

CHIMERIX INC  
Form 10-Q  
November 14, 2013

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended September 30, 2013**

**OR**

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

**For the transition period from                      to**

**Commission file number: 001-35867**

**CHIMERIX, INC.**

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

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**Delaware**

(State or Other Jurisdiction of Incorporation or  
Organization)

**33-0903395**

(I.R.S. Employer Identification No.)

**2505 Meridian Parkway, Suite 340**

**Durham, North Carolina**

(Address of Principal Executive Offices)

**27713**

(Zip Code)

**(919) 806-1074**

(Registrant's Telephone Number, Including Area Code)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of November 1, 2013, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 26,420,393.



**CHIMERIX, INC.**

**FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2013**

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**PART I — FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CHIMERIX, INC.****BALANCE SHEETS****(in thousands, except share and per share data)****(unaudited)**

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 115,891	\$ 19,906
Short-term investments, available-for-sale	1,004	9,849
Accounts receivable	190	783
Prepaid and other current assets	2,683	983
Deferred financing costs, current portion	20	33
Total current assets	119,788	31,554
Property and equipment, net of accumulated depreciation	335	407
Deposits	20	22
Deferred financing costs, less current portion	15	48
Total assets	\$ 120,158	\$ 32,031
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,770	\$ 1,964
Accrued liabilities	1,601	906
Loan payable, current portion	5,597	4,753
Total current liabilities	8,968	7,623
Other long-term liabilities	345	337
Loan payable, less current portion	5,715	9,867
Redeemable convertible preferred stock warrant liability	—	7,512
Total liabilities	15,028	25,339
Redeemable convertible preferred stock	—	107,723

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Stockholders' equity (deficit):

Common stock, \$0.001 par value, 200,000,000 and 89,700,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 25,974,809 and 1,533,996 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	26	3	
Additional paid-in capital	259,661	—	
Accumulated other comprehensive loss		(2	)
Accumulated deficit	(154,557	)	(101,032 )
Total stockholders' equity (deficit)	105,130	(101,031	)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 120,158	\$ 32,031	

See accompanying notes to financial statements.

**CHIMERIX, INC.****STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS****(in thousands, except share and per share data)****(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenues:				
Contract revenue	\$ 912	\$ 3,411	\$ 3,491	\$ 12,694
Collaboration and licensing revenue	—	17,445	—	17,445
Total revenues	912	20,856	3,491	30,139
Operating expenses:				
Research and development	5,319	7,748	18,379	23,823
General and administrative	2,029	1,836	5,753	4,956
(Loss) income from operations	(6,436 )	11,272	(20,641 )	1,360
Other expense:				
Interest expense, net	(270 )	(130 )	(1,041 )	(367 )
Fair value adjustments to warrant liability	—	—	(6,590 )	(1,073 )
Net (loss) income	(6,706 )	11,142	(28,272 )	(80 )
Other comprehensive gain (loss):				
Unrealized gain (loss) on securities available-for-sale	1	(3 )	3	4
Comprehensive (loss) income	\$ (6,705 )	\$ 11,139	\$ (28,269 )	\$ (76 )
Per share information:				
Net (loss) income per common share, basic	\$ (0.26 )	\$ 6.70	\$ (3.69 )	\$ (1.82 )
Weighted-average shares outstanding, basic	25,866,109	1,529,442	16,911,592	1,524,489
Net (loss) income per common share, diluted	\$ (0.26 )	\$ 0.11	\$ (3.69 )	\$ (1.82 )
Weighted-average shares outstanding, diluted	25,866,109	52,933,956	16,911,592	1,524,489

See accompanying notes to financial statements.





**CHIMERIX, INC.****STATEMENTS OF CASH FLOWS****(in thousands)****(unaudited)**

	Nine Months Ended September 30,	
	2013	2012
Operating activities:		
Net loss	\$(28,272 )	\$(80 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	197	210
Non-cash interest expense	46	175
Amortization/accretion of premium/discount on investments	416	29
Share-based compensation costs	2,853	1,133
Fair value measurement of redeemable convertible preferred stock warrant liability	6,590	1,073
Changes in operating assets and liabilities:		
Accounts receivable	593	3,155
Prepaid expenses and other current assets and deposits	(1,698 )	171
Accounts payable and accrued liabilities	501	(3,093 )
Net cash (used) provided in operating activities	(18,774 )	2,773
Investing Activities:		
Purchase of property and equipment	(125 )	(120 )
Purchase of short-term investments	(1,852 )	—
Sales of short-term investments	750	—
Maturities of short-term investments	9,758	5,893
Net cash provided by investing activities	8,531	5,773
Financing Activities:		
Proceeds from exercise of stock options	582	8
Proceeds from exercise of warrant	1,537	—
Proceeds from loan payable	—	15,000
Proceeds from initial public offering, net of offering costs	107,634	—
Debt discount	—	(75 )
Repayment of loan payable	(3,525 )	(2,600 )
Deferred financing costs	—	(24 )
Net cash provided by financing activities	106,228	12,309
Increase in cash and cash equivalents	95,985	20,855
Cash and cash equivalents, beginning of period	19,906	13,607
Cash and cash equivalents, end of period	\$ 115,891	\$ 34,462
Supplemental cash flow information:		
Interest payments	\$ 862	\$ 170

See accompanying notes to financial statements.

**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 (CMX001) and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety in convenient, orally administered dosing regimens. The Company believes that brincidofovir has the potential to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by double-stranded DNA (dsDNA) viruses. Brincidofovir has shown broad-spectrum activity against dsDNA viruses, including herpesviruses, adenoviruses and polyomaviruses. Chimerix initiated the Phase 3 SUPPRESS trial in the third quarter of 2013 for the prevention of cytomegalovirus infection in hematopoietic cell transplant recipients. The Company recently completed a Phase 2 trial of brincidofovir as a preemptive therapy for adenovirus infection. Additionally, the Company 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.

On October 23, 2013, the Company completed an underwritten secondary public offering of 2,476,995 shares of common stock held by certain of the Company's existing stockholders. The Company did not issue any shares of common stock and received no proceeds in connection with such offering. The principal purposes of the offering were to facilitate an orderly distribution of shares and to increase the Company's public float.

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

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.

### ***Reclassifications***

In certain instances, amounts previously reported in the Company's 2012 financial statements have been reclassified to conform to the Company's 2013 financial statement presentation. Such reclassifications had no effect on net loss or stockholders' equity (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 nine months ended September 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 September 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 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 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 September 30, 2013			
	Quoted Prices in September 30, 2013		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Active Markets for Identical Assets (Level 1)			
	(in thousands)			
Cash equivalents	\$ 113,816	\$ 113,816	\$ —	\$ —
Short-term investments	1,004	—	1,004	—

	Fair Value Measurements at December 31, 2012			
	Quoted Prices in December 31, 2012		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	Active Markets for Identical 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 September 30, 2013	\$ —

***Prepaid and Other Current Assets***

Prepaid and other current assets consist of the following:

	September 30, 2013	December 31, 2012
	(in thousands)	
Prepaid development expenses	\$ 2,241	\$ 486
Deferred public offering costs	—	273
Other prepaid and other current assets	442	224
	\$ 2,683	\$ 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:

	September 30, 2013	December 31, 2012
	(in thousands)	
Accrued compensation	\$ 565	\$ 560
Accrued development expenses	568	98
Other accrued liabilities	468	248
	\$ 1,601	\$ 906

### ***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 realized. The Company has incurred operating losses from April 7, 2000 (inception) through September 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) Income Per Share of Common Stock***

Basic net (loss) income per share of common stock is computed by dividing net (loss) income 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. All undistributed earnings are allocated first to the preferred shareholders based on their contractual rights to dividends. This right is calculated on a pro rated basis for the portion of the period the preferred shares were outstanding. Any remaining undistributed earnings are allocated between preferred and common shares on a weighted average basis. Prior to the IPO, the Company had common stock and redeemable convertible preferred stock outstanding.

Therefore, for the 2012 periods presented, the Company applied the two-class method for calculating net (loss) income per share since it has issued securities, other than common stock, that contractually entitle the holder to participate in dividends and earnings of the Company. This calculation does not assume that preferred shares are converted into common shares. The undistributed earnings are allocated first to the preferred shareholders based on their contractual rights to dividends. This right is calculated on a pro rated basis for the portion of the period the preferred shares were outstanding. Any remaining undistributed earnings are allocated between preferred and common shares on a weighted average basis.

For periods in which the Company has a net loss, such as for the three months ended September 30, 2013 and the nine months ended September 30, 2013 and 2012, basic and diluted earnings per share are the same. Consequently, diluted earnings per share for these periods are not presented separately in the table below.



The computation for basic and diluted EPS was as follows (in thousands, except share and per share data):

	Three Months Ended September 30, 2013		Nine Months Ended September 30, 2012	
	(in thousands, except per share data)		(in thousands, except per share data)	
Numerator for basic (loss) income per share:				
Net (loss) income	\$ (6,706	)	\$ 11,142	)
Accretion of redeemable convertible preferred stock	—		(900	)
Net income allocated to participating preferred shareholders	—		(4,271	)
Net (loss) income attributable to common shareholders	\$ (6,706	)	\$ 5,971	)
Numerator for diluted income per share:				
Net income			\$ 11,142	
Accretion of redeemable convertible preferred stock			(900	)
Net income allocated to participating preferred shareholders			(4,271	)
Net income attributable to common shareholders			\$ 5,971	
Denominator for basic and diluted loss (income) per share:				
Weighted average shares for basic EPS	25,866,109		1,529,442	
Weighted average effect of dilutive securities			51,404,514	
Weighted average shares for diluted EPS			52,933,956	
Basic EPS	\$ (0.26	)	\$ 6.70	)
Diluted EPS	\$ (0.26	)	\$ 0.11	)
			\$ (3.69	)
			\$ (1.82	)

Potentially dilutive securities excluded from the calculation of diluted net (loss) income per share attributable to common shareholders because to do so would be anti-dilutive were 3,253,638 and 11,304,141 for the three months ended September 30, 2013 and 2012, respectively, and 6,153,403 and 11,302,008 for the nine months ended September 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 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:

<b>September 30, 2013</b>				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(in thousands)				
Corporate bonds	\$ 1,004	\$ —	\$ —	\$ 1,004
Commercial paper	—	—	—	—
<b>Total</b>	<b>\$ 1,004</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 1,004</b>
<b>December 31, 2012</b>				
	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
<b>Total</b>	<b>\$ 9,851</b>	<b>\$ —</b>	<b>\$ (2)</b>	<b>\$ 9,849</b>

All of the Company's investments as of September 30, 2013 and December 31, 2012 had maturities of one year or less.

## 3. Property and Equipment

Property and equipment consist of the following:

	September 30, 2013	December 31, 2012
(in thousands)		
Lab equipment	\$ 1,032	\$ 958
Leasehold improvements	78	78
Computer equipment	429	393
Office furniture and equipment	227	212
	1,766	1,641

Less accumulated depreciation	(1,431 )	(1,234 )
	\$ 335	\$ 407

#### 4. Loan Payable

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

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

The Company met one of the financial and/or operational goals mentioned above and, in September 2012, the remaining \$12.0 million was borrowed in the second tranche. The second tranche has a six-month interest-only period followed by a 32 month principal and interest amortization period with interest being charged at the same rate as the first tranche. There are certain fees in accordance with the LSA which are being recorded as discounts or other long and short-term liabilities depending on the nature of the fees. The fees are being accreted through interest expense. Approximately \$34,000 and \$31,000 was included in interest expense for the three months ended September 30, 2013 and 2012, respectively. Approximately \$109,000 and \$111,000 was included in interest expense for the nine months ended September 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, 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 no expense for the three months ended September 30, 2013 and 2012, and other expense of \$171,000 and \$28,000 for the nine months ended September 30, 2013 and 2012, respectively. Upon the completion of the Company's 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 September 30, 2013 and 2012, respectively, and approximately \$0.4 million and \$0.3 million for the nine

months ended September 30, 2013 and 2012, respectively.

*Significance of Revenue Source*

The Company is the recipient of federal research contract funds from BARDA. Periodic audits are required under the grant and contract agreements and certain costs may be questioned as appropriate under the agreements. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the agreements has been made as of September 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 Company's IPO, these warrants were converted into warrants to purchase an aggregate of 1,549,628 shares of common stock at an exercise price of \$7.26 per share. The warrants are exercisable at any time and expire on February 4, 2018.

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

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

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

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

### *Warrants*

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The following warrants for the purchase of preferred stock on a one-to-one basis were issued, outstanding and exercisable at December 31, 2012:

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



As discussed in Note 1, the warrants exercisable for the Company's Series F preferred stock were classified as a liability and were required to be measured at fair value. Therefore, such warrants were recorded at the full fair value with the Company's Series F preferred stock being recorded at the residual value at the time of issuance. At each reporting date prior to the Company's IPO, the warrants exercisable for the Company's Series F preferred stock were recorded to fair value which was charged to other income. For the three months ended September 30, 2013 and 2012 there was no expense related to the valuation of the warrants. For the nine months ended September 30, 2013 and 2012, the Company recorded an expense of \$6.4 million and \$1.1 million, respectively, related to the valuation of the warrants. These amounts, coupled with the fair valuation of the warrants issued in relation to the Company's LSA (see note 4), total to the fair value adjustments to warrant liability amount per the statements of operations and comprehensive loss.

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

The following warrants for the purchase of common stock were issued, outstanding and exercisable at September 30, 2013:

<b>Class</b>	<b>Date</b>	<b>Shares</b>	<b>Price Per Share</b>	<b>Expiration</b>
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 September 30, 2013 and December 31, 2012, respectively, and 26.0 million and 1.5 million shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively.

### ***Shares Reserved for Future Issuance***

The following shares of common stock reserved for future issuances:

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	September 30, 2013	December 31, 2012
Conversion of preferred stock and preferred stock warrants	—	16,093,483
Exercise of common stock warrants	1,343,760	—
Stock options issued and outstanding	2,492,940	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	1,719,525	—
Authorized for future grants under the 2012 Equity Incentive Plan	—	427,933
	6,362,997	19,158,038

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### *Stock Options*

In connection with the Company's IPO, the Company adopted the 2013 Equity Incentive Plan (the 2013 Plan). The 2013 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit (RSU) awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Additionally, the 2013 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants. Initially, the aggregate number of shares of common stock that may be issued pursuant to stock awards under the 2013 Plan is the sum of (i) 1,408,450 shares, plus (ii) 244,717 shares, which was the number of shares reserved for issuance under the 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 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	241,313	9.63	—
Exercised	(217,338 )	2.68	—
Expired or Canceled	(2,816 )	1.56	—
Forfeited	(121,642 )	2.54	—
Balance, September 30, 2013	2,492,940	\$ 3.12	6.82
Exercisable at September 30, 2013	1,759,426	\$ 2.25	6.03
Vested or expected to vest at September 30, 2013	2,515,820	\$ 2.98	6.80

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(in thousands)		(in thousands)	
Research and development:				
Employee	\$ 109	\$ 68	\$ 422	\$ 234
Non-employee	7	28	28	59
General and administrative:				
Employee	100	459	350	781
Non-employee	48	39	125	59
	\$ 264	\$ 594	\$ 925	\$ 1,133

### ***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.

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, September 30, 2013	102,547

In April 2013, \$1.9 million in compensation expense had been recorded as the performance criterion was met upon the completion of the Company's 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 nine month period ended September 30, 2013 and is forecasting additional losses through the 4th 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 September 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.

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 three or nine months ended September 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 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.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2012 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission (SEC) on April 10, 2013 relating to our registration statement on Form S-1/A (File No. 333-187145) for our initial public offering.*

### **Forward-Looking Statements**

*The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item IA, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.*

### **OVERVIEW**

We are 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 lipid acyclic nucleoside phosphonates, brincidofovir (CMX001) and CMX157, which have demonstrated the potential for enhanced antiviral activity and safety in convenient, orally administered dosing regimens. We believe that brincidofovir has the potential to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by double-stranded DNA (dsDNA) viruses. Brincidofovir has shown broad-spectrum activity against dsDNA viruses, including herpesviruses, adenoviruses and polyomaviruses. We initiated the Phase 3 SUPPRESS trial in the third quarter of 2013 for the prevention of cytomegalovirus (CMV) infection in hematopoietic cell transplant (HCT) recipients. We recently completed a Phase 2 trial of brincidofovir as a preemptive therapy for adenovirus (AdV) infection. Additionally, we

are developing brincidofovir as a medical countermeasure against smallpox under a contract from the Biomedical Advanced Research and Development Authority (BARDA). Our second product candidate, CMX157, an oral nucleotide analog lipid-conjugate for the treatment of HIV infection, was licensed to Merck, Sharpe & Dohme Corp. (Merck) in July 2012.

### ***Recent Developments***

#### **Brincidofovir for the Prevention of CMV Infection**

We initiated our Phase 3 SUPPRESS trial of brincidofovir for the prevention of CMV in HCT recipients, also known as bone marrow transplant recipients. CMV, a dsDNA virus, causes life-threatening infections in patients whose immune systems are compromised after receiving a transplant or other therapies. Enrollment of the planned 450 subjects is on-track to deliver pivotal data in mid-2015. Positive results from SUPPRESS would be supportive of Accelerated Approval of brincidofovir for the prevention of CMV, the first approval of an antiviral for the prevention of CMV in HCT recipients.

Results from Study 201, our Phase 2 study that evaluated brincidofovir for the prevention of CMV in 230 HCT recipients, were published in the September 26, 2013 issue of the *New England Journal of Medicine*. This publication highlights the importance of brincidofovir and its potential to change the standard of care in this area of high unmet medical need.

#### **Brincidofovir as Preemptive Therapy for AdV**

Data from Study 202, our Phase 2 study of brincidofovir as a preemptive therapy for AdV infection, were presented during an oral, late-breaker session at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 2013. The results showed potential clinical benefit in reducing progression to AdV disease and all-cause mortality. The rates of adverse events leading to discontinuation were the same between the brincidofovir and placebo cohorts, and there were no new safety findings for brincidofovir.

We are in discussions with key opinion leaders and the U.S. Food and Drug Administration (FDA) regarding next steps for the AdV program and brincidofovir's overall pediatric program.

· Issuance of Additional Composition of Matter Patent Covering Brincidofovir

The United States Patent and Trademark Office issued U.S Patent No. 8,569,321 to Chimerix covering a method of synthesis and a morphic form of brincidofovir. With the addition of this most recent patent, composition of matter coverage for brincidofovir in the U.S is expected to extend to August 2031.

#### **Secondary Public Offering of Common Stock**

We completed a secondary public offering of 2,476,995 shares of common stock held by certain existing stockholders on October 23, 2013. We did not issue any shares of common stock and received no proceeds in connection with this offering. The principal purposes of the offering were to facilitate an orderly distribution of shares and increase our public float.

## **FINANCIAL OVERVIEW**

### ***Revenues***

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

In February 2011, we entered into a contract with BARDA, a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods of approximately one year each, referred to as option segments. The contract is a cost plus fixed fee development contract. Under the contract as currently in effect, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees. We are currently performing under the first option segment of the contract during which we may receive up to a total of \$5.0 million in expense reimbursement and fees. As of September 30, 2013, we had recognized revenue in aggregate of \$31.8 million with respect to the base performance segment and first extension period.

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

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

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

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

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

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



- Payments to third-party manufacturers, which produce, test and package our drug substance and drug product (including continued testing of process validation and stability); and
- Costs related to legal and compliance with regulatory requirements.

From our inception through September 30, 2013, we have incurred approximately \$147.3 million in research and development expenses, of which \$115.6 million relates to our development of brincidofovir. We plan to increase our research and development expenses for the foreseeable future as we continue development of brincidofovir for the prevention of CMV infection in HCT recipients and other indications and to advance further the development of our other product candidates, subject to the availability of additional funding.

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

	Nine months Ended September 30,	
	2013	2012
	(unaudited)	
	(in thousands)	
Direct research and development expense	\$ 10,098	\$ 16,711
Personnel costs	6,830	4,327
Indirect research and development expense	1,451	2,785
	\$ 18,379	\$ 23,823

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 tablets. In June 2013, we initiated performance under the first option segment of the contract with BARDA.

### *General and Administrative Expenses*

General and administrative expenses consist primarily of salaries and related costs for employees in executive, finance, corporate development, 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.

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

Interest income consists of interest earned on our cash, cash equivalents and short-term investments. We expect our interest income to increase as we invest the net proceeds from the initial public offering (IPO) of our common stock.

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

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

In conjunction with various financing transactions, we issued warrants to purchase shares of our preferred and common stock. The underlying security of the warrants related to the Series F financing and to our term loan was redeemable at the option of the security holder. As a result, these warrants were classified as a liability and were marked-to-market at each reporting date. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and are based, in part, on subjective assumptions. Non-cash changes in the fair value of the warrant liability were recorded as fair value adjustments to warrant liability. The final revaluation of the warrants occurred just 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 \$2.9 million and \$1.1 million was recognized in the nine months ended September 30, 2013 and 2012, 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

The preparation of our unaudited condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and the revenues and expenses incurred during the reported periods. 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 apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in Note 1 to our financial statements in our registration statement on Form S-1/A (File No. 333-187145) for our IPO. There have been no material changes to our critical accounting policies and estimates of those disclosed in our registration statement on Form S-1 for our IPO.

## RESULTS OF OPERATIONS

### *Comparison of the Three Months Ended September 30, 2013 and 2012*

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

	Three Months Ended September 30,		Dollar Change	% Change	
	2013	2012			
	(unaudited)				
	(in thousands)				
Revenues:					
Contract revenue	\$ 912	\$ 3,411	\$ (2,499	)	(73.3 )%
Collaboration and licensing revenue	—	17,445	(17,445	)	*
Total revenues	912	20,856	(19,944	)	(95.6 )%
Operating expenses:					
Research and development	5,319	7,748	(2,429	)	(31.4 )%
General and administrative	2,029	1,836	193		10.5 %
(Loss) income from operations	(6,436 )	11,272	(17,708	)	(157.1 )%
Interest expense, net	(270 )	(130 )	140		107.7 %
Net (loss) income	\$ (6,706 )	\$ 11,142	\$ (17,848	)	(160.2 )%

\*Not meaningful or not calculable.

### *Contract Revenue*

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For the three months ended September 30, 2013, contract revenue decreased to \$912,000 compared to \$3.4 million for the three months ended September 30, 2012. The decrease of \$2.5 million, or 73.3%, 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. In the three months ended September 30, 2012, we were fully engaged in conducting Chemistry, Manufacturing and Controls (CMC) validation and pre-clinical testing, compared to the three months ending September 30, 2013, during which we conducted pre-clinical activities.

***Collaboration and License Revenue***

Collaboration and license fee revenue for the three months ended September 30, 2012 consisted of revenue from an upfront license payment related to our collaboration and license arrangement with Merck for the exclusive rights to CMX157. The upfront license payment was fully recognized in the quarter in which execution of the definitive agreement took place. We did not have collaboration and license revenue during the three month period ended September 30, 2013.

***Research and Development Expenses***

For the three months ended September 30, 2013, our research and development expenses decreased to \$5.3 million compared to \$7.7 million for the three months ended September 30, 2012. The decrease of \$2.4 million, or 31.4%, is primarily related to the following:

- a decrease in clinical trial expenses of \$861,000 related to the completion of multiple Phase 1 and Phase 2 clinical studies in the three months period ended September 30, 2012;
- a decrease in license fee expenses of \$875,000 due to the payment of fees to UCSD associated with the exclusive license of CMX157 to Merck in July 2012; and
- a decrease in BARDA contracted work of \$546,000 related to CMC validation.

***General and Administrative Expenses***

For the three months ended September 30, 2013, our general and administrative costs increased to \$2.0 million compared to \$1.8 million for the three months ended September 30, 2012. The increase of \$193,000, or 10.5%, is related to increased costs associated with operating as a publicly traded company, including legal fees, accounting fees and non-employee director compensation.

***Interest Expense, Net***

For the three months ended September 30, 2013, our net interest expense increased to \$270,000 compared to \$130,000 for the three months ended September 30, 2012. The increase of \$140,000, or 107.7%, is attributable to the increased interest expense associated with the larger outstanding loan balance for the three months ended September 30, 2013 compared to the three months ended September 30, 2012 as we drew upon the second tranche of our loan late in the third quarter of 2012.

***Comparison of the Nine Months Ended September 30, 2013 and 2012***

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

Nine Months Ended September 30, Dollar Change % Change



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	2013	2012			
	(unaudited)				
	(in thousands)				
Revenues:					
Contract revenue	\$ 3,491	\$ 12,694	\$ (9,203	) (72.5	)%
Collaboration and licensing revenue	—	17,445	(17,445	) *	
Total revenues	3,491	30,139	(26,648	) (88.4	)%
Operating expenses:					
Research and development	18,379	23,823	(5,444	) (22.9	)%
General and administrative	5,753	4,956	797	16.1	%
(Loss) income from operations	(20,641	) 1,360	(22,001	) *	
Interest expense, net	(1,041	) (367	) 674	(183.7	)%
Fair value of warrant adjustments	(6,590	) (1,073	) 5,517	514.2	%
Net loss	\$ (28,272	) \$ (80	) \$ (28,192	) *	

\*Not meaningful or not calculable

### ***Contract Revenue***

For the nine months ended September 30, 2013, contract revenue decreased to \$3.5 million compared to \$12.7 million for the nine months ended September 30, 2012. The decrease of \$9.2 million, or 72.5%, is related to a decline in reimbursable expenses related to our contract with BARDA. During the nine months ended September 30, 2012, in connection with our performance under the base segment of the BARDA contract, we were fully engaged in clinical trials, drug product manufacturing and animal studies. The base segment of the BARDA contract ended in May 2013, and performance under the first option period began in June 2013. For the nine months ended September 30, 2013, we completed performance of the base segment of the BARDA contract and commenced performance under the first option segment.

### ***Collaboration and License Revenue***

Collaboration and license fee revenue for the nine months ended September 30, 2012 consisted of revenue from an upfront license payment related to our collaboration and license arrangement with Merck for the exclusive rights to CMX157. The upfront license payment was fully recognized in the quarter in which execution of the definitive agreement took place. We did not have collaboration and license revenue during the nine month period ended September 30, 2013.

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

For the nine months ended September 30, 2013, our research and development expenses decreased to \$18.4 million compared to \$23.8 million for the nine months ended September 30, 2012. The decrease of \$5.4 million, or 22.9%, is primarily related to:

- a decrease in BARDA contracted work of \$1.6 million related to CMC and animal studies;
- a decrease in clinical trial costs of \$2.9 million related to the completion of multiple Phase 1 and Phase 2 clinical studies;
- a decrease in license fee expenses of \$875,000 due to the payment of fees to UCSD associated with the exclusive license of CMX157 to Merck in July 2012; and
- an increase in non-cash compensation expense of \$1.4 million related to the vesting of RSUs upon completion of our IPO.

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

For the nine months ended September 30, 2013, our general and administrative costs increased to \$5.8 million compared to \$5.0 million for the nine months ended September 30, 2012. The increase of \$707,000, or 16.1%, is related to a one-time non-cash compensation expense related to the vesting of RSUs upon the completion of our IPO and an increase in professional fees associated with operations as a public company.

***Interest Expense, Net***

For the nine months ended September 30, 2013, our net interest expense increased to \$1.0 million compared to \$367,000 for the nine months ended September 30, 2012. The increase of \$674,000, or 183.7%, is attributable to the increased interest expense associated with a larger outstanding loan balance in the nine months ended September 30, 2013 compared to the nine months ended September 30, 2012 as we drew upon the second tranche of our loan late 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 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 nine months ended September 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.

**LIQUIDITY AND CAPITAL RESOURCES**

We have incurred losses since our inception in 2000 and, as of September 30, 2013, we had an accumulated deficit of \$154.6 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 September 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 \$31.8 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 September 30, 2013, we had cash, cash equivalents and short-term investments of approximately \$116.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

*Cash Flows*

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

	Nine Months Ended September 30,	
	2013	2012
	(unaudited)	
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (18,774 )	\$ 2,773
Investing activities	8,531	5,773
Financing activities	106,228	12,309
Net increase in cash	\$ 95,985	\$ 20,855

*Operating Activities*

Net cash used in operating activities of \$18.8 million for the nine months ended September 30, 2013 was primarily the result of our \$28.3 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 \$2.9 million for stock based compensation. The change in operating assets and liabilities includes an increase in prepaid expenses and other current assets and deposits of \$1.7 million primarily related to start-up activities of our Phase 3 SUPPRESS study offset by a decrease of \$593,000 in accounts receivable due to a decrease in reimbursable expenses related to our contract with BARDA and an increase in accounts payable and accrued liabilities of \$500,000. Net cash provided in operating activities of \$2.8 million during the nine months ended September 30, 2012 was primarily the result of our \$80,000 net loss, offset by the add-back of non-cash expenses of \$1.1 million related to the revaluation of our warrant liability and \$1.1 million for stock based compensation.

*Investing Activities*

Net cash provided by investing activities of \$8.5 million during the nine months ended September 30, 2013 and \$5.8 million during the nine months ended September 30, 2012 was primarily the result of maturity of certain short-term investments.

*Financing Activities*

Net cash provided by financing activities of \$106.2 million for the nine months ended September 30, 2013 was primarily the result of approximately \$107.6 million in net proceeds from the completion of our IPO and \$2.1 million from the exercise of stock options and a warrant offset by \$3.5 million in debt repayment. Net cash provided by financing activities of \$12.3 million during the nine months ended September 30, 2012 was primarily the result of loan proceeds from the first and second tranche of our loan offset by the repayment of our previous loan.

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

## **CONTRACTUAL OBLIGATIONS AND COMMITMENTS**

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments” in our final prospectus dated April 10, 2013 filed pursuant to Rule 424(b) of the Securities Act with the SEC on April 11, 2013.

### ***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.

## **ITEM 3: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

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

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

## **ITEM 4: CONTROLS AND PROCEDURES**

### ***Evaluation of Disclosure Controls and Procedures***

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or Exchange Act) as of September 30, 2013, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the three months ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1 A. RISK FACTORS.**

*You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (\*) those risk factors that reflect changes from the risk factors included in our final prospectus filed with the Securities and Exchange Commission on April 10, 2013 related to our registration statement on Form S1/A (File No. 333-187145) for our initial public offering.*

**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. We have incurred significant net losses in each year since our inception, including net losses of approximately \$28.3 million and \$80,000 for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, we had an accumulated deficit of approximately \$154.6 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.

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 completing Phase 3 clinical development;
- obtaining accelerated approval in the United States for brincidofovir, initially for the prevention of 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.

*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 increase substantially in connection with our ongoing activities, particularly as we advance our clinical programs for brincidofovir.

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

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

- significantly delay, scale back or discontinue the development or commercialization of our product candidates, including brincidofovir;
- seek corporate partners for brincidofovir or any of our other product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

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



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

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

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and will 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 September 30, 2013, we had \$11.5 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, of brincidofovir for the prevention of CMV infection in adult HCT recipients. We intend to use this trial as a basis to submit a new drug application (NDA) to the FDA under the accelerated approval pathway seeking regulatory approval to market brincidofovir in the United States and equivalent applications outside the United States. We also intend to conduct a confirmatory, second Phase 3 trial for the prevention of CMV infection in at-risk transplant recipients. This confirmatory, second trial should have a higher likelihood of clinical events in order to establish a correlation of CMV viremia (a “surrogate” endpoint) with the risk of CMV disease, and thus fulfill the requirements for traditional approval for prevention of CMV infection. Per FDA regulations, the confirmatory second trial would usually be in progress at the time of NDA submission for accelerated approval. Potential study design and patient populations for a confirmatory, second trial are under discussion with the FDA. There is no guarantee that our Phase 3 clinical trials will be completed or, if completed, will be successful. The success of brincidofovir will depend on several factors, including the following:

- successful completion of nonclinical studies and successful enrollment and completion of clinical trials;
- receipt of marketing approvals from the FDA and similar regulatory authorities outside the United States for our product candidates;
- establishing commercial manufacturing capabilities, either by building such facilities ourselves or making arrangements with third-party manufacturers;
- launching commercial sales of the product, whether alone or in collaboration with others;
- acceptance of the product by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the product following approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

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

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

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

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

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

Before obtaining regulatory approval for the sale of our product candidates, including brincidofovir, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

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

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

Negative or inconclusive results of our Phase 3 SUPPRESS trial of brincidofovir, 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 trial for the prevention of CMV in high-risk HCT recipients. These patients receive an HCT as a potential cure or remission for many cancers and genetic disorders.

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

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

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

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

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

For example, due to the specialized indication and patient population being studied in our Phase 3 clinical trial of brincidofovir, the number of study sites available to us is relatively limited, and therefore enrollment of suitable patients to participate in the trial may take longer than is typical for studies involving other indications. This may

result in a delay or unsuccessful completion of our Phase 3 clinical trial of brincidofovir.

If initiation or completion of any of our clinical trials for our product candidates, including our Phase 3 clinical trial of brincidofovir, are delayed for any of the above reasons, our development costs may increase, our approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may have more time to bring products to market before we do. Any of these events could impair our ability to generate revenues from product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

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

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

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

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified risk evaluation and mitigation strategy (REMS);
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

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

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

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

Brincidofovir and our other product candidates will also be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval, the pathway we are pursuing for an initial marketing approval of brincidofovir in the United States.



In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (cGMP), and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

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

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

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

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

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

be unrealized.

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

Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any products for which we 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 for which 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 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 custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

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

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

the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (collectively, the Health Care Reform Law), and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities.

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

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

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

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

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

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

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

## **RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES**

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

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

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

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

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

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

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.

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

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

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

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



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

Building an internal sales force involves many challenges, including:

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

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

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

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does 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 the prevention or treatment of CMV, including Merck's development of letermovir, ViroPharma Incorporated's development of maribavir and Vical Incorporated's and Astellas Pharma US, Inc.'s development of ASP0113 (TransVax). Many of our competitors have substantially greater financial, technical, commercial and other resources, such as larger research and development staff, stronger intellectual property portfolios and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

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

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

- discover and develop medicines that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates, including brincidofovir, 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. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. We cannot be sure that reimbursement will be available for brincidofovir, or any other product candidates.

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

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

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

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

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

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

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

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

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

unsuccessful.

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

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## **RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our

collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent and other proprietary rights of third parties.



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

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

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

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

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

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

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

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

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

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

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

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

## **RISKS RELATED TO OUR UNITED STATES GOVERNMENT CONTRACTS AND GRANTS**

***All of our immediately foreseeable future revenues to 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 under the first option segment of the contract. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at our discretion. There can be no assurance that we will reach agreement with BARDA on the most appropriate development pathway or that the FDA will ultimately agree with the experiments which we perform or the appropriateness of the results of these experiments for approval of brincidofovir for smallpox. In addition, there can be no assurance that any of the subsequent option segments will be exercised or that we will continue to receive revenues under this contract once the current option segment is completed. We do not anticipate continuing this program without ongoing support from BARDA.



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

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

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

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

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

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

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

FAR, and agency-specific regulations supplements to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts and implement federal procurement policy in numerous areas, such as employment practices, protection of the environment, accuracy and retention periods of records, recording and charging of costs, treatment of laboratory animals and human subject research; business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Act and the Foreign Corrupt Practices Act; export and import control laws and regulations; and laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

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

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

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

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

regulations and standards.

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

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

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

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

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



## **RISKS RELATED TO OUR BUSINESS OPERATIONS AND INDUSTRY**

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

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

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

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

As of September 30, 2013, we had 52 full-time employees. As our company matures, we expect to expand our employee base to increase our managerial, clinical, scientific and engineering, operational, sales, and marketing teams. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be

able to implement our business strategy. Our future financial performance and our ability to commercialize brincidofovir and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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

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

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

We currently carry \$5.0 million in product liability insurance covering our clinical trials. Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

## **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.\****

Based upon shares of common stock outstanding as of September 30, 2013, and after giving effect to the sale of shares by certain of our stockholders in our recently completed secondary public offering, our executive officers, directors, 5% stockholders and their affiliates beneficially owned approximately 48.9% of our voting stock. Therefore, these stockholders have the ability to substantially influence us through this ownership position. For example, these stockholders, if they choose to act together, may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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 the Company’s final prospectus filed with the Securities and Exchange Commission on April 10, 2013 and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

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

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

Pursuant to our 2013 Equity Incentive Plan (the 2013 Plan), our management is authorized to grant stock options to our employees, directors and consultants. The number of shares available for future grant under our 2013 Plan will automatically increase on January 1st each year, from January 1, 2014 through January 1, 2023, by an amount equal to 2.5% of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. In addition, our board of directors may grant or provide for the grant of rights to purchase shares of our common stock pursuant to the terms of our 2013 Employee Stock Purchase Plan (ESPP). The number of shares of our common stock reserved for issuance under our ESPP will automatically increase on January 1st each year, from January 1, 2014 through January

1, 2023, by an amount equal to the lesser of 422,535 shares or one percent of all shares of our capital stock outstanding as of December 31st of the preceding calendar year, subject to the ability of our board of directors to take action to reduce the size of such increase in any given year. Unless our board of directors elects not to increase the number of shares underlying our 2013 Plan and ESPP each year, our stockholders may experience additional dilution, which could cause our stock price to fall.



*A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.\**

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

A substantial number of our existing stockholders, optionholders, restricted stock unit (RSU) holders and warrant holders are subject to lock-up agreements with the underwriters of our recently completed secondary public offering that restrict their ability to transfer shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock for at least 90 days from the date of our final prospectus filed with the SEC on October 18, 2013.

The lock-up agreements limit the number of shares of common stock that may be sold immediately following our secondary public offering. As of November 1, 2013, there were 26,420,393 shares of stock outstanding. Subject to certain limitations, approximately 12,449,849 shares will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the “Shares Eligible for Future Sale” section of our final prospectus filed with the SEC on October 18, 2013. In addition, shares issued or issuable upon exercise of options, RSUs and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 90-day lock-up arrangement described above. At any time after 90 days following our recently completed secondary public offering holders of the registrable securities then outstanding, 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. 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 held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our equity compensation plans. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the “Underwriting” section of our final prospectus filed with the SEC on October 18, 2013.



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

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

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

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

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

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

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

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

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

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

- authorizing the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- allowing the authorized number of our directors to be changed only by resolution of our board of directors;
- limiting the removal of directors;
- creating a staggered board of directors;
- requiring that stockholder actions must be effected at a duly called stockholder meeting and prohibiting stockholder actions by written consent;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at duly called stockholder meetings.

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

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

## **Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

From January 1, 2013 to September 30, 2013, we issued RSUs under our 2012 Equity Incentive Plan (the 2012 Plan) pursuant to which 59,348 shares of common stock are issuable to certain of our employees and during the same period we granted stock options under the 2012 Plan to purchase 184,506 shares of common stock to certain of our employees and directors, having exercise prices ranging from \$5.05 to \$7.57 per share. None of these options to purchase shares of common stock have been exercised through September 30, 2013.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act of 1933, as amended, as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. There were no underwriters employed in connection with any of the transactions set forth above.

### ***Purchase of Equity Securities***

We did not purchase any of our registered securities during the period covered by this Quarterly Report on Form 10-Q.

### ***Use of Proceeds***

#### ***Initial Public Offering***

We commenced our IPO pursuant to a registration statement on Form S-1 (File No. 333-187145) that was declared effective by the SEC on April 10, 2013 and registered an aggregate of 8,418,000 shares of our common stock for sale to the public at price of \$14.00 per share and an aggregate offering price of approximately \$117.9 million. On April 10, 2013, we sold 7,320,000 shares of our common stock to the public at a price of \$14.00 per share for an aggregate gross offering price of approximately \$102.5 million. In addition, 1,098,000 shares were sold pursuant to the underwriter's over-allotment option at a price of \$14.00 per share for additional gross proceeds of approximately \$15.4 million. On April 16, 2013, we completed the IPO. Morgan Stanley and Cowen and Company acted as joint book-running managers for the offering, and William Blair and Lazard Capital Markets served as co-managers for the offering.

The underwriting discounts and commissions connected with the offering totaled approximately \$8.2 million. We incurred additional costs of approximately \$2.1 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately \$10.3 million. Thus, net

offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were \$107.6 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents, money market funds and government agency securities. We intend to continue to invest these funds in the future in some combination of short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We plan to use the net proceeds from our IPO to fund clinical and research and development costs for brincidofovir and for working capital and other general corporate purposes.

Our expected use of net proceeds from our IPO represents our current intentions based upon our present plans and business condition. We cannot predict with certainty all of the particular uses for our current funds, or the amounts that we will actually spend on the uses set forth above.

The amounts and timing of our actual use of these funds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs, the amount and timing of additional revenues, if any, received from our collaboration and licensing agreement with Merck, whether we are able to enter into future licensing arrangements, and whether we are able to extend our agreement with BARDA. As a result, our management will have broad discretion in the application of these funds, and investors will be relying on our judgment regarding the application of the net proceeds of the offering.



### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 6. EXHIBITS**

The following exhibits are filed as part of this report:

<b>Number</b>	<b>Description</b>
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3.1(1)	Amended and Restated Certificate of Incorporation of Chimerix, Inc.
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3.2(1)	Amended and Restated Bylaws of Chimerix, Inc.
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4.1(2)	Form of Common Stock Certificate of the Registrant.
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4.2(2)	Form of Warrant to Purchase Stock issued to participants in the Registrant's Series F Preferred Stock financing dated February 7, 2011.
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4.3(2)	Warrant to Purchase Series F Preferred Stock issued to Silicon Valley Bank on January 27, 2012.
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4.4(2)	Amended and Restated Investor Rights Agreement dated February 7, 2011 by and among the Registrant and certain of its stockholders.
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31.1

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Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

31.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.

32.1 Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2 Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant Section 906 of the Sarbanes-Oxley Act of 2002.

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101.INS\* XBRL Instance Document.

101.SCH\* XBRL Taxonomy Extension Schema Document.

101.CAL\* XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF\* XBRL Taxonomy Extension Definition Linkbase Document.

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**Number Description**

101.LAB\* XBRL Taxonomy Extension Label Linkbase Document.

101.PRE\* XBRL Taxonomy Extension Presentation Linkbase Document.

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

(1) Incorporated by reference to Chimerix, Inc.’s Current Report on Form 8-K, filed on April 16, 2013.

(2) Incorporated by reference to Chimerix, Inc.’s Registration Statement on Form S-1 (No. 333-187145), as amended.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

### CHIMERIX, INC.

November 14, 2013 By: /s/ Kenneth I. Moch  
Kenneth I. Moch  
President and Chief Executive Officer

November 14, 2013 By: /s/ Timothy W. Trost  
Timothy W. Trost  
Senior Vice President, Chief Financial Officer and Corporate Secretary