



Chimerix Announces Second Quarter 2018 Financial Results

August 8, 2018

- Conference Call at 8:30 a.m. ET Today -

DURHAM, N.C., Aug. 08, 2018 (GLOBE NEWSWIRE) -- Chimerix (NASDAQ:CMRX), a biopharmaceutical company developing novel antivirals to address unmet medical needs, today reported financial results and provided a corporate update for the second quarter ended June 30, 2018.

"Throughout the second quarter of 2018, we continued to make steady progress advancing our novel antivirals across a number of important clinical studies. Our lead product candidate, brincidofovir (BCV), is moving forward as a treatment for life-threatening adenovirus infection in the AdAPT study, which we expect to be fully enrolled in 2019. We are opening sites for our Phase 2 studies for intravenous (IV) BCV in the United States and Europe. In addition to brincidofovir, we are advancing CMX521 in the clinic for the treatment and prevention of norovirus supported by results from a single dose study in healthy subjects and strong preclinical data," said M. Michelle Berrey, MD, MPH, President and Chief Executive Officer of Chimerix.

Corporate Highlights

Addressed Congressional Subcommittee in Support of Reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA)

In June, Dr. Berrey delivered remarks before the House Committee on Energy and Commerce Subcommittee on Health at a hearing titled "Examining the Reauthorization of the Pandemic and All-Hazards Preparedness Act" in Washington, D.C. The purpose of the hearing was to reauthorize certain programs under the Pandemic and All-Hazards Preparedness Act (PAHPA), which originally passed in 2006 and seeks to improve the United States' public health and medical preparedness and response capabilities for emergencies, whether deliberate, accidental or natural.

Program Updates

Oral BCV

The AdAPT study (Adenovirus after Allogeneic Pediatric Transplantation) is open for enrollment in the United States (US), the United Kingdom (UK), and Europe. Four of nine planned countries are currently undergoing regulatory or central ethics review; additional sites in the US, UK and Europe are also in the process of opening for enrollment.

IV BCV Phase 2 Studies Initiating in the US, UK and Europe

The Company is opening sites in the US, UK and Europe for enrollment in IV BCV Phase 2 studies in adult hematopoietic cell transplant recipients with adenovirus. Chimerix anticipates interim data in the second half of 2018.

Received Orphan Drug Designation for Brincidofovir for the Treatment of Smallpox

In June, Chimerix announced that the US Food and Drug Administration (FDA) granted Orphan Drug Designation for brincidofovir for the treatment of smallpox. The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders that affect fewer than 200,000 people in the United States. Orphan Drug Designation provides manufacturers with many benefits, including a waiver of the FDA Prescription Drug User Fee Act.

Chimerix intends to submit marketing applications for smallpox following the completion of the rabbit and mouse efficacy studies.

Presented Preclinical CMX521 Data at 31st International Conference on Antiviral Research (ICAR)

In June, Chimerix presented results from preclinical studies supporting clinical evaluation of CMX521, the first clinical-stage direct-acting antiviral specifically for the treatment and prevention of norovirus. CMX521 showed activity in vitro against all strains of norovirus tested, suggesting broad efficacy against human noroviruses and supporting the ongoing Phase 1 study. These data were presented in oral and poster presentations at the 31st International Conference on Antiviral Research (ICAR) in Porto, Portugal.

In late 2017, Chimerix initiated a first-time-in-human Phase 1 study of CMX521 to evaluate the pharmacokinetics, safety and tolerability of CMX521 in healthy adult subjects. The first presentation of clinical data on CMX521 will be in September at the European Society for Clinical Virology in Athens, Greece.

Second Quarter 2018 Financial Results

Chimerix reported a net loss of \$18.6 million, or \$0.39 per basic and diluted share, for the second quarter of 2018. During the same period in 2017, Chimerix recorded a net loss of \$16.7 million, or \$0.36 per basic and diluted share.

Revenues for the second quarter of 2018 increased to \$1.2 million, compared to \$0.7 million for the same period in 2017.

Research and development expenses increased to \$13.7 million for the second quarter of 2018, compared to \$11.6 million for the same period in 2017.

General and administrative expenses increased to \$6.7 million for the second quarter of 2018, compared to \$6.3 million for the same period in 2017.

Loss from operations was \$19.2 million for the second quarter of 2018, compared to a loss from operations of \$17.2 million for the same period in

2017.

Chimerix's balance sheet at June 30, 2018 included \$195.7 million of capital available to fund operations, no debt, and approximately 47.9 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss second quarter financial results and provide a business update today at 8:30 a.m. ET. To access the live conference call, please dial 877-354-4056 (domestic) or 678-809-1043 (international) at least five minutes prior to the start time and refer to conference ID 2976768.

A live audio webcast of the call will also be available on the Investors section of Chimerix's website, www.chimerix.com. An archived webcast will be available on the Chimerix website approximately two hours after the event.

About Brincidofovir

Chimerix's lead product candidate, brincidofovir, is a nucleotide analog that has antiviral activity against all five families of DNA viruses that affect humans, including the herpesviruses and adenoviruses. Brincidofovir has a high barrier to resistance, no myelosuppression and a low risk of nephrotoxicity. Brincidofovir has received Fast Track designation from the FDA and Orphan Medicinal Product Designation from the European Commission for adenovirus, cytomegalovirus, and smallpox.

About CMX521

CMX521 is a nucleoside antiviral identified from the Chimerix Chemical Library as a potential treatment and/or prevention for norovirus, the most common cause of acute gastroenteritis worldwide. An ongoing Phase 1 study is evaluating the pharmacokinetics, safety and tolerability of CMX521.

About Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing medicines that improve outcomes for immunocompromised patients. Chimerix's proprietary lipid conjugate technology and compound library have produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and CMX521, the first clinical-stage direct-acting antiviral for the treatment and prevention of norovirus. For further information, please visit Chimerix's website, www.chimerix.com.

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility our current or future clinical trials of brincidofovir may not be successful, that FDA and other regulatory authorities may not approve brincidofovir or brincidofovir-based regimens, and that marketing approvals, if granted, may have significant limitations on their use. As a result, brincidofovir may never be successfully commercialized. In addition, Chimerix may be unable to file for regulatory approval for brincidofovir with other regulatory authorities. Similar risks and uncertainties apply to the Company's development of CMX521. These risks, uncertainties and other factors could cause actual results to differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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CHIMERIX, INC.

CONSOLIDATED BALANCE SHEETS

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

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,447	\$ 18,548

Short-term investments, available-for-sale	147,316	132,972
Accounts receivable	219	1,682
Prepaid expenses and other current assets	3,329	3,331
Total current assets	178,311	156,533
Long-term investments	21,115	76,731
Property and equipment, net of accumulated depreciation	1,502	1,894
Other long-term assets	52	72
Total assets	\$ 200,980	\$ 235,230

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 1,426	\$ 3,812
Accrued liabilities	7,976	9,384
Total current liabilities	9,402	13,196
Lease-related obligations	185	224
Total liabilities	9,587	13,420

Stockholders' equity:

Preferred stock, \$0.001 par value, 10,000,000 shares authorized at June 30, 2018 and December 31, 2017; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2018 and December 31, 2017; 47,855,025 and 47,505,532 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	48	47
Additional paid-in capital	717,414	709,514
Accumulated other comprehensive loss, net	(842)	(963)
Accumulated deficit	(525,227)	(486,788)
Total stockholders' equity	191,393	221,810
Total liabilities and stockholders' equity	\$ 200,980	\$ 235,230

CHIMERIX, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Contract revenue	\$ 1,193	\$ 675	\$ 1,983	\$ 1,753
Operating expenses:				
Research and development	13,712	11,636	28,071	24,378
General and administrative	6,650	6,284	13,388	12,880
Total operating expenses	20,362	17,920	41,459	37,258
Loss from operations	(19,169)	(17,245)	(39,476)	(35,505)
Other (expense) income:				
Unrealized loss on equity investment	(78)	-	(212)	-
Interest income	634	565	1,249	1,071
Net loss	(18,613)	(16,680)	(38,439)	(34,434)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	225	(1,366)	122	(1,035)
Comprehensive loss	\$ (18,388)	\$ (18,046)	\$ (38,317)	\$ (35,469)
Per share information:				
Net loss, basic and diluted	\$ (0.39)	\$ (0.36)	\$ (0.81)	\$ (0.74)
Weighted-average shares outstanding, basic and diluted	47,811,552	46,863,753	47,725,209	46,719,367



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Source: Chimerix, Inc.