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Reason for report:

EARNINGS

## CEMPRA, INC.

## 3Q:12 -- Steady Progress Toward Phase III

• **Bottom Line:** CEMP reported earnings yesterday and provided an update on pipeline programs. The company recently reported positive Phase II data (intravenous, IV) from its lead candidate solithromycin in gonococcal infection and has also identified 400mg QD dose for the IV-to-oral Phase III study. The company is in final preparation to initiate a Phase III trial to evaluate oral solithromycin in community acquired bacterial pneumonia by YE12 with data readout anticipated in 1H:14. CEMP is also at the final stage to initiate a Phase II trial by YE12 to evaluate the second candidate Taksta in prosthetic joint infections. We view these progresses encouraging, and we await further data readout in 2014. We maintain our Outperform rating, and \$11 valuation for CEMP.

• **Solithromycin initial data promising.** In a Phase II trial to evaluate solithromycin in uncomplicated urogenital gonococcal infections, all 22 evaluable patients were cleared of infections at all infected body sites following a single dose of solithromycin. The data demonstrated a broad activity of solithromycin and a good safety profile. Of note, early data have more predicative value for later stage trials for anti-infectious drugs vs. other drugs. The company is evaluating options to move forward in this indication. A separate IV Phase I dose escalation study suggested a dose selection of 400mg QD for solithromycin for the IV-to-oral Phase III study, which is also being planned with FDA input.

• **3Q12 financial performance.** CEMP reported 3Q12 EPS of (\$0.24) vs. our estimate of (\$0.30) and consensus of (\$0.39). Total operating expenses were \$5M, slightly lower than our estimate of \$6.3M. CEMP expected an increase in R&D expenses in 4Q12 due to the initiation of clinical trials. The company ended the quarter with \$51.6M. Including recent \$23.4M net proceeds from a private placement, total cash is guided to be support operation into 2015. We update our model to reflect these changes.



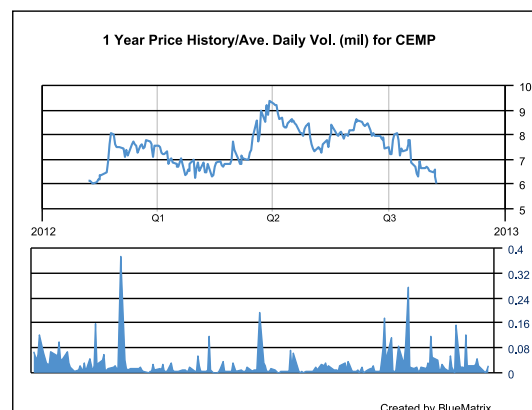
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HEALTHCARE EQUITY RESEARCH

## Key Stats:

(NASDAQ:CEMP)

<b>S&amp;P 600 Health Care Index:</b>	<b>791.49</b>
<b>Price:</b>	<b>\$6.01</b>
52 Week High:	\$9.56
52 Week Low:	\$6.00
Shares Outstanding (mil):	21.0
Market Capitalization (mil):	\$126.2
Book Value/Share:	\$(4.43)
Cash Per Share:	\$2.45
Dividend (ann):	\$0.00
Dividend Yield:	0.0%
Valuation:	\$11 on multiple of sales & royalties



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2011A	0.0	0.0	0.0	0.0	0.0	--	--	(\$40.49)	(\$7.12)	(\$47.53)	NM
2012E - New	0.0A	0.0A	0.0A	0.0	0.0	(\$0.26)A	(\$0.45)A	(\$0.24)A	(\$0.37)	(\$1.32)	NM
2012E - Old	0.0A	0.0A	0.0A	0.0	0.0	(\$0.26)A	(\$0.25)	(\$0.30)	(\$0.44)	(\$1.27)	NM
2013E - New	--	--	--	--	\$4.0	--	--	--	--	(\$1.17)	NM
2013E - Old	--	--	--	--	\$4.0	--	--	--	--	(\$1.40)	NM

Source: Company Information and Leerink Swann LLC Research

Revenues in \$MM; EPS on PF average diluted shares. Quarterly figures may not sum to annual total due to rounding.

3Q11 figures represent results for first 3 qtrs of 2011 as reported in the S-1 filing.



## INVESTMENT THESIS

We rate Cempira shares Outperform with a 12-month valuation of \$11. Cempira is a late-stage biopharmaceutical company focused on the development of novel antibiotics with the lead agent CEM-101 (solithromycin) starting Phase III for Community Acquired Bacterial Pneumonia (CABP) and Taksta (fusidic acid), an antibiotic marketed ex-U.S. that is starting Phase II for prosthetic joint infections (PJI). Macrolides are commonly used antibiotics for respiratory tract and soft-tissue infections and past blockbusters included PFE's (MP) Zithromax and ABT's (MP) Biaxin with sales totaling ~\$3B annually. MEDACorp infectious disease key opinion leader (KOL) commented that CEM-101 has the potential to be the best macrolide, due to its broad spectrum coverage and activity against Zithromax- and Biaxin-resistant strains that can represent 35% of strains in certain settings. We believe past regulatory difficulties with other ketolides may not generalize to CEM-101. Fraudulent conduct in Ketek trials may have contributed to the hard line that the FDA took on Ketek (SNY, OP). A large safety study was not required for another ketolide developed later, cethromycin (Advanced Life Sciences). The requirement of a superiority study for cethromycin is likely related to its profile of weak efficacy and, as a result, the need to be tested in a healthier population, but recent FDA guidance would indicate that this will not be generally required. The Phase II of CEM-101 demonstrated non-inferiority to Levaquin. Questions that arise include numerically worse efficacy by certain analysis and a different comparator to be used in the Phase III (Avelox). While there are uncertainties, we do not believe these are alarming concerns and to us the risk/reward looks very favorable considering the valuation.

### CEMP Expected Events

Timing	Drug	Event
YE12	solithromycin	Initiation of oral Phase III trial in CABP
4Q:12	Taksta	Initiation of Phase II PJI trial
2012-13	solithromycin	Potentially Establish partner for CEM-101
1H:13	solithromycin	Initiate IV Phase III trial in CABP
2H:13	solithromycin	Initiate Phase III (IV to oral) trial in CABP
1H:14	Taksta	Data from Phase II PJI trial
1H:14	solithromycin	Top line data from Phase III oral CABP trial
1H:15	solithromycin	Potential top line data from Phase III IV CABP trial

*CABP - community acquired bacterial pneumonia*

*PJI - prosthetic joint infection*

Source: Company reports and Leerink Swann LLC



## CEMP Product Pipeline

Stage	Indication	Patients	Design	Status
<b>CEM-101 (Solithromycin)</b>				
Phase III- (oral) <i>planned</i>	CABP	~800	NI - vs. Avelox (moxifloxacin)	Expected to begin YE12
Phase II- (oral)	CABP	132	vs. Levoquin (levofloxacin)	Completed in 2011
Phase I - (IV)	CABP	370	PK, dose-escalating	Completed in 4Q12
Preclinical- (oral suspension)	Pediatric settings	--		
<b>Taksta (Fusidic acid)</b>				
Phase II	ABSSSi	155	vs. Zyvox	Completed in 2011
Phase II - <i>planned</i>	PJI	50	w/ Vancomycin+ Rifampin, followed by Taksta+ Rifampin	Expected to begin YE12

NI= Non-inferiority design; CABP= community-acquired bacterial pneumonia; ABSSSi= acute bacterial skin and skin structure infections; PJI= prosthetic joint infections

Source: Company reports and Leerink Swann LLC

## VALUATION

Our 12-month valuation on CEMP shares is \$11 that we reach using a multiple-of-sales analysis based on a 5x multiple applied to Cempira's shares of 2019E probability-weighted U.S. sales of solithromycin (CEM-101) in CABP (assuming 50/50 co-promote in the U.S and 65% probability of success) totaling \$134M, and an 11x multiple applied to 2019E royalties for ex-U.S. probability-weighted sales of solithromycin (CEM-101) in CABP (assuming same likelihood of success) of \$37M, and 2x 2019E collaborative revenue of \$13M, each discounted back at 20% for 5.8 periods. Based on the size of the U.S. and WW macrolide market and examples of rapid adoption for drugs possessing favorable resistance profiles, we believe that the valuation of ~\$230M or \$11/share is reasonable. Our solithromycin (CEM-101) sales estimates assume a 2015 launch with CEM-101 penetrating into the ~16% of potential Community Acquired Bacterial Pneumonia (CABP) market by 2019. We view the multiples used in our valuation analysis to be in the range used for comparable biotechnology companies.



## RISKS TO VALUATION

Risks to our valuation include clinical and commercial risks associated with further safety and efficacy evaluation with solithromycin in larger Phase III trials with a different comparators as in Phase II, and uncertainties in whether CEM-101 is able to meaningfully differentiate itself from current treatment standards. The company's programs also may have regulatory risks as the approval of new antibiotics has not always been straightforward. Additionally, the completion of the Phase III program is dependent on securing more funding through either corporate partnership or equity financing, and the company will likely require additional financing prior to becoming profitable.

## Cempra Income Statement

Numbers in (\$000) except EPS

	2009A	2010A	2011A	Mar-12A	Jun-12A	Sep-12A	Dec-12E	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E
CEM-101 US sales (probability weighted)								0		0	13,234	69,848	132,716	207,497	268,329
<b>Cempra's US Share (50%)</b>								0		0	<b>6,617</b>	<b>34,924</b>	<b>66,358</b>	<b>103,748</b>	<b>134,164</b>
CEM-101 ROW sales (probability weighted)								0		0	0	3,970	48,893	126,081	217,872
<b>CEM-101 ROW royalties (probability weighted)</b>								0				<b>675</b>	<b>8,312</b>	<b>21,434</b>	<b>37,038</b>
Taksta US sales (probability weighted)								0		0	0	0	0	0	0
Collaborative revenues								0	4,000	7,750	10,875	10,875	13,375	13,375	13,375
<b>Revenue</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>\$0</b>	<b>\$4,000</b>	<b>\$7,750</b>	<b>\$17,492</b>	<b>\$46,474</b>	<b>\$88,045</b>	<b>\$138,557</b>	<b>\$184,578</b>
COGS								-	-	-	794	4,191	7,963	12,450	16,100
R&D Expense	13,674	15,474	16,872	1,876	7,424	3,156	6,000	18,456	25,680	26,964	28,312	29,728	31,214	32,463	33,761
G&A Expense	3,027	3,198	3,708	972	1,777	1,495	1,540	5,784	8,006	16,006	39,009	42,520	48,898	51,832	53,905
Other								0							
<b>Total Operating Expenses</b>	<b>16,701</b>	<b>18,673</b>	<b>20,580</b>	<b>2,848</b>	<b>9,201</b>	<b>4,651</b>	<b>7,540</b>	<b>24,240</b>	<b>33,686</b>	<b>42,970</b>	<b>68,116</b>	<b>76,439</b>	<b>88,075</b>	<b>96,745</b>	<b>103,766</b>
<b>Operating Income</b>	<b>(16,701)</b>	<b>(18,673)</b>	<b>(20,580)</b>	<b>(2,848)</b>	<b>(9,201)</b>	<b>(4,651)</b>	<b>(7,540)</b>	<b>(\$24,240)</b>	<b>(\$29,686)</b>	<b>(\$35,220)</b>	<b>(\$50,624)</b>	<b>(\$29,965)</b>	<b>(\$30)</b>	<b>\$41,812</b>	<b>\$80,811</b>
Interest Income	17	4	2	15	1	1	(2)	14	(1)	(18)	(44)	(59)	(61)	(63)	(66)
Interest Expense	(1,927)	(1,495)	(643)	(316)	(327)	(331)	(331)	(1,305)	(1,305)	(1,358)	(1,412)	(1,468)	(1,527)	(1,588)	(1,652)
Net Interest Expense	(1,911)	(1,491)	(641)	(301)	(327)	(330)	(333)	(1,291)	(1,306)	(1,376)	(1,456)	(1,527)	(1,588)	(1,652)	(1,718)
Other Income		489						0							
Pretax Income	(18,612)	(19,675)	(21,221)	(3,149)	(9,528)	(4,981)	(7,873)	(25,531)	(30,992)	(36,596)	(52,079)	(31,492)	(1,619)	40,161	79,093
Income Taxes								0							
<b>Net Income</b>	<b>(18,612)</b>	<b>(19,675)</b>	<b>(21,221)</b>	<b>(3,149)</b>	<b>(9,528)</b>	<b>(4,981)</b>	<b>(7,873)</b>	<b>(25,531)</b>	<b>(30,992)</b>	<b>(36,596)</b>	<b>(52,079)</b>	<b>(31,492)</b>	<b>(1,619)</b>	<b>40,161</b>	<b>79,093</b>
Accretion of redeemable convertible preferred shares	(2,291)	(3,238)	(3,763)	(314)				(314)							
Net income for common shareholders	(20,903)	(22,913)	(24,984)	(3,463)	(9,528)	(4,981)	(7,873)	(25,845)	(30,992)	(36,596)	(52,079)	(31,492)	(1,619)	40,161	79,093
Stock option expense	75	108	296	190	192	194	196	771	787						
<b>EPS</b>	<b>(\$42.57)</b>	<b>(\$46.60)</b>	<b>(\$47.53)</b>	<b>(\$0.26)</b>	<b>(\$0.45)</b>	<b>(\$0.24)</b>	<b>(\$0.37)</b>	<b>(\$1.32)</b>	<b>(\$1.17)</b>	<b>(\$1.35)</b>	<b>(\$1.66)</b>	<b>(\$0.99)</b>	<b>(\$0.05)</b>	<b>\$1.12</b>	<b>\$2.17</b>
GAAP Shares Outstanding	491	492	526	13,251	21,035	21,038	21,143	19,117	26,566	27,097	31,306	31,932	32,571	33,222	33,887
Pro Forma Average Diluted Shares Outstanding				15,647	22,398	22,443	23,543	21,008	29,066	29,597	33,806	34,432	35,071	35,722	36,387

Source: Leerink Swann LLC, Company reports



## Disclosures Appendix

### Analyst Certification

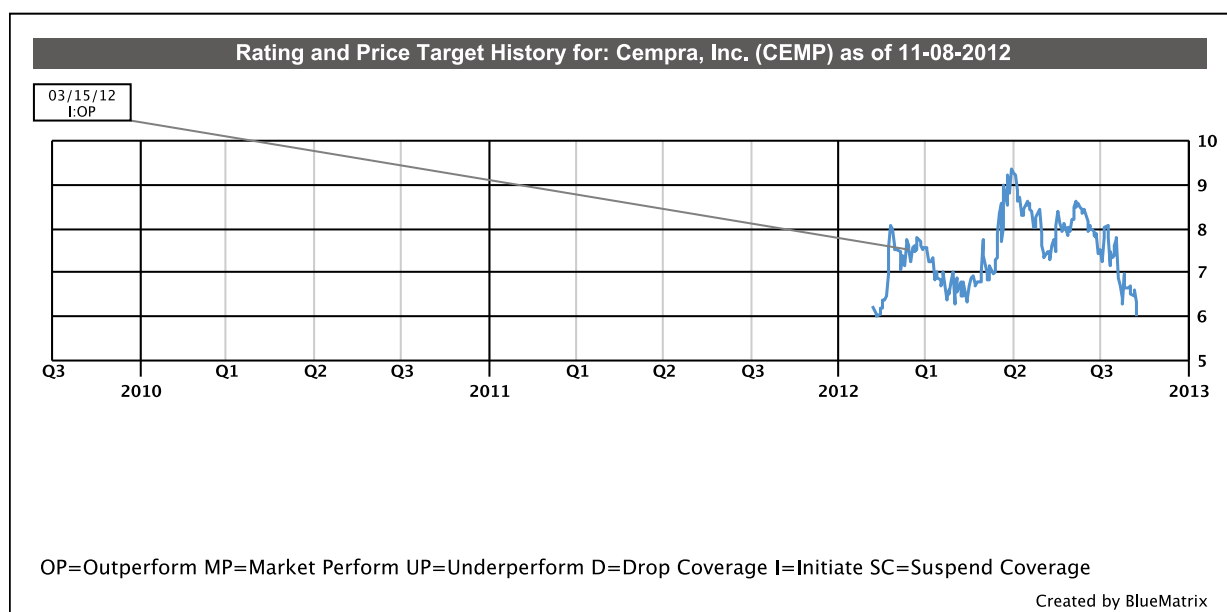
I, Howard Liang, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### Valuation

Our 12-month valuation on CEMP shares is \$11 that we reach using a multiple-of-sales analysis based on a 5x multiple applied to Cempira's shares of 2019E probability-weighted U.S. sales of solithromycin (CEM-101) in CABP (assuming 50/50 co-promote in the U.S and 65% probability of success) totaling \$134M, and an 11x multiple applied to 2019E royalties for ex-U.S. probability-weighted sales of solithromycin (CEM-101) in CABP (assuming same likelihood of success) of \$37M, and 2x 2019E collaborative revenue of \$13M, each discounted back at 20% for 5.8 periods. Based on the size of the U.S. and WW macrolide market and examples of rapid adoption for drugs possessing favorable resistance profiles, we believe that the valuation of ~\$230M or \$11/share is reasonable. Our solithromycin (CEM-101) sales estimates assume a 2015 launch with CEM-101 penetrating into the ~16% of potential Community Acquired Bacterial Pneumonia (CABP) market by 2019. We view the multiples used in our valuation analysis to be in the range used for comparable biotechnology companies.

### Risks to Valuation

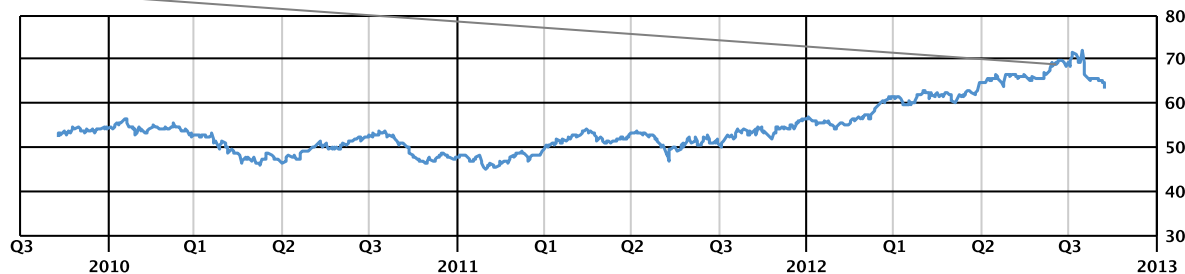
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### Rating and Price Target History for: Abbott Laboratories (ABT) as of 11-08-2012

09/18/12  
MP



Leerink Swann placed an Outperform rating on ABT on October 31, 2005.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

### Rating and Price Target History for: Pfizer Inc. (PFE) as of 11-08-2012

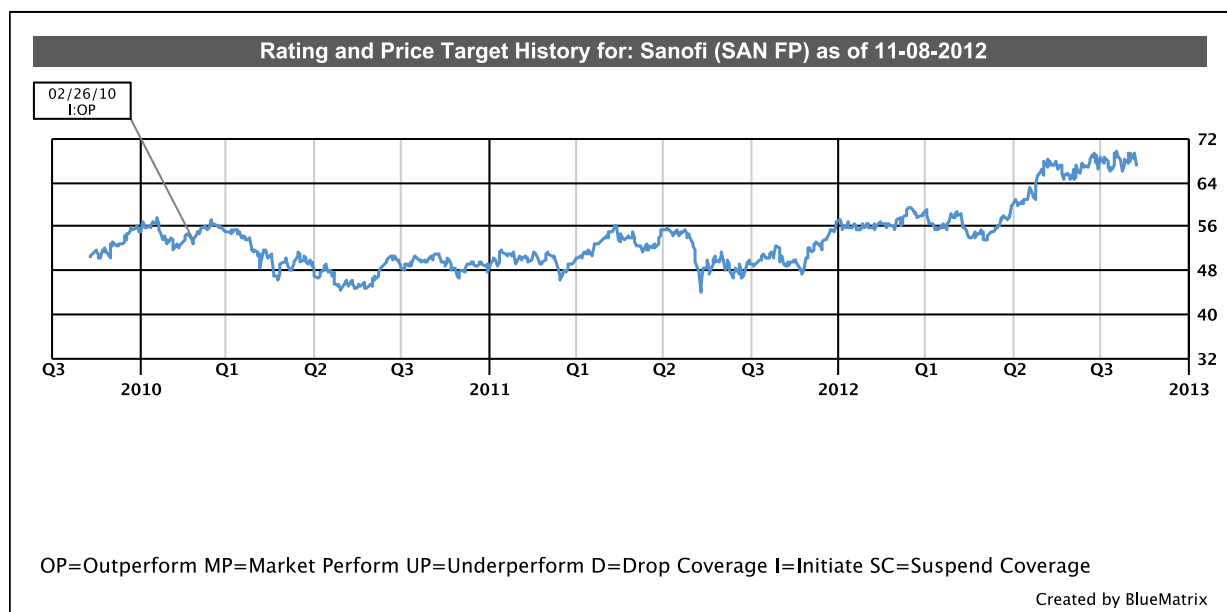
11/14/11  
MP



Leerink Swann placed an Outperform rating on PFE on Feb. 12, 2009.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix







Distribution of Ratings/Investment Banking Services (IB) as of 09/30/12				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	102	58.30	29	28.40
HOLD [MP]	73	41.70	3	4.10
SELL [UP]	0	0.00	0	0.00

## Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

**Outperform (Buy):** We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Index for issuers with a market capitalization over \$2 billion.



## Important Disclosures

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Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Cempra, Inc.

Leerink Swann LLC makes a market in Cempra, Inc.

Leerink Swann LLC is willing to sell to, or buy from, clients the common stock of Abbott Laboratories, Pfizer Inc. and Sanofi on a principal basis.

In the past 12 months, an affiliate of the Firm, Leerink Swann Consulting LLC, has received compensation for providing non-securities services to: Abbott Laboratories and Pfizer Inc.

Leerink Swann LLC has acted as a co-manager for a public offering of Cempra, Inc. in the past 12 months.

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