

CHIMERIX INC  
Form 10-Q  
November 08, 2018  
UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-Q  
(Mark One)

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

For the quarterly period ended September 30, 2018

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

2505 Meridian Parkway, Suite 100  
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  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes  No

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

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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of October 31, 2018, the number of outstanding shares of the registrant's common stock, par value \$0.001 per share, was 50,724,102.

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CHIMERIX, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2018

INDEX

	Page
<u>Part I — Financial Information</u>	
<u>Item 1. Financial Statements</u>	<u>3</u>
<u>Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017 (unaudited)</u>	<u>3</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2018 and 2017 (unaudited)</u>	<u>4</u>
<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2018 and 2017 (unaudited)</u>	<u>5</u>
<u>Notes to the Consolidated Financial Statements (unaudited)</u>	<u>6</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>17</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>26</u>
<u>Item 4. Controls and Procedures</u>	<u>26</u>
<u>Part II — Other Information</u>	
<u>Item 1. Legal Proceedings</u>	<u>27</u>
<u>Item 1A. Risk Factors</u>	<u>27</u>
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>55</u>
<u>Item 3. Defaults Upon Senior Securities</u>	<u>55</u>
<u>Item 4. Mine Safety Disclosures</u>	<u>55</u>
<u>Item 5. Other Information</u>	<u>55</u>
<u>Item 6. Exhibits</u>	<u>56</u>
<u>Signatures</u>	<u>57</u>

## PART I - FINANCIAL INFORMATION

## ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

## CHIMERIX, INC.

## CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

(unaudited)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$22,991	\$18,548
Short-term investments, available-for-sale	160,367	132,972
Accounts receivable	332	1,682
Prepaid expenses and other current assets	3,028	3,331
Total current assets	186,718	156,533
Long-term investments	10,564	76,731
Property and equipment, net of accumulated depreciation	1,363	1,894
Other long-term assets	51	72
Total assets	\$198,696	\$235,230
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,609	\$3,812
Accrued liabilities	7,776	9,384
Total current liabilities	9,385	13,196
Lease-related obligations	167	224
Total liabilities	9,552	13,420
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at September 30, 2018 and December 31, 2017; no shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 50,627,237 and 47,505,532 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	51	47
Additional paid-in capital	731,060	709,514
Accumulated other comprehensive loss, net	(661)	(963)
Accumulated deficit	(541,306)	(486,788)
Total stockholders' equity	189,144	221,810
Total liabilities and stockholders' equity	\$198,696	\$235,230

The accompanying notes are an integral part of the consolidated financial statements.



## CHIMERIX, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Contract revenue	\$369	\$897	\$2,352	\$2,650
Operating expenses:				
Research and development	11,892	12,157	39,963	36,535
General and administrative	5,187	6,650	18,575	19,530
Total operating expenses	17,079	18,807	58,538	56,065
Loss from operations	(16,710 )	(17,910 )	(56,186 )	(53,415 )
Other (expense) income:				
Unrealized loss on equity investment	(99 )	—	(311 )	—
Interest income	730	598	1,979	1,669
Net loss	(16,079 )	(17,312 )	(54,518 )	(51,746 )
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	180	(6 )	302	(1,041 )
Comprehensive loss	\$(15,899)	\$(17,318 )	\$(54,216)	\$(52,787 )
Per share information:				
Net loss, basic and diluted	\$(0.33 )	\$(0.37 )	\$(1.14 )	\$(1.10 )
Weighted-average shares outstanding, basic and diluted	48,172,354	47,065,756	47,875,895	46,836,099

The accompanying notes are an integral part of the consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(54,518)	\$(51,746)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	691	828
Amortization of premium/discount on investments	(447)	) 49
Share-based compensation	10,608	12,478
Unrealized loss on equity investment	311	—
Amortization of lease-related obligations	(44)	) (298)
Changes in operating assets and liabilities:		
Accounts receivable	1,350	1,328
Prepaid expenses and other assets	202	268
Accounts payable and accrued liabilities	(3,578)	) (909)
Net cash used in operating activities	(45,425)	) (38,002)
Cash flows from investing activities:		
Purchases of property and equipment	(160)	) (30)
Purchases of short-term investments	(59,259)	) —
Purchases of long-term investments	(6,031)	) (144,536)
Proceeds from sales of short-term investments	26,000	4,000
Proceeds from maturities of short-term investments	78,500	144,445
Net cash provided by investing activities	39,050	3,879
Cash flows from financing activities:		
Proceeds from exercise of stock options	115	121
Proceeds from employee stock purchase plan	606	712
Payments of deferred offering costs	(363)	) —
Proceeds from issuance of common stock, net of commissions	10,460	—
Net cash provided by financing activities	10,818	833
Net increase (decrease) in cash and cash equivalents	4,443	(33,290)
Cash and cash equivalents:		
Beginning of period	18,548	51,463
End of period	\$22,991	\$18,173

The accompanying notes are an integral part of the consolidated financial statements.

CHIMERIX, INC.  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(unaudited)

Note 1. The Business and Summary of Significant Accounting Policies

Description of Business

Chimerix, Inc. (the Company) is a biopharmaceutical company committed to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. The Company was founded in 2000 based on the promise of its proprietary lipid conjugate technology to unlock the potential of some of the most broad-spectrum antivirals by enhancing their antiviral activity and safety profiles in convenient dosing regimens. The Company's lead compound, brincidofovir, is in development as an oral and intravenous (IV) formulation for the prevention and treatment of DNA viruses, including smallpox, adenoviruses, and the human herpesviruses. The Company is developing CMX521, the first clinical-stage direct-acting antiviral specifically for the treatment and prevention of norovirus. In addition, the Company has an active discovery program focusing on viral targets for which limited or no therapies are currently available.

Basis of Presentation

The accompanying unaudited consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information, the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's audited financial statements and notes thereto included in its Annual Report on Form 10-K for the year ended December 31, 2017. In the opinion of the Company's management, all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented have been included. Operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the full year, for any other interim period or for any future year.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments, including accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of such instruments.

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. The determination of where an asset or liability falls in the hierarchy requires significant judgment. These levels are:

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

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

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

At September 30, 2018 and December 31, 2017, the Company had cash equivalents including money market accounts and short-term investments and long-term investments including U.S. Treasury securities, whose value is based on using quoted market prices. Accordingly, these securities are classified as Level 1.

At September 30, 2018 and December 31, 2017, the Company had short-term investments including stock of a U.S. corporation. The Company's investment in ContraVir Pharmaceuticals (ContraVir) common stock was categorized as a Level 1 asset and value based on ContraVir's common stock value at September 30, 2018 and December 31, 2017. For the three and nine months ended September 30, 2018, the Company recorded \$0.1 million and \$0.3 million, respectively, of unrealized loss related to the Company's investment in ContraVir common stock to unrealized loss on equity investment in the Consolidated Statements of Operations and Comprehensive Loss. For the three and nine months ended September 30, 2017, the Company recorded \$0.1 million and \$0.7 million, respectively, of unrealized loss related to the Company's investment in ContraVir common stock to unrealized gain (loss) on investments, net in the Consolidated Statements of Operations and Comprehensive Loss.

At September 30, 2018 and December 31, 2017, the Company had cash equivalents including commercial paper, and at September 30, 2018, the Company had short-term investments including corporate bonds and commercial paper. As quoted prices are not available for these securities, they are valued using independent pricing models or other model-based valuation techniques such as the present value of future cash flows, adjusted for the security's credit rating, prepayment assumptions and other factors such as credit loss assumptions. Accordingly, these securities are classified as Level 2.

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. For additional information regarding the Company's investments, please refer to Note 2, "Investments."

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Below are tables that present information about certain assets measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements September 30, 2018			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Cash equivalents</b>				
Money market funds	\$10,231	\$ 10,231	\$ —	\$ —
Commercial paper	1,996	—	1,996	—
Total cash equivalents	12,227	10,231	1,996	—
<b>Short-term investments</b>				
Corporate bonds	11,447	—	11,447	—
Commercial paper	38,004	—	38,004	—
U.S. treasury securities	110,841	110,841	—	—
Common stock of U.S. corporation	75	75	—	—
Total short-term investments	160,367	110,916	49,451	—
<b>Long-term investments</b>				
U.S. treasury securities	10,564	10,564	—	—
Total long-term investments	10,564	10,564	—	—
Total	\$183,158	\$ 131,711	\$ 51,447	\$ —

	Fair Value Measurements December 31, 2017			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Cash equivalents</b>				
Money market funds	\$10,816	\$ 10,816	\$ —	\$ —
Commercial paper	3,995	—	3,995	—
Total cash equivalents	14,811	10,816	3,995	—
<b>Short-term investments</b>				
U.S. treasury securities	132,586	132,586	—	—
Common stock of U.S. corporation	386	386	—	—
Total short-term investments	132,972	132,972	—	—
<b>Long-term investments</b>				
U.S. treasury securities	76,731	76,731	—	—
Total long-term investments	76,731	76,731	—	—
Total	\$224,514	\$ 220,519	\$ 3,995	\$ —

## Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Accrued research and development expenses	\$ 5,161	\$ 3,384
Accrued compensation	1,764	3,678
Other accrued liabilities	851	1,322
Accrued indemnification claim	—	1,000
Total accrued liabilities	\$ 7,776	\$ 9,384

## Revenue Recognition

## Policy

The Company's revenues generally consist of (i) contract revenue - revenue generated under federal contracts, and (ii) collaboration and licensing revenue - revenue related to non-refundable upfront fees, royalties and milestone payments earned under license agreements. Revenue is recognized in accordance with the criteria outlined in Accounting Standards Codification (ASC) 606 issued by the Financial Accounting Standards Board (FASB). Following this accounting pronouncement, a five-step approach is applied for recognizing revenue, including (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the entity satisfies a performance obligation.

## Biomedical Advanced Research and Development Authority (BARDA)

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. Under the contract, the Company may receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees over the performance of 1 base segment and 4 option segments. Exercise of each option segment is solely at the discretion of BARDA. Currently, option segments 1 through 3 have been exercised. The Company assessed the services in accordance with the authoritative guidance and concluded that there is a potential of 5 separate contracts (1 base segment and 4 option segments) within this agreement, each of which has a single performance obligation. The transaction price for each segment, based on the transaction price as defined in each segment contract, is allocated to the single performance obligation for each contract. The transaction price is recognized over time by measuring the progress toward complete satisfaction of the performance obligation. The progress toward complete satisfaction is estimated based on the costs incurred to date relative to the total estimated costs per the terms of each contract. The Company typically invoices BARDA monthly as costs are incurred. The base segment and first option segment were completed prior to adoption of ASC 606. The Company is currently performing under the second and third option segments of the contract during which the Company may receive up to a total of \$21.6 million and \$14.1 million in expense reimbursement and fees, respectively. The second and third option segments are scheduled to end on March 30, 2019.

## ContraVir Pharmaceuticals

The Company entered into a license agreement with ContraVir on December 17, 2014 for the development and commercialization of CMX157 for certain antiviral indications. The Company is eligible to receive up to approximately \$20 million in clinical, regulatory and initial commercial milestones as well as royalties and additional milestones based on commercial sales. The Company assessed the agreement in accordance with the authoritative guidance and concluded that the ContraVir contract includes multiple performance obligations, which had all been

satisfied in 2015 prior to the adoption of ASC 606. The ContraVir contract has one fixed and several variable transaction amounts. The fixed fee portion of the contract was for the license to CMX157 rights. The Company recognized revenue for the fixed fee portion of the contract in 2015 when the performance obligations were satisfied. All variable transaction amounts, which relate to clinical, regulatory and commercial milestones as well as royalties and milestones based on commercial sales, are fully constrained. The Company will begin recognizing revenue on the variable transaction amounts when those transaction amounts are no longer fully constrained.

#### Research and Development Prepaids and Accruals

As part of the process of preparing financial statements, the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its research and development efforts. The financial terms of these contracts are subject to negotiations which vary contract to contract and may result in payment

9

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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 research and development 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 its research and development efforts. The Company determines prepaid and accrual estimates through discussion with applicable personnel and outside service providers as to the progress or state of communication of clinical trials, or other services completed. The Company adjusts its rate of research and development expense recognition if actual results differ from its estimates. The Company makes estimates of its prepaid and 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 September 30, 2018, there had been no material adjustments to the Company's prior period estimates of prepaid and accruals for research and development expenses. The Company's research and development prepaids and accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors.

#### Basic and Diluted Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of warrants to purchase common stock, non-vested restricted stock, stock options, and employee stock purchase plan purchase rights. Diluted net loss per share of common stock is computed by dividing net loss by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of warrants to purchase common stock, non-vested restricted stock, stock options, and employee stock purchase plan purchase rights 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 and nine months ended September 30, 2018 and 2017.

#### Impact of Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Update (ASU) No. 2016-02, "Leases (Topic 842)", which increases transparency and comparability among companies accounting for lease transactions. The most significant change of this update will require the recognition of lease assets and liabilities on the balance sheet for lessees for operating lease arrangements with lease terms greater than 12 months. This update will require a modified retrospective application which includes a number of optional practical expedients related to the identification and classification of leases commenced before the effective date. This ASU is effective for financial statements issued for annual periods and interim periods within those annual periods, beginning after December 15, 2018. The Company is currently analyzing the impact of the adoption of ASU No. 2016-02 on its consolidated financial statements.

#### Impact of Recently Adopted Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers (Topic 606)." The ASU establishes a principles-based approach for accounting for revenue arising from contracts with customers and supersedes existing revenue recognition guidance. The ASU provides that an entity should apply a five-step approach for recognizing revenue, including (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when, or as, the entity satisfies a performance obligation. Also, the entity must

provide various disclosures concerning the nature, amount and timing of revenue and cash flows arising from contracts with customers. The FASB has issued several updates to the standard which (1) deferred the original effective date to annual periods and interim periods within those annual periods beginning after December 15, 2017, while allowing for early adoption as of January 1, 2017 (ASU 2015-14); (2) clarify the application of the principal versus agent guidance (ASU 2016-08); and (3) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10). The Company adopted ASU No. 2014-09 as of January 1, 2018 using the full retrospective approach and determined that there was no impact on its consolidated financial statements. In preparation for adoption of the standard, the Company implemented internal controls to enable the preparation of financial information, including the assessment of the impact of the standard.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments-Overall (Subtopic 825-10)-Recognition and Measurement of Financial Assets and Financial Liabilities." The new standard enhances reporting for financial instruments. The ASU is effective for financial statements issued for annual periods and interim periods within those annual periods beginning after December 15, 2017. The Company adopted ASU No. 2016-01 on January 1, 2018 on a prospective basis. As a result of this

standard, changes in fair value of available-for-sale equity securities that were previously recognized in other comprehensive income are now recognized in earnings. As of January 1, 2018, the Company had no unrealized gains or losses in other comprehensive income that had to be reclassified to retained earnings.

Note 2. Investments

The following tables summarize the Company's short-term and long-term debt investments (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate bonds	\$11,456	\$	—\$ (9 )	\$11,447
U.S. treasury securities	122,033	—	(628 )	121,405
Commercial paper	38,028	—	(24 )	38,004
Total investments	\$171,517	\$	—\$ (661 )	\$170,856

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	\$210,280	\$	—\$ (963 )	\$209,317
Total investments	\$210,280	\$	—\$ (963 )	\$209,317

The following tables summarize the Company's debt investments with unrealized losses, aggregated by investment type and the length of time that individual investments have been in a continuous unrealized loss position (in thousands, except number of securities):

	September 30, 2018					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds	\$11,447	\$ (9 )	\$—	\$ —	\$11,447	\$ (9 )
Commercial paper	38,004	(24 )	—	—	38,004	(24 )
U.S. treasury securities	30,049	(176 )	91,356	(452 )	121,405	(628 )
Total	\$79,500	\$ (209 )	\$91,356	\$ (452 )	\$170,856	\$ (661 )
Number of securities with unrealized losses		27		21		48

	December 31, 2017					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
U.S. treasury securities	\$170,390	\$ (871 )	\$38,927	\$ (92 )	\$209,317	\$ (963 )
Total	\$170,390	\$ (871 )	\$38,927	\$ (92 )	\$209,317	\$ (963 )
Number of securities with unrealized losses		39		7		46



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. The Company evaluates, among other things, the duration and extent to which the fair value of a security is less than its cost; the financial condition of the issuer and any changes thereto; and the Company's intent to sell, or whether it will more likely than not be required to sell, the security before recovery of its cost basis. At September 30, 2018, the Company did not intend to sell, and

11

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was not more likely than not to be required to sell, the available-for-sale debt securities in an unrealized loss position before recovery of the cost basis of the securities, which may be at maturity. There were no such declines in value for the three and nine months ended September 30, 2018 and 2017. Unrealized gains and losses on debt investments are recorded to unrealized gain (loss) on investments, net in the Consolidated Statements of Operations and Comprehensive Loss. The Company recognizes interest income on an accrual basis in interest income in the Consolidated Statements of Operations and Comprehensive Loss.

The following table summarizes the scheduled maturity for the Company's debt investments at September 30, 2018 (in thousands):

Maturing in one year or less	\$	160,292
Maturing after one year through two years	10,564	
Total debt investments	170,856	
Common stock of U.S. corporation	75	
Total investments	\$	170,931

### Note 3. 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 2021. Rent expense under non-cancelable operating leases and other month-to-month equipment rental agreements, including common area maintenance fees, totaled approximately \$0.2 million and \$0.1 million for the three months ended September 30, 2018 and 2017, respectively, and \$0.5 million and \$0.4 million for the nine months ended September 30, 2018 and 2017, respectively.

#### Significance of Revenue Source

The Company is the recipient of federal research contract funds from BARDA, the sole source of the Company's contract revenue. Periodic audits are required under the Company's BARDA agreement and certain costs may be questioned as appropriate under the BARDA agreement. Management believes that such amounts in the current year, if any, are not significant. Accordingly, no provision for refundable amounts under the BARDA agreement had been made as of September 30, 2018 and December 31, 2017.

### Note 4. Equity Transactions and Share-based Compensation

#### Warrants

During the three and nine months ended September 30, 2018, there were no exercises of warrants for the purchase of shares of the Company's common stock. All outstanding warrants expired in February 2018. As of September 30, 2018 no warrants were outstanding.

#### 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), non-statutory 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. The number of shares of common stock reserved for future issuance automatically increases on January 1 of each calendar year by 4% 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. On January 1, 2018, the common stock reserved for issuance under the 2013 Plan was automatically increased by 1.9 million shares. As of September 30, 2018, there was a total of 1.5 million shares reserved for future issuance under the 2013 Plan. The Company issued no shares of common stock pursuant to the exercise of stock options during the three months ended September 30, 2018. The Company issued approximately 29,000 shares of common stock pursuant to the exercise of stock options during the nine months ended September 30, 2018.

## Employee Stock Purchase Plan

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. Initially, the ESPP authorized the issuance of 704,225 shares of common stock pursuant to purchase rights granted to the Company's employees or to employees of any of its designated affiliates. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year, from January 1, 2014 through January 1, 2023 by the lesser 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). On January 1, 2018, the common stock reserved for issuance under the ESPP was automatically increased by an additional 0.4 million shares.

The Company has reserved a total of 2.6 million shares of common stock to be purchased under the ESPP, of which 2.1 million shares remained available for purchase as of September 30, 2018. The ESPP provides for an automatic reset feature to start participants on a new twenty-four month participation period in the event that the common stock market value on a purchase date is less than the common stock value on the first day of the twenty-four month offering period. Eligible employees may authorize an amount up to 15% of their salary to purchase common stock at the lower of a 15% discount to the beginning price of their offering period or a 15% discount to the ending price of each six-month purchase interval. The Company issued 77,000 and 164,000 shares of common stock pursuant to the ESPP during the three and nine months ended September 30, 2018, respectively. Compensation expense for shares purchased under the ESPP related to the purchase discount and the "look-back" option and were determined using a Black-Scholes option pricing model.

## Restricted Stock Units

The Company has issued RSUs to certain employees which vest based on service criteria. When vested, the RSU represents the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The grant date fair value for RSUs is based upon the market price of the Company's common stock on the date of the grant. The fair value is then amortized to compensation expense over the requisite service period or vesting term. The Company issued no shares of common stock pursuant to the vesting of RSUs during the three months ended September 30, 2018. The Company issued 233,000 shares of common stock pursuant to the vesting of RSUs during the nine months ended September 30, 2018.

In January 2017, the Company also granted performance-based RSUs which, when vested, represent the right to be issued the number of shares of the Company's common stock that is equal to the number of RSUs granted. The grant date fair value for performance-based RSUs is based upon the market price of the Company's common stock on the date of the grant. For the portion of the performance-based RSUs of which the achievement of the performance condition is considered probable, the Company recognizes stock-based compensation expense on the related estimated fair value of such RSUs ratably for each vesting tranche from the service inception date to the end of the requisite service period. For the performance conditions that are not considered probable of achievement at the grant date or upon quarterly re-evaluation, prior to the event actually occurring, the Company begins recognizing the related stock-based compensation expense ratably when the event occurs or when the Company can determine that achievement of the performance condition is probable. In those cases, the Company recognizes the change in estimate at the time it determines the performance condition is probable of achievement (by recognizing stock-based compensation expense as cumulative catch-up adjustment as if the Company had estimated at the grant date that the performance condition would have been achieved) and recognize the remaining compensation cost through the end of the requisite service period. The Company issued no shares of common stock pursuant to the vesting of performance-based RSUs during the three and nine months ended September 30, 2018.

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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. Total share-based compensation expense recognized related to stock options, the ESPP and RSUs was as follows (in thousands):

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,	30,	2018	2017
	2018	2017	2018	2017
Research and development expense	\$1,370	\$1,853	\$4,226	\$5,468
General and administrative expense	1,811	2,365	6,382	7,010
Total share-based compensation expense	\$3,181	\$4,218	\$10,608	\$12,478

#### At-The-Market Equity Offering

On November 8, 2017, the Company entered into an at-the-market (ATM) sales agreement with Cowen and Company, LLC to sell up to \$75 million of the Company's common stock under a shelf registration statement filed in November 2017. In July 2018, the Company began selling shares of common stock through this ATM sales agreement. During the three and nine months ended September 30, 2018, the Company sold 2.7 million shares of common stock at a weighted average price per share of \$4.00 for net offering proceeds of \$10.5 million. As of November 2, 2018, the Company had sold an aggregate of 2.8 million shares of common stock at a weighted average price per share of \$4.00 for net offering proceeds of \$10.9 million.

#### Note 5. Income Taxes

The Company estimates an annual effective tax rate of 0% for the year ending December 31, 2018 as the Company incurred losses for the nine month period ended September 30, 2018 and is forecasting additional losses through the fourth quarter, resulting in an estimated net loss for both financial statement and tax purposes for the year ending December 31, 2018. 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 full valuation allowance, since the Company does not currently believe that realization of its deferred tax assets is more likely than not.

At September 30, 2018, the Company had no unrecognized tax benefits that would reduce the Company's effective tax rate if recognized.

At September 30, 2018, the Company's accounting for the 2017 Tax Cuts and Jobs Act is incomplete; however, it expects to complete the accounting by December 31, 2018. As discussed in our 2017 Annual Report on Form 10-K, the Company recorded provisional adjustments related to deferred taxes for stock compensation and the deferred rate change. The Company is continuing to evaluate the impact of the recently enacted tax law on its business and consolidated financial statements. For the third quarter of 2018, the Company has not made any measurement-period adjustments related to these provisional items. Updates to the Company's calculations may result in changes to the provisional adjustments recorded at December 31, 2017.

#### Note 6. 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. 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. In April 2018, a fifth amendment was executed to alter the rights and obligations of the parties in light of the Company's current business plans and to extend the term of the agreement to the later of the longest-lived Patent Rights (as defined in the agreement) or May 2028.

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 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. In addition, upon commercialization of any product utilizing the UC Patent Rights (which would include the commercialization of brincidofovir), the Company will be required to pay low single digit royalties on net sales of such product.

The license agreement requires that we diligently develop, manufacture and commercialize compounds that are covered by the UC Patent Rights, and we have agreed to meet certain development and commercialization milestones. UC may, at its option, either terminate the license agreement or change the license granted from an exclusive license to a non-exclusive license if we fail to meet such development and commercialization milestones. We are currently in compliance with these milestone requirements.

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 amount of any payments 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, the fee payable to UC will not exceed 5% of the sublicense fee. 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.

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

In February 2011, the Company entered into a contract with BARDA for the advanced development of brincidofovir as a medical countermeasure in the event of a smallpox release. Under the contract, BARDA will reimburse the Company, plus pay a fixed fee, for the research and development of brincidofovir as a broad-spectrum therapeutic antiviral for the treatment of smallpox infections. The contract consists of an initial performance period, referred to as the base performance segment, plus up to four extension periods, 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 second and third option segments of the contract during which the Company may receive up to a total of \$21.6 million and \$14.1 million in expense reimbursement and fees, respectively. The second and third option segments are scheduled to end on March 30, 2019. For the three months ended September 30, 2018 and 2017, the Company recognized revenue under this contract of \$0.4 million and \$0.9 million, respectively, and for the nine months ended September 30, 2018 and 2017, the Company recognized revenue under this contract of \$2.4 million and \$2.7 million, respectively.

#### ContraVir Pharmaceuticals

On December 17, 2014, the Company entered into a license agreement with ContraVir (NASDAQ:CTRV) for the development and commercialization of CMX157 for certain antiviral indications. Under the terms of the agreement, ContraVir has sole responsibility with respect to the control of the development and commercialization of CMX157.

In exchange for the license to CMX157 rights, the Company received ContraVir Series B Convertible Preferred Stock which the Company converted into shares of ContraVir common stock in 2016. As of September 30, 2018 and December 31, 2017, the fair value of the investment was recorded as a short-term investment of \$0.1 million and \$0.4 million, respectively.

In addition, the Company is eligible to receive up to approximately \$20 million in clinical, regulatory and initial commercial milestones in the United States and Europe, as well as royalties and additional milestones based on commercial sales in those territories. Either party may terminate the license agreement upon the occurrence of a material breach by the other party (subject to standard cure periods), or upon certain events involving the bankruptcy



or insolvency of the other party. ContraVir may also terminate the license agreement without cause on a country-by-country basis upon sixty days' prior written notice.

#### University of Michigan

In 2006, the Company entered into a license agreement with The Regents of the University of Michigan (UM) under which the Company obtained an exclusive, worldwide license to UM's patent rights in certain inventions (UM Patent Rights) related to certain compounds originally synthesized at UM. Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UM Patent Rights, and to sublicense such rights subject to certain sublicensing fees and royalty payments. The agreement was amended in 2016.

In connection with the Company's commercialization or sublicensing of certain products covered by the license agreement, including CMX521, the Company could be required to pay royalties on net sales of such products ranging from 0.25% to 2%. Beginning in 2024, the Company is also subject to certain minimum annual royalty payments.

The UM license agreement requires that the Company uses commercially reasonable efforts to develop and make commercially available licensed products as soon as practicable. Specifically, the Company has agreed to make the first commercial sale of a licensed product by June of 2026. UM may terminate the license agreement if the Company materially breaches the license agreement. The Company is currently in compliance with its milestone requirements.

Note 7. Subsequent Events

The Company has evaluated subsequent events through the issuance date of these financial statements to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of September 30, 2018, and events which occurred subsequently but were not recognized in the financial statements.

## 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 consolidated 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, 2017 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, 2017, filed with the Securities and Exchange Commission (SEC) on March 1, 2018. 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, Inc. is a biopharmaceutical company committed to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. We were founded in 2000 based on the promise of our proprietary lipid conjugate technology to unlock the potential of some of the most broad-spectrum antivirals by enhancing their antiviral activity and safety profiles in convenient dosing regimens. Our lead compound, brincidofovir (BCV), is in development as an oral and intravenous (IV) formulation for the prevention and treatment of DNA viruses, including smallpox, adenoviruses, and the human herpesviruses. We are developing CMX521, the first clinical-stage direct-acting antiviral specifically for the treatment and prevention of norovirus. In addition, we have an active discovery program focusing on viral targets for which limited or no therapies are currently available.

### Recent Developments

#### AdAPT Study of Oral Brincidofovir

The AdAPT study (Adenovirus after Allogeneic Pediatric Transplantation) is open for enrollment at sites in the United States, the United Kingdom, and in continental Europe. All targeted countries and clinical sites are anticipated to be open for enrollment by the end of 2018. This study is targeting enrollment of 141 pediatric and young adult allogeneic hematopoietic cell transplant (HCT) recipients with confirmed adenovirus (AdV) infection. In the study, subjects are randomized 2:1 to receive short-course oral BCV or local standard-of-care (SOC) treatment.

The primary endpoint of the study is a comparison of AdV viral burden, as measured by the time-Averaged Area Under the Curve for AdV viremia over 16 weeks (AdV AAUC<sub>0-16</sub>) in subjects treated with short-course oral BCV versus those who receive local SOC. The study is 90% powered to show the superiority of reduced AdV viral burden (i.e., lower AdV AAUC<sub>0-16</sub>) in BCV-treated patients compared to local SOC. The study will also evaluate the correlation of AdV AAUC<sub>0-16</sub> with clinical outcomes, including survival. A strong correlation between AdV viral burden and mortality was described in data collected from the AdVance study. In the AdVance study, patients with the highest AdV AAUC<sub>0-16</sub> had the highest observed mortality. In addition, across the pediatric patients with AdV viremia, each 1.0 log<sub>10</sub> increase in AdV AAUC<sub>0-16</sub> was associated with a two-fold increase in mortality. We anticipate that enrollment in the AdAPT study will be completed in 2019 and obtaining results from the 16 week primary endpoint in 2020; however, this forecast will likely be updated once we have several months of enrollment rate data from a majority of planned clinical centers.

On October 19, 2018, the European Medicines Agency (EMA) issued a positive opinion to the Company for our adenovirus Pediatric Investigation Plan (PIP). An approved PIP, or a waiver thereof, is required by the EMA prior to marketing authorization application (MAA) submission.

### Oral Treatment for Smallpox

We are collaborating with the Biomedical Advanced Research and Development Authority (BARDA) for the development of BCV as a potential medical countermeasure for smallpox. Efficacy is to be demonstrated via two animal models under the FDA's Animal Rule. We reached agreement with the U.S. Food and Drug Administration (FDA) and BARDA on the design and conduct of an adjunct pivotal rabbitpox study and it was recently initiated. We are working with the FDA and BARDA on the design and conduct of a pivotal mouse study and we expect to initiate that study early next year. Following successful completion of the animal efficacy studies, we plan to meet with the FDA to discuss any additional required data for a regulatory decision. Data from both animal efficacy studies are expected in 2019. We anticipate submitting marketing applications in 2020.

On October 19, 2018, the EMA issued a positive opinion to the Company for our smallpox PIP. An approved PIP, or a waiver thereof, is required by the EMA prior to MAA submission.

### IV Brincidofovir Progresses to Phase 2 Studies

We are continuing to open sites in the United States and Europe for enrollment in our IV BCV Phase 2 studies in adult allogeneic HCT recipients with AdV. We anticipate interim data to be available during 2019. These studies may also provide data on other viral infections such as cytomegalovirus (CMV) and/or BK virus (BKV) in patients with multi-viral infections. The studies will evaluate pharmacokinetics (PK) and tolerability of multiple doses of IV BCV in adult allogeneic HCT recipients. We will also evaluate the relationship between BCV dose and observed change-from-baseline in AdV. Data from these studies are expected to inform the design of future Phase 2/3 studies.

Following availability of data from adult patients in the studies described above, we will evaluate the potential for IV BCV to treat other DNA viral infections, such as BKV, CMV, or other herpesviruses such as HHV-6. In addition, the higher drug concentrations in the central nervous system (CNS) achieved with IV BCV in animal studies could support the study of IV BCV in viral CNS infections such as herpes encephalitis and JC virus infection.

In October 2018, we presented data from our Phase 1 study evaluating the safety and PK of multiple ascending doses (MAD) of IV BCV in healthy subjects. The Phase 1 study evaluated the safety and PK of IV BCV in 27 healthy individuals who were randomized 3:1 to receive IV BCV or placebo in sequential MAD cohorts. Individuals receiving IV BCV were given a 10 mg dose in a two-hour infusion twice a week for two weeks or a 20 mg dose in either a one- or two-hour infusion once a week for four weeks. Twice weekly doses of IV BCV at 10 mg provided similar blood levels of the drug as the oral BCV 100 mg dose previously studied in late-stage clinical trials, with no reported diarrhea or other gastrointestinal adverse events.

### CMX521 for Norovirus

CMX521, a nucleoside analog identified from our proprietary chemical library, is the first clinical-stage direct-acting antiviral specifically for the treatment and/or prevention of norovirus. One recent study estimates that norovirus outbreaks account for approximately \$60 billion in lost productivity/economic impact and no antivirals or vaccines are currently available. Chronic norovirus infection is increasingly being diagnosed in immunocompromised patients. Approximately 15-20 percent of HCT and solid organ transplant (SOT) recipients are diagnosed with norovirus within the first 1-2 years after transplant, a diagnosis that has been associated with chronic diarrhea, electrolyte disturbances, and graft rejection.

In September 2018, we presented data on CMX521 at the European Society for Clinical Virology in Athens, Greece. The data presented included:

CMX521 plasma exposures increased in a less-than-proportional manner with escalating single oral dose administration;

Single oral doses of CMX521 up to 2400 mg were generally well-tolerated; and

No safety concerns were identified.

Clinical testing of CMX521 is ongoing in conjunction with in vitro studies in cultured human intestinal cells and recently described animal models of norovirus to assess antiviral efficacy.

## FINANCIAL OVERVIEW

### Revenues

To date, we have not generated any revenue from product sales. All of our revenue to date has been derived from a government grant and contract and the receipt of up-front proceeds under our collaboration and license agreements.

18

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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, referred to as option segments. Subsequent option segments to the contract are not subject to automatic renewal and are not exercisable at our discretion. The contract is a cost plus fixed fee development contract. Under the contract as currently in effect, we may cumulatively receive up to \$75.8 million in expense reimbursement and \$5.3 million in fees if all remaining option segments are exercised. We are currently performing under the second and third option segments of the contract during which we may receive up to a total of \$21.6 million and \$14.1 million in expense reimbursement and fees, respectively. The second and third option segments are scheduled to end on March 30, 2019. As of September 30, 2018, we had recognized revenue in aggregate of \$58.5 million with respect to the base performance segment and the first three extension periods. Under the BARDA contract, we recognized revenue of \$0.4 million and \$0.9 million during the three months ended September 30, 2018 and 2017, respectively, and we recognized revenue of \$2.4 million and \$2.7 million during the nine months ended September 30, 2018 and 2017, respectively.

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

#### Research and Development Expenses

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. We recognize research and development expenses as they are incurred. 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, restricted stock units and employee stock purchase program 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);
- costs related to legal and compliance with regulatory requirements; and
- license fees for and milestone payments related to licensed products and technologies.

From our inception through September 30, 2018, we have incurred approximately \$444.8 million in research and development expenses, which predominately relates to our development of BCV. These costs were largely related to the conduct of our clinical trials of BCV.

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.



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The table below summarizes our research and development expenses for the periods indicated (in thousands):

	Three Months		Nine Months	
	Ended		Ended September	
	September 30,	30,	2018	2017
	2018	2017	2018	2017
Direct research and development expenses	\$6,290	\$5,733	\$21,718	\$17,745
Research and development personnel costs - excluding stock-based compensation	3,197	3,552	9,971	10,265
Research and development personnel costs - stock-based compensation	1,370	1,853	4,226	5,468
Indirect research and development expenses	1,035	1,019	4,048	