

Chimerix, Inc.

Fourth-Quarter Financials Non-event; Expanding Brincidofovir in New Territories and Indications

On Friday, March 7, before markets opened, Chimerix reported fourth quarter 2013 financial results. The company ended the fourth quarter with \$110.0 million in cash and \$9.9 million in debt. We estimate the current cash should sustain operations through the data release from SUPPRESS expected by mid-2015 (exhibit 1), although potential fund raising could be expected before the initiation of the second Phase III study in renal transplant later in 2014; we note that the IPO proceeds did not budget for a pivotal study other than SUPPRESS. Net loss for the quarter was \$8.2 million, with a per share loss of \$0.31 versus our estimates of \$11.4 million and \$0.44, respectively. We updated our model as illustrated in exhibit 1, on page 3.

Phase III SUPPRESS study enrollment is on track, and top-line data continues to be expected by mid-2015. The incremental development is the strides being made in the expansion into the pediatric population in the hematopoietic stem cell transplant (HSCT) setting, the design of the second pivotal study in the renal transplant setting, opening of European sites for SUPPRESS, and preparation for the next commercialization opportunities for brincidofovir.

- **Management reiterated that SUPPRESS top-line data is expected by mid-2015. Several European sites are opened, and enrollment is on track to complete by year end 2014.** A primary catalyst for 2014 is study enrollment completion for the Phase III SUPPRESS study by year end. As the study enrollment is progressing, management has elected to expand SUPPRESS by opening a few study sites in Europe. We note that this is not intended to speed up the timeline but is expected to serve as a gateway to aid in the European regulatory process.
- **Expansion into the pediatric population in HSCT is imminent with a decision from the FDA expected in 2014.** Recently, management met with the FDA to discuss its pediatric plan to extend brincidofovir into this key patient population in the HSCT setting. We note that the SUPPRESS study enrolls patients over 18 years old, and, at the time, it was unclear whether a similar study in pediatric patients was needed for the label expansion into that population. Following recent discussions, management reiterated its belief that a bridging pharmacokinetic (PK) and safety study would be the only requirement for the label expansion, which is much easier than previously thought.

Chimerix, Inc., a biopharmaceutical company based in Durham, North Carolina, focuses its research-and-development efforts on antiviral therapies.

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Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: \$28.00

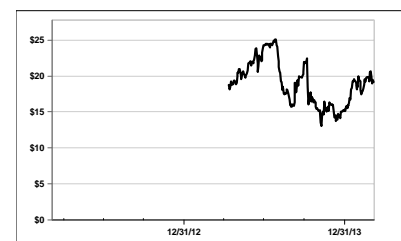
Symbol: CMRX (NASDAQ)
Price: \$18.73 (52-Wk.: \$13-\$27)
Market Value (mil.): \$495
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS FY	\$-3.65	\$-1.69	\$-2.23
CY		\$-1.69	\$-2.23
Sales (mil.)	4	3	0
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	26
Float (mil.)	14
Average Daily Volume	166,820

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.0
Enterprise Value (mil.)	261.5
EBITDA (TTM)	0.0
Enterprise Value/EBITDA (TTM)	0.0x
Return on Equity (TTM)	-35.4

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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- **Moving brincidofovir into a broader range of DNA viruses, new patient populations, and new territories starting with a second Phase III study of brincidofovir for the prevention of CMV in renal transplant recipients.** The study will serve as a confirmatory Phase III study and is expected to begin by year end 2014 or first quarter 2015. Currently, the company is in negotiations with the Food and Drug Administration (FDA) regarding the exact patient population, control arm, and duration for a CMV prevention study in renal transplant patients. The primary endpoint of the study might be CMV disease caused by CMV viremia. Secondary endpoints might include improvement in renal function, as measured by glomerular filtration rate (GFR) and serum creatinine with a concomitant decrease in urinary blood and reduction of graft loss. We look for further details regarding study design over the next several months. In particular, it would be of interest to see whether the study would incorporate placebo or Roche's (RHHBY \$37.05) Valcyte (valganciclovir) as the comparator arm, as well as the size and endpoints of the study.
- **Broadening the potential indications of brincidofovir will be the primary task of Chimerix's new chief commercial officer, Linda Richardson; scanning the current database and literature has yielded a number of potential therapeutic areas.** Chimerix has been reviewing data from its emergency investigational new drug program (EIND) and data from Study 350, an open label clinical study of brincidofovir in 36 U.S. transplant centers, as well as literature to identify the next commercial opportunities for brincidofovir. Data from the aforementioned studies covers over 400 patients treated with brincidofovir for various DNA viral infections. Aside from HSCT and solid organ transplant, management noted brincidofovir's activity across the double-stranded DNA viruses, including herpes viruses, adenovirus, polyomavirus, and poxvirus, albeit in uncontrolled settings. Management believes there are a number of potentially viable indications to expand brincidofovir's utility into and highlighted three on the call, the first two coming from the safety database and last from literature: 1) treatment of HPV related recurrent respiratory papillomatosis (two juvenile patients were treated through the EIND program); 2) treatment of John Cunningham (JC) virus (a well-documented area); and 3) evidence of valganciclovir inhibiting glioblastoma growth in vitro, in animal xenograft and extended survival in glioblastoma patients who are CMV positive (*New England Journal of Medicine* 2013; 369:2066-2067).

We are encouraged with the progress and see Chimerix stock at this level as an ideal buying opportunity as the company moves toward the binary event in mid-2015 while building a pipeline in a drug. While top-line SUPPRESS data is over a year away, we expect the stock to gain momentum with the finalization of the renal transplant study and the HSCT pediatric expansion, along with the exploration of other commercial opportunities. More simply put, the brincidofovir program may seem like a one trick pony with a binary event in 2015, but the reality is that brincidofovir is more than just CMV in hematopoietic cell transplant (HCT) patients. We expect the stock to gain momentum toward the 2015 binary event as the story gains traction and additional indications amass.

We maintain our Outperform rating and \$28 price target (exhibit 2, on page 4). In our probability adjusted NPV model, we expect brincidofovir to reach the market by early 2016 and become the market leader in the CMV prevention setting. We assume brincidofovir achieves peak sales of roughly \$530 million in the United States and \$410 million in Europe; for Europe, we project that Chimerix will license out the commercial rights to brincidofovir to a partner and receive 30% royalties on EU sales. We assign an 80% probability of success to brincidofovir in the HSCT setting. Chimerix's second asset, CMX157, has been licensed to Merck (MRK \$57.47) for development of novel HIV combo therapies that could have certain advantages over Gilead's (GILD \$79.58; Outperform) industry-leading regimens. We assign \$4 per share to the program, which is in Phase I development. We estimate a 35% probability for the CMX157-containing combo to reach the market in 2019, \$1.1 billion in peak worldwide sales, and 15% royalties to Chimerix. Adding net cash of about \$2 per share to our valuation of brincidofovir and CMX157, we derive our 12-month price target of \$28 per share.

Key risks to our Outperform rating and price target include: 1) failure of brincidofovir to meet primary or second endpoints in the SUPPRESS study, 2) a worse-than-expected tolerability profile for brincidofovir, 3) failure of CMX157 to advance in Merck's HIV pipeline, 4) other clinical and business-development setbacks, and 5) financing risks.

Phase III SUPPRESS study remains on track to deliver pivotal data in mid-2015; we continue to assign an 80% probability of success to the study. In September, Chimerix reported that the first patient in the SUPPRESS study evaluating brincidofovir in hematopoietic stem cell transplantation (HSCT) patients had been dosed. Management noted that enrollment of the planned 450 patients is continuing and is on track to deliver results by mid-2015.

- **Phase III SUPPRESS study design.** SUPPRESS plans to enroll and randomize 450 allogeneic HSCT patients who are cytomegalovirus (CMV) seropositive (R+) 2-to-1 to either 100 mg twice weekly (BIW) brincidofovir or placebo. Dosing of study drug will commence shortly after patients receive their transplant and will continue through week 14 post-

transplant. The primary objective of the study is the rate of clinically significant CMV infection through the first 24 weeks post-transplant. The study is powered at 85%, with one-sided p-value of 0.025 in the superiority design, to detect 50% reduction in treatment failure for brincidofovir versus placebo; the design assumes the prevention failure rate for the placebo arm is 30%. Secondary endpoints include clinical and virologic evidence of double-stranded DNA (dsDNA) viral infections including adenovirus (AdV), BK-virus (BKV), and other herpes viruses. The double-blind, placebo-controlled study will be conducted at 40 sites in the United States and Canada, and a few European sites, with significant site overlap with the Phase II brincidofovir Study 201.

- **Positive SUPPRESS Phase III results should lead to accelerated approval in the United States of brincidofovir in late 2015 or early 2016; full approval could come with pending SOT study, which must have a clinical endpoint.** The first brincidofovir indication is prevention of CMV infection in the HSCT setting, with potential approval and launch in late 2015 or early 2016. Chimerix intends to use the single pivotal SUPPRESS study to obtain conditional approval followed a supplemental new drug application (sNDA) with a solid-organ transplant (SOT) study in kidney transplant patients, to obtain full approval.

Exhibit 1
Chimerix, Inc.
Income Statement
(dollars in thousands)

	2011A FY:11A	2012A FY:12A	2013					2014E FY:14E	2015E FY:15E
			Q1A	Q2A	Q3A	Q4A	FY:13A		
Revenues									
Brincidofovir U.S. revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Brincidofovir EU royalties	-	-	-	-	-	-	-	-	-
CMX157 royalties	-	-	-	-	-	-	-	-	-
Collaboration and licensing revenue	55	17,445	-	-	-	-	-	-	-
Contract and grant revenue	12,046	16,275	1,771	808	912	879	4,370	2,500	-
Total Revenues	12,101	33,720	1,771	808	912	879	4,370	2,500	0
Expenses									
COGS	-	-	-	-	-	-	-	-	-
R&D expense	27,695	27,821	6,498	6,276	5,319	6,284	24,377	32,086	40,065
SG&A expense	9,398	8,682	1,821	2,188	2,029	2,574	8,612	13,738	17,831
Total Operating Expenses	37,093	36,503	8,319	8,464	7,348	8,858	32,989	45,824	57,895
Operating income	(24,992)	(2,783)	(6,548)	(7,656)	(6,436)	(7,979)	(28,619)	(43,324)	(57,895)
Interest expense, net	(212)	(776)	(356)	(415)	(270)	(195)	(1,236)	(749)	(375)
Fair value adjustments to warrant liability	(385)	(847)	(2,203)	(4,388)	-	-	(6,591)	(720)	(720)
Other income/(expense)	-	-	-	-	-	-	-	-	-
Pretax income/(loss)	(25,589)	(4,406)	(9,107)	(12,459)	(6,706)	(8,174)	(36,446)	(44,793)	(58,990)
Other comprehensive gain/(loss)	(4)	2	(1)	-	1	-	-	-	-
Accretion of redeemable convertible preferred stock	(9,565)	(4,357)	(25,525)	(8,582)	-	(1)	(34,108)	-	-
Provision for income taxes/(income)	-	-	-	-	-	-	-	-	-
Net Income/(Loss)	(\$35,154)	(\$8,763)	(\$34,632)	(\$21,041)	(\$6,705)	(\$8,175)	(\$70,554)	(\$44,793)	(\$58,990)
GAAP EPS	(\$23.17)	(\$5.71)	(\$22.58)	(\$0.91)	(\$0.26)	(\$0.31)	(\$3.65)	(\$1.69)	(\$2.23)
Weighted average shares outstanding, diluted	1,517	1,534	1,534	23,067	25,866	26,417	19,307	26,442	26,482

Sources: Chimerix, Inc. and William Blair & Company, L.L.C. estimates

Exhibit 2
Chimerix, Inc.
Sum-of-the-Parts Fair Value
(dollars in thousands)

Drug Candidate	Peak Sales	Stage of Development	Estimated Launch Date	Probability of Commercialization	Percentage of Sales to Company	Probability-Adjusted NPV	Value per Share	Percentage of Fair Value
Brincidofovir—United States	\$526,017	Phase III start mid-2013	H1:2016	80%	100%	\$441,177	\$16.69	59.1%
Brincidofovir—European Union	\$413,065	Phase III start mid-2013	H1:2017	80%	30%	\$114,102	\$4.32	15.3%
CMX157—HIV	\$1,074,060	Phase I	H1:2019	35%	15%	\$112,361	\$4.25	15.1%
Subtotal						\$667,639	\$25.25	89.5%
Net Cash at mid-2014						\$89,591	\$3.39	12.0%
Net Present Value of additional Gain (Loss)*						(\$11,364)	(\$0.43)	(1.5%)
Sum-of-Parts Fair Value						\$745,867	\$28.21	100.0%

*Includes costs not directly related to programs above

Sources: Company reports and William Blair & Company, L.L.C. estimates

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Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Chimerix, Inc.

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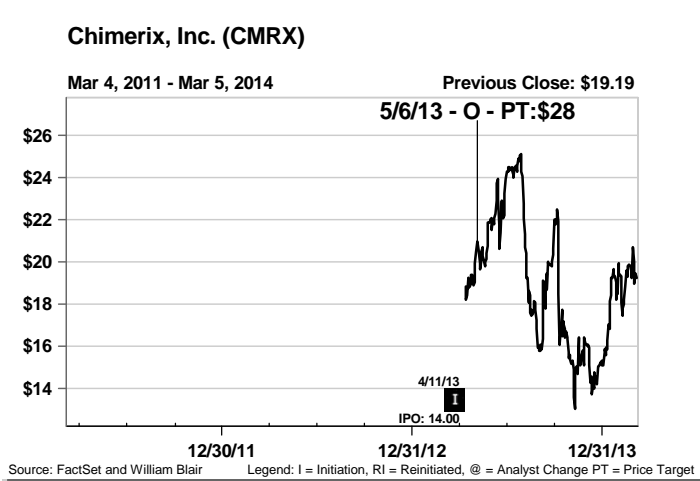
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DOW JONES: 16,452.72

S&P 500: 1,878.04

NASDAQ: 4,336.22



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	13
Market Perform (Hold)	33	Market Perform (Hold)	2
Underperform (Sell)	1	Underperform (Sell)	0

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