CHIMERIX INC Form 10-Q May 09, 2014

# **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 $^{\rm x}{\rm ACT}$ OF 1934

For the quarterly period ended March 31, 2014

OR

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

For the transition period from to

Commission file number: 001-35867

CHIMERIX, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	33-0903395
(State or Other Jurisdiction of Incorporation or	
	(I.R.S. Employer Identification No.)
Organization)	
2505 Meridian Parkway, Suite 340	
Durham, North Carolina	27713
(Address of Principal Executive Offices)	(Zip Code)

(919) 806-1074

(Registrant's Telephone Number, Including Area Code)

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 x No<sup> $\cdot$ </sup>

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 x No o

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 o

Accelerated filer o

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company o

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

As of May 1, 2014, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 26,965,570.

# FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2014

# INDEX

	Page
<u>Part I — Financial Informati</u> on	3
Item 1. Financial Statements	3
Balance Sheets as of March 31, 2014 and December 31, 2013 (unaudited)	3
Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2014 and 2013	4
(unaudited)	4
Statements of Cash Flows for the Three Months Ended March 31, 2014 and 2013 (unaudited)	5
Notes to Financial Statements (unaudited)	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
<u>Part II — Other Informati</u> on	25
Item 1. Legal Proceedings	25
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	64
Item 3. Defaults Upon Senior Securities	65
Item 4. Mine Safety Disclosures	65
Item 5. Other Information	65
Item 6. Exhibits	65
Signatures	67

# PART I — FINANCIAL INFORMATION

# **ITEM 1. FINANCIAL STATEMENTS**

# CHIMERIX, INC.

# **BALANCE SHEETS**

# (in thousands, except share and per share data)

# (unaudited)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$37,421	\$ 109,976
Short-term investments, available-for-sale	62,500	—
Accounts receivable	89	248
Prepaid and other current assets	1,691	2,765
Deferred financing costs, current portion	20	20
Total current assets	101,721	113,009
Property and equipment, net of accumulated depreciation	387	338
Deposits	32	30
Deferred financing costs, less current portion	13	10
Total assets	\$102,153	\$ 113,387
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$1,806	\$ 2,214
Accrued liabilities	1,894	2,420
Loan payable, current portion	5,590	5,573
Total current liabilities	9,290	10,207
Other long-term liabilities	350	347
Loan payable, less current portion	2,889	4,294
Total liabilities	12,529	14,848

Stockholders' equity:

Preferred stock, \$0.001 par value, 10,000,000 shares authorized at March 31, 2014		
and December 31, 2013; no shares issued and outstanding as of March 31, 2014 and		_
December 31, 2013		
Common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2014		
and December 31, 2013; 26,932,607 and 26,664,972 shares issued and outstanding	27	26
as of March 31, 2014 and December 31, 2013, respectively		
Additional paid-in capital	262,739	261,243
Accumulated other comprehensive loss	(32)	
Accumulated deficit	(173,110)	(162,730
Total stockholders' equity	89,624	98,539
Total liabilities and stockholders' equity	\$102,153 \$	113,387
as of March 31, 2014 and December 31, 2013, respectively Additional paid-in capital Accumulated other comprehensive loss Accumulated deficit Total stockholders' equity	262,739 (32) (173,110) 89,624	261,243 

See accompanying notes to financial statements.

)

# STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

# (in thousands, except share and per share data)

# (unaudited)

	Three Months Ended March 31,		
	2014	2013	
Revenues:			
Contract revenue	\$780	\$1,771	
Total revenues	780	1,771	
Operating expenses:			
Research and development	8,292	6,783	
General and administrative	2,672	1,536	
Loss from operations	(10,184	) (6,548 )	
Other expense:			
Interest expense, net	(196	) (356 )	
Fair value adjustments to warrant liability		(2,203)	
Net loss	(10,380	) (9,107 )	
Other comprehensive loss:			
Unrealized loss on securities available-for-sale	(32	) (1 )	
Comprehensive loss	\$(10,412	) \$(9,108 )	
Net loss	\$(10,380	) \$(9,107 )	
Accretion of redeemable convertible preferred stock	—	(25,525)	
Net loss attributable to common stockholders	(10,380	) (34,632 )	
Per share information:			
Net loss per common share, basic and diluted	\$(0.39	) \$(22.58)	
Weighted-average shares outstanding, basic and diluted	26,762,264	1,534,016	

See accompanying notes to financial statements.

# STATEMENTS OF CASH FLOWS

# (in thousands)

# (unaudited)

	Three Mor Ended March 31,	
	2014	2013
Operating activities:		
Net loss	\$(10,380)	\$(9,107)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	50	68
Non-cash interest expense	42	65
Amortization/accretion of premium/discount on investments	108	74
Share-based compensation costs	772	265
Deferred lease obligation	3	
Fair value measurement of redeemable convertible preferred stock warrant liability	—	2,203
Changes in operating assets and liabilities:		
Accounts receivable	159	(445)
Prepaid expenses and other current assets and deposits	1,064	(722)
Accounts payable and accrued liabilities	(934)	1,554
Net cash used by operating activities	(9,116)	(6,045)
Investing activities:		
Purchase of property and equipment	(99)	(52)
Purchase of short-term investments	(62,640)	(1,853)
Maturities of short-term investments		750
Net cash used by investing activities	(62,739)	(1,155)
Financing activities:		
Proceeds from exercise of stock options	496	8
Proceeds from employee stock purchase plan issuance	229	
Repayment of loan payable	(1,425)	(675)
Net cash used by financing activities	(700)	(667)
Decrease in cash and cash equivalents	(72,555)	(7,867)
Cash and cash equivalents, beginning of period	109,976	
Cash and cash equivalents, end of period	\$37,421	\$12,039
Supplemental cash flow information:		
Interest payments	\$198	\$44

See accompanying notes to financial statements.

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

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

On April 10, 2013, the Company completed the initial public offering (IPO) of its common stock pursuant to a registration statement on Form S-1. In the IPO, the Company sold an aggregate of 7,320,000 shares of common stock under the registration statement at a public offering price of \$14.00 per share. Net proceeds were approximately \$93.3 million, after deducting underwriting discounts and commissions of \$7.1 million and offering expenses of \$2.1 million. Upon the completion of the IPO, all outstanding shares of the Company's redeemable convertible preferred stock and dividends accrued on Series F redeemable convertible preferred stock were converted into 15,556,091 shares of common stock and all outstanding warrants to purchase redeemable convertible preferred stock were converted into warrants to purchase 1,613,395 shares of common stock. On April 16, 2013, the underwriters exercised the full over-allotment option pursuant to which the Company sold an additional 1,098,000 shares of common stock 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 generally accepted accounting principles (GAAP) in the United States of America. 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 for the year ended December 31, 2013 and notes thereto set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 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 2013 financial statements have been reclassified to conform to the Company's 2014 financial statement presentation. Such reclassifications had no effect on net loss or stockholders' equity 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, commercial paper and certificates of deposit. 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 equity. 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 short-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 three months ended March 31, 2014 and the year ended December 31, 2013.

#### **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 March 31, 2014 and December 31, 2013 consisted of amounts billed and unbilled under the Company's contract with the Biomedical Advanced Research and Development Authority (BARDA). Receivables under the BARDA contract are recorded as qualifying research activities as conducted and invoices from the Company's vendors are received. The Company carries its accounts receivable at cost less an allowance for doubtful accounts. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables. The Company does not accrue interest on trade receivables. If accounts become uncollectible, they will be written off through a charge to the allowance for doubtful accounts. The Company has not recorded a charge to allowance for doubtful accounts as management believes all receivables are fully collectible.

### Fair Value of Financial Instruments

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

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

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

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

*Level* 2 — Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for  $\cdot$  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.

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.

The following table presents information about certain assets and liabilities measured at fair value on a recurring basis:

	March 31, 2014	Fair Valu Measurer March 31 Quoted Prices in Active Markets for Identical Assets (Level 1)	nents at	Significant Unobserva Inputs (Level 3)	
	(in thousa				
Cash equivalents	\$36,509	\$28,560		\$	
Short-term investments	62,500		62,500		

	December 31, 2013	Fair Value Measuremen December 31 Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Unobservab Inputs (Level 3)	le
	(in thousan				
Cash equivalents	\$107,349	\$107,349	\$ —	- \$	—

Short-term investments consist of corporate bonds, commercial paper and certificates of deposit.

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

Prepaid and other current assets consist of the following:

	March 31, 2014	December 31, 2013
	(in thou	sands)
Prepaid development expenses	\$1,086	\$ 2,433
Interest receivable	341	
Other prepaid and other current assets	264	332
	\$1,691	\$ 2,765

#### **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 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:

	March 31, 2014	December 31, 2013
	(in thou	sands)
Accrued compensation	\$1,106	\$ 1,779
Accrued development expenses	594	350
Other accrued liabilities	194	291
	\$1,894	\$ 2,420

#### **Revenue Recognition**

The Company's revenues generally consist of contract revenue – revenue generated under federal contracts. 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.

# Clinical Trial Accruals/Prepaids

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. Depending on amounts paid to the contract research organization and other third-party vendors as compared to actual expenses incurred, there might be a prepaid balance recorded as a prepaid asset. The Company determines accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, the Company adjusts its rate of clinical trial expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too

high or too low for any particular period. Through March 31, 2014, there had been no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company's clinical trial accrual is dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

### **Research and Development**

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

# Interest Expense, Net

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

# Income Taxes

Deferred tax assets and liabilities are determined based on differences between the financial and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when the Company determines that it is more likely than not that some portion of a deferred tax asset will not be realized. The Company has incurred operating losses from April 7, 2000 (inception) through March 31, 2014, 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 Diluted Net Loss Per Common Share

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of converting redeemable convertible preferred stock, warrants to purchase redeemable convertible preferred stock and common stock, restricted stock and options. Diluted net loss per common share is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of redeemable convertible preferred stock, and options outstanding during the period plus the potential dilutive effects of redeemable convertible preferred stock, and options outstanding during the period calculated in accordance with the treasury stock method, but are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during the periods of net loss, there was no difference between basic and diluted loss per share of common stock for the three months ended March 31, 2014 and 2013.

The calculation of weighted-average diluted shares outstanding excludes the dilutive effect of converting redeemable convertible preferred stock, warrants to purchase convertible preferred stock and options to purchase common stock, as the impact of such items are anti-dilutive during periods of net loss. Shares excluded from the calculations were 3,100,454 and 11,511,182 for the three months ended March 31, 2014 and 2013, respectively.

# Segments

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

#### Impact of Recently Issued Accounting Standards

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

# 2. Investments

The following table summarizes available-for-sale securities:

	March 31	, 2014	1				
	Amortize	Gros	s	Gı	OSS		Estimated
	Cost	Unre	alized	Uı	nrealized	1	Fair
	Cost	Gain	S	Lo	osses		Value
	(in thousa	ands)					
Corporate bonds	\$35,258	\$	1	\$	(27	)	\$35,232
Commercial paper	22,474		1				22,475
Certificates of deposit	4,800				(7	)	4,793
Total	\$62,532	\$	2	\$	(34	)	\$62,500

The Company had no short or long-term investments at December 31, 2013. All of the Company's investments as of March 31, 2014 had maturities of one year or less.

# 3. Property and Equipment

Property and equipment consist of the following:

	March 31, 2014 (in thousa	December 31, 2013
<b>.</b>		
Lab equipment	\$904	\$ 873
Leasehold improvements	117	78
Computer equipment	352	324
Office furniture and equipment	223	222
	1,596	1,497
Less accumulated depreciation	(1,209) \$387	(1,159) \$338

#### 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 \$27,000 and \$38,000 was included in interest expense for the three months ended March 31, 2014 and 2013, respectively.

Concurrently with entering into the LSA, the Company also granted SVB a warrant to purchase shares of Series F 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. 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 March 31, 2014 and 2013, 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 March 31, 2014 and December 31, 2013.

13

### 6. Stockholders' Equity

#### **Common Stock**

The Company's common stock consists of 200.0 million shares authorized at March 31, 2014 and December 31, 2013, respectively, and 26.9 million and 26.7 million shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively.

#### Shares Reserved for Future Issuance

The following shares of common stock reserved for future issuances:

	March 31, 2014	December 31, 2013
Preferred stock		
Exercise of common stock warrants	1,337,845	1,337,845
Stock options issued and outstanding	2,446,246	1,946,823
Authorized for future purchases under the Company's 2013 Employee Stock Purchase Plan	956,690	704,225
Authorized for future grants under the Company's 2013 Equity Incentive Plan	1,595,682	1,681,932
	6,336,463	5,670,825

#### Warrants

Upon the completion of the Company's IPO, all outstanding warrants to purchase redeemable convertible preferred stock were marked to market resulting in a \$2.2 million fair value adjustment for the three months ended March 31, 2013. The warrants were then converted into warrants to purchase 1,613,395 shares of common stock and were no longer required to be measured at fair value. On April 16, 2013, a warrant was exercised to purchase 211,783 shares of the Company's common stock. The Company received proceeds of \$1.5 million in connection with such exercise. On May 24, 2013, a warrant was net exercised which resulted in the issuance of 37,600 shares of the Company's common stock. On November 5, 2013, a warrant was net exercised which resulted in the issuance of 3,906 shares of the Company's common stock.

The following warrants for the purchase of common stock were issued, outstanding and exercisable at March 31, 2014:

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

#### 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. On January 1, 2014, the common stock reserved for issuance under the 2013 Plan was automatically increased by 666,624 shares.

14

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. On January 1, 2014, the common stock reserved for issuance under the ESPP was automatically increased by 266,649 shares.

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

				Weighted-
	Number of	Weighted-		Average
	Options	A١	verage Exercise	Remaining
	Outstanding	Price		Contractual Life
				(in Years)
Balance, December 31, 2013	1,946,823	\$	3.54	7.03
Granted	754,620		18.39	
Exercised	(253,451)		1.96	
Forfeited	(1,746)		2.35	
Balance, March 31, 2014	2,446,246	\$	8.29	7.90
Exercisable at March 31, 2014	1,135,239	\$	2.93	6.41
Vested or expected to vest at March 31, 2014	2,406,254	\$	8.21	7.88

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	
	Month	ıs
	Ended	l
	March 31,	
	2014	2013
	(in	
	thousands)	
Research and development:		
Employee	\$303	\$107
Non-employee		16
General and administrative:		
Employee	366	142
Non-employee		
	\$669	\$265

### **Employee Stock Purchase Plans**

The Company has reserved a total of 970,874 shares of common stock to be purchased under the ESPP, of which 956,690 shares remain available for purchase at March 31, 2014. Eligible employees may authorize up to 15% of their salary to purchase common stock at the lower of 85% of the beginning price or 85% of the ending price during each six-month purchase interval. The Company issued 14,184 shares of common stock pursuant to the ESPP during the three months ended March 31, 2014. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option were determined using a Black-Scholes option pricing model. For the three months ended March 31, 2014, \$0.1 million was recorded. There was no compensation expense recorded for the three months ended March 31, 2013 since the ESPP was not active during that period.

# 7. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2014 as the Company incurred losses for the three month period ended March 31, 2014 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, 2014. 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 March 31, 2014, the Company had no unrecognized tax benefits that would reduce the Company's effective tax rate if recognized.

# 8. 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 granted to the Company under the license agreement, the Company is required to pay certain cash milestone payments in connection with the development and commercialization of compounds that are covered by the UC Patent Rights. In connection with the development and commercialization of brincidofovir and CMX157, the Company could be required to pay UC up to an aggregate of \$3.4 million in milestone payments, assuming the achievement of all applicable milestone events under the license agreement.

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

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

In the event the Company sublicenses a UC Patent Right (including UC Patent Rights relating to brincidofovir or CMX157) the Company is obligated to pay to UC a fee, which amount will vary depending upon the size of any upfront payment the Company receives and the clinical development stage of the compound being sublicensed, but which could be up to approximately 50% of the sublicense fee in certain circumstances. 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.

The Company did not recognize expenses under this agreement for the three months ended March 31, 2014 or the year ended December 31, 2013.

# Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the development of brincidofovir as a medical countermeasure in the event of a smallpox release. The contract has been amended several times, most recently on April 10, 2014, to extend the first option segment until August 31, 2014.

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

The Company is currently performing under the first option segment of the contract during which the Company may receive up to a total of \$5.3 million in expense reimbursement and fees. In April 2014, the Company and BARDA extended the term of the first option segment to a period of 15 months, currently scheduled to end on August 31, 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.

# 9. Subsequent Event

Kenneth I. Moch, the Company's Chief Executive Officer, resigned on April 9, 2014. The Company entered into a severance agreement with the former CEO that provides for severance benefits to him in connection with his resignation. Under the severance agreement, he will receive the benefits to which he would have been entitled under the amended severance plan upon a termination without cause. These benefits are (i) continued payment of his base salary for fifteen months following his separation date (the "Severance Period"), (ii) payment of COBRA benefits for the Severance Period and (iii) accelerated vesting of all of his outstanding stock options as if he had continued service over the Severance Period. In addition, Mr. Moch will have until December 31, 2014 to exercise his vested stock options. The continued payment of Mr. Moch's base salary for fifteen months will amount to approximately \$0.6 million, which will be expensed through general and administrative expense on the date of his resignation. The acceleration of vesting of Mr. Moch's outstanding stock options as if he had completed service for the severance period and the extension of the period in which to exercise his options each represents a modification of his option award. The expense related to these modifications will be recorded to general and administrative expense on the resignation date. The amount of expense related to the modifications is in the process of being analyzed by the Company.

# 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, 2013 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission on March 7, 2014. Past operating results are not necessarily indicative of results that may occur in future periods.

#### 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**

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

## **RECENT DEVELOPMENTS**

·Appointment of M. Michelle Berrey as Chief Executive Officer

On April 9, 2014, our Board of Directors appointed M. Michelle Berrey, M.D., M.P.H. to the position of President and Chief Executive Officer. In addition, Dr. Berrey will continue to serve as our Chief Medical Officer. Dr. Berrey osucceeds Kenneth I. Moch as Chief Executive Officer following his resignation from that role to pursue other interests.

·Brincidofovir for the Prevention of CMV Infection

Enrollment of subjects is ongoing in our Phase 3 SUPPRESS trial of brincidofovir for the prevention of CMV in HCT recipients. CMV, a dsDNA virus in the herpes virus family, 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 used to support accelerated approval of brincidofovir for the prevention of CMV, the first approval of an antiviral for the prevention of CMV in HCT recipients.

·Brincidofovir for the treatment of AdV Infection

In March 2014, we initiated a pilot open-label study of brincidofovir for the treatment of AdV infections in immunocompromised pediatric and adult patients. The final study design for the Phase 3 study is anticipated in the second half of 2014, and is likely to include evaluation of two durations of brincidofovir therapy for the treatment of odisseminated adenovirus infection. We are in discussions with the U.S. Food and Drug Administration (FDA) regarding the design of a Phase 3 study that would include patients similar to those participating in this pilot trial and which could provide data to support the marketing application of brincidofovir for treatment of disseminated adenovirus infections.

We remain in discussions with key advisors and the FDA regarding next steps for the AdV program and obrincidofovir's overall pediatric program.

# FINANCIAL OVERVIEW

#### Revenues

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

In February 2011, we entered into a contract with BARDA, a U.S. governmental agency that supports the advanced research and development, manufacturing, acquisition, and stockpiling of medical countermeasures. The contract originally consisted of an initial performance period, referred to as the base performance segment, which ended on May 31, 2013, plus up to four extension periods of approximately one year each, referred to as option segments.

Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at Chimerix's discretion. The contract is a cost plus fixed fee development contract. Under the contract as currently in effect, we may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees. We are currently performing under the first option segment of the contract during which we may receive up to a total of \$5.3 million in expense reimbursement and fees which is scheduled to end in August 2014. As of March 31, 2014, we had recognized revenue in aggregate of \$33.5 million with respect to the base performance segment and first extension period. For the three months ended March 31, 2014, we recognized \$780,000 with respect to the BARDA contract.

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.

19

## **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. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors. We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our product candidates. Our research and development expenses consist primarily of:

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

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; and

·License fees for and milestone payments related to license products and technologies.

From our inception through March 31, 2014, we have incurred approximately \$161.9 million in research and development expenses, of which \$129.9 million relates to our development of brincidofovir. We plan to increase our research and development expenses for the foreseeable future as we continue development of brincidofovir for the prevention of CMV infection in HCT recipients, for the treatment of AdV infections, and for other indications and to advance 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.

	Three		
	Months Ended March		
	31,		
	2014	2013	
	(unaudited)		
	(in thousands)		
Direct research and development expense	\$ 5,018	\$ 4,461	
Personnel costs	2,632	1,784	
Indirect research and development expense	642	538	
	\$ 8,292	\$ 6,783	

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 Phase 3 trial of brincidofovir for prevention of CMV in HCT recipients, SUPPRESS, our recently initiated pilot study of brincidofovir as a treatment for AdV, 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 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:

20

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

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. In April 2014, we entered into an amendment to our agreement with BARDA to extend the period of performance under the first option segment from May 2014 to August 2014.

# General and Administrative Expenses

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

## Interest Income (Expense), Net

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

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

## **Revaluation of Warrants**

In conjunction with various financing transactions, we issued warrants to purchase shares of our preferred and common stock. The underlying security of the warrants related to the Series F financing and to our term loan was redeemable at the option of the security holder. As a result, these warrants were classified as a liability and were marked-to-market at each reporting date. The fair value estimates of these warrants were determined using a Black-Scholes option-pricing model and are based, in part, on subjective assumptions. Non-cash changes in the fair value of the warrant liability were recorded as fair value adjustments to warrant liability. The final revaluation of the warrants occurred 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 \$772,000 and \$265,000 was recognized in the three months ended March 31, 2014 and 2013, respectively. The stock-based compensation expense recognized included expense from performance-based stock options, restricted stock units (RSUs) and the employee stock purchase plan.

We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes pricing model. This estimate is affected by our stock price as well as assumptions including the risk-free interest rate, expected dividend yield, expected volatility, expected term, expected rate of forfeiture and the fair value of the underlying common stock on the date of grant

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

Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission on March 7, 2014. There have been no material changes during the first quarter of 2014 to our critical accounting policies, significant judgments and estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

#### **RESULTS OF OPERATIONS**

#### Comparison of the Three Months Ended March 31, 2014 and 2013

The following table summarizes our results of operations for the three months ended March 31, 2014 and 2013, together with the changes in those items in dollars and percentage:

	Three Months Ended March 31,			Dollar Change Change				
	2014		2013	Increase	Increase/(Decrease)			
	(unaudited)	)						
	(in thousan	ds)						
Revenues:								
Contract revenue	\$ 780		\$ 1,771	\$ (991	)	(56.0	)%	
Total revenues	780		1,771	(991	)	(56.0	)%	
Operating expenses:								
Research and development	8,292		6,783	1,509		22.2	%	
General and administrative	2,672		1,536	1,136		74.0	%	
Loss from operations	(10,184	)	(6,548	) 3,636		55.5	%	
Interest expense, net	(196	)	(356	) (160	)	(44.9	)%	
Fair value of warrant adjustments			(2,203	) (2,203	)	*		
Net loss	\$ (10,380	)	\$ (9,107	) \$1,273		14.0	%	

\*Not meaningful or not calculable.

#### **Contract Revenue**

For the three months ended March 31, 2014, contract revenue decreased to \$780,000 compared to \$1.8 million for the three months ended March 31, 2013. The decrease of \$991,000, or 56.0%, is related to a decline in reimbursable expenses related to our contract with BARDA. In the three months ended March 31, 2013, we were completing our CMX-350 clinical trial and various pre-clinical testing, compared to the three months ended March 31, 2014, during which we were engaged only in various non-clinical research activities.

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

For the three months ended March 31, 2014, our research and development expenses increased to \$8.3 million compared to \$6.8 million for the three months ended March 31, 2013. The increase of \$1.5 million, or 22.2%, is primarily related to the following:

an increase in clinical trial expenses of \$1.4 million related to our ongoing Phase 3 SUPPRESS trial for the three months ended March 31, 2014; and

an increase in compensation expense of \$848,000 due to the accrual of potential annual 2014 bonuses, increased stock compensation expense and the addition of five new employees;

offset by a \$500,000 decrease in BARDA contracted work related to non-clinical research and a \$257,000 decrease in BARDA contracted work related to CMC validation.

#### General and Administrative Expenses

For the three months ended March 31, 2014, our general and administrative costs increased to \$2.7 million compared to \$1.5 million for the three months ended March 31, 2013. The increase of approximately \$1.2 million or 74.0% is related to the following:

an increase in compensation expense of \$710,000 related to the accrual of potential 2014 bonuses, increased stock compensation expense and the addition of three new employees; and

an increase in costs associated with operating as a publicly traded company, including filing fees, investor relations, insurance and non-employee director compensation.

## Interest Expense, Net

For the three months ended March 31, 2014, our net interest expense decreased to \$196,000 compared to \$356,000 for the three months ended March 31, 2013. The decrease of \$160,000, or 44.9%, is attributable to the decreased interest expense associated with the lower outstanding loan balance for the three months ended March 31, 2014 compared to the three months ended March 31, 2013 as we continued to pay down the outstanding principal balance.

#### Fair Value of Warrant Adjustment

Prior to our IPO, 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 \$2.2 million for the three months ended March 31, 2013. These losses were 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 were not valued at each reporting period subsequent to our IPO.

## LIQUIDITY AND CAPITAL RESOURCES

We have incurred losses since our inception in 2000 and, as of March 31, 2014, we had an accumulated deficit of \$173.1 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.

On May 1, 2014, we filed a shelf registration statement with the SEC. The shelf registration statement, once declared effective by the SEC, will allow us to issue various securities from time to time for an aggregate initial offering price of up to \$200 million. The specific terms of offerings, if any, under the shelf registration statement would be established at the time of such offerings. We cannot assure you that adequate funding will be available on terms acceptable to us, if at all. Any additional equity financings will be dilutive to our stockholders and any additional debt may involve operating covenants that may restrict our business. If adequate funds are not available through these means, we may be required to curtail significantly one or more of our research or development programs. We cannot assure you that we will successfully develop our products under development or that our products, if successfully developed, will generate revenues sufficient to enable us to earn a profit.

We believe that 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.

Since our inception through March 31, 2013, we have funded our operations principally with \$209.5 million (net of issuance costs of \$10.3 million) from the sale of common stock and preferred stock and the exercise of common stock warrants, including \$107.6 million in net proceeds from our IPO in April 2013, approximately \$37.4 million of research funding from our various National Institute of Allergy and Infectious Diseases awards and approximately \$33.5 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 March 31, 2014 we had cash, cash equivalents

and short-term investments of approximately \$99.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

During 2012, we entered into a loan and security agreement with SVB and MidCap allowing for borrowing up to \$15.0 million. In January 2012, we borrowed \$3.0 million under this agreement which had an interest only period for twelve months, followed by a thirty month principal and interest period at a rate of 8.25%. In September 2012, we borrowed an additional \$12.0 million under this agreement which had an interest only period of six months, followed with a thirty-two month principal interest period at a rate of 8.25%. As of March 31, 2014, the balance of the loan was \$8.5 million

## Cash Flows

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

	Three Months Ended March 31,							
	2014		2013					
	(unaudited)							
	(in thousands)							
Net cash used in:								
Operating activities	\$ (9,116	)	\$ (6,045	)				
Investing activities	(62,739	)	(1,155	)				
Financing activities	(700	)	(667	)				
Net decrease in cash	\$ (72,555	)	\$ (7,867	)				

#### **Operating Activities**

Net cash used in operating activities of \$9.1 million for the three months ended March 31, 2014 was primarily the result of our \$10.4 million net loss, offset by the add-back of non-cash expenses of \$772,000 for stock based compensation. The change in operating assets and liabilities includes a decrease in prepaid expenses and other current assets of \$1.1 million primarily related to the ongoing activities of our Phase 3 SUPPRESS trial and a decrease of \$159,000 in accounts receivable due to a decrease in reimbursable expenses related to our contract with BARDA offset by a decrease in accounts payable and accrued liabilities of \$934,000. Net cash used in operating activities of \$6.0 million during the three months ended March 31, 2013 was primarily the result of our \$9.1 million net loss, offset by the add-back of non-cash expenses of \$2.2 million related to the revaluation of our warrant liability and \$265,000 for stock based compensation.

#### Investing Activities

Net cash used by investing activities of \$62.7 million during the three months ended March 31, 2014 and \$1.2 million during the three months ended March 31, 2013 was primarily the result of purchasing certain short-term investments.

#### Financing Activities

Net cash used by financing activities of \$700,000 for the three months ended March 31, 2014 was primarily the result of approximately \$725,000 in proceeds from the exercise of stock options and stock purchases under the Employee Stock Purchase Plan offset by \$1.4 million in debt repayment. Net cash used by financing activities of \$667,000 during the three months ended March 31, 2013 was primarily the result of payments against our outstanding loan.

# 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" as contained in our Annual Report on Form 10-K for the year ended December 31, 2013 filed by us with the SEC on March 7, 2014 except on May 5, 2014, we entered in a Severance Agreement and Release with Kenneth Moch our former President and CEO. Under this agreement, we have a contractual obligation to pay Mr. Moch a total of approximately \$586,000 over a fifteen month period that begins on April 10, 2014. Of this total amount, \$332,000 will be paid through December 31, 2014 and the remaining \$254,000 will be paid during the period starting on January 1, 2015 and ending July 10, 2015.

## **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 three months ended March 31, 2014 and 2013.

# **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 March 31, 2014, 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.

24

#### 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 March 31, 2014 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.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information contained elsewhere 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 Annual Report on Form 10-K for the year ended December 31, 2013 filed with the Securities and Exchange Commission on March 7, 2014.

## 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 \$10.4 million and \$9.1 million for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, we had an accumulated deficit of approximately \$173.10 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;

pursue the development of brincidofovir for the treatment of adenovirus (AdV) infection in immunocompromised patients;

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.

For example, on May 1, 2014, we filed a shelf registration statement with the SEC. The shelf registration statement, once declared effective by the SEC, will allow us to issue various securities from time to time for an aggregate initial offering price of up to \$200 million. 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. For example, on May 1, 2014, we filed a shelf registration statement with the SEC. The shelf registration statement, once declared effective by the SEC, will allow us to issue various securities from time to time for an aggregate initial offering price of up to \$200 million. 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 March 31, 2014, we had \$8.5 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.

29

## 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 second, confirmatory 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 second, confirmatory trial for the prevention of CMV infection are under discussion with the FDA. Brincidofovir has also completed a Phase 2 trial in asymptomiatic adenovirus (AdV) infection and is currently enrolling an open-label study for the treatment of adenovirus (AdV) infections in immunocompromised pediatric and adult patients. 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;

aunching 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 asymptomatic 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 or our Phase 2 trial of brincidofovir as preemptive therapy for asymptomatic AdV infection 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.

We are also conducting a pilot study for the treatment of AdV infection in immunocompromised pediatric and adult patients. These patients have an impaired immune system that not only makes them more likely to acquire an infection but also more likely to suffer adverse outcomes as a result of infection.

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;

elinical 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.

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

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

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

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

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act) changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

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

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

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

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

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

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

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

inability to meet our product specifications and quality requirements consistently;

delay or inability to procure or expand sufficient manufacturing capacity;

manufacturing and product quality issues related to scale-up of manufacturing;

costs and validation of new equipment and facilities required for scale-up;

failure to comply with cGMP and similar foreign standards;

inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;

reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;

lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;

operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;

carrier disruptions or increased costs that are beyond our control; and

failure to deliver our products under specified storage conditions and in a timely manner.

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

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

Manufacturing of drug components are subject to certain FDA qualifications with respect to manufacturing standards. 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, 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.

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

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

We rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our ongoing clinical programs for brincidofovir and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of 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 market 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 market acceptance by physicians, patients, health care payors and others in the medical community, 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 limited 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, Shire Plc's development of maribavir and Vical Incorporated's and Astellas Pharma US, Inc.'s development of ASP0113 (TransVax). Many of our competitors have substantially greater financial, technical, commercial and other resources, such as larger research and development staff, stronger intellectual property portfolios and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors.

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

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

- discover and develop medicines that are superior to other products in the market;
- demonstrate through our clinical trials that our product candidates, including brincidofovir, are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals;
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines; and
- negotiate 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 reimbursement issues or the reluctance of physicians to switch from existing drug products to brincidofovir, or if physicians switch to other new drug products or choose to reserve brincidofovir for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may 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 maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third-party payors, such as private 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

our collaboration partners may change their development profiles for potential product candidates or abandon a therapeutic area.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research

programs to identify new product candidates require substantial technical, financial and human resources. We may focus our research efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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

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

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

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

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

We believe that consistent achievement of short-term performance goals is likely to result in long-term growth and increased shareholder value. We, therefore, maintain an EOCPS Plan for our executive officers and a cash profit sharing plan for other qualified employees to motivate them to achieve these short-term performance goals, both of which we believe have significantly contributed to our growth.

The EOCPS Plan helped us meet the requirements of Internal Revenue Code section 162(m) for us to fully deduct the cash awards granted to our NEOs in excess of the \$1,000,000 limit as "strategic compensation" thereunder. While the performance-

based exception under section 162(m) was repealed by the Tax Cuts and Jobs Act of 2017, EOCPS payments made beginning in 2019 will continue to be subject to a cap of two times base salary.

The CLDC is responsible for administrating the EOCPS Plan. The CLDC measures our or our subsidiaries' performance against the pre-determined performance goals, which are currently based on our or our subsidiaries' operating profits, and approves our NEOs' individual awards. An EOCPS award is generally determined by an officer's applicable percentage of the amount (each, a "Qualified Amount") by which the net profit, operating income or any other performance goal of the Company or the officer's relevant branch or subsidiary, including Simpson Strong-Tie Company Inc., our primary operating subsidiary, for the applicable period surpass a qualifying level for the Company, branch or subsidiary for that same period, a threshold that must be exceeded before the award may be made to the officer.

Under the EOCPS Plan, any award will be paid at such time as determined by the CLDC as long as all awards with respect to periods within a fiscal year are paid by March of the succeeding fiscal year. We currently pay four quarterly and one annual awards out of the portion of our profits that exceeded a specified qualifying level to our NEOs. For each of the four quarters in a year, a NEO will receive the awards based on 50% of his or her applicable individual percentage of the respective quarterly Qualified Amount. As for the last payment, the NEO will receive the awards based on 50% of his or her applicable individual percentage of the five payments (four quarterly and one annual) is to increase the target amount of awards made following the end of the year (the target annual award equaling the sum of the four target quarterly awards), with the year-end awards contingent on achieving the Qualified Amount for the entire year.

If the qualified operating profit is less than the qualifying level in one or more quarters, our NEOs will receive no quarterly EOCPS payments for such quarters. If the annual qualified operating profit is less than the annual qualifying level for a year, our NEOs will receive no annual EOCPS awards following the year end but may still receive one or more quarterly EOCPS payments during the year. If the qualified operating profit is less than the qualifying level in each quarter and the annual qualified operating profit is less than the qualifying level in EOCPS awards for that year.

We compute the Qualified Amount, if any, as the difference between the actual operating profit and the actual qualifying level. The Qualified Amount is the basis for the computation of amounts available to be distributed under both our EOCPS Plan and our Cash Profit Sharing Plan for other qualified employees. The CLDC may adjust the pool and their percentage from time to time so that our EOCPS will continue to create equitable results for our NEOs. We then allocated EOCPS awards among our NEOs based on their participating percentages as approved by the CLDC at the beginning of the year based on the officer's level of responsibility and contribution to the success of the Company or the home office operating unit. Unless the composition or responsibilities of our NEOs change, their participating percentages generally do not change substantially from year to year, although the CLDC has discretion to make any changes that it considers appropriate.

2018 Operating Profit Achievements and EOCPS Awards

The CLDC has determined to use qualified operating profits of Simpson Strong-Tie Company Inc., our primary operating subsidiary, as the performance goals for 2019 under the EOCPS Plan, the same methodology used in 2018 and prior fiscal years to measure Qualified Amounts under the EOCPS Plan.

Qualified operating profit of Simpson Strong-Tie Company Inc. is generally calculated as follows:

Income from operations

Plus: Stock compensation charges

Certain incentive compensation and commissions

Salaried pension contributions

Self-insured workers' compensation costs

Equals: Qualified operating profit

The CLDC established the 2018 annual qualifying level at \$130,000,000 and the 2018 quarterly qualifying level at \$32,500,000, respectively. Our annual target qualified operating profit, qualifying level and target annual Qualified Amounts for 2018 are as follows:

	2018
	EOCPS
	Targets
Target Annual Qualified Operating Profit	\$228,800,000
Less: Qualifying Level	130,000,000
Target Annual Qualified Amount	\$98,800,000

The target and maximum annual amounts that may be paid out under the EOCPS Plan to each of our NEOs for 2018 are as follows:

	2018	2018
	Target	Maximum
	Annual	Annual
	Payouts <sup>(1)</sup>	Payouts
Karen Colonias	\$740,000	\$1,480,000
Brian J. Magstadt	250,000	500,000
Roger Dankel	230,000	460,000
Ricardo Arevalo	230,000	460,000
Kevin Swartzendruber	130,000	260,000

(1) Amounts (four quarterly and one annual awards) expected to be paid to the NEO for 2018 if 2018 qualified operating profit of Simpson Strong-Tie Company Inc. is \$228,800,000.

Qualified operating profit for each of the four quarters of 2018 and the full-year 2018 and the resulting company-wide and home office branch Qualified Amounts are set forth in the table above:

	Actual	-	
Quarter	Qualified	Qualifying	Qualified
	Operating	Level	Amount <sup>(1)</sup>
	Profit		
First	\$42,947,933	\$32,500,000	\$10,447,933
Second	79,957,253	32,500,000	47,457,253
Third	74,135,581	32,500,000	41,635,581
Fourth	28,531,668	32,500,000	
Full Year	\$225,572,435	5\$130,000,000	\$95,572,435

Actual qualified operating profit was less than the qualifying level during the fourth quarter by \$3,968,332, (1) resulting in zero payout for the quarter.

1		Individu	al		j
NEO/Quarter		Share of	Roundin		Payouts (\$)
Karen Colonias					
First	0.7490 % 0.3745			)	\$39,127
Second	0.7490 % 0.3745	% 177,727	(1	)	177,726
Third	0.7490 % 0.3745	% 155,925	(2	)	155,923
Fourth	0.7490 % 0.3745	%—			
Full Year	0.7490 % 0.3745	% 357,913	(2	)	357,911 \$730,687
Brian J. Magstadt					
First	0.2530 % 0.1265	% \$13,217	\$ 2		\$13,219
Second	0.2530 % 0.1265	% 60,033	9		60,042
Third	0.2530 % 0.1265	% 52,669	8		52,677
Fourth	0.2530 % 0.1265	%			
Full Year	0.2530 % 0.1265	% 120,917	(1	)	120,916 \$246,854
Roger Dankel					-
First	0.2328 % 0.1164	% \$12,161	\$ —		\$12,161
Second	0.2328 % 0.1164	-	(1	)	55,239
Third	0.2328 % 0.1164		(2	)	48,462
Fourth	0.2328 % 0.1164				
Full Year	0.2328 % 0.1164	% 111,243			111,243
Ricard Arevalo					\$227,105
First	0.2328 % 0.1164	% \$12,161	\$ —		\$12,161
Second	0.2328 % 0.1164			)	55,239
Third	0.2328 % 0.1164	-		)	48,462
Fourth	0.2328 % 0.1164		\$		
Full Year	0.2328 % 0.1164		3\$ —		111,243 \$227,105
Kevin Swartzendrube	r				<i><b>4</b>227,105</i>
First	0.1316 % 0.0658	% \$6 875	\$ (1	)	\$6,874
Second	0.1316 % 0.0658		(5	)	31,222
Third	0.1316 % 0.0658	% 27,396	(5	)	27,391
Fourth	0.1316 % 0.0658	% <u> </u>		,	
Full Year	0.1316 % 0.0658	% 62,877	—		62,877 \$128,364

The payouts for our NEOs for each of the four quarters of 2018 and the full-year 2018 were as follows:

(1) The amount is calculated by multiplying the Qualified Amount with 50% of the applicable individual share (%).

(2) The amount represents rounding differences between the amounts used in the actual calculations and the amount calculated using the rounded amounts presented in the tables above.

EOCPS awards paid to each of our NEOs with respect to each of the three years ended December 31, 2018, 2017 and 2016, respectively are set forth in the "Summary Compensation Table" below.

2019 EOCPS Awards Outlook

Based on its review and Mercer's recommendation, the CLDC decided to continue our current EOCPS structure for 2019. As a result, the 2019 awards under the EOCPS Plan are also expected to be made through five payments, with

each of the first

four payments to be made quarterly and the last payment for 2019 to be made at the beginning of 2020. For each of the four quarters in 2019, the NEO will receive the awards based on his or her applicable individual percentage of the respective quarterly Qualified Amount. As for the last payment, the NEO will receive an award based on his or her applicable individual percentage of the annual Qualified Amount for 2019.

The CLDC has determined to use 2019 qualified operating profit of Simpson Strong-Tie Company Inc. as the performance goal for 2019. Qualified operating profit of Simpson Strong-Tie Company Inc. is generally calculated as follows:

Income from operations

Plus: Stock compensation charges

Certain incentive compensation and commissions

Salaried pension contributions

Self-insured workers' compensation costs

Equals: Qualified operating profit

The CLDC has also established the 2019 quarterly and annual target qualified operating profit, qualifying level and target qualified amounts for 2019 as follows (\$'s in thousands):

	2019	2019
	Target	Maximum
	Annual	Annual
	Payouts <sup>(1)</sup>	Payouts
Karen Colonias	\$775,000	\$1,550,000
Brian J. Magstadt	250,000	500,000
Roger Dankel	230,000	460,000
Ricardo Arevalo	230,000	460,000
Kevin Swartzendruber	144,450	288,900

(1) Amounts (four quarterly and one annual awards) expected to be paid to the NEO for 2019 if 2019 qualified operating profit of Simpson Strong-Tie Company Inc. is \$278,900,000.

Long-Term Equity Awards

Our NEOs' long-term compensation is entirely equity-based. We grant equity awards to our key employees, including our NEOs, and our independent directors pursuant to the Company's current equity incentive plan, the amended and restated 2011 Incentive Plan (the "2011 Incentive Plan"). For additional information regarding the 2011 Incentive Plan, please refer to Exhibit A of Simpson Manufacturing Co., Inc.'s Schedule 14A Proxy Statement dated March 9, 2015, which is a complete copy of the 2011 Incentive Plan.

Restricted Stock Units

In 2018, we awarded approximately 189,000 restricted stock units to our employees, including our NEOs and independent directors, and no stock options. We awarded restricted stock units to our employees and NEOs in the first quarter of 2018 on the

day that the CLDC met to approve the awards based on the achievement of our qualified operating profit goals set by the Board for the preceding fiscal year.

Our NEOs' 2018 awards of restricted stock units were made in the following two forms:

time-based restricted stock units ("RSUs") that are subject to a three-year staggered vesting with 20%, 40% and 40% vesting on each of the first, second and third anniversary of the grant date, respectively; and

performance-based restricted stock units ("PSUs") that vest based on the achievement of both revenue growth and long-term shareholder returns at the end of a multi-year performance period.

RSUs accounted for approximately 20% of the 2018 target equity awards of our NEOs while PSUs accounted for the other 80%.

Our NEOs' 2018 RSU Awards

On granting RSU awards, the CLDC established, and specified in the grant agreement, the vesting schedule for the awards. The number of shares of our common stock subject to RSU awards will generally vest periodically in increments over years.

In 2018, the CLDC granted each of our NEOs RSUs as indicated below:

	Shares
Named Executive Officer	Under
	2018
	RSUs
Karen Colonias	5,320
Brian J. Magstadt	1,912
Roger Dankel	1,479
Ricardo Arevalo	1,479
Kevin Swartzendruber	602

With respect to our NEOs' 2018 RSU awards, 20% of the shares of our common stock subject to the awards vested or will vest on the first anniversary of the award date and 40 % will vest on each of the second and third anniversaries of the award date. See "Accelerated Vesting and Payout" and "Potential Payments on Termination or Change in Control" below for a discussion on early vesting of such RSU awards.

Our NEOs' 2018 PSU Awards

The CLDC set the performance goals for our NEOs' 2018 PSU awards in early 2018, which consist of one set of goals based on the Company's revenue growth (the "Revenue Growth Goals") and another set of goals based on the return on our shareholders' invested capital (the "ROIC Goals"). Our NEOs' 2018 PSUs would be measured against such goals for a three-year cliff-vesting performance period starting on January 1, 2018, and ending on December 31, 2020. The CLDC also determined that, during the performance period, half of the 2018 PSU awards to be granted to each of our NEOs would be measured against the Revenue Growth Goals and the other half would be measured against the ROIC Goals. Consequently, the number of PSU shares that would vest in favor of a NEO under his or her 2018 PSU awards is between 0% and 200% of his or her target shares, depending on the extent to which the performance goals would have been achieved at the end of 2020. The number of the target shares of our common stock and the maximum amount of shares of common stock that could potentially vest under the 2018 PSU awards granted to each of our NEOs is as follows:

	Target PSU Shares Under 2018 PSU Awards	Maximum PSU Shares Under 2018 PSU Awards <sup>(1)</sup>
Karen Colonias	21,274	42,548
Brian J. Magstadt	7,648	15,296
Roger Dankel	5,908	11,816
Ricardo Arevalo	5,908	11,816
Kevin Swartzendruber	2,432	4,864

(1) No fractional shares will be issued pursuant to any PSU award, and therefore, any fractional shares may be forfeited or otherwise eliminated as determined by the CLDC.

Our NEOs' 2018 Total Awards of Restricted Stock Units

Therefore, the maximum number of shares of our common stock that could potentially vest under each of our NEOs' 2018 RSUs and 2018 PSUs are as follows:

	Maximum Shares <sup>(1)</sup>		
	RSU Maximum PSU Total Shares Shares		
	RSU PSU	Total	
	Shares		
Karen Colonias	5,32042,548	47,868	
Brian J. Magstadt	1,91215,296	17,208	
Roger Dankel	1,47911,816	13,295	
Ricardo Arevalo	1,47911,816	13,295	
Kevin Swartzendruber	602 4,864	5,466	

(1) The 2011 Incentive Plan, as approved by shareholders at our 2015 annual meeting of shareholders, limits awards of restricted stock units to any one participant in any calendar year, which was previously intended to qualify for the performance-based exception from the tax deductibility limitations of Internal Revenue Code section 162(m) to 100,000 shares prior to the provision's elimination.

Equity awards granted to each of our NEOs with respect to each of the three years ended December 31, 2018 are set forth in the "Summary Compensation Table" below.

Accelerated Vesting and Payout

Under the current 2011 Incentive Plan, the vesting of restricted stock units may accelerate in two situations. First, when an employee ceases employment with us upon his or her retirement (depending on whether the employee meets certain age and/or service tenure conditions), death or disability, all of the employee's unvested restricted stock units vest. Second, all outstanding restricted stock units of an employee vest on a change in our control that involves a substantial change in his or her terms of employment or involuntary termination. In addition, the CLDC may cause awards granted pursuant to the 2011 Incentive Plan, including awards to our NEOs, to vest earlier in certain other situations.

Our NEOs have entered into grant agreements with the Company with respect to their 2018 PSU and RSU awards, which provide for early vesting in case of death or disability. The 2018 grant agreements also provide that for the PSU or RSU awards to vest ahead of schedule, a recipient may retire at age 55 after having worked at the Company or its subsidiaries for 15 years (but for each year that the recipient delays his or her retirement after reaching age 55, he or she may work one year less and still retire). In addition, to increase the compatibility of the awards with the Internal Revenue Code section 409A and avoid potential negative tax implications for the recipient and the Company, the grant agreements for 2018 RSU awards provide that, in case the awards vest ahead of schedule and are determined by

the CLDC to be subject to section 409A, they may only be paid out in the enumerated situations as allowed under section 409A. In particular, in case a recipient is a specified employee under Section 409A, the awards cannot be paid out until the date that is six months after the employee's separation of service, which generally is when the employee completely stops working for the Company and its subsidiaries. Similarly, the 2018 grant agreements for PSU awards provide

that, irrespective of when the PSU awards vest, they may only be paid out following the last day of the applicable vesting period after the performance period has concluded and subject to achievement of the applicable performance goals. Further, the 2018 grant agreements for PSU awards require the PSU shares that could eventually become payable in favor of the recipient following the last day of the applicable vesting period after the performance period to be prorated based on the early-vesting date and the date when the applicable vesting period is scheduled to expire. Change in Control or Asset Sale

The 2011 Incentive Plan currently provides that, on a change in control, if the surviving or resulting entity refuses to continue the PSU or RSU awards and does not substitute similar awards, and if the nature and terms of employment or engagement, including compensation and benefits, of a recipient will change significantly as a result of the change in control, then the awards will vest ahead of schedule. Individual grant agreements may alter this default arrangement. Our NEOs' 2018 grant agreements do not change the default rule under the 2011 Incentive Plan, but additionally provide that, in the case of an asset sale, the PSU or RSU awards will vest ahead of schedule in certain situations, including where a recipient is not subsequently employed or engaged by the surviving or resulting entity or the successor to the sold business or there is a significant change in the nature and terms of the subsequent employment or engagement of the recipient. For ease of administration, our NEOs' 2018 grant agreements also use a broader definition, "sale event," to encompass both change-in-control and asset-sale situations, and therefore override the 2011 Incentive Plan with respect to any change in control of the Company affecting the awards thereunder.

In addition, in order to provide a double-trigger mechanism as recommended by proxy advisors, our NEOs' 2018 grant agreements for PSU and RSU awards require that for the PSU or RSU awards to vest ahead of schedule on a sale event, a NEO's employment with the Company and its subsidiaries (or the acquiring, surviving or resulting entity) will first need to be terminated, either by the officer for good reason or by his or her employer without cause within 2 years from the sale event. In case of early vesting of the PSU awards because of a sale event, the PSU shares thereunder will be subject to the proration described in the "Accelerated Vesting and Payout" section above.

See "Potential Payments on Termination or Change in Control" below for a more detailed discussion on early vesting of our NEOs' PSU and RSU awards.

Cap through 2018 on Annual Awards under the Equity Incentive Plan

Under the 2011 Incentive Plan, the maximum aggregate number of the shares underlying any and all RSU and PSU awards issuable or deliverable to such officer in any calendar year, which was previously intended to qualify for the performance-based exception from the tax deductibility limitations of Internal Revenue Code section 162(m) cannot exceed 100,000 shares. All of our NEOs' 2018 RSU and PSU awards are subject to this limitation. With respect to equity awards made beginning in 2018, however, the performance-based exception under section 162(m) was repealed by the Tax Cuts and Jobs Act of 2017.

#### 2019 Equity Awards

We will grant RSUs and PSUs to our NEOs in 2019, with the target shares being split 20% and 80% between a NEO's 2019 RSU awards and his or her 2019 PSU awards.

Our NEOs' 2019 RSU awards as indicated in the table below will vest over the three years from the effective date of the award, with 20% of the RSUs expected to vest after one year, 40% of the RSUs expected to vest after three years:

Named Executive Officer	Shares
	Under
	2019
	RSUs
Karen Colonias	7,459
Brian J. Magstadt	1,955
Roger Dankel	1,616
Ricardo Arevalo	1,616
Kevin Swartzendruber	764

Similar to their 2018 PSU awards, our NEOs' 2019 PSU awards are subject to performance goals consisting of Revenue Growth Goals and ROIC Goals, and half of the 2019 PSU awards would be measured against the Revenue Growth Goals and the other half would be measured against the ROIC Goals for a three-year cliff-vesting performance period starting on January 1, 2019, and ending on December 31, 2021. Consequently, the number of PSU shares that would vest in favor of a NEO under his or her 2019 PSU awards is between 0% and 200% of his or her target shares, depending on the extent to which the performance goals would have been achieved at the end of 2021. The number of the target shares of our common stock and the maximum amount of shares of common stock that could potentially vest under the 2019 PSU awards granted to each of our NEOs is as follows:

Target	Maximum
	PSU
Shares	Shares
Under	Under
2019	2019 PSU
PSU	Awards <sup>(1)</sup>
Awards	Awalus
29,834	59,668
7,812	15,624
6,464	12,928
6,464	12,928
3,054	6,108
	PSU Shares Under 2019 PSU Awards 29,834 7,812 6,464

(1) No fractional shares will be issued pursuant to any PSU award, and therefore, any fractional shares may be forfeited or otherwise eliminated as determined by the CLDC.

Therefore, the maximum number of shares of our common stock that could potentially vest under each of our NEOs' 2019 RSUs and 2019 PSUs are as follows:

Maximum Shares		
DSU Maximum		
KSU Chama	PSU	Total
Share	Shares	
7,459	59,668	67,127
1,955	15,624	17,579
1,616	12,928	14,544
1,616	12,928	14,544
764	6,108	6,872
	RSU Share 7,459 1,955 1,616 1,616	Maximum Shar RSU PSU Shares 7,45959,668 1,95515,624 1,61612,928 1,61612,928 764 6,108

Comparative Market Information

Designation of Peer Companies for Setting Executive Compensation

Based on shareholder feedback, Mercer's advice, the latest guidelines from proxy advisors, and peer companies' practices, among other considerations, we identify certain companies in the building products or construction material industries that we consider our peer companies for setting compensation for NEOs. These companies designated as peers individually had revenues between \$0.4 million and \$2.1 billion in 2017 which is approximately 0.4 to 2.1 times the Company's 2017 revenue. During 2018, NCI Building Systems, Inc. acquired Ply Gem Holdings, Inc., both of which were included as our peer companies for our 2017 proxy statement. These two companies are not included as peer companies this year. We review our peer companies annually against revenue, industry and other company characteristics and as a result, we no longer consider these companies to be peers as of the acquisition date. As a result of this review, we also added two new peer companies to the peer group this year, Advanced Drainage Systems and Armstrong World Industries.

The following 16 companies in the building products or construction material industries are now considered our peer companies in the process of setting compensation for our NEOs. These 16 companies and the Company, ranked based on their 2017 revenues, are set forth below:

	2017	2017
	Revenues	Assets
	(in	(in
	thousands)	thousands)
Insteel Industries, Inc.	\$ 389,000	\$ 283,000
AAON, Inc	405,000	297,000
Continental Building Products, Inc.	489,000	642,000
PGT Innovations, Inc.	511,000	453,000
Trex Company, Inc.	565,000	326,000
Quanex Building Products Corp.	867,000	774,000
Armstrong World Industries	894,000	1,874,000
Simpson Manufacturing Co., Inc.	977,000	1,038,000
Gibraltar Industries, Inc.	987,000	991,000
American Woodmark Corp.	1,250,000	1,645,000
Apogee Enterprises, Inc.	1,326,000	1,022,000
Advanced Drainage Systems, Inc.	1,330,000	1,043,000
U.S. Concrete, Inc.	1,336,000	1,276,000
Eagle Materials, Inc.	1,387,000	2,368,000
Patrick Industries, Inc.	1,636,000	867,000
Summit Materials, Inc.	1,933,000	3,787,000
Masonite International Corp.	2,033,000	1,680,000

Mercer gathered data on the salary, bonus, total cash compensation, long-term incentives and total direct compensation paid in 2017 by such 16 companies to support the CLDC's compensation decisions. Other Compensation Considerations and Practices

The Board believes that it is in the best interests of the Company and its shareholders to create and maintain a company culture that emphasizes integrity and accountability and a compensation philosophy that focuses on pay-for-performance. Our shareholders currently have the opportunity to vote on our NEOs' compensation every year. In addition, all of our NEOs are subject to and currently in compliance with our compensation and governance guidelines and policies described in detail below.

Board-Recommended Frequency of the Shareholder Advisory Vote on NEO Compensation

The Board has determined that an annual advisory vote by our shareholders on the compensation of our NEOs allows shareholders to provide timely, direct input on our compensation philosophy, policies and practices. The Board continues to believe that such an annual vote is consistent with our continuing efforts to engage in an open dialogue with our shareholders on the compensation of our NEOs and related governance matters and therefore is in the best interests of our shareholders.

#### Stock Ownership Guidelines for NEOs

The Board seeks a strong alignment of the interests of our management and shareholders and maintains robust stock ownership guidelines for our NEOs. The guideline counts only common stock owned by our NEOs and does not include their stock options or RSUs. Each NEO has until 2020 to comply with his or her guideline. The guideline for stock ownership for each of our NEOs is as follows:

	Stock
	Ownership
	Guideline
Karen Colonias	\$3,000,000
Brian J. Magstadt	700,000
Roger Dankel	700,000
Ricardo Arevalo	700,000
Kevin Swartzendruber	150,000

Executive Compensation Recovery ("Claw-back") Policy

Reinforcing our pay-for-performance compensation philosophy, the Board has adopted a compensation recovery policy to permit the recoupment of executive compensation. If we ever are required to prepare an accounting restatement to correct one or more errors that are material to those financial statements, the Company may recover from (x) any current or former executive officers and (y) any other employees who have been designated by the Board or the CLDC as being subject to this policy (each of such officers or employees, a "Covered Person"), regardless of fault or responsibility, that portion of incentive-based compensation, received by a Covered Person during any Covered Period (defined below) in excess of what would have been paid to a Covered Person during the Covered Period under the accounting restatement. A Covered Period means (i) the three completed fiscal years preceding the date on which the Company is required to prepare an accounting restatement due to material noncompliance with any financial reporting requirement under the securities law; and (ii) in case the Company has changed its fiscal year end during the three-year period, the transition period between the new fiscal year that resulted from the change and the prior fiscal year not exceeding nine months. The Board will decide the manner in which the Company seeks and enforces recovery. If, after the Company makes a reasonable attempt to recover, the Board determines that the direct costs of seeking recovery would exceed the recoverable amount, the Company may decide not to seek recovery. Restrictions on Hedging and Pledging Arrangements for All Employees and Directors

The Board believes that it is inappropriate and undesirable for the Company's directors, officers or employees to engage in hedging or pledging transactions that lock in the value of holdings in the equity securities of the Company or its affiliates, including our common stock, as such transactions allow the insiders to own the Company's equity securities without the full risks and rewards of ownership and potentially separate the insiders' interests from the public shareholders.

The Board has therefore adopted an anti-hedging and anti-pledging policy. Directors, officers, and employees of the Company or any subsidiary of the Company, as well as their designees, are generally prohibited from: (a) purchasing any financial instruments or engaging in any transactions that are designed to hedge or offset or have the effect of hedging or offsetting any decrease in the market value of our equity securities (such as our common stock), including, without limitation, prepaid variable forward contracts, equity swaps, collars, exchange funds and transactions with economic consequences comparable to the foregoing financial instruments; and (b) further pledging our equity securities as collateral for a loan, purchasing such securities on margin, or holding such securities in a margin account. Material Risk Considerations of Compensation Policies

We face various types of risk daily, including market risk, credit risk and currency risk, as well as general business risk. Our compensation programs generally look at longer time frames, currently from one quarter to three or four years. Therefore, we do not feel that they expose us to undue risk-taking. To successfully compete in and expand our markets and to attract and retain talent, however, some risks are unavoidable, such as the risks, uncertainties and factors discussed in the Company's Annual Report to Shareholders on Form 10-K for the period ended December 31, 2018, under the heading Item 1A - "Risk Factors" and the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in some cases are desirable and appropriate.

In addition to rewarding our employees for time spent at work and for the achievement of specific performance goals, we also seek to use our compensation programs to balance risk-taking. We believe that our cash profit sharing and equity-based awards promote a measured approach to areas of risk that we face as an organization. While the overall objective of our compensation programs is to increase shareholder value, we believe they also encourage sound financial management and the safeguarding of our assets. In addition, we believe our compensation programs promote a sense of unity, fairness and cooperation among all of our employees, not just our management, and afford less opportunity and incentive for individual employees to take undue risk in an attempt to increase their own compensation at the expense of the long-term health of the Company.

Through our cash profit sharing incentive plans, including the EOCPS Plan, our NEOs and other employees are encouraged to maximize our short-term profits, for example, by increasing revenues and reducing operating costs. The qualifying level component under the EOCPS Plan is intended to reward prudent stewardship of assets and sound allocation of resources. Payouts under the EOCPS Plan are based 50% on quarterly operating profit and 50% on annual operating profit. Accordingly, each of our NEOs receive four quarterly payouts and one annual payout. If the operating profit or other performance goal is less than the qualifying level in one or more quarters of any year, our NEOs will receive no quarterly payments. In addition, if the annual qualified operating profit or other performance goal is less than the annual qualified operating profit or other performance goal is less than the quarterly payments during the year. We believe that these aspects of the EOCPS Plan reduce the risk that the quarterly time horizon could potentially create opportunities for employees to maximize income in one quarter at the expense of a future quarter.

Through our equity-based compensation, including the RSUs and PSUs, our NEOs and other employees are encouraged to drive our continued growth and increase long-term value for our shareholders, for example, by growing our revenues and increasing the return on our shareholders' invested capital. Because our NEOs' and other employees' equity awards generally vest over several years after grant, the value of such awards is affected by our performance over time. As a result, any attempt to maximize our short-term profits at the expense of our long-term financial health would work against our employees' incentive to maximize their total compensation.

#### SUMMARY COMPENSATION TABLE

The table below provides information on all compensation received by our Named Executive Officers ("NEOs") - our Principal Executive Officer, our Principal Financial Officer and our three other most highly compensated executive officers - from us for all their services provided to us and our subsidiaries in all capacities during the three years ended December 31, 2018.

		Stock	Non-Equity	All Other		
		SIOCK	Incentive Plan			
	Salary	Awards	Compensation	Compens	atior	nTotal
Name and Principal Position	Year (\$)	(\$) <sup>(1)</sup>	$(\$)^{(2)}$	$(\$)^{(3)}$		(\$)
Karen Colonias,	2018740,000	)1,457,671	730,687	29,430	(4)	2,957,788
Our President and	2017740,000	)2,146,877	513,031	27,902	(5)	3,427,810
Chief Executive Officer	2016371,316	51,781,207	1,860,346	27,044	(6)	4,039,913
Brian J. Magstadt,	2018500,000	)524,003	246,854	29,430	(4)	1,300,287
Our Chief Financial	2017500,000	01,102,092	2173,323	28,393	(5)	1,803,808
Officer, Treasurer and Secretary	2016258,157	742,038	788,374	26,331	(6)	1,814,900
Roger Dankel	2018460,000	)404,897	227,105	27,930	(4)	1,119,932
President of North	2017460,000	)771,172	159,456	27,339	(4)	1,417,967
American Sales of Simpson	2016222,789	9519,749	741,785	43,723	(6)	1,528,046
Strong-Tie Company Inc.	,	,		,		
Ricardo M. Arevalo	2018460,000	)404,897	227,105	29,430	(4)	1,121,432
Chief Operating Officer	2017460,000	)771,172	159,456	27,339	(5)	1,417,967

of Simpson Strong-Tie Company Inc.	2016222,789519,749	741,785	43,723	(6)	1,528,046
Kevin Swartzendruber Senior Vice President, Finance	2018270,000166,684	128,364	28,930	(4)	593,978

Amounts in this column reflect the grant date fair value of target shares underlying the restricted stock units granted to the applicable NEO under the 2011 Incentive Plan in the fiscal year indicated. There were two kinds of restricted stock units granted to our NEOs: time-based restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"). See "Executive Compensation Analysis - Long-Term Equity Awards" above. We determined the value of such awards by multiplying the target number of shares of our common stock that may become vested pursuant to the terms of the applicable awards by the fair value of our common stock as of the grant date in accordance with FASB Accounting Standards Codification Topic 718 "Compensation - Stock Compensation." Our NEOs' 2018 RSU and PSU awards were made on February 15, 2018 and fair value was calculated as \$55.34 and \$54.68 per share, respectively, based on the closing price of our common stock reported by the New York Stock Exchange ("NYSE") at the close of trading on February 14, 2018, discounted for dividends that these awards did not participate in. Our NEOs' 2017 RSU and PSU awards were made on February 4, 2017 and fair value was calculated as \$34.96 and \$35.58 per share, respectively, based on the closing price of our common stock reported by the NYSE at the close of trading on February 3, 2017, discounted for dividends that these awards did not participate in. Our NEOs' 2016 RSU and PSU awards were granted on February 1, 2016. Our NEOs' 2016 RSUs were valued at \$31.68 per share, based on the closing price of our common stock reported by the NYSE at the close of trading on January 29, 2016, discounted for dividends that the RSU awards did not participate in. Vesting of all unvested restricted stock unit awards may be accelerated in certain enumerated circumstances, including a change in our control. For a discussion of the valuation assumptions used in determining the grant date fair value of these awards see Note 2 "Stock-Based Compensation" to the Consolidated Financial Statements

- included in our Annual Report to Shareholders on Form 10-K for the period ended December 31, 2018. Amounts in this column reflect cash incentive compensation earned by the applicable NEO pursuant to the terms of our EOCPS Plan with respect to the year indicated (regardless of the year in which such amounts were actually paid). Quarterly EOCPS awards received by our NEOs were earned in one quarter and paid in the following quarter. As a result, quarterly awards with respect to the fourth quarter of 2016, 2017 and 2018, which are paid in
- (2) the first quarter of 2017, 2018 and 2019, respectively, are reflected in the year with respect to which they were earned (that is, 2016, 2017 and 2018, respectively). Annual EOCPS awards received by our NEOs were earned in one year and paid in the following year. As a result, annual awards with respect to 2016, 2017 and 2018, which are paid in 2017, 2018 and 2019, respectively, are reflected in the year with respect to which they were earned (that is 2016, 2017 and 2018). See "Executive Compensation Analysis Executive Officer Cash Profit Sharing (EOCPS) Awards" above.

Amounts in this column include our contribution to the applicable NEO's profit sharing trust account, pursuant to a defined contribution profit sharing trust plan we maintained for U.S.-based employees, including our NEOs, with respect to the year indicated (regardless of the year in which such amounts were actually paid) in an amount equal to the sum of (i) 7% of the applicable NEO's qualifying salary, which is subject to a 6-year vesting period, (ii) a quarterly safe harbor contribution equal to 3% of the applicable NEO's qualifying salary, which is not forfeitable and fully vests when made, and (iii) a proportionate share

(3) of contributions from employees who terminated employment with us before such contributions fully vest; provided, however, that the profit sharing trust plan limits our contributions only to trust amounts deductible for federal income tax purposes under section 404(a) of Internal Revenue Code and thus imposes a contribution limit of \$27,000 for 2016 and \$27,500 for each of 2017 and 2018. The contributions earned with by the applicable NEO respect to the fourth quarter of 2016, 2017 and 2018, which were paid as of the first quarter of 2017, 2018 and 2019, respectively, are reflected in the year with respect to which they were earned (that is, 2016, 2017 and 2018, respectively).

(4) Each of our NEOs' all other compensation with respect to 2018 includes:

Profit sharing trust Heal	th Charitable	Total
contribution and Savin	ngs gift	(\$)
share of forfeitures Acco	ount matching	
(\$) Mate	ching contributions	
Cont	ributions (\$)	

		(\$)		
Karen Colonias	27,930	500	1,000	29,430
Brian J. Magstadt	27,930	500	1,000	29,430
Roger Dankel	27,930	_	_	27,930
Ricardo M. Arevalo	27,930	500	1,000	29,430
Kevin Swartzendrube	r 27,430	500	1,000	28,930

(5) Each of our NEOs' all other compensation with respect to 2017 includes:

	Profit sharing trust contribution and share of forfeitures (\$)	Account	Charitable gift matching contributions (\$)	Total (\$)
Karen Colonias	27,402	500		27,902
Brian J. Magstadt	27,393	500	500	28,393
Roger Dankel	27,339			27,339
Ricardo M. Arevalo	0 27,339	—	1,000	28,339

(6) Each of our NEOs' all other compensation with respect to 2016 includes:

	Profit sharing trust contribution and share of forfeitures (\$)	living	Charitable gift matching contributions (\$)	Total <sub>3</sub> (\$)
Karen Colonias	27,044	_		27,044
Brian J. Magstadt	26,331	_		26,331
Roger Dankel	22,723	21,000		43,723
Ricardo M. Arevalo	22,723	24,500	1,000	48,223

(#) In connection with Mr. Dankel's promotion to President of North American Sales of Simpson Strong-Tie Company Inc. and Mr. Arevalo's promotion to Chief Operating Officer of Simpson Strong-Tie Company Inc., both in July 2014, we agreed to provide each of them with a supplemental cost of living adjustment in the amount of \$3,500 per month for a 24-month period. This supplemental cost of living adjustment expired in July 2016. Grants of Plan-Based Awards

The following table summarizes the cash awards granted to our NEOs during 2018 under our Executive Officer Cash Profit Sharing Plan (the "EOCPS Plan") and the equity awards under our current equity incentive plan, the amended and restated 2011 incentive plan (the "2011 Incentive Plan"). The Compensation and Leadership Development Committee (the "CLDC") approved the cash awards to our NEOs because our 2018 annual and quarterly operating profits exceeded the qualifying levels established by the CLDC at the beginning of 2018. The CLDC approved the restricted stock unit awards to our NEOs because we achieved our 2016 operating profit goal approved by the CLDC at the beginning of 2017.

		Estimated Futu Non-Equity Ind	ire Payouts Under centive Plan Award		d Future Pa acentive Pla		All other stock awards Numbe of shares (2) f stock or units <sup>(3)</sup>	r Grant date fair value cof stock Awards <sup>(4)</sup>
	Grant	Tlargettold	Maximum	Threshol	dTarget	Maximur		
Name Karen Colonias	Date	(( <b>\$</b> )) -740,000	(\$) 1,480,000	(#)	(#)	(#)	(#)	(\$)
	2/15/2018 <sup>(2)</sup> 2/15/2018 <sup>(3)</sup>			10,637	21,274	42,548	5,320	1,163,262 294,409
Brian J. Magstadt		-250,000	500,000				,	
C C	2/15/2018 <sup>(2)</sup> 2/15/2018 <sup>(3)</sup>			3,824	7,648	15,296	1,912	418,193 105,810
Roger Dankel		-230,000	460,000				,	,
	2/15/2018 <sup>(2)</sup> 2/15/2018 <sup>(3)</sup>			2,954	5,908	11,816	1,479	323,049 81,848
Ricardo M. Arevalo	Э	-230,000	460,000					
	2/15/2018 <sup>(2)</sup> 2/15/2018 <sup>(3)</sup>			2,954	5,908	11,816	1,479	323,049 81,848
Kevin								
Swartzendruber	2/15/2018(2) 2/15/2018(3)		260,000	1,216	2,432	4,864	609	132,982 33,702
	2/15/2018 <sup>(3)</sup> 2/15/2018(2)	)-1-30,000	260,000	-			,	81,848 132,982

Amounts in these columns reflect the target and maximum amounts that could become payable under the EOCPS Plan for each of our NEOs with respect to 2018, and did not have a threshold value. Actual amounts payable to our

(1)NEOs under the EOCPS Plan were determined based on the level at which our quarterly and annual qualified operating profit exceeded the qualifying level for the applicable quarter or year. See "Executive Compensation Analysis - Executive Officer Cash Profit Sharing (EOCPS) Awards" above.

Amounts reflect the threshold, target and maximum number of performance-based restricted stock units ("PSUs") of our shares of common stock that could be earned pursuant to each of our NEOs' 2018 PSU awards. Our NEOs' PSU awards are subject to two types of performance goals: one set of goals based on our revenue growth, and another set of goals based on the return on our shareholders' invested capital. The threshold amounts are calculated,

(2) assuming that the threshold levels of both types of performance goals would be achieved. The actual amounts of PSUs that could be earned pursuant to our NEOs' 2018 PSU awards, therefore, could be less than the threshold amounts if only one of the threshold levels is achieved. In addition, no fractional shares will be issued pursuant to any PSU award. See "Compensation Discussion and Analysis - Long-Term Equity Awards - Our NEOs' 2017 PSU Awards" above.

Amounts reflect the actual number of time-based restricted stock units ("RSUs") of our shares of common stock

(3) granted as being subject to continued vesting. See "Executive Compensation Analysis - Long-Term Equity Awards -Our NEOs' 2017 RSU Awards" above.

The amounts in this column reflect the grant date fair value of the equity awards granted to our NEOs in 2018 computed in accordance with FASB Accounting Standards Codification Topic 718. The grant date fair value was

(4) calculated as \$55.34 and \$54.68 per share, respectively, based on the closing price of our common stock reported by the NYSE at the close of trading on February 14, 2018, discounted for dividends that these awards did not participate in.

### CEO Pay Ratio

We believe our executive compensation to be internally consistent and equitable to motivate our employees to create shareholder value. We are committed to internal pay equity, and the Compensation and Leadership Development Committee monitors the relationship between the pay our executive officers receive and the pay our non-managerial employees receive. The Compensation and Leadership Development Committee reviewed a comparison of CEO pay to the pay of all our employees in 2018.

Our CEO to median employee pay ratio disclosed in this Proxy Statement is calculated pursuant to Item 402(u) of Regulation S-K. In 2017, we identified the median employee by examining the 2017 total compensation (as defined under Item 402(u)), based on our payroll records, for all individuals (excluding our CEO) who were employed by us, including our consolidated subsidiaries, on December 31, 2017, the last day of the prior payroll year. We used prior year employee data because there have been no changes in our operations that would lead us to believe the data has changed meaningfully from the prior year. We included all employees, whether employed on a full-time, part-time, or seasonal basis. We also used widely recognized tests that the Company would otherwise use to determine whether its workers are employees (including the relevant employment or tax law standards and recognized tests under the laws of foreign countries normally used to determine whether local workers in such countries are employees). We did not make any assumptions, adjustments, or estimates with respect to the calculation of total compensation, except we annualized the base salary pay for any full-time employees that were not employed by us for the entire 2017 payroll year. We used the average foreign exchange rate for all of 2017 when calculating total compensation for non-U.S. based employees. We calculated annual total compensation for such employee using the same methodology that we use for our named executive officers as set forth in the Summary Compensation Table above, and then increased total compensation for the median employee identified in 2017 by 3% as an estimate of the overall increase in pay for our employees excluding named executive officers. Our CEO's 2018 total compensation was \$2,957,788, and our median employee's 2018 total compensation was estimated as \$51,151, which resulted in a pay ratio of approximately 58:1.

Outstanding Equity Awards at Fiscal Year End

As of December 31, 2018, our NEOs held the following restricted stock units awarded under the 2011 Incentive Plan:

	, our r.		une	iono wing i	estricted s	
Name	Grant Date	Number Shares of Units of Stock T Have N Vested (#) <sup>(1)</sup>	or f 'hat	Market Value of Shares or Units of Stock That Have Not Vested (\$) <sup>(5)</sup>	Equity incentive plan awards: Number of shares or units o stock that have not vested (#) <sup>(6)</sup>	Equity incentive plan awards: market value of shares or units of stock that have not vested (\$) <sup>(5)</sup>
Karen Colonias	2/2/2015	5,147	(2)	278,607		
	2/1/2016	6,813	(3)	368,788	33,020 <sup>(7)</sup>	1,787,373
	2/4/2017	12,450	(3)	673,919	43,048	2,330,188
	2/15/2018	5,320	(4)	287,972	42,548	2,303,123
Brian J. Magstadt	2/2/2015	2,132	(2)	115,405		
	2/1/2016	2,838	(3)	153,621	13,759 <sup>(7)</sup>	744,775
	2/4/2017	5,188	(3)	280,826	24,936	1,349,786
	2/15/2018	1,912	(4)	103,497	15,296	827,972
Roger Dankel	2/2/2015	870	(2)	,	(2)	
	2/1/2016	1,988	(3)	107,610	9,531 (8)	,
	2/4/2017	3,630	(3)	196,492	17,448	944,460
	2/15/2018	1,479	(4)	80,058	11,816	639,600
	0/0/0015	070	(2)	17.002		
Ricardo M. Arevalo	2/2/2015	870	(2)	47,093	0.501 (9)	515.012
	2/1/2016	1,988	(3)	107,610	9,531 (8)	515,913

	/		196,492 80,058	,	,
Kevin Swartzendruber 2/15/2018	609	(4)	32,965	4,864	263,288

- (1) Vesting of restricted stock units may be accelerated under certain circumstances. See "Executive Compensation Analysis Long-Term Equity Awards" above and "Potential Payments on Termination or Change in Control" below.
- (2) Represent RSUs, 75% of which are scheduled to vest (or vested) on the third anniversary of the award date and 25% of which are scheduled to vest on the fourth anniversary of the award date.
- (3) Represent RSUs, 25% of which vested on the award date and 25% of which are scheduled to vest (or vested) on each of the first, second and third anniversary of the award date.
- (4) Represents RSUs, 20% of which are scheduled to vest on the first anniversary of the award date, and 40% of which are scheduled to vest on each of the second and third anniversary of the award date.
- (5) Calculated based on the \$54.13 per share closing price of our common stock reported by the NYSE at the close of trading on December 31, 2017.
- (6) Represents the maximum number of PSUs that could vest subject to meeting the applicable performance goals. The number of PSUs that will actually vest will be determined following the performance period.
- Represents actual number of PSUs vested based on actual performance for the three-year measurement period ending December 31, 2018. On February 4, 2017, the CLDC set New Performance Goals for our CEO's and CFO's 2016 PSU awards, of which one half consist of goals based on Revenue Growth and one half is based on Average ROIC. With respect to the Revenue Growth Goal, if the Company's CAGR for revenue during a two-year
- (7) performance period (from January 1, 2017 to December 31, 2018), is 15% or more, the number of shares that would actually vest is 120% of the target shares. If our CAGR for revenue during the performance period is less than 5%, no shares will vest. If the Company's CAGR for revenue falls between 5% and 10% during the performance period, the number of shares that actually vest is pro-rated between 50% and 100% of the target share amount. If our CAGR for revenue during the performance period is between 10% and 15%, the number of shares that actually vest is pro-rated between 10% and 15%, the number of shares that actually vest is pro-rated between 10% and 15%, the number of shares that actually vest is pro-rated between 100% and 120% of the target shares.

With respect to the ROIC Goal, if the Company's Average ROIC during the same two-year performance period (from January 1, 2017 to December 31, 2018), is 12% or more, the number of shares that would actually vest is 120% of the target shares. If our Average ROIC during the performance period is less than 7%, no shares will vest. If the Company's Average ROIC falls between 7% and 10% during the performance period, the number of shares that actually vest is pro-rated between 50% and 100% of the target share amount. If our Average ROIC during the performance period is between 10% and 12%, the number of shares that actually vest is pro-rated between 100% and 120% of the target shares.

The number of target shares of our common stock and the maximum amount of shares of our common stock that could potentially vest under each of our CEO's and CFO's amended 2016 PSU awards is as follows:

Ν	Maximum Shares Under 2016			
P	SUs			
S uu A 20 P	Yarget hares nder 20% Amend <b>Ed</b> rformance 016 Multiplier SU	Maximum Shares under Amended 2016 PSU Awards		
Karen Colonias 2	8,9905,798	34,788		
Brian Magstadt 12	2,0802,416	14,496		

As of December 31, 2018, the Company's two-year CAGR for revenue was 11.96%, resulting in a performance adjustment of 107.8% for half of the targeted shares, and Average ROIC was 12.5% during the same performance period, which exceeded the maximum target resulting in a performance adjustment of 120% for the other half of the targeted award amount. Accordingly, on February 1, 2019, Ms. Colonias received 33,020 shares, which is 4,030 incremental shares, or 113.9% over the targeted award, and Mr. Magstadt received 13,579, which is 1,679 incremental shares, or 113.9%, over the targeted award amount.

Represents actual number of PSUs vested based on actual performance for the three-year measurement period ending December 31, 2018. Upon granting Mr. Dankel and Mr. Arevalo 2016 PSUs, the CLDC established that the target shares would be modified up or down by up to 20% based the Company's total shareholder return ("TSR") during a three-year performance period (from January 1, 2016 to December 31, 2018), which would be measured based on our relative performance in the S&P Small Cap 600 Index. If the Company's TSR ranks at or above the 85th percentile in the index during the performance period, the number of shares that would actually vest is 120% of the target the start the star

(8) of the target shares. If the Company's TSR ranks at or below the bottom 40th percentile in the index during the performance period, the number of shares that would actually vest is 80% of the target shares. If the Company's TSR falls between the 40th percentile and the 50th percentile in the index during the performance period, the number of shares that would actually vest are prorated between 80% and 100% of the target shares. If the Company's TSR falls between the 50th percentile and the 85th percentile in the index during the performance period, the number of shares that would actually vest are prorated between 100% and 120% of the target shares.

The target shares, the upward 20% TSR multiplier and the maximum number of shares with respect to each of Mr. Dankel's and Mr. Arevalo's 2016 PSUs are as follows:

	Target PSU Shares	20% TSR Multiplier	Maximum PSU Shares
Roger Dankel	8,160	1,632	9,792
Ricardo Aravelo	8,160	1,632	9,792

As of December 31, 2018, the Company achieved a TSR ranked at 79.4% versus the S&P Small Cap 600 Group for the three-year period ended December 31, 2018, which is between the 50<sup>th</sup> and 85<sup>th</sup> percentile in the index and subject to pro-ration between 100% and 120% of the targeted shares. Accordingly, on February 1, 2019, Mr. Dankel and Mr. Arevalo each received 9,531 shares, which includes 1,371 incremental shares, or 84%, of the 1,632 TSR multiplier.

As of December 31, 2018, our NEOs did not hold outstanding options with respect to our common stock. Stock Vested

The following table provides information on the number of shares of our common stock that vested during 2018 under restricted stock units granted to each of our NEOs pursuant to the 2011 Incentive Plan:

	Stock Awards
	Number
	of Shar
	Acquir Reohized on
Name	Vesting (\$) <sup>(1)</sup>
Karen Colonias	33,9681,987,960
Brian J. Magstadt	14,098825,059
Roger Dankel	6,409 374,457
Ricardo M. Arevalo	6,409 374,457
Kevin Swartzendruber	

(1)Calculated by multiplying the number of shares that vested by the market value of such shares on the vesting date. No Pension Benefits

Except for a small number of employees in our recently acquired Swiss subsidiary, we do not currently have or plan to adopt any defined benefit deferred compensation programs, or supplemental executive retirement plans.

No Non-Qualified Deferred Compensation Plans

We do not currently maintain a non-qualified deferred compensation plan.

Potential Payments on Termination or Change in Control

We generally do not offer any severance payments or pay benefits after termination of employment. As discussed above under "Executive Compensation Analysis - Long-Term Equity Awards," the vesting of a NEO's outstanding restricted stock units, or a portion thereof, may accelerate on, following or in connection with (i) retirement after reaching certain age and/or service tenure conditions, (ii) death, (iii) disability or (iv) certain situations linked to a change in our control or a sale of our asset. On, following or in connection with the applicable NEO's death, disability or retirement after reaching certain age and/or service tenure conditions, or a change in control or asset sale related situation, in each case assumed to have occurred on December 31, 2018, the potential payments that would be provided to each of our NEOs are as follows:

	Estimated Payments and Benefits Of Accelerated Stock						
	Options a	Options and Restricted Stock Units In Connection With					
	Retireme	nDeath(1)	Disability <sup>(1)</sup>	) Change in $Control^{(1)(3)}$			
Name	(\$)	(\$)	(\$)	(\$)			
Karen Colonias	1,240,497	77,857,327	77,857,327	7,857,327			
Brian J. Magstadt		3,503,943	33,503,943	3,503,943			
Roger Dankel	276,550	2,531,227	72,531,227	2,531,227			
Ricardo M. Arevalo	323,643	2,531,227	72,531,227	2,531,227			
Kevin Swartzendruber	r —	296,253	296,253	296,253			

Calculated based on the \$54.13 per share closing price of our common stock reported by the NYSE at the close of (1)trading on December 31, 2018. No material conditions or obligations are currently expected to apply to the receipt of payments on early-vesting of equity awards granted to our NEOs.

(2) As of December 31, 2018, Ms. Colonias, Mr. Dankel and Mr. Arevalo were the only NEOs eligible for retirement with respect to certain of their equity awards.

(3)Includes potential payments in connection with a sale of our assets.

Under the 2011 Incentive Plan, or the applicable grant agreement, the vesting of our NEOs' restricted stock unit awards may accelerate in four situations: (1) retirement after meeting certain age and/or service tenure conditions, (2) death, (3) disability, and (4) certain situations linked to a change in our control or a sale of our asset. In addition, the CLDC may cause awards granted under the 2011 Incentive Plan, including awards granted to our NEOs, to vest earlier in certain other situations.

To increase the compatibility of the PSU and RSU awards with the Internal Revenue Code section 409A and avoid potential negative tax implications for the recipient and the Company, our NEOs' 2018 grant agreements provide that, in case the applicable NEO's RSU awards vest ahead of schedule and are determined by the CLDC to be subject to section 409A, they may only be paid out in the enumerated situations as allowed under section 409A. In particular, in case the applicable NEO is a specified employee under section 409A, his or her RSU awards cannot be paid out until the date that is six months after the employee's separation of service, which generally is when the employee completely stops working for the Company and its subsidiaries. Similarly, irrespective of when the PSU awards vest, they may only be paid out following the last day of the applicable vesting period after the performance-measurement period has concluded. In addition, while still providing for early vesting in case of death or disability, our NEOs' 2018 grant agreements provide that, for the PSU or RSU awards to vest ahead of schedule, a NEO may retire at age 55, but only after having worked at the Company or its subsidiaries for 15 years. For each year, however, that the recipient delays his or her retirement after reaching age 55, he or she may work one year less and still retire with accelerated vesting.

The 2011 Incentive Plan currently defines "change in control" as any of the following transactions; (i) the consummation of a consolidation or merger of the Company in which the Company is not the surviving corporation; (ii) the consummation of a reverse merger in which the Company is the surviving corporation but the shares of our common stock outstanding immediately preceding such reverse merger are converted by virtue of such reverse merger into other property, whether securities, cash or otherwise; or (iii) the approval by our shareholders of a plan or proposal for the dissolution and liquidation of the Company; provided that a "change in control" shall not be deemed to have occurred by virtue of the consummation of any transaction or series of related transactions immediately following which the record holders of our common stock immediately before such transaction or transactions continue to have substantially the same proportionate ownership in an entity that owns all or substantially all of the assets of the Company immediately thereafter. Our NEOs' 2018 grant agreements use a broader definition, "sale event," to encompass both change in control and asset sale situations, and therefore override the 2011 Incentive Plan with respect to any change in control of the Company affecting the awards thereunder.

To provide a double-trigger mechanism as recommended by proxy advisors, under our NEOs' 2018 grant agreements, for any PSU or RSU award to vest ahead of schedule upon a sale event, the applicable NEO's employment or engagement with the Company and its subsidiaries (or the acquiring, surviving or resulting entity) will first need to be

terminated, either by the officer for good reason or by his or her employer without cause within 2 years from the sale event. Our NEOs' 2018 grant agreements use standard definitions for what constitutes good reason or cause that can typically be found in employment agreements. Under our NEOs' 2018 grant agreements, before a NEO may quit for good reason, he or she will first need to provide written notice within 90 days of the underlying incident and inform his or her employer about the reason. In addition, the NEO has up to 30 days to cure following such notice. Similarly, for the Company, a subsidiary thereof, or the acquiring, surviving or resulting entity to terminate a NEO with cause, which results in forfeiture of the NEO's PSU or RSU awards, the employer will need to provide notice and the NEO has up to 15 days to cure. In case

of early vesting of our NEOs' 2018 PSU awards, shares thereunder that could eventually vest in favor of the officer will be prorated based on the early-vesting date and the date when the applicable vesting period is scheduled to expire. The 2011 Incentive Plan currently provides that on a change in control, if the surviving or resulting entity refuses to continue our NEOs' PSU or RSU awards and does not substitute similar awards, and if the nature and terms of employment or engagement, including compensation and benefits, of the applicable NEO will change significantly as a result of the change in control, then the awards will vest ahead of schedule. The 2011 Incentive Plan, however, allows individual grant agreements to alter this default arrangement. Our NEOs' 2018 grant agreements do not change the default rule under the 2011 Incentive Plan but additionally provide that, in the case of an asset sale, the PSU or RSU awards will vest ahead of schedule in certain situations, including where a recipient is not subsequently employed or engaged by the surviving or resulting entity or the successor to the business or there is a significant change in the nature and terms of the subsequent employment or engagement of the recipient.

#### DIRECTOR COMPENSATION

The following table provides information on compensation paid to our non-employee directors for the year ended December 31, 2018. The amounts shown include compensation for all services provided to us during 2018.

	Fees			
	Earned or	Equity	All Other	Total
	Paid in	Awards	Compensation	Total
	Cash			
Name	(\$)	(\$) <sup>(1)</sup>	(\$) <sup>(2)</sup>	(\$)
James S. Andrasick	91,000	81,627	1,000	173,627
Peter N. Louras, Jr.	129,500	81,627		211,127
Jennifer A. Chatman	77,000	81,627		158,627
Gary M. Cusumano	85,000	81,627		166,627
Robin G. MacGillivray	91,000	81,627	500	173,127
Celeste Volz Ford	75,000	81,627		156,627
Michael A. Bless	65,000	81,627		146,627
Philip E. Donaldson	48,750	81,627		130,377

(1) Reflects the value of restricted stock units granted on April 24, 2018, calculated by multiplying the maximum number of shares that may vest thereunder by the fair value per share of our common stock as of the award date in accordance with FASB Accounting Standards Codification Topic 718 "Compensation - Stock Compensation." Each outside director's equity award corresponded to the approximate amount of his or her 2018 annual retainer, and was valued at \$55.34 per share, the closing price of our common stock reported by the NYSE at the close of trading on April 24, 2018. For a discussion of the valuation assumptions used in determining the grant date fair value of these awards, see Note 2 "Stock-Based Compensation" to the Consolidated Financial Statements included in our Annual Report to Shareholders on Form 10-K for the period ended December 31, 2018.

(2) Represents matching contributions made by us for charitable gifts made by the director. We generally match up to \$1,000 for gifts made to qualifying charities.

As of December 31, 2018, our outside directors held no unvested restricted stock units or outstanding options with respect to our common stock.

In 2018, we paid each of our non-employee directors an annual cash retainer of \$65,000 and an annual equity retainer of \$85,000. We paid the Chair of the Board an additional annual fee of \$56,500 and the Chair of each of the Audit and Finance Committee, the Compensation and Leadership Development Committee, the Corporate Strategy and Acquisitions Committee, and the Nominating and Governance Committee an additional annual fee of \$10,000. The annual retainers are generally paid quarterly and the fees for the Chair of the Board and each of its committees are paid at the time of our annual meeting of shareholders each year. Outside directors also received \$2,000 for every day, in excess of 12 days during a single calendar year, that a Board and/or committee meeting is held. We also reimbursed outside directors for expenses that they incurred to attend Board and committee meetings or to participate in

educational programs. We paid each outside director \$3,000 per day and reimbursed his or her expenses when he or she visited our facilities to observe operations.

In 2019, we are updating our director compensation to better match the practices of our peers. Following the 2019 Annual Meeting, our non-employee directors will receive an annual cash retainer of \$75,000 and an annual equity retainer of \$95,000.

We will pay the Chair of the Board the same additional annual cash fee of \$56,500 as in previous years, and in addition will provide \$25,000 in equity to the Chair of the Board. We will pay all members of the Audit and Finance Committee and the Compensation and Leadership Development Committee an additional fee of \$10,000 for their service on these committees, and all members of the Nominating and Governance Committee and the Corporate Strategy and Acquisitions Committee an additional fee of \$7,000 for their service on these committees. The Chair of each committee will receive an additional \$10,000 for their service as Chair. The annual retainers are generally paid quarterly and the committee and Chair fees are generally paid at the time of our next annual meeting of shareholders each year. Because James S. Andrasick was elected to become the Chairperson of the Board as of January 1, 2019, he will also receive a prorated annual fee based on the 2018 fee schedule to reflect his new position. Outside directors will no longer be compensated for attending in excess of 12 days of meetings during a single calendar year, nor will directors be compensated for site visits to our facilities to observe operations.

Stock Ownership Guidelines for Outside Directors

In February 2015, the Compensation and Leadership Development Committee created stock ownership guidelines for each of our directors, who is not also an officer or employee. The guideline counts only our common stock owned by them and does not include their stock options or restricted stock units. Each of such directors has until 2020, or five years from joining the board to comply with this guideline. The guideline for the minimum value for stock ownership of the Company for each of such directors is computed as 3 times their annual cash retainer, which is currently \$195,000. In addition, all of our directors are subject to and currently in compliance with our anti-hedging and anti-pledging policy that was adopted by the Board in 2017.

### CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Transactions with Related Persons

Since January 1, 2018, other than the compensation arrangements discussed under "Executive Compensation" and "Director Compensation" above, we did not have any transactions to which we have been a participant, in which the amount involved in the transaction exceeds or will exceed \$120,000 and in which any of our directors, executive officers or holders of more than 5% of our common stock, or any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of, or person (other than a tenant or employee) sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Since 2016, Karen Colonias, the Company's Chief Executive Officer, President and Director, has been a director of Reliance Steel & Aluminum Co. ("Reliance"). Reliance, through its subsidiaries, has been a provider of steel processing and handling services for the Company for several years. In 2018, the Company paid Reliance \$0.6 million for its services. The relationship between the Company and Reliance is expected to be continuing in 2019. Pursuant to instructions to Item 404(a) of Regulation S-K, we do not deem Ms. Colonias to have a direct or indirect material interest in our relationship with Reliance solely because of her position as a director of Reliance. Review, Approval or Ratification of Transactions with Related Persons

In 2018, the Board adopted a revised written Related Party Transactions Policy for the Company and all of its branches and subsidiaries, which applies to any transaction or series of transactions in which we or any of our branches or subsidiaries is a participant and covers our directors, NEOs and 5% shareholders. Pursuant to the Related Party Transactions Policy, the Nominating and Governance Committee or entire Board, as applicable, is responsible for review, approval, and ratification of transactions between the Company or its branches or subsidiaries and related persons. In addition to "related persons" defined in Item 404 of Regulation S-K, our Related Party Transactions Policy also cover members of our leadership team as designated by the Nominating and Governance Committee or Board from time to time. In accordance with the Related Party Transactions Policy, except for pre-approved transactions, if a transaction involves a covered employee (or an immediate family member thereof) and is valued at less than \$1 million U.S. dollars, then a transaction review committee (the "TRC"), which serves as an advisory committee of the Company and generally include our Chief Financial Officer, or his or her designee, and outside counsel (provided that if the Chief Financial Officer is a related party, he or she will be replaced by another officer of the Company), will make recommendations to the Nominating and Governance Committee and the Nominating and Governance

Committee will decide whether to approve or ratify the transaction; and if a transaction involves a director or a 5% shareholder (or an immediate family member thereof) or involves a covered employee (or an immediate family member thereof) but is valued at \$1 million or more, the TRC will make recommendations to the Board, and the Board will decide whether to approve or ratify the transaction (provided that no director shall participate in any discussion or approval of a transaction for which he or she or any of his or her immediate family members is involved). In determining whether to approve, ratify, disapprove or reject a related party transaction, the Nominating and Governance Committee or Board will consider, among other factors, whether the transaction is entered into on terms no less favorable to us than terms generally available to an unaffiliated third-party under the same or similar circumstances; the results

of an appraisal, if any; whether there was a bidding process and the results thereof; review of the valuation methodology used and alternative approaches to valuation of the transaction; and the extent of the related person's interest in the transaction. All transactions identified in the "Transactions with Related Persons" above have been reviewed, approved or ratified by the Nominating and Governance Committee or Board and our then-current related-parties policies and procedures have been followed with respect to all such transactions.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires our directors, officers and beneficial owners of more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership of our common stock with the SEC. SEC regulations require such reporting persons to furnish us with copies of all section 16(a) reports and amendments thereto that they file. Based solely on our review of the copies of such reports and amendments that we received and/or written representations from such reporting persons that no reports on Form 5 were required for them, we believe that in 2018 two Form 4s for one 10% shareholder were filed late. Otherwise our directors, officers and 10% shareholders met all of the section 16(a) filing requirements regarding our common stock in 2018.

## WHERE YOU CAN FIND MORE INFORMATION

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public at the SEC's website at www.sec.gov. You may also obtain free copies of the documents we file with the SEC by going to our website, the address of which is http://www.simpsonmfg.com. The information provided on our website is not part of this Proxy Statement, and therefore is not incorporated by reference.

Shareholders may express their views regarding the topics raised in this Proxy Statement or other matters directly to the Company through written communications sent directly to the attention of the Board, any individual director or the non-employee directors as a group, by written communications addressed to our Secretary, at Simpson Manufacturing Co., Inc., 5956 W. Las Positas Blvd., Pleasanton, California, 94588.

### HOUSEHOLDING OF PROXY MATERIALS

SEC rules permit companies and intermediaries such as brokers to satisfy delivery requirements for proxy materials with respect to two or more shareholders sharing the same address by delivering a single copy of the proxy materials addressed to those shareholders. This process, which is commonly referred to as "householding," provides cost savings for companies. Some brokers household proxy materials, delivering a single proxy statement and annual report to multiple shareholders sharing an address unless contrary instructions have been received from the affected shareholders. Once you have received notice from your broker that they will be householding materials to your address, householding will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in householding and would prefer to receive a separate proxy statement in the future, or if you and other shareholders sharing your address are receiving multiple copies of the proxy materials and you would like to receive only a single copy of such materials in the future, please notify your broker. You may also call (866) 540-7095 or write to: Householding Department, Broadridge, 51 Mercedes Way, Edgewood, New York 11717, and include your name, the name of your broker or other nominee, and your account number(s). If you share an address with another shareholder and have received only one set of this year's proxy materials and you wish to receive a separate copy, please notify us in writing to our Secretary at Simpson Manufacturing Co., Inc., 5956 W. Las Positas Blvd., Pleasanton, California, 94588 and we will deliver a separate copy to you promptly. **OTHER BUSINESS** 

As of the date of this Proxy Statement, we are not aware of any matters that are expected to come before the 2019 Annual Meeting other than those described in this Proxy Statement. If any other matter should be presented at the 2019 Annual Meeting upon which a vote may be properly taken, shares represented by all proxy cards received by the Board will be voted with respect thereto at the discretion of the persons named as proxies in the enclosed proxy card. DISCLAIMER REGARDING INCORPORATION BY REFERENCE OF THE REPORTS OF THE AUDIT AND COMPENSATION AND LEADERSHIP DEVELOPMENT COMMITTEES ANY INFORMATION SHOWN IN THE SECTIONS ENTITLED "REPORT OF THE AUDIT COMMITTEE" AND "REPORT OF THE COMPENSATION AND LEADERSHIP DEVELOPMENT COMMITTEE" SHALL NOT BE

DEEMED TO BE INCORPORATED BY REFERENCE BY ANY GENERAL STATEMENT INCORPORATING BY REFERENCE THIS PROXY STATEMENT INTO ANY FILING BY SIMPSON MANUFACTURING CO., INC. WITH THE SECURITIES AND

EXCHANGE COMMISSION UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, EXCEPT TO THE EXTENT THAT SIMPSON MANUFACTURING CO., INC. INCORPORATES THE INFORMATION BY SPECIFIC REFERENCE, AND SUCH INFORMATION SHALL NOT OTHERWISE BE DEEMED "SOLICITING MATERIAL" OR "FILED" UNDER SUCH ACTS. SHAREHOLDER PROPOSALS AND PROXY ACCESS NOTICES

Proposals of shareholders for inclusion in the Company's proxy statement for the 2020 annual meeting of shareholders pursuant to Rule 14a-8 promulgated under the Securities Exchange Act of 1934, as amended ("Rule 14a-8") must satisfy the requirements of Rule 14a-8 and be received by the Secretary, Simpson Manufacturing Co., Inc., 5956 W. Las Positas Blvd., Pleasanton, California, 94588, no later than November 15, 2019.

Nominations for director elections (other than shareholder nominees submitted for inclusion in the Company's proxy materials pursuant to the proxy access provision of our Bylaws) or other business proposals that shareholders of the Company wish to put before the shareholders of the Company at the 2020 annual meeting of shareholders must meet the requirements of Article II, Section 5 of our Bylaws and must be received by the Secretary of the Company, at the address stated above, not less than 75 days nor more than 90 days prior to the meeting. However, in the event that less than 85 days' notice or prior public disclosure of the date of the meeting is given or made to shareholders, notice by the shareholder to be timely must be so received not later than the close of business on the 10<sup>th</sup> day following the day on which such notice of the date of the 2020 annual meeting was mailed or such public disclosure was made. Notices for submitting nominees for election to the Board and being included in the Company's proxy materials for the 2020 annual meeting of shareholders pursuant to the proxy access provision (Article II, Section 9) of our Bylaws must meet the requirements thereunder and must be received by the Secretary of the Company, at the address stated above, not earlier than the close of business on October 16, 2019 nor later than the close of business on November 15, 2019; provided, however, that in the event that the date of the 2020 annual meeting of shareholders is more than 30 days before or more than 60 days after March 14, 2020, such notices must be so received by our Secretary not earlier than the close of business on the 150<sup>th</sup> day prior to such annual meeting and not later than the close of business on the later of the 120<sup>th</sup> day prior to such annual meeting or, if the first public announcement of the date of such annual meeting is less than 100 days prior to the date of such annual meeting, the 10<sup>th</sup> day following the day on which public announcement of the date of such meeting is first made by the Company.

### BY ORDER OF THE BOARD

Brian J. Magstadt

#### Secretary

TO ASSURE THAT YOUR SHARES ARE REPRESENTED AT THE MEETING, WE URGE YOU TO COMPLETE, DATE AND SIGN THE ENCLOSED PROXY AND MAIL IT PROMPTLY IN THE POSTAGE-PAID ENVELOPE PROVIDED, OR VOTE BY TELEPHONE OR THE INTERNET AS INSTRUCTED ON THE PROXY OR THE NOTICE REGARDING THE AVAILABILITY OF PROXY MATERIALS, WHETHER OR NOT YOU PLAN TO ATTEND THE MEETING. YOU CAN REVOKE YOUR PROXY AT ANY TIME BEFORE IT IS VOTED.

# OUR ANNUAL REPORT TO SHAREHOLDERS ON FORM 10-K IS AVAILABLE UPON WRITTEN REQUEST TO OUR SECRETARY, SENT TO:

SIMPSON MANUFACTURING CO., INC.

#### 5956 W. Las Positas Blvd.

Pleasanton, California 94588

WE WILL PROVIDE YOU, WITHOUT CHARGE, A COPY OF OUR ANNUAL REPORT TO SHAREHOLDERS ON FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018, INCLUDING THE FINANCIAL STATEMENTS AND THE FINANCIAL STATEMENTS SCHEDULES FILED THEREWITH, ACCOMPANIED BY A LIST BRIEFLY DESCRIBING ALL THE EXHIBITS NOT CONTAINED THEREIN. PROVISION OF SUCH EXHIBITS WILL BE SUBJECT TO THE ADVANCE PAYMENT OF OUR REASONABLE EXPENSES IN FURNISHING THE EXHIBITS.

© 2016 Simpson Manufacturing Co., Inc. P71198 PR16