



CHIMERIX

November 7, 2016

Chimerix Announces Third Quarter 2016 Financial Results

- Brincidofovir IV Single and Multiple Dose Data Expected to Report Out in 2017 -

- Comparative Adenovirus Trial with Oral Brincidofovir Expected to Start in 2017 -

- CMX521 for Norovirus Advancing Toward the Clinic -

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

DURHAM, N.C., Nov. 07, 2016 (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 third quarter ended September 30, 2016.

"We are optimistic about 2017 and believe our novel intravenous formulation of brincidofovir may prove to be the optimal way to prevent or treat DNA viral infections, by achieving effective drug levels in the plasma and infected organs while avoiding gastrointestinal side-effects," said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix. "In addition, the learnings from AdVise, specifically the stepwise reduction in mortality observed in pediatric patients as the study progressed, underscore the potential for oral brincidofovir in these patients with life-threatening adenovirus infection. A shorter time from diagnosis to first dose of brincidofovir is thought to be a significant driver of the observed improvement. Early identification of adenovirus and intervention with brincidofovir are being incorporated in the design of our next comparative trial of oral brincidofovir which we expect to initiate in 2017. Additionally, we are excited to announce CMX521 from the Chimerix Chemical Library as our lead clinical candidate for the treatment of norovirus."

Recent Highlights and Program Updates:

Development of Intravenous Brincidofovir Formulation Continues

Chimerix remains on track to provide pharmacokinetic, safety and tolerability data from a single dose escalation study of intravenous (IV) brincidofovir in early 2017, with multiple dose studies in patients with active viral infection to follow. In preclinical testing, animals given four weeks of IV brincidofovir showed no signs of gastrointestinal injury, even at plasma exposures several fold higher than those ever achieved with oral dosing. If these early clinical studies of IV-administered brincidofovir continue to demonstrate low or no gastrointestinal side-effects, IV brincidofovir could be in late-stage registrational studies in 2018. Once brincidofovir enters the target cells and is converted to the active antiviral, the drug remains at effective concentrations for several days, potentially allowing for once-weekly dosing. The potential to provide higher drug exposures may allow a much-needed treatment for cytomegalovirus (CMV), adenoviruses (AdV), BK virus, and other DNA viral infections, potentially even in difficult to reach anatomical regions such as the brain.

Detailed 24-Week Data from AdVise Study Presented at IDWeek™

In October 2016, Chimerix announced the presentation of detailed 24-week interim results from the AdVise trial of brincidofovir for the treatment of AdV infection in allogeneic hematopoietic cell transplant (HCT) patients.

Building upon the Company's 24-week top-line data announced in May 2016, the presentation at IDWeek highlighted that treatment with brincidofovir generally resulted in robust declines in AdV viral loads. Furthermore, rapid reductions in AdV viremia correlated with improved survival in both adults and pediatric patients. In an analysis of the data based on enrollment in the trial, a stepwise reduction in mortality was observed as the study progressed: 60% mortality was observed in the initial quarter of pediatric patients enrolled in AdVise, with steady declines to 14% mortality for those patients enrolled in the last quartile. A shorter time from diagnosis to first dose of brincidofovir is thought to be a significant driver of the observed improvement.

Chimerix currently expects to present final 36-week data from the AdVise trial at a medical meeting during the first quarter of 2017.

Additional evidence regarding the need for a broad spectrum antiviral was presented at IDWeek by Dr. Josh Hill and

colleagues. An analysis of over 400 HCT recipients from the Fred Hutchinson Cancer Research Center showed that quantity and duration of viremia for CMV, AdV, EBV, HHV6 or BK correlated with mortality. The authors concluded that improved strategies to prevent reactivation of these viruses are needed to improve transplant outcomes.

Continuing Demand for Brincidofovir through our Expanded Access Programs

The Company continues to receive requests for brincidofovir via our expanded access programs. Through the first ten months of 2016, the Company has granted 263 requests for AdV alone, highlighting the unmet need in this area.

Brincidofovir for Smallpox

The development of brincidofovir for smallpox continues in collaboration with the Biomedical Advanced Research and Development Authority (BARDA). Following completion of the second animal efficacy study, the Company plans to meet with the FDA to discuss any additional required data for a regulatory decision. Earlier in 2016, Chimerix provided regulators with a summary of the clinical safety and tolerability of the intended three week course of oral brincidofovir in healthy adults and immunocompromised adults and children. In addition, the final study report for the rabbitpox efficacy study of brincidofovir has been submitted to the FDA.

In October 2016, Chimerix was notified that the European Medicines Agency's Committee for Orphan Medicinal Products issued a positive opinion for an Orphan Designation for brincidofovir for the treatment of smallpox.

Clinical Candidate CMX521 for Norovirus

Chimerix is currently conducting final preclinical studies of a novel norovirus antiviral, designated CMX521, that are required to file an Investigational New Drug application (IND). CMX521 is a nucleoside analog identified from the Chimerix Chemical Library which targets the norovirus polymerase, a part of the virus that is common to all strains and is required for viral replication. It is therefore expected to be active against the multiple genetically diverse norovirus strains that circulate each year and cause disease in humans.

In addition to the approximately 20 million acute cases of norovirus that occur each year in the U.S., chronic norovirus infection is increasingly being diagnosed in immune compromised patients. Approximately 15-20 percent of HCT and SOT recipients are diagnosed with norovirus within the first year after transplant, a diagnosis that has been associated with chronic diarrhea, electrolyte disturbances, and graft rejection. The Company plans to file an IND for CMX521 in 2017, which, upon acceptance, would enable clinical testing.

Third Quarter 2016 Financial Results

Net loss narrowed to \$17 million, or \$0.37 per basic and diluted share, for the third quarter of 2016 compared to a net loss of \$32.4 million, or \$0.70 per basic and diluted share during the same period in 2015.

Revenues for the third quarter of 2016 decreased to \$0.7 million compared to \$2.3 million for the same period in 2015. Revenue during these periods related to reimbursable expenses associated with the Company's ongoing development contract with BARDA.

Research and development expenses decreased to \$12.2 million for the third quarter of 2016, compared to \$26.5 million for the same period in 2015. This decrease was primarily due to a decrease in the Company's clinical trial expenses associated with the completion of the Phase 3 SUPPRESS and AdVise trials and close-out of the kidney trials, partially offset by an increase in costs related to the development of the IV formulation of brincidofovir and the conduct of the Expanded Access Programs.

General and administrative expenses decreased to \$5.8 million for the third quarter of 2016, compared to \$8.5 million for the same period in 2015. The decrease was primarily due to a decrease in commercialization expense.

Loss from operations was \$17.4 million for the third quarter of 2016, compared to a loss from operations of \$32.7 million for the same period in 2015. The narrowed loss was primarily due to decreased research and development expenses, and general and administrative expenses, as previously discussed.

Chimerix's balance sheet at September 30, 2016 included \$288.3 million of capital available to fund operations, no debt, and approximately 46.3 million outstanding shares of common stock.

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss its third quarter 2016 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 97022450.

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 Chimerix

Chimerix is a biopharmaceutical company dedicated to discovering, developing and commercializing novel antivirals in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (BCV, CMX001); CMX157, which was licensed to ContraVir Pharmaceuticals; and earlier-stage clinical candidates. Chimerix is also advancing a clinical candidate for norovirus infection, CMX521. 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 that there may not be a viable continued development path for brincidofovir, 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. 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.

CHIMERIX, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(unaudited)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 49,358	\$ 20,605
Short-term investments, available-for-sale	200,315	199,729
Accounts receivable	379	2,432
Prepaid expenses and other current assets	4,318	6,071
Total current assets	254,370	228,837
Long-term investments	39,801	124,040
Property and equipment, net of accumulated depreciation	3,048	3,045
Other long-term assets	34	70
Total assets	\$ 297,253	\$ 355,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,280	\$ 10,458
Accrued liabilities	6,338	9,721
Total current liabilities	9,618	20,179
Deferred rent	285	354
Total liabilities	9,903	20,533
Stockholders' equity:		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at September 30, 2016 and December 31, 2015; no shares issued and outstanding as of September 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at September 30, 2016 and December 31, 2015; 46,315,425 and 46,162,525 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	46	46
Additional paid-in capital	688,518	675,591
Accumulated other comprehensive loss, net	(366)	(764)
Accumulated deficit	(400,848)	(339,414)
Total stockholders' equity	287,350	335,459

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Contract revenue	\$ 653	\$ 2,271	\$ 3,722	\$ 6,104
Collaboration and licensing revenue	—	—	—	1,548
Total revenues	653	2,271	3,722	7,652
Operating expenses:				
Research and development	12,247	26,495	46,924	65,611
General and administrative	5,827	8,524	19,359	22,068
Total operating expenses	18,074	35,019	66,301	87,679
Loss from operations	(17,421)	(32,748)	(62,579)	(80,027)
Interest income, net	396	299	1,146	498
Net loss	(17,025)	(32,449)	(61,433)	(47,080)
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(98)	(1,448)	398	321
Comprehensive loss	\$ (17,123)	\$ (33,897)	\$ (61,035)	\$ (79,208)
Per share information:				
Net loss, basic and diluted	\$ (0.37)	\$ (0.70)	\$ (1.33)	\$ (1.84)
Weighted-average shares outstanding, basic and diluted	46,236,749	46,059,112	46,199,110	43,112,314

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