



CHIMERIX

February 29, 2016

Chimerix Announces Fourth Quarter and Full Year 2015 Financial Results

*- Company to hold conference call at 8:30am ET today -
- Survival and other key data from AdVise and matched controls
to be reviewed with regulators in Summer 2016 -*

DURHAM, N.C., Feb. 29, 2016 (GLOBE NEWSWIRE) -- Chimerix, Inc. (NASDAQ:CMRX), a biopharmaceutical company developing novel, oral antivirals in areas of high unmet medical need, today reported financial results for the fourth quarter and full year ended December 31, 2015.

The Company also provided a strategic update on expected 2016 milestones and corporate highlights, including:

- | Adenovirus response and survival data from the open-label AdVise study and historic controls will be reviewed with regulators in the summer of 2016; guidance regarding any potential additional studies required for marketing submission will be provided shortly thereafter
- | Clinical studies with the new intravenous (IV) formulation of brincidofovir are expected to initiate in the second half of 2016
- | Oral brincidofovir for smallpox is expected to complete the second animal efficacy study in the fourth quarter of 2016, enabling an End Of Phase 2 meeting for the treatment of smallpox
- | We are evaluating options for development of oral and intravenous brincidofovir for the prevention and treatment of cytomegalovirus (CMV) in hematopoietic cell transplant (HCT) recipients and kidney transplant recipients to allow for upcoming discussions with regulators on potential paths forward in these populations
- | A Phase 2 study of brincidofovir in kidney transplant recipients at high risk of BK virus associated disease is under development based on decreased BK viremia seen in the SUPPRESS study
- | The company is actively reviewing business development opportunities in the antiviral and transplant solutions therapeutic areas that could potentially complement the brincidofovir development and commercial programs
- | Patent exclusivity for brincidofovir through 2034 allows for development in multiple future indications
- | \$343 million in capital at year-end 2015 provides adequate runway to pursue development of brincidofovir

"We remain confident in the antiviral activity shown by brincidofovir, and its significant potential as a much-needed treatment option for patients with adenovirus and other DNA viral infections," said M. Michelle Berrey, MD, MPH, President and CEO of Chimerix. "With the observation of a day 90 mortality of less than 40 percent in the approximately 100 patients with disseminated adenovirus disease in the AdVise study, and the anticipated spring readout of the historic controlled data, we strongly believe that there is a near-term path forward for this antiviral, and are well-capitalized to conduct any additional confirmatory study required for an adenovirus treatment submission. Following the recent presentation of 100 percent survival in the rabbitpox pivotal study of brincidofovir, we also anticipate completing the second pivotal animal study this year to enable an End of Phase 2 meeting with FDA for the treatment of smallpox."

Dr. Berrey added, "As we presented at the BMT Tandem meetings, analyses of the SUPPRESS data have confirmed the antiviral effect of brincidofovir for preventing CMV infections in HCT recipients during the on-treatment period. We also saw improved outcomes for patients who were managed according to the safety monitoring and management plan with dose interruption for gastrointestinal side effects. The positive outcomes in certain subsets of high-risk patients are helping us better understand how the timing of initiation of brincidofovir in the post-transplant period and management of GVHD risk need to be addressed in future clinical studies. The encouraging early data on brincidofovir's impact on development of BK viremia trends will help inform our development in solid organ transplant patients. With this data in-hand, we look forward to discussions with the FDA as we consider our clinical paths forward."

"Meanwhile, we continue to move our intravenous formulation of brincidofovir toward clinical studies in the second half of 2016, and anticipate a lower risk of gastrointestinal side effects based on preclinical observations to date. We expect to provide a broad clinical update during the second half of 2016 for the development plans for each of our potential indications."

Recent Company Highlights

Updated Interim Data from Phase 3 AdVise Study of Brincidofovir For Adenovirus Infection

In August of 2015, the Company completed enrollment of the AdVise trial, which is evaluating brincidofovir for the treatment of serious adenovirus infections in over 200 pediatric and adult patients. Patients who have undergone allogeneic HCT are at especially high risk for developing adenovirus due to profound and persistent immunodeficiency. In this susceptible population, the development of adenovirus infection can be rapidly fatal without treatment. In the literature, mortality rates of 50 to 80 percent are reported for allogeneic HCT recipients with disseminated disease.

Patients who are enrolled in the AdVise study are placed into Cohort A, B, or C based on their underlying immunodeficiency and extent of disease:

- 1 Cohort A - allogeneic HCT recipients with asymptomatic or limited adenovirus infection
- 1 Cohort B - allogeneic HCT recipients with disseminated adenovirus disease
- 1 Cohort C - autologous HCT recipients, SOT recipients, other immunocompromised patients

All subjects enrolled in the AdVise trial receive 12 weeks of open-label oral brincidofovir, and are followed for at least 12 weeks after completing treatment. The final data will include follow-up through Week 36 (24 weeks after treatment).

In December 2015, Chimerix provided an update from the AdVise study. At the time of the report, all-cause mortality at day 90 remained less than 40 percent for the full Cohort B population of ~100 HCT recipients with disseminated adenovirus infection.

Survival data from pediatric and adult HCT recipients enrolled in AdVise Cohort A and Cohort B will be compared with outcomes from matched historical controls from the same medical centers. Chimerix anticipates meeting with the U.S. Food and Drug Administration (FDA) and other regulators during the summer of 2016 to review data from the AdVise trial and from historic controls, and to discuss any additional requirements for a proposed submission for brincidofovir for the treatment of adenovirus.

Presented Positive Results from Brincidofovir Pivotal Study in Animal Model for Smallpox

Brincidofovir is in development for the treatment of smallpox under the FDA's Animal Rule, which allows for the conduct of efficacy studies in well-established models of infections for conditions that are not appropriate for study in human subjects. On February 8, 2016, Chimerix presented positive results from a pivotal study of brincidofovir in a well-established animal model for smallpox (rabbitpox virus) at the ASM Biodefense and Emerging Diseases Research Meeting in Arlington, Virginia. Clinically and statistically significant ($p < 0.05$) reduction in mortality was demonstrated for animals with confirmed infection that were treated with immediate brincidofovir, or treatment delayed by 24 or 48 hours. The brincidofovir doses used in this animal study were scaled to equivalent doses used in the clinical trials of brincidofovir for CMV and adenovirus in humans. Final data from the rabbitpox study together with efficacy data from a mouse model of smallpox will be submitted to the FDA for discussion of next steps.

Reported Data from Phase 3 SUPPRESS Trial for the Prevention of Cytomegalovirus (CMV) in Allogeneic Hematopoietic Cell Transplant (HCT) Recipients

In late December 2015, the Company reported top-line results from its Phase 3 SUPPRESS trial. Though antiviral activity was clearly demonstrated through Week 14 (24 percent of patients experienced clinically significant CMV infection with brincidofovir, versus 38 percent in the placebo group, $p=0.002$), brincidofovir did not achieve the primary endpoint of prevention of clinically significant CMV infection through Week 24 after transplant.

On February 20, 2016, lead physician investigator Francisco Marty, MD, of Dana-Farber Cancer Institute in Boston presented the detailed results from the SUPPRESS trial at the BMT Tandem Meetings in Honolulu, Hawaii. The failure to achieve the trial's primary endpoint of prevention of CMV infection at Week 24 was driven by the inability to differentiate drug-related side-effects from initial symptoms of gut graft-vs-host-disease (GVHD), and the subsequent treatment of presumed GVHD with high-dose corticosteroids. The use of corticosteroids is known to increase the risk of infections, including CMV infections that occur when patients discontinue antiviral therapy. The rate of CMV infections thus was higher in the brincidofovir arm between Weeks 14 and 24 (22 percent versus 11 percent on placebo), when patients were no longer on study drug.

Among secondary endpoints, an analysis of banked plasma from subjects during the first 8 weeks following transplant revealed a positive trend in favor of brincidofovir versus placebo: a decreased rate of BK virus in the blood (viremia) was observed in the brincidofovir arm (13 percent) vs placebo (20 percent, Fisher $p=0.08$, log-rank $p=0.06$). This finding may be particularly relevant in kidney transplant recipients, in whom BK viremia is associated with BKV nephropathy, with a high risk of failure of the new kidney graft. Although not complete, other analyses have not shown a benefit on prospectively-identified clinical secondary.

Company to Update Next Steps for Brincidofovir CMV Program During Second Half of 2016

Following the availability of the SUPPRESS results, Chimerix plans to discuss the findings in full with the FDA and foreign regulators, including the benefit-to-risk profile for the prevention of CMV in specific HCT sub-populations demonstrated in the SUPPRESS trial. The Company is also pursuing the development of an IV formulation of brincidofovir that is progressing toward clinical testing, with its potential to decrease the gastrointestinal (GI) side effects of orally-administered brincidofovir in the critical first weeks after HCT, when the GI tract is recovering from conditioning chemotherapy. Intravenous brincidofovir could potentially provide a means of preventing CMV and other double-stranded DNA viruses that reactivate in the first weeks post-transplant period in patients undergoing HCT, with the opportunity to transition to oral brincidofovir at the time of hospital discharge.

In light of the unexpected results in the SUPPRESS trial, Chimerix has elected to close the Phase 3 SUSTAIN and SURPASS trials in kidney transplant recipients, and to pursue smaller trials of brincidofovir designed to confirm activity against BK virus and to establish management strategies for potential brincidofovir-related adverse events in the solid organ transplant population.

The Company remains committed to moving brincidofovir forward as a preventive therapy for CMV in HCT and solid organ transplant recipients pending discussions with regulators. Chimerix anticipates providing a broader update on these development decisions during the second half of 2016.

Fourth Quarter 2015 Financial Results

Chimerix reported a net loss of \$37.8 million, or \$0.82 per basic and diluted share, for the fourth quarter of 2015. During the same period in 2014, Chimerix recorded a net loss of \$20.2 million, or \$0.52 per basic and diluted share.

Revenues for the fourth quarter of 2015 increased to \$3.1 million, compared to \$1.2 million for the same period in 2014, due to an increase in the fourth quarter of 2015 in reimbursable expenses associated with Chimerix's ongoing development contract with the Biomedical Advanced Research and Development Authority (BARDA).

Research and development expenses were \$31.6 million for the fourth quarter of 2015, and \$15.7 million for the same period in 2014. This increase was primarily due to the effect of costs related to the Company's SUSTAIN and SURPASS studies, and increased headcount and activities in the Company's clinical, regulatory, development and manufacturing departments. General and administrative expenses increased to \$9.8 million for the fourth quarter of 2015, compared to \$5.7 million for the same period in 2014. The increase was driven by expenses related to commercialization preparations for brincidofovir, and increased headcount and activities in the Company's infrastructure.

Loss from operations was \$38.2 million for the fourth quarter of 2015, compared to a loss from operations of \$20.2 million for the same period in 2014. The variance is due primarily to the increase in research and development and general and administrative expenses.

Interest income was \$381,000 in the fourth quarter of 2015, compared to net interest expense of \$20,000 in the same period in 2014. The change is due to interest earned on higher cash and investment balances over the prior year and decreased interest expense in connection with the full repayment of debt in 2015.

Chimerix's balance sheet as of December 31, 2015, included \$342.9 million of capital available to fund operations, no debt and approximately 46.2 million outstanding shares of common stock.

Full Year 2015 Financial Results

Chimerix reported a net loss of \$117.4 million, or \$2.67 per basic and diluted share, for the year ended December 31, 2015. For the year ended December 31, 2014, the Company recorded net loss of \$59.3 million, or \$1.80 per basic and diluted share.

Revenues for 2015 increased to \$10.8 million, compared to \$4.0 million in 2014 due primarily to an increase in the reimbursable expenses associated with Chimerix's ongoing contract with BARDA.

Research and development expenses were \$97.2 million for the year ended December 31, 2015, compared to \$45.4 million for the year ended December 31, 2014. This increase was primarily due to the effect of increased costs related to the Company's SUSTAIN and SURPASS studies, the AdVise study, and increased headcount and activities in the Company's clinical, regulatory, development and manufacturing departments. General and administrative expenses increased to \$31.8 million for the year ended December 31, 2015, compared to \$17.5 million for the year ended December 31, 2014. The

increase was driven by expenses related to commercialization preparations for brincidofovir, and increased headcount and activities in the Company's infrastructure.

Loss from operations was \$118.3 million for the year ended December 31, 2015, compared to a loss from operations of \$58.9 million for the year ended December 31, 2014. The variance is due primarily to increased research and development and general and administrative expenses.

Net interest income was \$0.9 million for the year ended December 31, 2015, compared to net interest expense of \$0.4 million for the year ended December 31, 2014. The change is due to interest earned on higher cash and investment balances over the prior year and decreased interest expense in connection with the full repayment of debt in 2015.

"We remain well-capitalized with \$343 million on hand at the end of 2015, and plan to use this financial strength to efficiently fund the development of brincidofovir and our other pipeline programs based upon a careful portfolio analysis and discussion with regulatory leaders in the months ahead," said Tim Trost, Chief Financial Officer of Chimerix. "In light of the SUPPRESS results, in early 2016 we completed an approximate 20 percent reduction in our workforce. We expect our research and corporate expenses to trend downward this year prior to discussions with regulators and agreement on further clinical development requirements. Once that path forward has been set, we would expect to provide more granular expense guidance."

Today's Conference Call and Webcast

Chimerix will host a conference call and live audio webcast to discuss its fourth quarter and full year 2015 accomplishments and financial results 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 51992168.

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, oral antivirals in areas of high unmet medical need. Chimerix's proprietary lipid conjugate technology has produced brincidofovir (CMX001), a clinical-stage nucleotide analog, CMX157 which was licensed to ContraVir Pharmaceuticals in 2014, and early clinical candidates, including CMX669. Chimerix is working with BARDA to develop brincidofovir as a potential medical countermeasure against smallpox. 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 Current Report on Form 8-K 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)

	December 31,	
	2015	2014
ASSETS		
Current assets:		

Cash and cash equivalents		\$ 20,605	\$ 128,462
Short-term investments, available-for-sale		199,729	106,114
Accounts receivable		2,432	106
Prepaid expenses and other current assets		6,071	2,775
Total current assets		<u>228,837</u>	<u>237,457</u>
Long-term investments		124,040	52,973
Property and equipment, net of accumulated depreciation		3,045	1,310
Other long-term assets		70	138
Total assets		<u>\$ 355,992</u>	<u>\$ 291,878</u>
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable		\$ 10,458	\$ 5,938
Accrued liabilities		9,721	6,833
Loan payable, net, current portion		—	4,296
Total current liabilities		<u>20,179</u>	<u>17,067</u>
Other long-term liabilities		354	175
Total liabilities		<u>20,533</u>	<u>17,242</u>
Stockholders' equity:			
Preferred stock, \$0.001 par value, 10,000,000 shares authorized at December 31, 2015 and 2014; no shares issued and outstanding as of December 31, 2015 and 2014		—	—
Common stock, \$0.001 par value; 200,000,000 shares authorized at December 31, 2015 and 2014; 46,162,525 and 41,031,770 shares issued and outstanding at December 31, 2015 and 2014, respectively		46	41
Additional paid-in capital		675,591	496,602
Accumulated other comprehensive (loss) gain		(764)	35
Accumulated deficit		<u>(339,414)</u>	<u>(222,042)</u>
Total stockholders' equity		<u>335,459</u>	<u>274,636</u>
Total liabilities and stockholders' equity		<u>\$ 355,992</u>	<u>\$ 291,878</u>

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

	<u>Three Months Ended December 31,</u>		<u>Years Ended December 31,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenues:				
Contract revenue	\$ 3,110	\$ 1,156	\$ 9,214	\$ 4,040
Collaboration and licensing revenue	—	—	1,548	—
Total revenues	<u>3,110</u>	<u>1,156</u>	<u>10,762</u>	<u>4,040</u>
Operating expenses:				
Research and development	31,579	15,667	97,190	45,379
General and administrative	9,754	5,715	31,823	17,527
Total operating expenses	<u>41,333</u>	<u>21,382</u>	<u>129,013</u>	<u>62,906</u>
Loss from operations	(38,223)	(20,226)	(118,251)	(58,866)
Other income (expense):				
Interest income (expense), net	381	(20)	879	(445)
Loss on disposition of assets	—	(1)	—	(1)
Net loss	<u>(37,842)</u>	<u>(20,247)</u>	<u>(117,372)</u>	<u>(59,312)</u>
Other comprehensive loss:				
Unrealized (loss) gain on investments, net	(1,120)	(1)	(799)	35
Comprehensive loss	<u>\$ (38,962)</u>	<u>\$ (20,248)</u>	<u>\$ (118,171)</u>	<u>\$ (59,277)</u>
Per share information:				
Net loss, basic and diluted	<u>\$ (0.82)</u>	<u>\$ (0.52)</u>	<u>\$ (2.67)</u>	<u>\$ (1.80)</u>
Weighted-average shares outstanding, basic and diluted	<u>46,151,384</u>	<u>39,128,297</u>	<u>43,878,326</u>	<u>33,003,714</u>

CONTACT :

Investor Relations:

ir@chimerix.com

or

Jesse Baumgartner

Stern Investor Relations

Jesse@sternir.com

212-362-1200

Media:

Becky Vonsiatsky

W2O Group

bvonsiatsky@w2ogroup.com

413-478-2003

 Primary Logo

Source: Chimerix, Inc.

News Provided by Acquire Media