acceleration in an individual award agreement or in any other written agreement between a participant and us. Our form of option agreement provides for acceleration in full of the stock option if a participant is terminated without cause or resigns for good reason (which includes a resignation due to a material reduction in authority, duties or responsibilities, a material reduction in base salary or a relocation of employment by more than 50 miles) within thirteen months after a change of control transaction. A change of control transaction is generally (i) a sale or disposition of all of our assets; (ii) a merger or consolidation following which we are not the surviving entity and our stockholders own less than 50% of the voting power of the surviving entity or its parent; (iii) a reverse merger where we are the surviving entity but our stockholders own less than 50% of the voting power; or (iv) an acquisition by a person, group or entity of 50% of our voting power.

### **2013 Employee Stock Purchase Plan**

Our board of directors adopted the ESPP in February 2013 and our stockholders approved the ESPP in March 2013.

The ESPP became effective in connection with our IPO in April 2013. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

*Share Reserve.* The ESPP authorizes the issuance of 704,225 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2014 through January 1, 2023 by the least of (a) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

*Administration.* Our board of directors has delegated its authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of our common stock on the first date of an offering or (b) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (a) customarily employed for more than 20 hours per week, (b) customarily employed for more than five months per calendar year or (c) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d)

of the Code.

*Changes to Capital Structure.* In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (a) the number of shares reserved under the ESPP, (b) the

141

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TABLE OF CONTENTS

maximum number of shares by which the share reserve may increase automatically each year and (c) the number of shares and purchase price of all outstanding purchase rights.

*Corporate Transactions.* In the event of certain significant corporate transactions, including: (i) a sale of all our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

*Plan Amendments, Termination.* Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

## Director Compensation

In 2012, we provided compensation to Ms. Demski in the form of a \$25,000 annual cash retainer. Prior to the effectiveness of our IPO in April 2013, we generally had not paid cash or equity compensation to directors who are also our employees for their service on our board of directors, nor have we paid cash or equity compensation to our non-employee directors who are associated with our principal stockholders for service on our board of directors. We have reimbursed and will continue to reimburse all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors.

The following table sets forth in summary form information concerning the compensation that we paid or awarded during the year ended December 31, 2012 to each of our non-employee directors that served as a director during 2012:

Name <sup>(1)</sup>	Fees Earned or Paid in Cash (\$)	Option Awards (\$) <sup>(2)</sup>	Total (\$)
Farah Champsi			
Martha J. Demski	25,000		25,000
Wende Hutton			
Ernest Mario, Ph.D			
James Niedel, M.D., Ph.D			
Arthur M. Pappas			
Timothy J. Wollaeger			

Mr. Moch was an employee director during 2012 and his compensation is fully reflected in the Summary Compensation Table above. George Painter, Ph.D. was an executive officer and director from January 1, 2012 until his resignation from our board of directors on July 20, 2012. Dr. Painter did not receive any compensation in 2012 for services provided as a member of our board of directors.

We did not grant any stock options to our non-employee directors in 2012. The aggregate number of shares subject (2) to each non-employee director's outstanding option awards as of December 31, 2012 was as follows: Martha J. Demski, 46,477 outstanding and unexercised.

In connection with Dr. Mario's appointment as the Chairman of our board of directors, we granted Dr. Mario an option to purchase 84,507 shares of our common stock in February 2013. The option has an exercise price equal to \$5.05 and vests over a four year period, subject to Dr. Mario's continued service with us. In addition, Dr. Mario has agreed to forego receiving the first four annual cash retainers that would otherwise be payable to him under the compensation policy applicable to our non-employee directors.

TABLE OF CONTENTS

In connection with our IPO, our board of directors has adopted a compensation policy applicable to all of our non-employee directors. This compensation policy provides that each such non-employee director receives the following compensation for service on our board of directors:

an annual cash retainer of \$25,000 and payment of travel expenses to attend meetings of the board of directors and committees of the board of directors;

an additional annual cash retainer of \$6,000 for service as chairman of the audit committee, \$3,000 for service as chairman of the compensation committee and \$2,500 for service as chairman of the nominating and corporate governance committee;

upon first joining our board of directors, an automatic initial grant of an option having a Black-Scholes value of \$50,000 on the date of grant;

for each non-employee director whose term continues on the date of our annual meeting each year, an automatic annual grant of an option having a Black-Scholes value of \$25,000 on the date of grant; and

for the chairman of our board of directors, an additional automatic annual option grant having a Black-Scholes value of \$10,000 on the date of grant.

Each of the option grants described above vests and becomes exercisable over a four year period following the date of grant, subject to the director continuing to provide services to us during such period. Additionally, each option vests in full upon a change in control (as defined under our 2013 plan). The term of each option is 10 years. The options are granted under our 2013 plan, the terms of which are described in more detail above under Equity Benefit Plans 2013 Equity Incentive Plan.

In accordance with our compensation policy for non-employee directors, upon his appointment as a director in August 2013, Mr. Drake was granted an initial grant consisting of a nonqualified stock option to purchase 4,907 shares of our common stock at an exercise price equal \$22.04, the closing price of our common stock on the date of grant, and which will vest and become exercisable over a four year period following the date of grant.

TABLE OF CONTENTS**CERTAIN RELATIONSHIPS AND RELATED PARTY  
TRANSACTIONS**

The following includes a summary of transactions since January 1, 2009 to which we have been a party, in which the amount involved in the transaction exceeded \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under Executive and Director Compensation.

**Preferred Stock Financings****Series E Preferred Stock Financing**

In July and August 2009, we issued and sold to investors an aggregate of 7,894,871 shares of Series E preferred stock, at a purchase price of \$2.045 per share, for aggregate consideration of \$16,145,011.

The participants in this preferred stock financing included the following holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in this financing:

Participants <sup>(1)</sup>	Series E Preferred Stock
5% or Greater Stockholders	
Canaan VII L.P. <sup>(2)</sup>	2,992,666
Alta Biopharma Partners III, L.P. and its affiliated entities <sup>(3)</sup>	2,444,990
Sanderling Venture Partners V, L.P. and its affiliated entities <sup>(4)</sup>	2,200,490

(1) Additional details regarding these stockholders and their equity holdings is provided in Principal and Selling Stockholders.

Includes 2,933,986 shares of Series E preferred stock issued to Canaan VII L.P., 48,900 shares of Series E

(2) preferred stock issued to Dan T. Ciporin, 4,890 shares of Series E preferred stock issued to Stephen M. Bloch and 4,890 shares of Series E preferred stock issued to Warren Lee.

Includes 2,239,404 shares of Series E preferred stock issued to Alta Biopharma Partners III, L.P., 150,397 shares of

(3) Series E preferred stock issued to Alta Biopharma Partners III GmbH & Co. Beteiligungs KG, and 55,189 shares of Series E preferred stock issued to Alta Embarcadero Biopharma Partners III, LLC.

Includes 19,461 shares of Series E preferred stock issued to Sanderling Venture Partners V, L.P., 4,744 shares of Series E preferred stock issued to Sanderling V Biomedical, L.P., 16,015 shares of Series E preferred stock issued to Sanderling V Ventures Management, 404,708 shares of Series E preferred stock issued to Sanderling V

(4) Biomedical Co-Investment Fund, L.P., 667,542 shares of Series E preferred stock issued to Sanderling Venture Partners V Co-Investment Fund, L.P., 1,033,315 shares of Series E preferred stock issued to Sanderling Venture Partners VI Co-Investment Fund, L.P., 19,998 shares of Series E preferred stock issued to Sanderling CI Beteiligungs GmbH & Co. KG, 23,827 shares of Series E preferred stock issued to Sanderling VI Limited Partnership, and 10,880 shares of Series E preferred stock issued to Sanderling Ventures Management VI.

## **Series F Preferred Stock Financing**

In February 2011, we issued and sold to investors an aggregate of 22,004,895 shares of Series F preferred stock, at a purchase price of \$2.045 per share, for aggregate consideration of \$45,000,010. At the closing, for no additional consideration, we issued each investor in this financing a warrant to purchase a number of shares of Series F preferred stock, at an exercise price of \$2.045 per share, equal to 25% of the number of shares otherwise purchased by such participant in the financing.

144

---

TABLE OF CONTENTS

The participants in this preferred stock financing included the following holders of more than 5% of our capital stock or entities affiliated with them. The following table presents the number of shares issued to these related parties in this financing:

Participants <sup>(1)</sup>	Series F Preferred Stock <sup>(2)</sup>
5% or Greater Stockholders	
New Leaf Ventures II, L.P.	8,557,458
A.M. Pappas Life Science Ventures IV, L.P. and its affiliated entities <sup>(3)</sup>	3,168,706
Canaan VII L.P. <sup>(4)</sup>	3,014,670
Sanderling Venture Partners V, L.P. and its affiliated entities <sup>(5)</sup>	2,811,735
Alta Biopharma Partners III, L.P. and its affiliated entities <sup>(6)</sup>	1,955,991

(1) Additional details regarding these stockholders and their equity holdings is provided in Principal and Selling Stockholders.

(2) Share amounts exclude shares of Series F preferred stock that may be acquired upon the exercise of warrants that were issued in connection with our Series F preferred stock financing.

(3) Includes 2,333,903 shares of Series F preferred stock issued to A.M. Pappas Life Science Ventures IV, L.P., 111,086 shares of Series F preferred stock issued to PV IV CEO Fund, L.P., 681,356 shares of Series F preferred stock issued to A.M. Pappas Life Science Ventures III, L.P., and 42,361 shares of Series F preferred stock issued to PV III CEO Fund L.P.

(4) Includes 3,007,335 shares of Series F preferred stock issued to Canaan VII L.P., 2,445 shares of Series F preferred stock issued to Stephen M. Bloch, and 4,890 shares of Series F preferred stock issued to Dan T. Ciporin.

(5) Includes 115,968 shares of Series F preferred stock issued to Sanderling Ventures Management V, and 2,695,767 shares of Series F preferred stock issued to Sanderling V Strategic Exit Fund, L.P.

(6) Includes 1,791,523 shares of Series F preferred stock issued to Alta Biopharma Partners III, L.P., 120,317 shares of Series F preferred stock issued to Alta Biopharma Partners III GmbH & Co. Beteiligungs KG, and 44,151 shares of Series F preferred stock issued to Alta Embarcadero Biopharma Partners III, LLC.

Some of our directors are associated with our principal stockholders as indicated in the table below:

Director	Principal Stockholder
Timothy J. Wollaeger	Sanderling Venture Partners V, L.P. and its affiliated entities
Wende Hutton	Canaan VII L.P.
James Niedel, M.D., Ph.D.	New Leaf Ventures II, L.P.
Farah Champs	Alta Biopharma Partners III, L.P. and its affiliated entities
Arthur M. Pappas	A.M. Pappas Life Science Ventures IV, L.P. and its affiliated entities

## Investor Rights, Voting and Co-Sale Agreements

In connection with our preferred stock financings, we entered into amended and restated investor rights, voting and right of first refusal and co-sale agreements containing voting rights, information rights, rights of first refusal and registration rights, among other things, with certain holders of our preferred stock and certain holders of our common

stock. These stockholder agreements terminated upon the closing of our IPO in April 2013, except for the registration rights granted under our amended and restated investor rights agreement, as more fully described below in Description of Capital Stock Registration Rights.

## Employment Arrangements

For more information about our employment and consulting agreements and offer letters with our named executive officers, refer to Executive and Director Compensation Employment Agreements with Executive Officers.

We currently maintain a written employment agreement with our President and Chief Executive Officer, Kenneth I. Moch. Pursuant to the terms of his employment agreement, in November 2009 we issued a promissory note in the principal amount of \$125,000 to Mr. Moch. The promissory note bore interest at the rate of 0.71% per annum. The entire outstanding principal balance and accrued interest under the promissory note was repaid in full by Mr. Moch in April 2011.

## TABLE OF CONTENTS

Between January 2009 and July 2012, George Painter, Ph.D. was employed as our Chief Scientific Officer, and received an annual base salary ranging between \$392,500 and \$200,000, received annual cash bonuses ranging between \$20,000 and \$130,000 and was granted stock options to purchase an aggregate of 310,432 shares of our common stock. Concurrently during this period, Dr. George Painter also served as a member of our board of directors.

Between January 2009 and August 2009, Gwendolyn Painter, M.D. served as a consultant to us, earned consulting fees of approximately \$225,000 and was granted a stock option to purchase 2,816 shares of our common stock. Thereafter, between August 2009 and February 2012, Dr. Gwendolyn Painter was employed as our Chief Medical Officer, and received an annual base salary ranging between \$375,000 and \$394,000, received annual cash bonuses ranging between \$28,750 and \$100,000 and was granted stock options to purchase an aggregate of 176,056 shares of our common stock. Starting in March 2012, Dr. Gwendolyn Painter reduced her efforts to a part-time employee working 20 hours a week at an annual salary rate of \$210,993. Concurrently during each of these periods, Dr. George Painter, her husband, served as a member of our board of directors.

## **Stock Options Granted to Executive Officers and Directors**

We have granted stock options to our executive officers and directors, as more fully described in Executive and Director Compensation.

## **Indemnification Agreements**

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. For more information regarding these indemnification arrangements, see Management Limitation on Liability and Indemnification of Directors and Officers. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We have agreed to reimburse the selling stockholders for fees and disbursements of counsel incurred in connection with the sale of shares in this offering.

## **Policies and Procedures for Transactions with Related Persons**

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions. For purposes of our policy only, a related-person transaction is a transaction, arrangement or relationship (or any series of similar transactions,



arrangements or relationships) in which we and any related person are participants involving an amount that exceeds \$120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than five percent of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors)

TABLE OF CONTENTS

for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

the risks, costs and benefits to us;

the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

the terms of the transaction;

the availability of other sources for comparable services or products; and

the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

147

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TABLE OF CONTENTS**PRINCIPAL AND SELLING STOCKHOLDERS**

The following table sets forth information regarding beneficial ownership of our capital stock by:

each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;  
 each of our directors;  
 each of our named executive officers;  
 all of our current executive officers and directors as a group; and  
 each selling stockholder.

The percentage ownership information before the offering shown in the table is based upon 25,974,809 shares of common stock outstanding as of September 30, 2013. The information relating to percentages of shares beneficially owned after the offering assumes the sale of 427,283 shares of common stock by a selling stockholder upon the exercise of options subsequent to September 30, 2013 in this offering.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before November 29, 2013, which is 60 days after September 30, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Except as otherwise noted below, the selling stockholders have represented to us that they are not, nor are they affiliated with, a registered broker-dealer.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Chimerix, Inc., 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Before Offering	Number of Shares To Be Sold in the Offering	Number of Shares Beneficially Owned After Offering	Percentage of Shares Beneficially Owned	
				Before Offering	After Offering
5% or greater stockholders					
Sanderling Venture Partners V, L.P. and its affiliated entities <sup>(1)</sup>	4,453,834		4,453,834	17.0%	16.7%
400 South El Camino Real, Suite 1200 San Mateo, CA 94402					
New Leaf Ventures II, L.P. <sup>(2)</sup>	3,431,633	585,602	2,846,031	12.9%	10.5%
Time Square Tower 7 Times Square, Suite 3502					

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New York, NY 10036

Canaan VII L.P.<sup>(3)</sup>

285 Riverside Avenue, Suite 250

Westport, CT 06880

Alta Biopharma Partners III, L.P.

and its affiliated entities<sup>(4)</sup>

One Embarcadero Center, 37<sup>th</sup> Floor

San Francisco, CA 94111

3,259,761 674,771 2,584,990 12.5% 9.8%

2,299,573 447,499 1,852,074 8.8% 7.0%

148

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TABLE OF CONTENTS

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Before Offering	Number of Shares To Be Sold in the Offering	Number of Shares Beneficially Owned After Offering	Percentage of Shares Beneficially Owned	
				Before Offering	After Offering
Directors and named executive officers					
Timothy J. Wollaeger <sup>(1)</sup>	4,453,834		4,453,834	17.0%	16.7%
James Niedel, M.D., Ph.D. <sup>(2)</sup>	3,431,633	585,602	2,846,031	12.9%	10.5%
Wende S. Hutton <sup>(5)</sup>	3,272,158	674,771	2,597,387	12.6%	9.8%
Farah Champs <sup>(4)</sup>	2,299,573	447,499	1,852,074	8.8%	7.0%
Arthur M. Pappas <sup>(6)</sup>	1,270,681	216,840	1,053,841	4.9%	4.0%
Kenneth I. Moch <sup>(7)</sup>	820,714		820,714	3.1%	3.0%
Timothy W. Trost <sup>(8)</sup>	172,423		172,423	*	*
Ernest Mario, Ph.D. <sup>(9)</sup>	99,571		99,571	*	*
Martha J. Demski <sup>(10)</sup>	61,265		61,265	*	*
M. Michelle Berrey, M.D., M.P.H. <sup>(11)</sup>	49,554		49,554	*	*
Michael Grindel, Ph.D. <sup>(12)</sup>	14,084		14,084	*	*
Dorothy J. Margolskee, M.D.	14,084		14,084	*	*
Rodman L. Drake				*	*
All current executive officers and directors as a group (12 persons) <sup>(13)</sup>	16,029,997	1,924,712	14,105,285	56.4%	48.9%
Additional Selling Stockholders					
A.M. Pappas Life Science Ventures IV, L.P. and its affiliated entities <sup>(6)</sup>					
P.O. Box 110287 Research Triangle Park, NC 27709	1,270,681	216,840	1,053,841	4.9%	4.0%
George Painter, Ph.D. <sup>(14)</sup> 3630 Peachtree Road, N.E. Unit 2801 Atlanta, GA 30326	571,588	427,283	144,305	2.2%	*
Hostetler Family Trust UTD 3/18/92 <sup>(15)</sup> 14024 Rue St. Raphael Del Mar, CA 92014	563,380	125,000	438,380	2.2%	1.7%

\*

Represents beneficial ownership of less than one percent.

(1) Includes 1,116,596 shares of common stock held by Sanderling Venture Partners V, L.P., 273,434 shares of common stock held by Sanderling V Biomedical, L.P., 155,143 shares of common stock held by Sanderling V Limited Partnership, 138,046 shares of common stock held by Sanderling V Beteiligungs GmbH & Co. KG, 94,634 shares of common stock held by Sanderling V Ventures Management, 281,053 shares of common stock held by Sanderling V Biomedical Co-Investment Fund, L.P., 463,582 shares of common stock held by Sanderling Venture Partners V Co-Investment Fund, L.P., 891,188 shares of common stock and a warrant to purchase 189,842 shares of common stock held by Sanderling V Strategic Exit Fund, L.P. (collectively, the Sanderling V Shares), 797,346 shares of common stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., 15,431 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, 18,384 shares of common stock held by Sanderling VI Limited Partnership, 7,543 shares of common stock and a warrant to purchase 8,166 shares of

common stock held by Sanderling Ventures Management VI (collectively, the Sanderling VI Shares) and 3,446 shares of common stock held by Middleton-McNeil Retirement Trust. Timothy J. Wollaeger, one of our directors, Fred A. Middleton, Robert G. McNeil and Timothy C. Mills share voting and investment power with respect to the Sanderling V Shares. Robert G. McNeil, Fred A. Middleton, Timothy C. Mills and Timothy J. Wollaeger share voting and investment power with respect to the Sanderling VI Shares. Fred A. Middleton and Robert G. McNeil share voting and investment power with respect to the shares held by the Middleton-McNeil Retirement Trust. Each of these individuals disclaims beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The address for this stockholder is 400 S. El Camino Real, Suite 1200, San Mateo, CA 94402. Includes 2,828,996 shares of common stock and a warrant to purchase 602,637 shares of common stock held by New Leaf Ventures II, L.P. James Niedel, one of our directors, Philippe O. Chambon, Jeani Delagardelle, Ronald M. Hunt and Vijay K. Lathi, the members of the investment committee of New Leaf Venture Associates II, L.P., which is the General Partner of New Leaf Ventures II, L.P., have the power to vote or dispose of these shares and (2) therefore each of the foregoing members of the investment committee may be deemed to have voting and investment power with respect to such shares. Each of the foregoing members of the investment committee disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address for this stockholder is Times Square Tower, 7 Times Square, Suite 3502, New York, NY 10036.

149

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TABLE OF CONTENTS

Includes 3,259,761 shares of common stock held by Canaan VII L.P. (the Canaan VII Shares). Canaan Partners VII LLC (Canaan VII) is the sole General Partner of Canaan VII L.P. and may be deemed to have voting and investment power over the Canaan VII Shares. The managers of Canaan VII are Wende S. Hutton, one of our (3) directors, Brenton K. Ahrens, John V. Balen, Stephen M. Bloch, Maha S. Ibrahim, Deepak Kamra, Gregory Kopchinsky, Seth A. Rudnick, Guy M. Russo and Eric A. Young. Each of these individuals disclaims beneficial ownership of the Canaan VII Shares. The address for Canaan VII L.P. is 285 Riverside Avenue, Suite 250, Westport, CT 06880.

Includes 1,980,055 shares of common stock and a warrant to purchase 126,163 shares of common stock held by Alta Biopharma Partners III, L.P., 132,978 shares of common stock and a warrant to purchase 8,472 shares of common stock held by Alta Biopharma Partners III GmbH & Co. Beteiligungs KG and 48,796 shares of common stock and a warrant to purchase 3,109 shares of common stock held by Alta Embarcadero Biopharma Partners III, LLC (collectively, the Alta Shares). Alta Partners III, Inc. provides investment advisory services to Alta Biopharma Partners III, L.P., Alta Biopharma Partners III GmbH & Co. Beteiligungs KG and Alta Embarcadero Biopharma Partners III, LLC (collectively, the Alta Funds). The directors of Alta Biopharma Management III, (4) LLC, which is a general partner of Alta Biopharma Partners III, L.P., the managing limited partner of Alta Biopharma Partners III GmbH & Co. Beteiligungs KG, and the manager of Alta Embarcadero Biopharma Partners III, LLC, exercise sole dispositive and voting power over the shares owned by the Alta Funds. Farah Champsi, one of our directors, Edward Penhoet and Edward Hurwitz, are directors of Alta Biopharma Management III, LLC and managers of Alta Embarcadero Biopharma Partners III, LLC. These individuals may be deemed to share dispositive and voting power over the shares held by the Alta Funds. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address for this stockholder is One Embarcadero Center, Suite 3700, San Francisco, CA 94111.

Includes 3,259,761 shares of common stock held by Canaan VII L.P. (the Canaan VII Shares) and 12,397 shares of common stock held by The Hutton Living Trust dated 12/10/96. Ms. Hutton is a trustee of The Hutton Living Trust dated 12/10/96 (The Hutton Trust) and has shared voting and investment power over the shares held by The Hutton (5) Trust. Ms. Hutton is one of the managers of Canaan Partners VII LLC, which is the sole general partner of Canaan VII L.P. Ms. Hutton disclaims beneficial ownership of the Canaan VII Shares. Ms. Hutton's address is c/o Canaan VII L.P., 2765 Sand Hill Road, Menlo Park, CA 94025.

Includes 771,561 shares of common stock and a warrant to purchase 164,359 shares of common stock held by A.M. Pappas Life Science Ventures IV, L.P., 36,723 shares of common stock and a warrant to purchase 7,822 shares of common stock held by PV IV CEO Fund, L.P., 225,248 shares of common stock and a warrant to purchase 47,982 shares of common stock held by A.M. Pappas Life Science Ventures III, L.P. and 14,003 shares of common stock and a warrant to purchase 2,983 shares of common stock held by PV III CEO Fund, L.P. AMP&A Management IV, LLC is the general partner of each of A.M. Pappas Life Science Ventures IV, L.P. and PV IV CEO Fund, L.P. (collectively, the IV Funds), and AMP&A Management III, LLC is the general partner of each of (6) A.M. Pappas Life Science Ventures III, L.P. and PV III CEO Fund, L.P. (collectively with the IV Funds, the Funds), and each of AMP&A Management IV, LLC and AMP&A Management III, LLC has a management agreement with A.M. Pappas & Associates, LLC whereby A.M. Pappas & Associates, LLC provides management services for the Funds. As a result, A.M. Pappas & Associates, LLC's investment committee exercises sole dispositive and voting power over the shares owned by the Funds. By virtue of these relationships, AMP&A Management IV, LLC, AMP&A Management III, LLC and A.M. Pappas & Associates, LLC may be deemed to beneficially own the shares owned directly by the Funds. Each of the foregoing entities disclaims beneficial ownership of such shares except to the extent of each of its pecuniary interest therein. The address for this stockholder is 2520 Meridian Parkway, Suite 400, Durham, NC 27713.

(7) Represents 820,714 shares which Mr. Moch has the right to acquire from us within 60 days of September 30, 2013 pursuant to the exercise of stock options, 162,864 of which will be unvested but exercisable as of November 29, 2013, 8,479 of which are issuable pursuant to vested restricted stock unit awards and 358,709 of which are held by The 2012 Kenneth Moch Irrevocable GST Trust F/B/O Ellen Gray Stolzman and Descendants dated May 25, 2012,

of which Ellen Gray Stolzman, Mr. Moch's wife, is trustee.

Represents 172,423 shares which Mr. Trost has the right to acquire from us within 60 days of September 30, 2013  
(8) pursuant to the exercise of stock options, 28,169 of which will be unvested but exercisable as of November 29, 2013 and 3,409 of which are issuable pursuant to vested restricted stock unit awards.

Includes 84,507 shares which Dr. Mario has the right to acquire from us within 60 days of September 30, 2013  
(9) pursuant to the exercise of stock options, 68,662 of which will be unvested but exercisable as of November 29, 2013.

Includes 14,788 shares held by the Martha J. Demski Trust u/a 10/01/94, and 46,477 shares which Ms. Demski  
(10) has the right to acquire from us within 60 days of September 30, 2013 pursuant to the exercise of stock options, 5,136 of which will be unvested but exercisable as of November 29, 2013.

Includes 5,540 shares held by the M. Michelle Berrey Revocable Trust u/a 12/30/08, and 44,014 shares which Dr.  
(11) Berrey has the right to acquire from us within 60 days of September 30, 2013 pursuant to the exercise of stock options.

Represents 14,084 shares which Dr. Grindel has the right to acquire from us within 60 days of September 30,  
(12) 2013 pursuant to the exercise of stock options.

Includes 13,601,736 shares held by all current executive officers and directors as a group and 2,428,261 shares  
(13) that all current executive officers and directors as a group have the right to acquire from us within 60 days of September 30, 2013 pursuant to the exercise of stock options and warrants, 368,329 of which will be unvested but exercisable as of November 29, 2013.

Includes 427,283 shares which Dr. Painter has the right to acquire from us within 60 days of September 30, 2013  
(14) pursuant to the exercise of stock options.

(15) Karl Y. Hostetler, M.D., as trustee, has dispositive and voting power over these shares.

150

---



TABLE OF CONTENTS

## **DESCRIPTION OF CAPITAL STOCK**

Our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.001 per share and 10,000,000 shares of preferred stock, par value \$0.001 per share. The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

### **Common Stock**

#### **Outstanding Shares**

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 in this offering, there were 26,402,092 shares of common stock outstanding held of record by 83 stockholders.

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 in this offering, there were 2,065,657 shares of common stock subject to outstanding options under our equity incentive plans, 102,547 shares of common stock issuable pursuant to outstanding restricted stock units under our equity incentive plans and 1,343,760 shares of common stock issuable upon the exercise of outstanding warrants.

#### **Voting**

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

#### **Dividends**

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

#### **Liquidation**

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

## **Rights and Preferences**

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

## **Fully Paid and Nonassessable**

All of our outstanding shares of common stock are, including the shares of common stock to be sold in this offering, fully paid and nonassessable.

## **Preferred Stock**

Under our amended and restated certificate of incorporation, our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights,

## TABLE OF CONTENTS

preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

## **Stock Options and Restricted Stock Units**

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 in this offering, 2,065,657 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of \$3.32 per share, and 102,547 shares of common stock were issuable pursuant to outstanding restricted stock units.

## **Warrants**

As of September 30, 2013, 5,915 shares of common stock were issuable upon exercise of an outstanding warrant issued to General Electric Capital Corporation with an exercise price of \$5.33 per share. This warrant is exercisable until November 5, 2013. The warrant provides for cashless exercise at the option of the holder, and also contains provisions for the adjustment of the number of shares issuable upon the exercise of the warrant in the event of stock splits, recapitalizations, reclassifications and consolidations.

As of September 30, 2013, an aggregate of 1,337,845 shares of common stock were issuable upon exercise of outstanding warrants with an exercise price of \$7.26 per share. These warrants were issued in connection with an equity financing agreement with certain investors for the sale of Series F preferred stock. The warrants issued in connection with the Series F preferred stock financing are exercisable for seven years after the issuance date of each respective warrant (each of which was issued in February of 2011), unless terminated earlier as a result of certain reorganizations or changes in control as set forth in the warrant. These warrants provide for cashless exercise at the option of the holder, and also contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of stock dividends, stock splits, reorganizations and reclassifications and consolidations.

## **Registration Rights**

Certain holders of our common stock, or their transferees, are entitled to the registration rights set forth below with respect to registration of the resale of such shares under the Securities Act pursuant to an amended and restated investors' rights agreement by and among us and certain of our stockholders.

### **Demand Registration Rights**

Upon the written request of certain of the holders of the registrable securities then outstanding that we file a registration statement under the Securities Act with an anticipated aggregate price to the public of at least \$5 million,

we will be obligated to notify all holders of registrable securities of such request and to use our reasonable best efforts to register the sale of all registrable securities that holders may request to be registered. We are not required to effect more than two registration statements which are declared or ordered effective, subject to certain exceptions. We may postpone the filing of a registration statement for up to 60 days twice in a 12-month period if in the good faith judgment of our board of directors such registration would be detrimental to us, and we are not required to effect the filing of a registration statement during the period beginning 60 days prior to our good faith estimate of the date of the filing of, and ending on a date 180 days following the effective date of, a registration initiated by us.

152

---

TABLE OF CONTENTS

## **Form S-3 Registration Rights**

If we are eligible to file a registration statement on Form S-3, holders of registrable securities have the right to demand that we file a registration statement on Form S-3 so long as the aggregate amount of securities to be sold under the registration statement on Form S-3 is at least \$2.5 million, subject to specified exceptions, conditions and limitations.

## **Piggyback Registration Rights**

If we register any securities for public sale, holders of registration rights will have the right to include their shares in the registration statement. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement, but not below 30% of the total number of shares included in the registration statement.

## **Expenses of Registration**

Generally, we are required to bear all registration and selling expenses incurred in connection with the demand, piggyback and Form S-3 registrations described above, other than underwriting discounts and commissions.

## **Expiration of Registration Rights**

The demand, piggyback and Form S-3 registration rights discussed above will terminate in April 2018 or, as to a given holder of registrable securities, when such holder is able to sell all of its registrable securities in a single 90-day period under Rule 144 of the Securities Act.

# **Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law**

## **Delaware Anti-Takeover Law**

We are subject to Section 203 of the Delaware General Corporation Law (Section 203). Section 203 generally prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;  
any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;  
subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;

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TABLE OF CONTENTS

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

## **Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws**

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control); provide that the authorized number of directors may be changed only by resolution adopted by a majority of the board of directors;

provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;

provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our board of directors into three classes;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;

do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);

provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exists any vacancies); and

provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against the us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine.

154

TABLE OF CONTENTS

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.

## **Nasdaq Global Market Listing**

Our common stock is listed on the Nasdaq Global Market under the symbol CMRX.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is P.O. Box 43078, Providence, Rhode Island 02940.

155

---



TABLE OF CONTENTS

## **SHARES ELIGIBLE FOR FUTURE SALE**

Prior to our initial public offering (IPO) in April 2013, there was no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices.

Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of September 30, 2013, upon closing of this offering, 26,402,092 shares of common stock will be outstanding, assuming no exercise of options or warrants, except for 427,283 shares issued upon the exercise of options subsequent to September 30, 2013 that will be sold in this offering by a selling stockholder. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Except as set forth below, the remaining 12,449,849 shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. In addition, any shares sold in this offering to entities affiliated with the selling stockholders, certain other existing shareholders and our directors will be subject to lock-up agreements. These remaining shares will generally become available for sale in the public market as follows:

No restricted shares will be eligible for immediate sale upon the closing of this offering;

Up to 772,825 restricted shares will be eligible for sale under Rule 144 or Rule 701 upon expiration of lock-up agreements at least 90 days after the date of this offering; and

The remainder of the restricted shares will be eligible for sale from time to time thereafter upon expiration of their respective holding periods under Rule 144, but could be sold earlier if the holders exercise any available registration rights.

### **Rule 144**

In general, under Rule 144 as currently in effect, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately without regard to whether current public information about us is available.

A person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

1% of the number of shares of our common stock then outstanding, which will equal approximately 264,020 shares immediately after this offering; or

the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

## Rule 701

In general, under Rule 701, any of our stockholders who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement before we became subject to the reporting requirements of Section 13 or 15(d) of the Exchange Act is eligible to resell those shares in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirements of Rule 144, and a non-affiliate of the issuer can resell shares in reliance on

156

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## TABLE OF CONTENTS

Rule 144 without having to comply with the holding period requirements of Rule 144 and without regard to the volume of such sales or the availability of public information about the issuer.

As of September 30, 2013, after giving effect to the sale of shares pursuant to this offering, options to purchase a total of 2,065,657 shares of common stock were outstanding, of which 1,297,865 were vested. In addition, as of September 30, 2013, 102,547 shares of common stock were issuable pursuant to outstanding restricted stock units. 829,260 of the total number of shares of our common stock issuable under these options and restricted stock units are subject to contractual lock-up agreements with the underwriters described below under **Lock-Up Agreements** and **Underwriters** and will become eligible for sale in accordance with Rule 701 at the expiration of those agreements.

## **Lock-Up Agreements**

We, along with our directors, executive officers, the selling stockholders and certain of our other existing stockholders that hold 12,449,849 shares of common stock, have agreed that for a period of 90 days (the restricted period), after the date of this prospectus, subject to specified exceptions, they will not offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock. The lock-up agreements do not prohibit the selling stockholders from selling shares of our common stock in this offering. Upon expiration of the restricted period, certain of our stockholders and warrant holders will have the right to require us to register their shares under the Securities Act. See **Registration Rights** below and **Description of Capital Stock** **Registration Rights**.

Certain of our employees, including our executive officers and/or directors, have entered into, and may in the future enter into, written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under existing trading plans are exempt from the restrictions of the lock-up agreements relating to the offering described above. Sales under any trading plan entered into in the future, if any, would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

## **Registration Rights**

Upon closing of this offering, the holders of 15,199,074 shares of our common stock (including shares of our common stock issuable upon the exercise of outstanding warrants) will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described under **Lock-Up Agreements** above.

Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See **Description of Capital Stock** **Registration Rights**.

## **Equity Incentive Plans**

Shares of our common stock issued under the 2002 Plan, 2012 Plan, 2013 Plan and the ESPP are available for sale in the open market, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.



TABLE OF CONTENTS

# **MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following discussion describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below).

This discussion does not address all aspects of U.S. federal income and estate taxes, does not discuss the potential application of the Medicare Contribution tax, and does not deal with state, local or non-U.S. tax consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences other than income and estate taxes. Rules different from those described below may apply to certain

Non-U.S. Holders that are subject to special treatment under the Code such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a straddle, conversion transaction, or other risk reduction strategy, partnerships and other pass-through entities, and investors in such pass-through entities or entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their places of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income or estate tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary. This discussion assumes that the Non-U.S. Holder holds our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice for any Non-U.S. Holders under their particular circumstances. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income and estate tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local and non-U.S. tax consequences and any U.S. federal non-income tax consequences.

For the purposes of this discussion, a Non-U.S. Holder is, for U.S. federal income tax purposes, a beneficial owner of common stock that is not a U.S. Holder. A U.S. Holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. Also, partnerships, or other entities that are treated as partnerships for U.S. federal income tax purposes (regardless of their place of organization or formation) and entities that are treated as disregarded entities for U.S. federal income tax purposes (regardless of their place of organization or formation) are not addressed by this discussion and are, therefore, not considered to be Non-U.S. Holders for the purposes of this discussion.

## Distributions

Subject to the discussion below, distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock generally will constitute dividends for U.S. tax purposes to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN, or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty. In the case of a Non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding

158

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## TABLE OF CONTENTS

an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific treaty exemption applies. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce your adjusted basis in our common stock as a non-taxable return of capital, but not below zero, and then any excess will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

## **Gain on Disposition of Our Common Stock**

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder's holding period.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States). With respect to (c) above, in general, we would be a United States real property holding corporation if interests in U.S. real estate constituted (by fair market value) at least half of our assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation, however, there can be no assurance that we will not become a U.S. real property holding corporation in the future. Even if we are treated as a U.S. real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than five percent of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or

(ii) the holder's holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market.

## **Information Reporting Requirements and Backup Withholding**

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of

159

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## TABLE OF CONTENTS

the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or non-U.S., unless the holder provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax refund or credit with respect to the amount withheld.

## **Foreign Accounts**

A U.S. federal withholding tax of 30% may apply to dividends and the gross proceeds of a disposition of our common stock paid to a foreign financial institution (as specifically defined by applicable rules), including when the foreign financial institution holds our common stock on behalf of a Non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from the rules. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. Holders are encouraged to consult with their own tax advisors regarding the possible implications of this withholding tax on their investment in our common stock.

The withholding provisions described above will generally apply to payments of dividends made on or after July 1, 2014 and to payments of gross proceeds from a sale or other disposition of common stock on or after January 1, 2017.

## **Federal Estate Tax**

An individual who at the time of death is not a citizen or resident of the United States and who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her taxable estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the United

States for federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be Non-U.S. Holders for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S. OR U.S. FEDERAL NON-INCOME TAX LAWS.

TABLE OF CONTENTS**UNDERWRITERS**

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and Cowen and Company, LLC are acting as representatives, have severally agreed to purchase, and the selling stockholders have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	1,114,647
Cowen and Company, LLC	743,099
William Blair & Company, L.L.C.	371,549
Canaccord Genuity Inc.	247,700
Total:	2,476,995

The underwriters and the representatives are collectively referred to as the underwriters and the representatives, respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from the selling stockholders and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$0.594 a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

Certain of selling stockholders have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 371,549 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to the selling stockholders. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 371,549 shares of common stock.

Public offering price	Per Share	Total	
		No Exercise	Full Exercise
	\$ 16.50	\$40,870,417	\$47,000,976
	\$ 0.99	\$2,452,225	\$2,820,058

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Underwriting discounts and commissions to be paid by the selling stockholders

Proceeds, before expenses, to the selling stockholders \$ 15.51 \$38,418,192 \$44,180,917

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$485,000. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, Inc. up to \$50,000.

Our common stock is listed on the Nasdaq Global Market under the trading symbol CMRX.

TABLE OF CONTENTS

We, all of our directors and officers, the selling stockholders and certain of our other existing stockholders have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus (the restricted period):

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock, whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we have agreed that, without the prior written consent of the representatives on behalf of the underwriters, we will not, during the restricted period, file any registration statement with the SEC relating to the offering of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock (other than on Form S-8 with respect to our equity incentive plans described in this prospectus), and such other person have agreed that they will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of, any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply to:

the sale of the shares to the underwriters;

the issuance by us of shares of our common stock or other securities convertible into or exercisable for shares of our common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus; *provided* that, prior to the issuance of any such shares of common stock within the restricted period, we cause each recipient of such shares to sign and deliver a lock-up letter substantially to the effect of the restrictions described in this and the immediately preceding paragraph (unless such recipient has previously executed and delivered a lock-up letter in such form);

the issuance by us of shares of our common stock or other securities convertible into or exercisable for shares of our common stock pursuant to our equity incentive plans described in this prospectus; *provided* that, prior to the issuance of any such shares of common stock or other securities where the shares of common stock or other securities vest within the restricted period, we cause each recipient of such shares or other securities to sign and deliver a lock-up letter substantially to the effect of the restrictions described in this and the immediately preceding paragraph;

(i) the entry into an agreement providing for the issuance by us of shares of our common stock or any security convertible into or exercisable for shares of our common stock in connection with the acquisition by us or any of our subsidiaries of the securities, business, or other assets of another person or entity or pursuant to an employee benefit plan assumed by us in connection with such acquisition, and the issuance of any such securities pursuant to any such agreement, and (ii) the entry into an agreement providing for the issuance of shares of Common Stock or any security convertible into or exercisable for shares of our common stock in connection with joint ventures, commercial relationships or other strategic transactions, and the issuance of any such securities pursuant to any such agreement; *provided* that the aggregate number of shares of common stock that we may sell or issue or agree to sell or issue, or that may be issuable upon conversion or exercise of all other securities that we may sell or issue or agree to sell or issue, pursuant to this bullet point shall not exceed 5% of the total number of shares of our common stock issued and outstanding immediately following the completion of this offering; and *provided further*, that each recipient of shares or other securities issued pursuant to this bullet point shall sign and deliver a lock-up letter substantially to the effect of the restrictions described in this and the immediately preceding paragraph, and we shall enter stop transfer instructions with the our transfer agent and registrar on

162



TABLE OF CONTENTS

such shares or other securities, which we agree we will not waive or amend without the prior written consent of the representatives;

transfers by a director, officer or stockholder of shares of common stock or any security convertible into common stock as a bona fide gift, by will or intestate succession, or to any trust for the direct or indirect benefit of such director, officer or stockholder and/or their immediate family, or certain distributions by a stockholder of shares of common stock or any security convertible into common stock to partners, members, stockholders or holders of similar equity interests in such stockholder; *provided* that in the case of any such transfer or distribution, (i) each donee, transferee or distributee shall sign and deliver a lock-up letter substantially to the effect of the restrictions described in this and the immediately preceding paragraph, and (ii) other than with respect to transfers or distributions by Sanderling Venture Partners V, L.P. and certain of its affiliates involving no more than 150,000 shares of our common stock in the aggregate, no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily made during the restricted period;

transactions by a director, officer or stockholder relating to shares of our common stock acquired in open market transactions after the completion of this offering; *provided* that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent dispositions of our common stock acquired in such open market transactions during the restricted period;

the establishment by a director, officer or stockholder of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of our common stock; *provided* that such plan does not provide for the transfer of shares of our common stock during the restricted period and no public announcement or filing under the Exchange Act regarding the establishment of such plan shall be required or shall be voluntarily made by or on behalf of such director, officer or stockholder or us during the restricted period;

transactions by an officer relating to shares of our common stock executed under a trading plan pursuant to Rule 10b5-1 under the Exchange Act in existence as of the date of this prospectus providing for the transfer of shares of our common stock; or

transfers by a director, officer or stockholder to us of shares of our common stock or other securities convertible into or exercisable or exchangeable for our common stock (i) upon a vesting event of our securities or the exercise of options issued pursuant to the our equity incentive plans in full or partial payment of taxes or tax withholding obligations required to be paid or satisfied upon such vesting or exercise, or (ii) in exercise of our right to repurchase or reacquire the securities of such director, officer or stockholder pursuant to agreements that permit us to repurchase or reacquire such securities upon termination of the services of such director, officer or stockholder to us; *provided* that in the case of any transfer pursuant to this bullet point, no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock, shall be required or shall be voluntarily made during the restricted period.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to





## TABLE OF CONTENTS

be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We, the selling stockholders and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

## **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

## **Selling Restrictions**

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State) an offer to the public of any shares of our common stock may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus

Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or

In any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of (c) shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to

TABLE OF CONTENTS

enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

**United Kingdom**

Each underwriter has represented and agreed that:

- (a) It has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

165

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TABLE OF CONTENTS

## **LEGAL MATTERS**

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. The underwriters are being represented by Davis Polk & Wardwell LLP, New York, New York.

## **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, has audited our financial statements at December 31, 2012 and 2011, and for each of the three years in the period ended December 31, 2012, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## **WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 2505 Meridian Parkway, Suite 340, Durham, North Carolina 27713 or telephoning us at (919) 806-1074.

We are subject to the information reporting requirements of the Exchange Act, and we file reports and other information with the SEC. These reports and other information are available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at [www.chimerix.com](http://www.chimerix.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. 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.

TABLE OF CONTENTS

# INDEX TO FINANCIAL STATEMENTS

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Balance Sheets as of December 31, 2011 and 2012</u>	<u>F-3</u>
<u>Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2010, 2011 and 2012</u>	<u>F-4</u>
<u>Statements of Redeemable Convertible Preferred Stock and Stockholders Deficit for the Years Ended December 31, 2010, 2011 and 2012</u>	<u>F-5</u>
<u>Statements of Cash Flows for the Years Ended December 31, 2010, 2011 and 2012</u>	<u>F-6</u>
<u>Notes to Financial Statements</u>	<u>F-7</u>
<u>Balance Sheets as of June 30, 2013 and December 31, 2012 (unaudited)</u>	<u>F-29</u>
<u>Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2013 and 2012 (unaudited)</u>	<u>F-30</u>
<u>Statements of Cash Flows for the Six Months Ended June 30, 2013 and 2012 (unaudited)</u>	<u>F-31</u>
<u>Notes to Financial Statements (unaudited)</u>	<u>F-32</u>

F-1

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TABLE OF CONTENTS

# Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Chimerix, Inc.

We have audited the accompanying balance sheets of Chimerix, Inc. as of December 31, 2011 and 2012 and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders deficit and cash flows for each of the three years in the period ended December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Chimerix, Inc. at December 31, 2011 and 2012 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
March 8, 2013, except for Note 14,  
as to which the date is March 26, 2013

TABLE OF CONTENTS**Chimerix, Inc.****Balance Sheets****(in thousands, except share and per share data)**

	December 31,		Pro Forma Stockholders' Equity at December 31, 2012 (unaudited)
	2011	2012	
Assets			
Current assets:			
Cash and cash equivalents	\$13,607	\$19,906	\$19,906
Short-term investments, available-for-sale	5,918	9,849	9,849
Accounts receivable	4,187	783	783
Prepaid and other current assets	1,048	983	983
Deferred financing costs, current portion	64	33	33
Total current assets	24,824	31,554	31,554
Property and equipment, net of accumulated depreciation	561	407	407
Deposits	22	22	22
Deferred financing costs, less current portion	25	48	48
Total assets	\$25,432	\$32,031	\$32,031
Liabilities, redeemable convertible preferred stock and stockholders' deficit			
Current liabilities:			
Accounts payable	\$4,120	\$1,964	\$1,964
Accrued liabilities	2,534	906	906
Loan payable, current portion	160	4,753	4,753
Total current liabilities	6,814	7,623	7,623
Other long-term liabilities		337	337
Loan payable, less current portion	2,441	9,867	9,867
Redeemable convertible preferred stock warrant liability	6,491	7,512	
Total liabilities	15,746	25,339	17,827
Redeemable convertible preferred stock	103,366	107,723	
Stockholders' deficit:			
Common stock, \$0.001 par value; 89,700,000 shares authorized at December 31, 2011 and 2012; 1,517,465 and 1,533,995 shares issued and outstanding at December 31, 2011 and 2012, respectively and 17,090,085 shares issued and outstanding pro forma (unaudited)	2	3	17
Additional paid-in capital			116,197
Accumulated other comprehensive loss	(4 )	(2 )	(2 )

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Accumulated deficit	(93,678 )	(101,032)	(102,008)
Total stockholders deficit	(93,680 )	(101,031)	14,204
Total liabilities, redeemable convertible preferred stock and stockholders deficit	\$25,432	\$32,031	\$32,031

*See accompanying notes.*

F-3

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TABLE OF CONTENTS**Chimerix, Inc.****Statements of Operations and Comprehensive Loss  
(in thousands, except per share data)**

	Year Ended December 31,		
	2010	2011	2012
Revenues:			
Collaboration and licensing revenue	\$	\$55	\$ 17,445
Contract and grant revenue	1,715	12,046	16,275
Total revenues	1,715	12,101	33,720
Operating expenses:			
Research and development	21,074	30,108	30,106
General and administrative	5,945	6,985	6,397
	27,019	37,093	36,503
Loss from operations	(25,304)	(24,992)	(2,783)
Other (expense) income:			
Interest expense, net	(154)	(212)	(776)
Fair value adjustments to warrant liability		(385)	(847)
Other income	1		
Net loss	(25,457)	(25,589)	(4,406)
Other comprehensive loss:			
Unrealized gain (loss) on securities available-for-sale		(4)	2
Comprehensive loss	\$(25,457)	\$(25,593)	\$(4,404)
Net loss	\$(25,457)	\$(25,589)	\$(4,406)
Accretion of redeemable convertible preferred stock		(9,565)	(4,357)
Net loss attributable to common stockholders	\$(25,457)	\$(35,154)	\$(8,763)
Per share information:			
Net loss, basic and diluted	\$(17.52)	\$(23.49)	\$(5.75)
Weighted-average shares outstanding, basic and diluted	1,453	1,496	1,525
Pro forma net loss, basic and diluted (unaudited)			\$(0.47)
Weighted-average pro forma shares outstanding, basic and diluted (unaudited)			9,369

*See accompanying notes.*

TABLE OF CONTENTS**Chimerix, Inc.**

**Statements of Redeemable Convertible Preferred  
Stock and Stockholders Deficit  
(in thousands)**

	Redeemable Convertible Preferred Stock	Common Stock	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Deficit
Balance, December 31, 2009	\$55,131	\$ 2	\$1,117	\$	\$(36,047 )	\$(34,928 )
Share-based compensation			753			753
Exercise of stock options			25			25
Comprehensive loss:						
Net loss					(25,457 )	(25,457 )
Total comprehensive loss						(25,457 )
Balance, December 31, 2010	55,131	2	1,895		(61,504 )	(59,607 )
Share-based compensation			966			966
Issuance of redeemable convertible preferred stock	38,670					
Issuance of common stock			89			89
Exercise of stock options			30			30
Dividends on redeemable preferred stock	3,235		(2,980)		(255 )	(3,235 )
Adjustment of redeemable preferred stock to redemption value	6,330				(6,330 )	(6,330 )
Comprehensive loss:						
Unrealized loss on investments, net				(4 )		(4 )
Net loss					(25,589 )	(25,589 )
Total comprehensive loss						(25,593 )
Balance, December 31, 2011	103,366	2		(4 )	(93,678 )	(93,680 )
Share-based compensation			1,396			1,396
Exercise of stock options		1	13			14
Dividends on redeemable preferred stock	3,600		(1,409)		(2,191 )	(3,600 )
Adjustment of redeemable preferred stock to redemption value	757				(757 )	(757 )
Comprehensive loss:						
Unrealized gain on investments, net				2		2
Net loss					(4,406 )	(4,406 )
Total comprehensive loss						(4,404 )
Balance, December 31, 2012	\$107,723	\$ 3	\$	\$ (2 )	\$(101,032 )	\$(101,031 )

*See accompanying notes.*

F-5

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TABLE OF CONTENTS**Chimerix, Inc.****Statements of Cash Flows  
(in thousands)**

	Year Ended December 31,		
	2010	2011	2012
Operating activities			
Net loss	\$(25,457)	\$(25,589)	\$(4,406)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation	213	270	280
Non-cash interest expense	38	50	238
Amortization/accretion of premium/discount on investments	119	118	84
Share-based compensation costs	753	1,055	1,396
Deferred lease obligation	(19)	(4)	
Fair value measurement of redeemable convertible preferred stock warrant liability		385	847
Net change in:			
Accounts receivable	937	(4,187)	3,404
Prepaid and other current assets and deposits	181	(442)	65
Accounts payable and accrued liabilities	1,554	2,065	(3,784)
Net cash used in operating activities	(21,681)	(26,279)	(1,876)
Investing activities			
Purchase of property and equipment	(117)	(321)	(126)
Purchase of short-term investments	(12,094)	(13,640)	(9,907)
Sales of short-term investments	2,925	500	
Maturities of short-term investments	9,050	7,100	5,894
Repayment of loan to officer		125	
Net cash used in investing activities	(236)	(6,236)	(4,139)
Financing activities			
Proceeds from issuance of redeemable convertible preferred stock and warrants		45,000	
Proceeds from exercise of stock options	25	30	14
Proceeds from loan payable	6,000		15,000
Debt discount			(75)
Repayment of loan payable	(1,434)	(1,965)	(2,601)
Stock offering and deferred financing costs	12	(249)	(24)
Net cash provided by financing activities	4,603	42,816	12,314
Increase (decrease) in cash and cash equivalents	(17,314)	10,301	6,299
Cash and cash equivalents:			
Beginning of period	20,620	3,306	13,607
End of period	\$3,306	\$13,607	\$19,906

Supplemental schedule of cash flow information

Interest payments	\$180	\$186	\$448
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*See accompanying notes.*

F-6

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TABLE OF CONTENTS

## **Chimerix, Inc.**

# **Notes to Financial Statements**

## **1. Description of Business**

Chimerix, Inc. (the Company) 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. The Company's proprietary lipid technology has given rise to two clinical-stage compounds, brincidofovir and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety inconvenient, orally administered dosing regimens. The Company has worldwide rights to its lead product candidate, brincidofovir, and initiated the Phase 3 SUPPRESS study in the third quarter of 2013 for the prevention of cytomegalovirus infection in hematopoietic stem cell transplant recipients. The Company recently completed a Phase 2 trial of brincidofovir as a preemptive therapy for adenovirus infection. Additionally, Chimerix is developing brincidofovir as a medical countermeasure against smallpox under a contract from the Biomedical Advanced Research and Development Authority (BARDA). The Company's 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.

To date, the Company has derived its revenue from the United States government, principally grants from the National Institute of Allergy and Infectious Diseases (NIAID) and a contract with BARDA, and pursuant to the license agreement it entered with Merck in July 2012. See Note 11 to these financial statements for further discussion of these arrangements.

The accompanying financial statements for the years ended December 31, 2010, 2011 and 2012 have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business for the foreseeable future. Since inception in 2000, the Company has not been profitable and has incurred operating losses in each year. The Company has not generated revenue from any product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. The Company has funded its operations primarily through the sale and issuance of preferred stock, loans with third parties, grant and contract awards from the United States government and amounts received pursuant to a license agreement with Merck. Net working capital at December 31, 2011 and 2012, was \$18.0 million and \$23.9 million, respectively. The Company expects to continue to incur losses for the foreseeable future. At December 31, 2012, the Company had capital resources consisting of cash, cash equivalents and short-term investments of \$29.8 million.

## **2. Significant Accounting Policies**

### **Basis of Presentation**

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

## Unaudited Pro Forma Stockholders Equity (Deficit)

In connection with the Company's initial public offering (IPO), all of the Company's redeemable convertible preferred stock automatically converted into common stock at the applicable conversion ratio then in effect. In addition, in connection with the Company's IPO, the Company issued shares of common stock underlying shares of the Company's Series F preferred stock in respect of the accumulated dividends on the Company's Series F preferred stock. Unaudited pro forma stockholders' equity assumes the conversion of all preferred stock into shares of common stock, the issuance of common stock in respect of the accumulated dividends on the Company's Series F preferred stock, and the conversion of all outstanding warrants exercisable for shares of preferred stock into warrants exercisable for a corresponding number of shares of common stock, resulting in the preferred stock warrant liability being reclassified to additional paid-in capital. The unaudited pro forma loss per share of common stock for the year ended December 31, 2012, was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding convertible preferred stock into shares of common stock and the issuance of shares of common stock in respect of the accumulated dividends on the Company's Series F

F-7

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TABLE OF CONTENTS

## **Chimerix, Inc.**

### **Notes to Financial Statements**

#### **2. Significant Accounting Policies (continued)**

preferred stock as if such conversion and issuance had occurred at the beginning of the respective period. See Note 15 to the these financial statements for further details on the completed IPO.

##### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

##### **Reclassifications**

During the second quarter of fiscal year 2013, the Company corrected the classification of its legal fees associated with patents and regulatory, license fees and rent. This resulted in a reclassification of \$1.7 million, and \$2.4 million and \$2.3 million from G&A expense to R&D expenses for the years ended December 31, 2010, 2011 and 2012. Such reclassifications had no effect on net loss or stockholders' deficit as previously reported.

##### **Segment Reporting**

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

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

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

##### **Investments**

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

Available-for-sale securities are carried at fair value as determined by quoted market prices, with the unrealized gains and losses, net of tax, reported as a separate component of stockholders' deficit. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis in interest income or expense, net. Investments with original maturities beyond three months at date of purchase and which



mature at, or less than twelve months from, the balance sheet date are classified as current. Investments with a maturity beyond twelve months from the balance sheet date are classified as long-term. The Company periodically reviews available-for-sale securities for other-than temporary declines in fair value below the cost basis, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Any such declines in value judged to be other-than-temporary on available-for-sale securities are reported in interest income or expense, net. There were no such declines in value for the years ended December 31, 2010, 2011 and 2012.

## **Accounts Receivable**

Accounts receivable at December 31, 2011 and 2012, consisted of amounts billed and unbilled under the Company's contract with BARDA. Receivables under the BARDA contract are recorded as qualifying research activities are conducted and invoices from the Company's vendors are received. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs

F-8

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TABLE OF CONTENTS

## **Chimerix, Inc.**

### **Notes to Financial Statements**

#### **2. Significant Accounting Policies (continued)**

and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded an allowance for doubtful contract receivable as management believes all receivables are fully collectible.

#### **Concentrations of Credit Risk**

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

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

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

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

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

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

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

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

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

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

F-9

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****2. Significant Accounting Policies (continued)**

At December 31, 2011 and 2012, the Company had short-term investments, comprised of corporate bonds and commercial paper, for which quoted prices are not available that were valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

The warrants issued for Series F redeemable convertible preferred stock are categorized as Level 3 as there are significant unobservable inputs. The valuation of the warrants reflects a two stage process. Using a contingent claims model in combination with the Company's Series F financing which occurred in February 2011, the fair value of total equity and all components of the Company's capital structure, including the warrants, is determined as of the time of the financing event. Using this value as a starting point, a series of equity values and associated probabilities are calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities consistent with market practice, a distribution of equity values was produced which covered the range of values that an informed market participant might expect. These outcomes were organized into ranges and a probability calculated based on the percent of the total falling into each range. This process created a range of equity values. Using a contingent claims framework, each equity value is allocated to the various components of the capital structure including the warrants. Each warrant value is weighted by its respective probability to determine the final fair value of the warrants as of December 31, 2011 and 2012. The key unobservable inputs used in the determination of the December 31, 2012 fair value are (i) volatility 79%, (ii) range of implied fair value of the Series F redeemable convertible preferred stock \$2.19 to \$2.85, (iii) time to liquidity 8 months to 5 years, and (iv) range of probabilities of liquidity event outcomes 2% to 31%.

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

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

Fair Value Measurements at December 31, 2011			
December 31, 2011	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

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	(Level 1)			
	(In thousands)			
Cash equivalents	\$9,326	\$9,326	\$	\$
Short-term investments	5,918		5,918	
Redeemable convertible preferred stock warrant liability	6,491			6,491

F-10

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****2. Significant Accounting Policies (continued)**

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

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

	Fair Value Measurements (Level 3) (in thousands)
Redeemable Convertible Preferred Stock Warrant Liability	
Balance at January 1, 2011	\$
Issuance	6,106
Fair value increase recorded in other income (expense)	385
Fair value at December 31, 2011	6,491
Issuance	174
Fair value increase recorded in other income (expense)	847
Fair value at December 31, 2012	\$ 7,512

**Prepaid and Other Current Assets**

Prepaid and other current assets consist of the following:

December 31,

	2011	2012
	(in thousands)	
Prepaid development expenses	\$ 816	\$ 486
Other prepaid and other current assets	232	497
	\$ 1,048	\$ 983

### **Property and Equipment**

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

Maintenance and repairs are charged against expense as incurred.

### **Impairment of Long-lived Assets**

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

F-11

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****2. Significant Accounting Policies (continued)****Deferred Public Offering Costs**

Deferred public offering costs totaling \$0.3 million at December 31, 2012 are included in prepaid and other current assets. These costs represent legal and accounting costs related to the Company's efforts to raise capital through a public sale of the Company's common stock. There were no IPO costs incurred prior to 2012. Future costs related to the Company's IPO activities were deferred until the completion of the IPO, at which time they were reclassified to additional paid-in capital as a reduction of the IPO proceeds.

**Deferred Rent**

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

**Accrued Liabilities**

Accrued liabilities consist of the following:

	December 31,	
	2011	2012
	(in thousands)	
Accrued compensation	\$ 693	\$ 560
Accrued development expenses	1,459	98
Other accrued liabilities	382	248
	\$ 2,534	\$ 906

**Redeemable Convertible Preferred Stock Warrant Liability**

Freestanding warrants for shares that are either puttable or redeemable are classified as liabilities on the balance sheet at fair value. As further discussed in Note 7 to these financial statements, the preferred stock underlying the warrants was redeemable in certain circumstances, and as such the freestanding warrants that are related to the purchase of the Company's Series F preferred stock are liabilities that should be recorded at the estimated fair value. At the end of each reporting period, changes in the estimated fair value during the period are recorded in other income.



## **Redeemable Convertible Preferred Stock**

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

## **Revenue Recognition**

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

For arrangements that involve the delivery of more than one element, each product, service and/or right to use assets is evaluated to determine whether it qualifies as a separate unit of accounting. This determination

F-12

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TABLE OF CONTENTS

## Chimerix, Inc.

### Notes to Financial Statements

#### 2. Significant Accounting Policies (continued)

is based on whether the deliverable has stand-alone value to the customer. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling prices of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods and services are delivered, limited to the consideration that is not contingent upon future deliverables. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered. Revisions to the estimated period of recognition are reflected in revenue prospectively.

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, it recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

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

For the year ended December 31, 2010, contract and grant revenue was derived from research grants with the NIAID. The activities related to the NIAID grant have been completed and there are no further performance obligations. In the years ended December 31, 2011 and 2012, contract and grant revenue consisted only of revenue from the BARDA contract as there was no grant revenue. The Company recognizes contract and grant revenue as qualifying research activities are conducted based on invoices received from the Company's vendors. Changes in fringe and indirect rates are recognized as a change in estimate in the period such rate changes are approved by BARDA.

#### Clinical Trial Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided

to the Company under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of trials, or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period. Through December 31,

F-13

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TABLE OF CONTENTS

## **Chimerix, Inc.**

### **Notes to Financial Statements**

#### **2. Significant Accounting Policies (continued)**

2012, there had been no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company's clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

#### **Research and Development**

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

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

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

#### **Income Taxes**

Deferred tax assets and liabilities are determined based on differences between the financial and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when the Company determines that it is more likely than not that some portion of a deferred tax asset will not be realized. The Company has incurred operating losses from April 7, 2000 (inception) through December 31, 2012, and therefore has not recorded any current provision for income taxes.

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

## Share-Based Compensation

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

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

### Basic and Dilutive Net Loss per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects converting

F-14

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****2. Significant Accounting Policies (continued)**

redeemable preferred stock, warrants to purchase redeemable convertible preferred stock, restricted stock and options. Diluted net loss per share of common stock is computed by dividing the net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock, and options outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock at December 31, 2010, 2011 and 2012.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of converting redeemable convertible preferred stock, warrants to purchase convertible preferred stock and options to purchase common stock, as the impact of such items are anti-dilutive during periods of net loss. Shares excluded from the calculations were 6,781,550, 11,034,134 and 11,259,579 for the years ended December 31, 2010, 2011 and 2012, respectively.

**Impact of Recently Issued Accounting Standards**

In May 2011, the FASB issued Accounting Standards Update (ASU) 2011-04, *Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurements and Disclosure Requirement in U.S. GAAP and IFRS*. This guidance includes amendments that clarify the intent about the application of existing fair value measurements and disclosures, and change a principle or requirement for fair value measurements or disclosures. This guidance is effective for interim and annual periods beginning after December 15, 2011. The standard was adopted as of January 1, 2012 and the retrospective application of this standard did not have a material impact on the Company's financial statements.

In June 2011, the FASB issued ASU 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*. This guidance requires that all nonowner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. This guidance is effective for interim and annual periods beginning after December 15, 2011. This standard was adopted as of January 1, 2012 and the retrospective application of this standard did not have a material impact on the Company's financial statements.

**3. Investments**

The following table summarizes available-for-sale securities:

December 31, 2011			
Amortized Cost	Gross Unrealized	Gross Unrealized	Estimated Fair

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		Gains	Losses	Value
	(in thousands)			
Corporate bonds	\$ 4,173	\$	\$ (4 )	\$ 4,169
Commercial paper	1,749			1,749
Total	\$ 5,922	\$	\$ (4 )	\$ 5,918

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Corporate bonds	\$ 8,353	\$	\$ (2 )	\$ 8,351
Commercial paper	1,498			1,498
Total	\$ 9,851	\$	\$ (2 )	\$ 9,849

All of the Company's investments as of December 31, 2011 and 2012 had maturities of one year or less.

F-15

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****4. Property and Equipment**

Property and equipment consist of the following:

	December 31,	
	2011	2012
	(in thousands)	
Lab equipment	\$ 900	\$ 958
Leasehold improvements	74	78
Computer equipment	340	393
Office furniture and equipment	201	212
	1,515	1,641
Less accumulated depreciation	(954 )	(1,234 )
	\$ 561	\$ 407

**5. Loans Payable**

On November 24, 2008, the Company entered into a Loan and Security Agreement (the loan) with Silicon Valley Bank (SVB) under which the Company could borrow up to \$6.0 million. On March 31, 2010, the Company drew the full amount of the loan with interest payable at 5%, the prime rate of interest plus 1% at the time of draw. The loan was secured by certain assets of the Company, excluding intellectual property. Borrowings under the loan were to be paid over a period of thirty-six months. The Company also granted the financial institution, concurrent with issuance of the loan, a warrant to purchase a total of 58,680 shares of the Company's Series D preferred stock at a price of \$2.045 per share. The Company incurred deferred financing costs of approximately \$0.2 million in connection with securing the loan and valuing the warrants which was amortized over the term of the loan through interest expense.

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

The first tranche was used to repay the remaining principal balance outstanding under the 2008 loan noted above of \$2.6 million. This repayment was deemed a modification of debt and therefore the remaining related deferred financing costs totaling \$0.1 million remained in deferred financing costs and are being amortized over the term of the LSA through interest expense. The first tranche has an interest only period of twelve months followed by a thirty month principal and interest amortization period with interest being charged at 8.25% per year for the full period of the LSA.

The Company met one of the financial and/or operational goals mentioned above and, in September 2012, the remaining \$12.0 million was borrowed in the second tranche. The second tranche has a six month interest only period



followed by a thirty-two month principal and interest amortization period with interest being charged at the same rate as the first tranche. There are certain fees in accordance with the LSA which are being recorded as discounts or other long and short-term liabilities depending on the nature of the fees. The fees are being accreted through interest expense. \$0.1 million was recorded in interest expense for the year ended December 31, 2012.

Concurrently with entering into the LSA, the Company also granted SVB a warrant to purchase shares of Series F preferred stock at a price of \$2.045 per share equal to 2% of the aggregate amount of the advances made to the Company pursuant to the LSA, divided by the exercise price. In relation to the first tranche, 29,340 warrants became exercisable, and in relation to the second tranche, an additional 117,360 warrants became exercisable. As discussed in Note 2 to these financial statements, the warrants are classified as a liability and are required to be measured at fair value. Therefore, the warrants were recorded as a debt

F-16

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****5. Loans Payable (continued)**

discount at their fair value at the time of grant and accreted over the life of the LSA using the effective interest method. The subsequent re-valuation of the warrants (at fair value) resulted in other expense of \$22,000 for the year ended December 31, 2012.

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

Years ending December 31,	
2013	\$ 6,042
2014	6,323
2015	4,508
	16,873
Less: amount representing interest	(1,873 )
Total payments under LSA	\$ 15,000

**6. Commitments and Contingencies****Leases**

The Company leases its facilities and certain office equipment under long-term noncancelable operating leases that expire at various dates through 2013. As of December 31, 2012, future minimum payments under noncancelable operating leases are as follows (in thousands):

Years Ending December 31,	
2013	\$ 169
2014	18
	\$ 187

Rent expense under non-cancelable operating leases and other month-to-month equipment rental agreements, including common area maintenance fees, totaled approximately \$0.4 million, \$0.5 million, and \$0.4 million for the years ended December 31, 2010, 2011 and 2012, respectively.

**Significance of Revenue Source**

The Company is the recipient of federal research grant funds from the U.S. Department of Health and Human Services through the NIAID and federal research contract funds from BARDA. Periodic audits are required under the grant and contract agreements and certain costs may be questioned as appropriate under the agreements. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the agreements has been made as of December 31, 2010, 2011 and 2012.

## 7. Redeemable Convertible Preferred Stock

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

In January 2012, the Company issued a warrant to SVB to purchase a number of shares of Series F redeemable convertible preferred stock at an exercise price of \$2.045 per share equal to 2% of the aggregate amount of the advances made to the Company pursuant to the LSA, divided by the exercise price. Following the first and second tranches of the LSA, the warrant was exercisable to purchase an aggregate of 146,700 shares of Series F redeemable convertible preferred stock. The warrant issued to SVB is exercisable until January 22, 2022.

F-17

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****7. Redeemable Convertible Preferred Stock (continued)**

The following table summarizes the authorized, issued and outstanding shares of redeemable convertible preferred stock as of December 31, 2011 and 2012:

	December 31, 2011		December 31, 2012	
	Authorized Shares	Issued and Outstanding Shares	Authorized Shares	Issued and Outstanding Shares
Series A	800,000	800,000	800,000	800,000
Series B	2,233,879	2,233,879	2,233,879	2,233,879
Series B-1	2,054,333	2,033,333	2,054,333	2,033,333
Series C	5,141,690	5,141,690	5,141,690	5,141,690
Series D	11,354,526	11,295,846	11,354,526	11,295,846
Series E	7,894,871	7,894,871	7,894,871	7,894,871
Series F	40,200,000	22,004,895	40,200,000	22,004,895
Total Shares	69,679,299	51,404,514	69,679,299	51,404,514

The Company's Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock, Series E preferred stock and Series F preferred stock (collectively, the Preferred Stock) have the following rights, preferences, and privileges:

**Dividend Provisions**

The Company's Series F preferred stock was entitled to receive dividends at the rate of 8% per annum of the original issuance price of \$2.045 per share (subject to adjustment in the event of any stock dividends, stock splits, combination of shares, recapitalization or similar events), whenever funds are legally available. These dividends accrued on a daily basis, whether or not declared by the Company's Board of Directors, and were cumulative to the extent not declared and paid for a period ending on the date immediately prior to the closing of the Company's initial public offering. Any future dividends shall be payable only when, as and if declared by the Company's Board of Directors and shall be non-cumulative. As of December 31, 2011 and 2012, dividends in the amount of \$3.2 million and \$6.8 million have been accrued and included in the balance of Series F preferred stock.

Each of the Company's Series A preferred stock, Series B preferred stock and Series B-1 preferred stock (collectively, the Junior Preferred Stock), the Company's Series C preferred stock and Series D preferred stock (collectively, the Mezzanine Preferred Stock), and the Company's Series E preferred stock was entitled to receive dividends at the rate 8% per annum of the applicable original issuance price per share. The original issuance price is \$0.50, \$1.00, \$1.50, \$2.045, \$2.045, \$2.045, and \$2.045 per share, respectively, for the Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock and Series E preferred stock (subject to adjustment in the event of any stock dividends, stock splits, combination of shares, recapitalization or similar events).

As of December 31, 2011 and 2012, no dividends for the Company's Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock or Series E preferred stock had been declared, and therefore none were accrued.

### **Liquidation Preference**

In the event of any liquidation, dissolution or winding up of the Company, the holders of the preferred stock were entitled to be paid out of the assets of the Company at an amount per share equal to the original issue price plus any accrued or declared and unpaid dividends on the preferred stock. The original purchase prices were \$2.045 for the Series F preferred stock, Series E preferred stock, Series D preferred stock and Series C preferred stock, and \$1.50, \$1.00 and \$0.50 for the Series B-1 preferred stock, Series B preferred stock and Series A preferred stock, respectively (in each case, subject to adjustment in the event of any stock dividends, stock splits, combination of shares, recapitalization or similar events).

F-18

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****7. Redeemable Convertible Preferred Stock (continued)****Voting Rights**

The holder of each share of preferred stock was entitled to the number of votes equal to the number of shares of common stock into which each share of preferred stock have been converted. Each share of common stock carried equivalent voting rights. In addition, certain actions required approval by the requisite holders of the Company's Series F preferred stock and/or the majority holders of the Company's Series E preferred stock.

**Automatic Conversion**

Each share of preferred stock automatically converted into shares of common stock at the then effective conversion rate immediately prior to the closing of the Company's IPO.

**Redemption**

The Company's Series F preferred stock was redeemable at the option of the holder in three annual installments occurring beginning February 7, 2018. The redemption value of the Company's Series F preferred stock was the greater of (i) the then fair value or (ii) the original issue price plus accrued dividends. See Note 8 to these financial statements for a discussion of the fair value considerations related to the Company's capital stock.

The Company determined that the Company's Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock and Series E preferred stock were contingently redeemable based on deemed liquidation events described above which are outside the control of the Company. Preferred Stock was recorded at fair value at the date of issuance and adjusts the carrying value to its redemption value at each balance sheet date. The redemption values of the Company's Series A preferred stock, Series B preferred stock, Series B-1 preferred stock, Series C preferred stock, Series D preferred stock and Series E preferred stock as of December 31, 2011 and 2012 would be each series' initial carrying amount, which is equal to \$0.4 million, \$2.2 million, \$3.1 million, \$10.4 million, \$22.9 million, and \$16.1 million, respectively. The redemption value of the Company's Series F preferred stock was estimated to be \$48.2 million and \$52.6 million at December 31, 2011 and 2012, respectively.

**Warrants**

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

Class	Date	Shares	Price Per Share	Expiration
Series B-1	November 5, 2003	21,000	\$ 1.500	November 2013

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Series D	November 24, 2008	58,680	\$ 2.045	November 2018
Series F	February 7, 2011	5,501,215	\$ 2.045	February 2018
Series F	January 27, 2012	146,700	\$ 2.045	January 2022

As discussed in Note 2 to these financial statements, the warrants exercisable for the Company's Series F preferred stock were classified as a liability and were required to be measured at fair value. Therefore, such warrants were recorded at the full fair value with the Company's Series F preferred stock being recorded at the residual value at the time of issuance. At each reporting date, the warrants exercisable for the Company's Series F preferred stock were recorded to fair value which is charged to other income. The fair valuation of such warrants resulted in other expense of \$0.4 million and \$0.8 for the years ended December 31, 2011 and 2012, respectively.

F-19

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****8. Stockholders Deficit****Common Stock**

The Company's common stock consists of 89.7 million authorized shares at December 31, 2011 and 2012 and 1.5 million shares issued and outstanding at December 31, 2011 and 2012, respectively.

**Shares Reserved for Future Issuance**

The following shares of common stock are reserved for future issuances are as follows:

	December 31, 2011	December 31, 2012
Conversion of preferred stock and preferred stock warrants	16,052,159	16,093,483
Stock options issued and outstanding	2,630,951	2,593,423
Restricted Stock units outstanding		43,199
Authorized for future grants under the 2012 Equity Incentive Plan	450,041	427,933
	19,133,151	19,158,038

**Stock Options**

The Company has stock option plans under which incentive or nonqualified stock options may be awarded to employees, directors and consultants. The Company's 2012 equity incentive plan (the 2012 Plan), which became effective in February 2012, is a continuation of and successor to the Company's 2002 equity incentive plan (the 2002 Plan). The Company's Board of Directors has authorized the grant of options for the purchase of up to 3,567,835 shares of the Company's common stock as of December 31, 2011 and 2012.

Under the 2012 Plan, the Company's Board of Directors determines the terms and conditions of options granted. The exercise price for stock options shall not be less than the fair market value at the date of grant, and the options expire no later than ten years from the date of grant. Options issued to employees generally vest one-fourth on the first anniversary date following the date of grant and ratably each month for the next three years. Any outstanding options that are cancelled are automatically returned to the option pool.

The 2012 Plan has an early exercise provision under which options to purchase common stock may be exercised prior to being fully vested; however, the shares issued for options exercised under the early exercise provision continue to vest under the same terms as the underlying exercised option. Upon termination of an employee prior to the vesting of such shares, the Company can either repurchase the unvested shares or let the repurchase right expire.

The Company estimates the fair value of its share-based awards to employees, directors and consultants using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of highly complex and subjective



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

F-20

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****8. Stockholders Deficit (continued)**

	Employees					
	Year Ended December 31,					
	2010		2011		2012	
Dividend yield	0.00	%	0.00	%	0.00	%
Weighted-average risk-free interest rate	2.69	%	2.85	%	0.86	%
Volatility	91.00	%	82.00	%	80.55	%
Expected term (in years)	7.0		7.0		6.0	
Weighted-average fair value per option	\$ 1.75		\$ 1.74		\$ 1.93	

	Non-Employees					
	Year Ended December 31,					
	2010		2011		2012	
Dividend yield			0.00	%	0.00	%
Weighted-average risk-free interest rate			0.40	%	0.78	%
Volatility			77.80	%	81.77	%
Expected term (in years)			2.7		5.8	
Weighted-average fair value per option			\$ 3.38		\$ 3.48	

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. For the years ended December 31, 2010, 2011 and 2012, the Company applied a forfeiture rate based on the Company's historical forfeitures.

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

	Number of Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in Years)
Balance, January 1, 2011	2,039,982	\$ 2.21	
Granted	878,990	2.34	
Exercised	(21,126 )	1.42	
Forfeited	(266,431 )	2.37	

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Balance, December 31, 2011	2,631,415	2.24	7.69
Granted	382,167	3.24	
Exercised	(16,530 )	0.82	
Expired	(102,228 )	2.63	
Forfeited	(301,401 )	1.69	
Balance, December 31, 2012	2,593,423	\$ 2.45	7.36
Exercisable at December 31, 2012	1,604,280	\$ 2.25	6.64
Vested or expected to vest at December 31, 2012	2,481,216	\$ 2.45	7.31

At December 31, 2012, the aggregate intrinsic value of options outstanding and exercisable was \$3.2 million. The total intrinsic value of options exercised was \$0.1 million, \$16,000 and \$18,000 for the years ended December 31, 2010, 2011 and 2012, respectively.

F-21

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****8. Stockholders Deficit (continued)**

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

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

	Year Ended December 31,		
	2010	2011	2012
	(in thousands)		
Research and development:			
Employee	\$ 299	\$ 315	\$ 336
Non-employee			80
General and administrative:			
Employee	454	651	921
Non-employee			59
	\$ 753	\$ 966	\$ 1,396

Cash received from option exercises under all share-based payment arrangements for 2011 and 2012, was \$30,000 and \$14,000, respectively. There was no actual tax benefit realized for the tax deductions from option exercises of the share-based payment arrangements during 2011 or 2012.

As of December 31, 2012, there was approximately \$1.7 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Company's 2012 Plan. That compensation cost is expected to be recognized over a weighted-average period of approximately 2.26 years.

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

**Restricted Stock Units**

In 2012, the Company issued restricted stock units (RSUs) to certain employees which vest based on specific performance criteria. The RSUs become immediately vested upon the earlier of (i) a change of control and (ii) the effective date of a registration statement for the Company's common stock, subject to the continuous service with the

Company at the applicable vesting event. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted.

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

	Number of Restricted Stock Units Outstanding
Balance, December 31, 2011	
Granted	48,226
Forfeited	(5,027 )
Balance, December 31, 2012	43,199

The grant date fair value of the RSUs was \$2.49 per unit. As of December 31, 2012, no compensation had been recorded as it was not considered probable that the performance criteria will be met.

TABLE OF CONTENTS

**Chimerix, Inc.**

**Notes to Financial Statements**

**8. Stockholders Deficit (continued)**

**Fair Value Estimate**

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

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

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

## 9. Related-Party Transactions

The Company paid consulting fees related to research and development activities in the amount of \$0.1 million and \$6,250 to the relatives of officers of the Company during the years ended December 31, 2010 and 2011, respectively.

No related party fees were paid during the year ended December 31, 2012.

On November 19, 2009, the Company issued a promissory note in the amount of \$0.1 million to an officer of the Company. The outstanding principal balance plus accrued interest, calculated at an annual rate of 0.71%, was repaid during 2011.

F-23

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****10. Income Taxes**

There is no provision for income taxes because the Company has incurred operating losses since inception. At December 31, 2012, the Company has concluded that it is more likely than not that the Company may not realize the benefit of its deferred tax assets due to its history of losses. Accordingly, the net deferred tax assets have been fully reserved.

In general, if the Company experiences a greater than 50% aggregate change in ownership of certain significant stockholders over a three-year period (a Section 382 ownership change), utilization of its pre-change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Internal Revenue Code (and similar state laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the net operating loss carryforwards before utilization and may be substantial.

The ability of the Company to use its net operating loss carryforwards may be limited or lost if the Company experiences a Section 382 ownership change in connection with this offering or as a result of future changes in its stock ownership. Losses from a specific period may be subject to multiple limitations, and would generally be limited by the lowest of those limitations.

The Company has determined that a Section 382 ownership change occurred in 2002, and as such, losses incurred prior to that date are subject to an annual limitation of at least \$64,000. Additionally, the Company has determined that a Section 382 ownership change occurred in 2007, and as such, losses incurred prior to that date are subject to an annual limitation of at least \$762,000. The Company evaluated Section 382 ownership changes subsequent to 2007 and concluded no additional change in ownership occurred.

The components of deferred tax assets and liabilities at December 31, 2011 and 2012 are as follows:

	December 31,	
	2011	2012
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	\$ 30,723	\$ 31,431
Research and development expenses	562	34
Capitalized Section 174 expenses	97	80
Research and development credits	941	941
Accrued bonuses	133	54
Other	411	445
Total gross deferred tax assets	32,867	32,985
Valuation allowance	(32,721 )	(32,841 )
	146	144
Deferred tax liabilities:		



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Other	(146 )	(144 )
Total deferred tax liabilities	(146 )	(144 )
Net deferred tax assets	\$	\$

At December 31, 2011, the Company has net operating loss carryforwards for federal and state tax purposes of approximately \$80.2 million and \$75.9 million, respectively. At December 31, 2012, the Company has net operating loss carryforwards for federal and state purposes of approximately \$83.4 million and \$65.8 million, respectively. The federal losses begin to expire in 2020 and the state losses begin to expire in 2018. In addition, the Company has tax credit carryforwards for federal tax purposes of approximately \$0.9 million as of December 31, 2012, which begin to expire in 2022. The future utilization of net operating

F-24

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TABLE OF CONTENTS**Chimerix, Inc.****Notes to Financial Statements****10. Income Taxes (continued)**

loss and tax credit carryforwards may be limited due to changes in ownership. Management has recorded a valuation allowance for all of the deferred tax assets due to the uncertainty of future taxable income.

The components of the net income tax benefit for the years ended December 31, 2010, 2011 and 2012 are as follows:

	December 31,		
	2010	2011	2012
	(in thousands)		
Deferred	\$ 9,559	\$ 9,115	\$ 120
Valuation allowance	(9,559 )	(9,115 )	(120 )
Net income tax benefit	\$	\$	\$

A reconciliation of the difference between the benefit for income taxes and income taxes at the statutory U.S. federal income tax rate is as follows for the years ended December 31, 2010, 2011, and 2012:

	2010		2011		2012	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
	(in thousands)					
Income tax benefit at statutory rate	\$(8,655)	34.0 %	\$(8,700)	34.0 %	\$(1,499)	34.0 %
State income taxes	(1,464)	5.8 %	(1,164)	4.6 %	(100 )	2.3 %
Research and development credits	(14 )	0.1 %	(1,169)	4.6 %		0.0 %
Permanent items	246	(1.0 )%	964	(3.8 )%	868	(19.7 )%
Provision to return adjustments	328	(1.3 )%	12	0.0 %	2	0.0 %
Effect of change in state tax rate		0.0 %	630	(2.5 )%	609	(13.9 )%
Increase in unrecognized tax benefits		0.0 %	314	(1.2 )%		0.0 %
Valuation allowance	9,559	(37.6)%	9,115	(35.7)%	120	(2.7 )%
Net benefit	\$	0.0 %	\$	0.0 %	\$	0.0 %

The Company has determined that there may be a future limitation on the Company's ability to utilize its entire federal R&D credit carryover. Therefore, the Company recognized an uncertain tax benefit associated with the federal R&D credit carryover during the year ended December 31, 2012, as follows (in thousands):

Balance at December 31, 2011	\$ 314
Increase related to 2012	
Balance at December 31, 2012	\$ 314

The Company has determined that it had no other material uncertain tax benefits for the year ended December 31, 2012. As of January 1, 2013, due to the carry forward of unutilized net operating losses and research and development credits, the Company is subject to U.S. Federal and state income tax examinations for the tax years 2000 through 2012. The Company recognizes accrued interest related to unrecognized tax benefits in interest expense and penalties in operating expense. No amounts were accrued for the payment of interest and penalties at January 1, 2013.

F-25

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TABLE OF CONTENTS

## **Chimerix, Inc.**

### **Notes to Financial Statements**

#### **11. Significant Agreements**

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

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

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

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

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

As a result of the Company meeting certain milestones and sublicense fees related to the license agreement, the Company incurred liabilities of \$0.2 million and \$0.9 million, for the years ended December 31, 2011 and 2012, respectively.

### **Biomedical Advanced Research and Development Authority**

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. The contract has been amended several times, most recently on February 21, 2013, to extend the period of performance through May 31, 2013.

Under the contract, BARDA will reimburse the Company's costs, plus pay the Company a fixed fee, for the research and development of brincidofovir as a broad-spectrum therapeutic antiviral for the treatment of

F-26

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TABLE OF CONTENTS

## Chimerix, Inc.

### Notes to Financial Statements

#### 11. Significant Agreements (continued)

smallpox infections and double-stranded DNA viruses. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods of around one year each, referred to as option segments, each of which may be exercised at BARDA's sole discretion. The Company must complete the agreed upon milestones and deliverables in each discrete work segment before the next option segment is eligible to be exercised. Under the contract as currently in effect, if each follow-on option segment is exercised by BARDA, the Company may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees.

The Company is currently completing the first option segment of the contract under which the Company may receive up to a total of \$5.0 million. If all option segments are exercised by BARDA, the term of the contract would be extended to February 15, 2016.

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

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

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

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

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

## **National Institute of Allergy and Infectious Diseases**

In September 2003, the Company was awarded a \$36.3 million grant from the NIAID to support the Company's development of an oral drug for the treatment of smallpox. The work performed under this grant resulted in the Company's selection of brincidofovir as a lead product candidate for commercial development. The grant, and the Company's activities conducted in connection therewith, were substantially complete in early 2010. However, the grant was not formally terminated until February 2011.

F-27

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TABLE OF CONTENTS

## **Chimerix, Inc.**

### **Notes to Financial Statements**

#### **12. Employee Benefit Plan**

The Company has an employee retirement plan under which eligible employees may defer a portion of their annual compensation, pursuant to Section 401(k) of the Internal Revenue Code. The Company can make discretionary contributions to the plan. For the years ended December 31, 2010, 2011 and 2012, the Company made no contributions to the plan.

#### **13. Subsequent Events**

The Company has evaluated subsequent events through March 26, 2013, the initial issuance date of these financial statements, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2012, and events which occurred subsequently but were not recognized in the financial statements.

In 2013, the Company extended two facility leases for the period beginning March 2013 and ending February 2015 and 2018. Future minimum payments under these extensions total \$0.2 million, \$0.3 million, \$0.3 million, \$0.2 million, \$0.2 million and \$40,686 in 2013, 2014, 2015, 2016, 2017 and 2018, respectively.

#### **14. Reverse Stock Split**

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

#### **15. Subsequent Events (unaudited)**

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



On May 30, 2013, the Company amended its contract with BARDA to extend the contract into the first option segment period of performance, during which the Company may receive up to a total of \$5.0 million in expense reimbursement and fees. The term of the first option segment is 12 months and is scheduled to end on May 30, 2014.

F-28

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TABLE OF CONTENTS**CHIMERIX, INC.****BALANCE SHEETS**

**(in thousands, except share and per share data)  
(unaudited)**

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$115,438	\$19,906
Short-term investments, available-for-sale	7,595	9,849
Accounts receivable	83	783
Prepaid and other current assets	3,034	983
Deferred financing costs, current portion	20	33
Total current assets	126,170	31,554
Property and equipment, net of accumulated depreciation	342	407
Deposits	22	22
Deferred financing costs, less current portion	20	48
Total assets	\$126,554	\$32,031
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$995	\$1,964
Accrued liabilities	1,471	906
Loan payable, current portion	5,584	4,753
Total current liabilities	8,050	7,623
Other long-term liabilities	341	337
Loan payable, less current portion	7,119	9,867
Redeemable convertible preferred stock warrant liability		7,512
Total liabilities	15,510	25,339
Redeemable convertible preferred stock		107,723
Stockholders' equity (deficit):		
Common stock, \$0.001 par value, 200,000,000 and 89,700,000 shares authorized at June 30, 2013 and December 31, 2012, respectively; 25,779,445 and 1,533,996 shares issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	26	3
Additional paid-in capital	258,870	
Accumulated other comprehensive loss	(1 )	(2 )
Accumulated deficit	(147,851)	(101,032)
Total stockholders' equity (deficit)	111,044	(101,031)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$126,554	\$32,031

See accompanying notes to financial statements.

F-29

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TABLE OF CONTENTS**CHIMERIX, INC.**

**STATEMENTS OF OPERATIONS AND  
COMPREHENSIVE LOSS**  
**(in thousands, except share and per share data)**  
**(unaudited)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Revenues:				
Contract revenue	\$808	\$6,205	\$2,579	\$9,283
Total revenues	808	6,205	2,579	9,283
Operating expenses:				
Research and development	6,276	9,082	13,059	16,075
General and administrative	2,188	1,545	3,725	3,120
Loss from operations	(7,656 )	(4,422 )	(14,205 )	(9,912 )
Other expense:				
Interest expense, net	(415 )	(128 )	(771 )	(237 )
Fair value adjustments to warrant liability	(4,388 )	226	(6,590 )	(1,073 )
Net loss	(12,459 )	(4,324 )	(21,566 )	(11,222 )
Other comprehensive loss:				
Unrealized gain on securities available-for-sale	1		1	4
Comprehensive loss	\$(12,458 )	\$(4,324 )	\$(21,565 )	\$(11,218 )
Net loss	(12,459 )	(4,324 )	(21,566 )	(11,222 )
Accretion of redeemable convertible preferred stock	(8,582 )	(900 )	(34,108 )	(1,800 )
Net loss attributable to common shareholders	\$(21,041 )	\$(5,224 )	\$(55,674 )	\$(13,022 )
Per share information:				
Net loss per common share, basic and diluted	\$(0.91 )	\$(3.44 )	\$(4.50 )	\$(8.58 )
Weighted-average shares outstanding, basic and diluted	23,067,201	1,518,753	12,360,125	1,518,112

See accompanying notes to financial statements.

TABLE OF CONTENTS**CHIMERIX, INC.**

**STATEMENTS OF CASH FLOWS**  
**(in thousands)**  
**(unaudited)**

	Six Months Ended June	
	30,	
	2013	2012
Operating activities:		
Net loss	\$ (21,566 )	\$ (11,222 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	135	141
Non-cash interest expense	224	54
Amortization/accretion of premium/discount on investments	149	29
Share-based compensation costs	2,589	539
Fair value measurement of redeemable convertible preferred stock warrant liability	6,590	1,073
Changes in operating assets and liabilities:		
Accounts receivable	700	692
Prepaid expenses and other current assets and deposits	(2,051 )	779
Accounts payable and accrued liabilities	(400 )	(1,672 )
Net cash used in operating activities	(13,630 )	(9,587 )
Investing Activities:		
Purchase of property and equipment	(70 )	(41 )
Purchase of short-term investments	(1,851 )	
Maturities of short-term investments	3,957	5,894
Net cash provided by investing activities	2,036	5,853
Financing Activities:		
Proceeds from exercise of stock options	55	2
Proceeds from exercise of warrant	1,537	
Proceeds from loan payable		3,000
Proceeds from initial public offering, net of offering costs	107,634	
Debt discount		(15 )
Repayment of loan payable	(2,100 )	(2,600 )
Deferred financing costs		(24 )
Net cash provided by financing activities	107,126	363
Increase (decrease) in cash and cash equivalents	95,532	(3,371 )
Cash and cash equivalents, beginning of period	19,906	13,607
Cash and cash equivalents, end of period	\$ 115,438	\$ 10,236
Supplemental cash flow information:		
Interest payments	\$ 505	\$ 107

See accompanying notes to financial statements.

F-31

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

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

**Description of Business**

Chimerix, Inc. (the Company) 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. The Company's proprietary lipid technology has given rise to two clinical-stage compounds, brincidofovir and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety in convenient, orally administered dosing regimens. Brincidofovir has shown broad-spectrum activity against double-stranded DNA viruses, including herpesviruses, adenoviruses and polyomaviruses. In the third quarter of 2013, Chimerix announced initiation of dosing in the Phase 3 SUPPRESS trial for the prevention of cytomegalovirus infection in hematopoietic cell transplant recipients. The Company recently presented results from a Phase 2 trial of brincidofovir as a preemptive therapy for adenovirus infection. Additionally, Chimerix is developing brincidofovir as a medical countermeasure against smallpox under a contract from the Biomedical Advanced Research and Development Authority (BARDA). The Company's 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.

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

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

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of the Company's financial statements requires

estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in the financial statements and accompanying notes. Although these estimates are based on knowledge of current events and actions the Company may undertake in the future, actual results may ultimately differ from these estimates and assumptions.

The accompanying interim financial statements are unaudited. The unaudited interim financial statements have been prepared in accordance with GAAP on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the Company's financial position, results of operations and cash flows for the dates and periods presented herein.

These financial statements should be read in conjunction with the financial statements and notes set forth in the Company's final prospectus dated April 10, 2013 filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission on April 11, 2013. Interim operating results are not necessarily indicative of operating results for the full year.

F-32

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**1. The Business and Summary of Significant Accounting  
Policies (continued)**

**Reclassifications**

During the second quarter of fiscal year 2013, the Company corrected the classification of its legal fees associated with patents and regulatory, license fees and rent. This resulted in a reclassification of \$721,000 from G&A expense to R&D expenses for the six months ended June 30, 2012. Such reclassifications had no effect on net loss or stockholders' deficit as previously reported.

**Cash and Cash Equivalents**

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

**Investments**

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

Available-for-sale securities are carried at fair value as determined by quoted market prices, with the unrealized gains and losses, net of tax, reported as a separate component of stockholders' deficit. Realized gains and losses are determined using the specific identification method and transactions are recorded on a settlement date basis in interest income or expense, net. Investments with original maturities beyond three months at the date of purchase and which mature on, or less than twelve months from, the balance sheet date are classified as long-term. The Company periodically reviews available-for-sale securities for other-than-temporary declines in fair value below the cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Any such declines in value judged to be other-than-temporary on available-for-sale securities are reported in interest income or expense, net. There were no such declines in value for the six months ended June 30, 2013 and the year ended December 31, 2012.

**Concentration of Credit Risk**

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

federal government.

## **Accounts Receivable**

Accounts receivable at June 30, 2013 and December 31, 2012 consisted of amounts billed and unbilled under the Company's contract with BARDA. Receivables under the BARDA contract are recorded as qualifying research activities as conducted and invoices from the Company's vendors are received. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded a charge to allowance for doubtful accounts as management believes all receivables are fully collectible.

## **Fair Value of Financial Instruments**

The carrying amounts of certain financial instruments, including accounts receivable, notes receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of such instruments. The carrying amount of borrowings under loans payable approximates its fair value based on the

F-33

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**1. The Business and Summary of Significant Accounting  
Policies (continued)**

determination that the stated rate on such loans payable is consistent with current interest rates for similar borrowing arrangements available to the Company.

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

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

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

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

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

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

The warrants issued for Series F redeemable convertible preferred stock included in the Company's 2012 financial statements are categorized as Level 3 as there are significant unobservable inputs. The valuation of the warrants at December 31, 2012 reflected a two stage process. Using a contingent claims model in combination with the Company's Series F financing, which occurred in February 2011, the fair value of total equity and all components of the Company's capital structure, including the warrants, was determined as of the time of the financing event. Using

this value as a starting point, a series of equity values and associated probabilities were calculated using simulation methodologies that incorporate both Monte Carlo and risk neutral frameworks. Based on assessments of expected returns and volatilities consistent with market practice, a distribution of equity values was produced which covered the range of values that an informed market participant might expect. These outcomes were organized into ranges and a probability calculated based on the percent of the total falling into each range. This process created a range of equity values. Using a contingent claims framework, each equity value was allocated to the various components of the capital structure including the warrants. Each warrant value was weighted by its respective probability to determine the final fair value of the warrants as of December 31, 2012. The key unobservable inputs used in the determination of the fair value were (i) volatility 79%, (ii) range of implied fair value of the Series F redeemable convertible preferred stock \$2.19 to \$2.85, (iii) time to liquidity 8 months to 5 years, and (iv) range of probabilities of liquidity event outcomes 2% to 31%. The warrants were valued again at April 10, 2013, just prior to the

F-34

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****1. The Business and Summary of Significant Accounting Policies (continued)**

Company's IPO, using a Black-Scholes valuation model. The key unobservable inputs used in determination of the fair value at that time were (i) volatility 79%, (ii) fair value of the Series F redeemable convertible preferred stock \$3.94, (iii) expected life 2.5 years, (iv) risk-free interest rate 0.24%, and (v) dividend yield 0%. As the warrants for Series F redeemable convertible preferred stock converted to warrants for common stock upon the IPO, no future valuations are necessary.

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

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

	Fair Value Measurements at June 30, 2013			
	June 30, 2013	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	(in thousands)			
Cash equivalents	\$ 115,123	\$ 115,123	\$	\$
Short-term investments	7,595		7,595	

  

	Fair Value Measurements at December 31, 2012			
	December 31, 2012	Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

	Assets (Level 1)			
	(in thousands)			
Cash equivalents	\$17,687	\$16,381	\$ 1,306	\$
Short-term investments	9,849		9,849	
Redeemable convertible preferred stock warrant liability	7,512			7,512

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

	Fair Value Measurements (Level 3) (in thousands)
Redeemable Convertible Preferred Stock Warrant Liability	
Balance at January 1, 2012	\$ 6,491
Issuance	174
Fair value increase recorded in other expense	847
Fair value at December 31, 2012	7,512
Fair value increase recorded in other expense	6,590
Reclassification of warrant liability to additional paid-in capital	(14,102 )
Fair value at June 30, 2013	\$

F-35

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****1. The Business and Summary of Significant Accounting  
Policies (continued)****Prepaid and Other Current Assets**

Prepaid and other current assets consist of the following:

	June 30, 2013	December 31, 2012
	(in thousands)	
Prepaid development expenses	\$ 2,353	\$ 486
Deferred public offering costs		273
Other prepaid and other current assets	681	224
	\$ 3,034	\$ 983

**Property and Equipment**

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

Maintenance and repairs are charged against expense as incurred.

**Impairment of Long-Lived Assets**

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

**Deferred Public Offering Costs**

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

## Deferred Rent

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

## Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2013	December 31, 2012
	(in thousands)	
Accrued compensation	\$ 512	\$ 560
Accrued development expenses	531	98
Other accrued liabilities	428	248
	\$ 1,471	\$ 906

F-36

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**1. The Business and Summary of Significant Accounting  
Policies (continued)**

**Revenue Recognition**

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

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

Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, the Company recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied. Analyzing the arrangement to identify deliverables requires the use of judgment and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation.

**Research and Development**

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

general and administrative costs.

### **Interest Expense, Net**

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

### **Income Taxes**

Deferred tax assets and liabilities are determined based on differences between the financial and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when the Company determines that it is more likely than not that some portion of a deferred tax asset will not be

F-37

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**1. The Business and Summary of Significant Accounting  
Policies (continued)**

realized. The Company has incurred operating losses from April 7, 2000 (inception) through June 30, 2013, and therefore has not recorded any current provision for income taxes.

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

**Share-Based Compensation**

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

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

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

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of converting redeemable convertible preferred stock, warrants to purchase redeemable convertible preferred stock and common stock, restricted stock and options. Diluted net loss per share of common stock is computed by dividing the net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of redeemable convertible preferred stock and warrants to purchase redeemable convertible preferred stock and common stock, and options outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock for the three months ended or the six months ended June 30, 2013 and 2012.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of converting redeemable convertible preferred stock, warrants to purchase convertible preferred stock and common stock and options to purchase common stock, as the impact of such items are anti-dilutive during periods of net loss. Shares excluded from the calculations were 4,244,971 and 11,370,551 for the three months ended June 30, 2013 and 2012, respectively, and 7,808,128 and 11,369,971 for the six months ended June 30, 2013 and 2012, respectively.

## Segments

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

## Impact of Recently Issued Accounting Standards

On February 5, 2013, the Financial Accounting Standards Board issued an amendment ASU 2013-2, Comprehensive Income (Topic 220) (ASU 2013-02) to the disclosure requirements for reporting reclassifications out of accumulated other comprehensive income (AOCI). ASU 2013-02 was effective for the

F-38

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****1. The Business and Summary of Significant Accounting Policies (continued)**

first interim or annual period beginning after December 15, 2012. The amendment requires companies to present information about reclassification adjustments from accumulated other comprehensive income to the income statement, including the income statement line items affected by the reclassification. The information must be presented in the financial statements in a single note or on the face of the financial statements. The new accounting guidance also requires the disclosure to be cross referenced to other financial statement disclosures for reclassification items that are not reclassified directly to net income in their entirety in the same reporting period. The Company adopted ASU 2013-02 in the first quarter of 2013. There was no material impact to the Company's consolidated financial position, results of operations or cash flows upon adoption of this guidance.

**2. Investments**

The following table summarizes available-for-sale securities:

	June 30, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Corporate bonds	\$ 7,596	\$	\$ (1 )	\$ 7,595
Commercial paper				
Total	\$ 7,596	\$	\$ (1 )	\$ 7,595

	December 31, 2012			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)			
Corporate bonds	\$ 8,353	\$	\$ (2 )	\$ 8,351
Commercial paper	1,498			1,498
Total	\$ 9,851	\$	\$ (2 )	\$ 9,849

All of the Company's investments as of June 30, 2013 and December 31, 2012 had maturities of one year or less.

### 3. Property and Equipment

Property and equipment consist of the following:

	June 30, 2013	December 31, 2012
	(in thousands)	
Lab equipment	\$ 1,009	\$ 958
Leasehold improvements	78	78
Computer equipment	410	393
Office furniture and equipment	214	212
	1,711	1,641
Less accumulated depreciation	(1,369 )	(1,234 )
	\$ 342	\$ 407

F-39

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**4. Loan Payable**

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

The first tranche was used to repay the remaining principal balance outstanding of \$2.6 million under a previous loan.

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

The Company met one of the financial and/or operational goals mentioned above and, in September 2012, the remaining \$12.0 million was borrowed in the second tranche. The second tranche has a six-month interest-only period followed by a thirty-two month principal and interest amortization period with interest being charged at the same rate as the first tranche. There are certain fees in accordance with the LSA which are being recorded as discounts or other long and short-term liabilities depending on the nature of the fees. The fees are being accreted through interest expense. Approximately \$37,000 and \$40,000 was recorded in interest expense for the three months ended June 30, 2013 and 2012, respectively. Approximately \$75,000 and \$80,000 was recorded in interest expense for the six months ended June 30, 2013 and 2012, respectively.

Concurrently with entering into the LSA, the Company also granted SVB a warrant to purchase shares of Series F preferred stock at a price of \$2.045 per share equal to 2% of the aggregate amount of the advances made to the Company pursuant to the LSA, divided by the exercise price. In relation to the first tranche, the warrant became exercisable to purchase an aggregate of 29,340 shares of Series F preferred stock, and in relation to the second tranche, the warrant became exercisable to purchase an additional 117,360 shares of Series F preferred stock. As discussed in Note 1 to these financial statements, the warrant is classified as a liability and is required to be measured at fair value. Therefore, the warrant was recorded as a debt discount at its fair value at the time of grant and accreted over the life of the LSA using the effective interest method. The subsequent re-valuation of the warrant (at fair value) resulted in other expense of \$114,000 and other income of \$6,000 for the three months ended June 30, 2013 and 2012, respectively, and other expense of \$171,000 and \$28,000 for the six months ended June 30, 2013 and 2012, respectively. Upon the completion of the IPO, this warrant was converted into a warrant to purchase 41,323 shares of common stock. In May 2013, SVB exercised the warrant in full and it is no longer outstanding.

**5. Commitments and Contingencies**

## Leases

The Company leases its facilities and certain office equipment under long-term non-cancelable operating leases that expire at various dates through 2018.

Rent expense under non-cancelable operating leases and other month-to-month equipment rental agreements, including common area maintenance fees, totaled approximately \$0.1 million and \$0.1 million for the three months ended June 30, 2013 and 2012, respectively, and approximately \$0.2 million and \$0.2 million for the six months ended June 30, 2013 and 2012, respectively.

F-40

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****5. Commitments and Contingencies (continued)****Significance of Revenue Source**

The Company is the recipient of federal research contract funds from BARDA. Periodic audits are required under the grant and contract agreements and certain costs may be questioned as appropriate under the agreements. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the agreements has been made as of June 30, 2013 and December 31, 2012.

**6. Redeemable Convertible Preferred Stock**

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

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

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

	Authorized Shares	Issued and Outstanding Shares
Series A	800,000	800,000
Series B	2,233,879	2,233,879
Series B-1	2,054,333	2,033,333
Series C	5,141,690	5,141,690
Series D	11,354,526	11,295,846

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Series E	7,894,871	7,894,871
Series F	40,200,000	22,004,895
Total Shares	69,679,299	51,404,514

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

F-41

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****6. Redeemable Convertible Preferred Stock (continued)****Warrants**

The following warrants for the purchase of preferred stock on a one-to-one basis were issued, outstanding and exercisable at December 31, 2012:

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

As discussed in Note 1 to these financial statements, the warrants exercisable for the Company's Series F preferred stock were classified as a liability and were required to be measured at fair value. Therefore, such warrants were recorded at the full fair value with the Company's Series F preferred stock being recorded at the residual value at the time of issuance. At each reporting date prior to the IPO, the warrants exercisable for the Company's Series F preferred stock were recorded to fair value which was charged to other income. The fair valuation of such warrants resulted in other expense of \$4.3 million and other income of \$0.2 million for the three months ended June 30, 2013 and 2012, respectively, and other expense of \$6.4 million and \$1.1 million for the six months ended June 30, 2013 and 2012, respectively. These amounts, coupled with the fair valuation of the warrants issued in relation to the Company's LSA (see note 4), total to the fair value adjustments to warrant liability amount per the statements of operations and comprehensive loss.

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

The following warrants for the purchase of common stock were issued, outstanding and exercisable at June 30, 2013:

Class	Date	Shares	Price Per Share	Expiration
Common	November 5, 2003	5,915	\$ 5.33	November 2013
Common	February 7, 2011	1,337,845	\$ 7.26	February 2018

## **7. Stockholders Equity (Deficit)**

### **Common Stock**

The Company's common stock consists of 200.0 million and 89.7 million authorized shares at June 30, 2013 and December 31, 2012, respectively, and 25.8 million and 1.5 million shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively.

F-42

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****7. Stockholders Equity (Deficit) (continued)****Shares Reserved for Future Issuance**

The following shares of common stock reserved for future issuances:

	June 30, 2013	December 31, 2012
Conversion of preferred stock and preferred stock warrants		16,093,483
Conversion of common stock warrants	1,343,760	
Stock options issued and outstanding	2,674,920	2,593,423
Restricted Stock units outstanding	102,547	43,199
Authorized for future purchases under the 2013 Employee Stock Purchase Plan	704,225	
Authorized for future grants under the 2013 Equity Incentive Plan	1,732,911	
Authorized for future grants under the 2012 Equity Incentive Plan		427,933
	6,558,363	19,158,038

**Stock Options**

In connection with the IPO, the Company adopted the 2013 Equity Incentive Plan (the 2013 Plan). The 2013 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Additionally, the 2013 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants. Initially, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2013 Plan is the sum of (i) 1,408,450 shares, plus (ii) 244,717 shares, which was the number of shares reserved for issuance under the 2012 Equity Incentive Plan (the 2012 Plan) at the time the 2013 Plan became effective, plus (iii) any shares subject to outstanding stock options or other stock awards that would have otherwise returned to the 2012 Plan (such as upon the expiration or termination of a stock award prior to vesting). Additionally, the number of shares of common stock reserved for issuance under the 2013 Plan will automatically increase on January 1 of each year, beginning on January 1, 2014 and continuing through and including January 1, 2023, by 2.5% of the total number of shares of capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2013 Plan is 2,816,901 shares. Following the effectiveness of the 2013 Plan in April 2013, no further grants were made under the 2012 Plan.

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

In February 2013 the Company's board of directors adopted the 2013 Employee Stock Purchase Plan (ESPP), which was subsequently ratified by stockholders and became effective in April 2013. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward the Company's success and that of its affiliates. The ESPP authorizes the issuance of 704,225 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each

F-43

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TABLE OF CONTENTS**CHIMERIX, INC.****NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)****7. Stockholders Equity (Deficit) (continued)**

calendar year, from January 1, 2014 through January 1, 2023 by the least of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 422,535 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986. As of the date hereof, no shares of common stock have been purchased under the ESPP.

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

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in Years)
Balance, December 31, 2012	2,593,423	\$ 2.45	7.36
Granted	184,506	6.39	
Exercised	(21,975 )	2.52	
Forfeited	(81,034 )	2.63	
Balance, June 30, 2013	2,674,920	\$ 2.71	7.03
Exercisable at June 30, 2013	1,851,699	\$ 2.28	6.29
Vested or expected to vest at June 30, 2013	2,644,743	\$ 2.71	7.00

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

	Three Months Ended June 30, 2013 2012 (in thousands)		Six Months Ended June 30, 2013 2012 (in thousands)	
Research and development:				
Employee	\$ 206	\$ 62	\$ 313	\$ 166
Non-employee	5	27	21	31
General and administrative:				
Employee	140	149	250	322
Non-employee	45	15	77	20
	\$ 396	\$ 253	\$ 661	\$ 539

## **Restricted Stock Units**

In 2013 and 2012, the Company issued RSUs to certain employees which vest based on specific performance criteria.

By their terms, the RSUs became immediately vested upon the effective date of the registration statement for the Company's common stock in connection with the IPO, subject to the continuous service with the Company at the vesting event. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted.

F-44

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**7. Stockholders Equity (Deficit) (continued)**

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

	Number of Restricted Stock Units Outstanding
Balance, December 31, 2012	43,199
Granted	59,348
Balance, June 30, 2013	102,547

As of June 30, 2013, \$1.9 million in compensation expense had been recorded as the performance criterion was met upon the completion of the IPO.

**8. Income Taxes**

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2013 as the Company incurred losses for the six month period ended June 30, 2013 and is forecasting additional losses through the 4<sup>th</sup> quarter, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2013. Therefore, no federal or state income taxes are expected and none have been recorded at this time. Income taxes have been accounted for using the liability method in accordance with FASB ASC 740.

Due to the Company's history of losses since inception, there is not enough evidence at this time to support that the Company will generate future income of a sufficient amount and nature to utilize the benefits of its net deferred tax assets. Accordingly, the deferred tax assets have been reduced by a valuation allowance, since it has been determined that it is more likely than not that all of the deferred tax assets will not be realized.

At June 30, 2013, the Company had no unrecognized tax benefits that would reduce the Company's effective tax rate if recognized.

**9. Significant Agreements**

**The Regents of the University of California**

In May 2002, the Company entered into a license agreement with The Regents of the University of California (UC) under which the Company obtained an exclusive, worldwide license to UC's patent rights in certain inventions (the UC Patent Rights) related to lipid-conjugated antiviral compounds and their use, including certain patents relating to

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

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

F-45

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**9. Significant Agreements (continued)**

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

In the event the Company sublicenses a UC Patent Right the Company is obligated to pay to UC a fee, which amount will vary depending upon the size of any upfront payment the Company receives and the clinical development stage of the compound being sublicensed, but which could be up to approximately 50% of the sublicense fee in certain circumstances. With respect to brincidofovir or CMX157, the fee payable to UC will not exceed 5% and 10% of the sublicense fee, respectively. In addition, the Company will also be required to pay to UC a low single digit sublicense royalty on net sales of products that use the sublicensed UC Patent Rights, but in no event will the Company be required to pay more than 50% of the royalties it receives in connection with the relevant sublicense. Any such royalty payment will be reduced by other payments the Company is required to make to third parties until a minimum royalty has been reached.

As a result of meeting certain milestones and sublicense fees related to the license agreement, the Company recognized expenses of \$0.9 million for the year ended December 31, 2012. The Company did not recognize expenses under this agreement for the six months ended June 30, 2013.

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

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. The contract has been amended several times, most recently on May 30, 2013, to extend the contract into the first option segment period of performance.

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

The Company is currently performing under the first option segment of the contract during which the Company may receive up to a total of \$5.0 million in expense reimbursement and fees. The term of the first option segment is 12 months and is scheduled to end on May 30, 2014.

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

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

As additional consideration, the Company is eligible to receive up to a total of \$151.0 million in milestone payments if certain development and regulatory milestones are achieved by Merck for products

F-46

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TABLE OF CONTENTS

**CHIMERIX, INC.**

**NOTES TO THE FINANCIAL STATEMENTS  
(unaudited)**

**9. Significant Agreements (continued)**

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

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

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

F-47

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TABLE OF CONTENTS