

Chimerix, Inc.

Update on Brincidofovir Confirmatory Study and Pediatric Expansion; SUPPRESS On Track; Third-Quarter Financials Non-Event

On Thursday, November 14, before markets opened, Chimerix reported third quarter 2013 financial results. The company ended the third quarter with \$116.9 million in cash and \$11.3 million in debt; we estimate the current cash should sustain operations through the data release from SUPPRESS expected by mid-2015 (exhibit 1). Net loss for the quarter was \$6.7 million, with a per share loss of \$0.26 versus our estimates of net loss of \$10.6 million and per share loss of \$0.41. We updated our model as illustrated in exhibit 1.

We believe the key incremental information from the call included proposed strategy to choose the renal transplant setting to conduct the second confirmatory study of brincidofovir, which we believe bears strong rationale given the brincidofovir's activity against BK virus; and the expansion strategy into the pediatric population in parallel to the adult SUPPRESS study, which seems much less onerous than previously thought. Further, the EU regulatory strategy is expected to be finalized during first half 2014. The new patent issuance extends brincidofovir's composition of matter protection from 2020 to 2031. Lastly, the continuing Phase III SUPPRESS study evaluating brincidofovir for the prevention of cytomegalovirus (CMV) infection remains on track to deliver results by mid-2015. We discuss each topic in detail herein.

We maintain our Outperform rating and \$28 price target (exhibit 2). 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 currently 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 currently assign an 80% probability of success to brincidofovir in the HSCT setting. Chimerix's second asset, CMX157, has been licensed to Merck (MRK \$47.79) for development of novel HIV combo therapies that could have certain advantages over Gilead's 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 roughly \$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.

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

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November 14, 2013

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

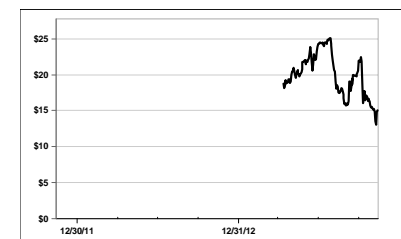
Symbol: CMRX (NASDAQ)
Price: \$16.14 (52-Wk.: \$13-\$27)
Market Value (mil.): \$382
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2012A	2013E	2014E
Estimates			
EPS Q1	NA	A\$-22.58	NA
Q2	NA	A\$-0.91	NA
Q3	NA	A\$-0.26	NA
Q4	NA	\$-0.44	NA
FY	\$-5.71	\$-3.87	\$-1.91
CY		\$-3.87	\$-1.91
Sales (mil.)	NA	5	3
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	23
Float (mil.)	14
Average Daily Volume	99,073

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	4.3
Enterprise Value (mil.)	228.5
EBITDA (TTM)	0.0
Enterprise Value/EBITDA (TTM)	0.0x
Return on Equity (TTM)	-7.5

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

The second, confirmatory study for brincidofovir is now expected to be in renal transplant recipients; details of Phase III study design are expected during first half 2014. In addition to SUPPRESS, which evaluates brincidofovir for CMV prevention in the hematopoietic stem cell transplant (HSCT) setting with a virology endpoint, Chimerix is required to conduct a second, confirmatory study with clinical endpoints to obtain full approval for brincidofovir. Recent scientific, medical, and regulatory discussions have focused Chimerix efforts toward a second pivotal study in renal transplant recipients, a high-risk patient population with a significant un-met medical need. We believe such strategy bears significant rationale as both CMV and BK viruses play a major role in mortality, morbidity, and graft loss in renal transplant patients. Therefore, a proposed study in renal transplants could offer an opportunity to evaluate brincidofovir's impact not only on the prevention of CMV but also against BK virus, with graft survival and renal function as potential clinical outcomes. Management also noted that if discussions with the Food and Drug Administration (FDA) continue according to plan, the company plans to finalize the design for the study during first half 2014. 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 Valcyte (valganciclovir) as the comparator arm, as well as the size and endpoints of the study.

Chimerix noted that roughly 20,000 renal transplants are performed annually in the United States, and nearly 100,000 patients remain on the wait list. While graft survival has improved, less than 50% of transplant kidneys survive 10 years.

Updated pediatric plan for brincidofovir is favorable; commercial formulation for pediatric patients is expected to be available by first half 2014. The SUPPRESS study enrolls patients older than 18 years, and it had been unclear whether a similar study in pediatric patients was needed for the label expansion into that population. Management noted that recent discussions with the FDA suggests that only a bridging pharmacokinetic (PK) and safety study would be required for the label expansion, which is much easier than previously thought.

To date, 150 pediatric patients have been treated with brincidofovir. Chimerix continues to develop a commercial formulation for pediatric patients, and expects to run relative bioavailability and PK studies to establish equivalence as well as safety in the pediatric population. Management expects to a pediatric plan to regulatory authorities in 2014.

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, 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 following a supplemental new drug application (sNDA) with a solid-organ transplant (SOT) study, likely in kidney transplant patients, to obtain full approval.

Discussions with EMA continue; we anticipate a resolution during first half 2014. Chimerix noted that discussions with the European Medicines Agency (EMA) regarding the regulatory pathway for brincidofovir are continuing. We expect a resolution to occur in first half 2014.

Recent composition of matter patent strengthens brincidofovir protection through August 2031. Chimerix also announced the issuance a new patent, No. 8,569,321, covering the method of synthesis and a morphic form of brincidofovir. The addition of this patent extends brincidofovir composition of matter protection from 2020 to 2031.

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

	2011A FY:11A	2012A FY:12A	2013				FY:13E	2014E FY:14E	2015E FY:15E
			Q1A	Q2A	Q3A	Q4E			
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	1,250	4,741	2,500	-
Total Revenues	12,101	33,720	1,771	808	912	1,250	4,741	2,500	0
Expenses									
COGS	-	-	-	-	-	-	-	-	-
R&D expense	27,695	27,821	6,498	6,276	5,319	9,502	27,595	39,748	46,092
SG&A expense	9,398	8,682	1,821	2,188	2,029	2,638	8,676	10,765	12,300
Total Operating Expenses	37,093	36,503	8,319	8,464	7,348	12,141	36,272	50,513	58,393
Operating income	(24,992)	(2,783)	(6,548)	(7,656)	(6,436)	(10,891)	(31,531)	(48,013)	(58,393)
Interest expense, net	(212)	(776)	(356)	(415)	(270)	(270)	(1,311)	(749)	(375)
Fair value adjustments to warrant liability	(385)	(847)	(2,203)	(4,388)	-	(240)	(6,831)	(720)	(720)
Other income/(expense)	-	-	-	-	-	-	-	-	-
Pretax income/(loss)	(25,589)	(4,406)	(9,107)	(12,459)	(6,706)	(11,401)	(39,673)	(49,483)	(59,487)
Other comprehensive gain/(loss)	(4)	2	(1)	-	1	-	-	-	-
Accretion of redeemable convertible preferred stock	(9,565)	(4,357)	(25,525)	(8,582)	-	-	(34,107)	-	-
Provision for income taxes/(income)	-	-	-	-	-	-	-	-	-
Net Income/(Loss)	(\$35,154)	(\$8,763)	(\$34,632)	(\$21,041)	(\$6,705)	(\$11,401)	(\$73,780)	(\$49,483)	(\$59,487)
GAAP EPS	(\$23.17)	(\$5.71)	(\$22.58)	(\$0.91)	(\$0.26)	(\$0.44)	(\$3.87)	(\$1.91)	(\$2.29)
Weighted average shares outstanding, diluted	1,517	1,534	1,534	23,067	25,866	25,876	19,086	25,901	25,941

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%	\$445,114	\$17.19	60.4%
Brincidofovir—European Union	\$413,065	Phase III start mid-2013	H1:2017	80%	30%	\$114,102	\$4.41	15.5%
CMX157—HIV	\$1,074,060	Phase I	H1:2019	35%	15%	\$112,361	\$4.34	15.2%
Subtotal						\$671,576	\$25.93	91.1%
Net Cash at mid-2014						\$76,742	\$2.96	10.4%
Net Present Value of additional Gain (Loss)*						(\$11,364)	(\$0.44)	(1.5%)
Sum-of-Parts Fair Value						\$736,955	\$28.46	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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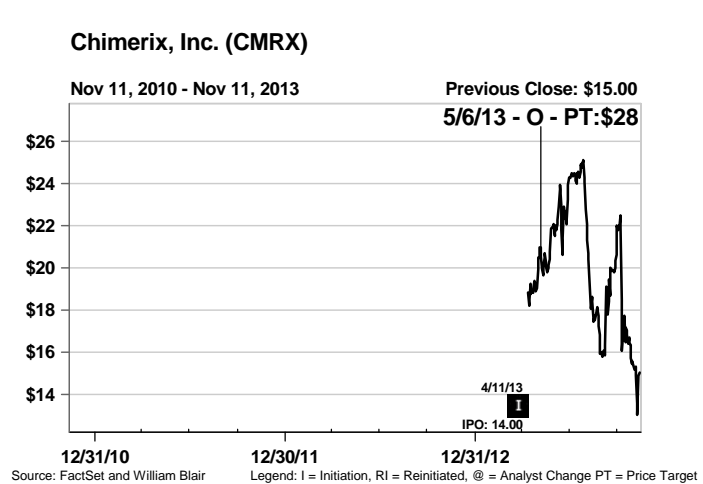
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DOW JONES: 15,821.63

S&P 500: 1,782.00

NASDAQ: 3,965.58



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Coverage Universe	Percent	Inv. Banking Relationships*	Percent
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