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Emerging Company Research

Cempra — Outperform (1)

Strong Clinical Newsflow As We Approach The End Of 2012

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Summary: Yesterday, after the close, Cempra reported 3Q12 financials and conducted an investor call. Cempra reported a loss per share of $0.24 as compared to our estimate of a loss per share of $0.47. The difference was largely related to a smaller than estimated R&D expense line. Cempra achieved significant progress in 3Q12 and ended the quarter with approximately $51.6MM in cash and cash equivalents. Cempra's focus on antibiotics and the superior clinical profiles of the drug candidates, as compared to competitors, continue to be the greatest asset to the company. We remain bullish on Cempra shares and reiterate our Outperform rating.

- **Phase III oral study of solithromycin in CABP will be initiated by YE2012.** Cempra received positive feedback from the FDA regarding the design of the pivotal Phase III trial, which closely follows the proposed FDA guidance. Additionally, positive results from Phase I intravenous study has positioned Cempra to initiate the first Phase III I.V. to oral step-down study of solithromycin in 2013, when funding is available.

- **Phase II trial of Taksta in prosthetic joint infections (PJI) will also begin in 2012.** Taksta would provide the first safe and efficacious oral medication in the U.S. for PJI that is also suitable for chronic treatment. Cempra plans to discuss with the FDA the impact of the Generating Antibiotic Incentives Now (GAIN) Act, which is part of PDUFA-V, on Taksta and the medication's eligibility for the five-year extension under the Hatch-Waxman Act.

- **Balance sheet strengthened with recent financing.** In October, Cempra conducted a private placement for gross proceeds of approximately $25MM. In addition to sustaining the company's daily operations, the strong cash balance could place Cempra into a more advantageous position in partnership discussions.

CEMP (11/09)	**$6.16**
Mkt cap	**$129.4MM**
Dil shares out	21.0MM
Avg daily vol	1.9K
52-wk range	$6.0-9.6
Dividend	Nil
Dividend yield	Nil
BV/sh	NA
Net cash/sh	$2.46
Debt/cap	10.0%
ROA (LTM)	NA
5-yr fwd EPS growth (Norm)	NA
S&P 500	**1390.7**

Revenue $MM

FY Dec	2011 Actual	2012E Prior	2012E Current	2013E Prior	2013E Current	2014E Current	2015E Current
Q1	0.0	—	0.0A	—	0.0	—	—
Q2	0.0	—	0.0A	—	0.0	—	—
Q3	0.0	—	0.0A	—	5.0	—	—
Q4	0.0	—	0.0	—	0.0	—	—
Year	**0.0**	**—**	**0.0**	**—**	**5.0**	**5.0**	**10.7**
EV/S	—	—	—	—	15.6x	15.6x	7.3x

EPS $

FY Dec	2011 Actual	2012E Prior	2012E Current	2013E Prior	2013E Current	2014E Current	2015E Current
Q1	(1.28)	—	(0.26)A	—	(0.34)	—	—
Q2	(1.24)	—	(0.45)A	—	(0.36)	—	—
Q3	(1.78)	—	(0.24)A	—	(0.15)	—	—
Q4	(7.62)	(0.52)	(0.29)	—	(0.31)	—	—
Year	**(47.53)**	**(1.45)**	**(1.24)**	**(1.06)**	**(1.16)**	**(1.21)**	**(0.91)**
P/E	—	—	—	—	—	—	—

Phase III Oral Solithromycin Pivotal Trial Likely To Succeed

Dosing regimen is the same as in the Phase II study. The first Phase III trial with the oral formulation of solithromycin will enroll approximately 800 patients to receive either solithromycin for five days or the active comparator moxifloxacin (Avelox) for seven days, both dosed once daily. Solithromycin will be administered at a loading dose of 800mg on day one and subsequently at the maintenance dose of 400mg for the remaining four days. This is the same dosing regimen as in the completed Phase II trial. In comparison, moxifloxacin will be dosed at 400mg on all seven days.

Active comparator sets a lower bar. The primary endpoint, as defined by the recently proposed FDA guidelines on CABP clinical studies, will be non-inferiority in early responses at 72 hours post treatment. Analysis of the Phase II trial results following the guidelines demonstrated that solithromycin was not inferior to levofloxacin, the active comparator used in the Phase II trial. Cempra expects the Phase III study to be completed in 2014. Given the numerous clinical studies that compared moxifloxacin to levofloxacin and demonstrated no significant difference, we are optimistic that solithromycin will reach the primary endpoint in the Phase III study as well.

Enrollment is progressing well. Clinical sites will cover multiple geographic areas and will include approximately 30 sites that participated in the Phase II study. Cempra has recruited a highly competent team with great enthusiasm and the CRO to be used worked on the development of Ceftaroline (Teflaro).

No effects on QTc have been observed. Cempra has conducted extensive studies on the safety profile of solithromycin and no heart-related issues have been detected. Cempra plans to submit QT study designs for both oral and I.V. formulations and expect to complete the studies prior to the initiation of the I.V. to oral step-down study.

I.V. to oral step-down study is being planned. Based on the positive results from the Phase I I.V. study of solithromycin, Cempra expects to have the end-of-Phase II meeting with the FDA in 1H13 and the company plans to initiate the first I.V.-to-oral Phase III study in 2013, upon availability of a partnership or with additional financing. The combination of the oral Phase III study and one I.V.-to-oral step-down Phase III study will potentially be sufficient to support an NDA filing.

Gonococcal Program Provides Upside Potential

In October 2012, Cempra announced positive top-line results from the Phase II clinical trial that evaluated the efficacy, safety and tolerability of solithromycin (CEM-101) in the treatment of uncomplicated urogenital gonococcal infections. A single oral dose of solithromycin achieved the primary endpoint of bacterial eradication in 100% of evaluable patients. All 22 patients who were defined as evaluable patients demonstrated bacterial eradication as measured by conversion to negative cultures at seven days after solithromycin treatment.

We believe solithromycin will provide an effective treatment for gonococcal infections, which, with a rising incidence, are becoming a serious public health problem in both the U.S. and other regions of the world. More serious is the increase of strains that are resistant to currently approved antibiotics.

In August 2012, The Centers for Disease Control and Prevention (CDC) revised the gonorrhea treatment guidelines. Recent evidence from the organization's Gonococcal Isolate Surveillance Project (GISP) suggests that cefixime (Suprax), previously the only CDC-recommended oral agent for the treatment of this indication, is becoming less effective. CDC no longer recommends cefixime as an effective oral treatment for gonorrhea but only maintains it as an alternative treatment option in some instances. According to the revised guideline, providers may prescribe a dual therapy of cefixime combined with either azithromycin or doxycycline when ceftriaxone, a more potent cephalosporin administered intramuscularly, is not available. Moreover, CDC now urges efforts to develop new treatments for gonorrhea.

Cempra has demonstrated solithomycin's efficacy against most gonococcal strains including those which are resistant to earlier generations of macrolides. We have not included the gonococcal program into our revenue buildup model. Therefore, if successfully developed, this program will provide further upside potential to Cempra shares which in our opinion are already discounted.

Cempra Quarterly P&L

	2011A	Q1:12A	Q2:12A	Q3:12A	Q4:12E	2012E	Q1:13E	Q2:13E	Q3:13E	Q4:13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total Product Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**5.7**	**22.6**	**85.1**	**180.4**	**253.2**	**310.5**
Total License Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**5.0**	**0.0**	**5.0**	**5.0**	**5.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**5.0**	**0.0**	**5.0**	**5.0**	**10.7**	**32.6**	**85.1**	**180.4**	**253.2**	**310.5**
COGS													0.9	3.4	12.8	27.1	38.0	46.6
Research and Development	16.9	1.9	7.4	3.2	4.0	16.5	5.2	5.5	5.8	6.0	22.5	28.0	25.0	24.0	23.0	25.0	25.0	26.0
Sales, General and Administrative	3.7	1.0	1.8	1.5	1.7	5.9	1.9	2.0	2.1	2.3	8.3	10.0	10.0	13.0	15.0	18.0	18.0	19.0
Total Operating Expenses:	**20.6**	**2.8**	**9.2**	**4.7**	**5.7**	**22.4**	**7.1**	**7.5**	**7.9**	**8.3**	**30.8**	**38.0**	**35.9**	**40.4**	**50.8**	**70.1**	**81.0**	**91.6**
Operating Income (Loss)	**(20.6)**	**(2.8)**	**(9.2)**	**(4.7)**	**(5.7)**	**(22.4)**	**(7.1)**	**(7.5)**	**(2.9)**	**(8.3)**	**(25.8)**	**(33.0)**	**(25.1)**	**(7.8)**	**34.3**	**110.3**	**172.2**	**218.9**
Interest income		0.1	0.0	0.0	0.0	0.2	0.1	0.1	0.0	0.0	0.2	0.2	0.3	0.2	0.1	0.2	0.1	0.1
Interest expense		(0.4)	(0.3)	(0.3)	(0.4)	(1.5)	(0.2)	(0.3)	(0.3)	(0.3)	(1.1)	(1.4)	(1.0)	(1.3)	(1.2)	(1.0)	(1.2)	(1.0)
Other Income (Loss)	(0.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	**(21.2)**	**(3.1)**	**(9.5)**	**(5.0)**	**(6.1)**	**(23.8)**	**(7.2)**	**(7.7)**	**(3.2)**	**(8.6)**	**(26.7)**	**(34.2)**	**(25.8)**	**(8.9)**	**33.2**	**109.5**	**171.1**	**218.0**
Accretion of Redeemable Convertible Preferred Shares	(3.8)	(0.3)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss) Attributable to Common Share Holders	**(25.0)**	**(3.5)**	**(9.5)**	**(5.0)**	**(6.1)**	**(23.8)**	**(7.2)**	**(7.7)**	**(3.2)**	**(8.6)**	**(26.7)**	**(34.2)**	**(25.8)**	**(8.9)**	**33.2**	**109.5**	**171.1**	**218.0**
Tax rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*2.5%*	*7.0%*	*12.5%*	*20.0%*
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.8	7.7	21.4	43.6
GAAP EPS, Basic and Diluted	**(47.53)**	**(0.26)**	**(0.45)**	**(0.24)**	**(0.29)**	**(1.24)**	**(0.34)**	**(0.36)**	**(0.15)**	**(0.31)**	**(1.16)**	**(1.21)**	**(0.91)**	**(0.31)**	**1.13**	**3.55**	**5.18**	**6.01**
Weighted Average Shares Outstanding - Basic and Diluted	0.5	13.3	21.0	21.0	21.1	19.1	21.2	21.3	21.5	28.0	23.0	28.2	28.3	28.5	28.6	28.7	28.9	29.0

Source: Cowen and Company

Cempra Annual P&L

	2011A	2012E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total Product Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**5.7**	**22.6**	**85.1**	**180.4**	**253.2**	**310.5**
Total License Revenue	**0.0**	**0.0**	**5.0**	**5.0**	**5.0**	**10.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total Revenue	**0.0**	**0.0**	**5.0**	**5.0**	**10.7**	**32.6**	**85.1**	**180.4**	**253.2**	**310.5**
COGS					0.9	3.4	12.8	27.1	38.0	46.6
Research and Development	16.9	16.5	22.5	28.0	25.0	24.0	23.0	25.0	25.0	26.0
Sales, General and Administrative	3.7	5.9	8.3	10.0	10.0	13.0	15.0	18.0	18.0	19.0
Total Operating Expenses:	**20.6**	**22.4**	**30.8**	**38.0**	**35.9**	**40.4**	**50.8**	**70.1**	**81.0**	**91.6**
Operating Income (Loss)	**(20.6)**	**(22.4)**	**(25.8)**	**(33.0)**	**(25.1)**	**(7.8)**	**34.3**	**110.3**	**172.2**	**218.9**
Interest income		0.2	0.2	0.2	0.3	0.2	0.1	0.2	0.1	0.1
Interest expense		(1.5)	(1.1)	(1.4)	(1.0)	(1.3)	(1.2)	(1.0)	(1.2)	(1.0)
Other Income (Loss)	(0.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	**(21.2)**	**(23.8)**	**(26.7)**	**(34.2)**	**(25.8)**	**(8.9)**	**33.2**	**109.5**	**171.1**	**218.0**
Accretion of Redeemable Convertible Preferred Shares	(3.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss) Attributable to Common Share Holders	**(25.0)**	**(23.8)**	**(26.7)**	**(34.2)**	**(25.8)**	**(8.9)**	**33.2**	**109.5**	**171.1**	**218.0**
Tax rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*2.5%*	*7.0%*	*12.5%*	*20.0%*
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.8	7.7	21.4	43.6
GAAP EPS, Basic and Diluted	**(47.53)**	**(1.24)**	**(1.16)**	**(1.21)**	**(0.91)**	**(0.31)**	**1.13**	**3.55**	**5.18**	**6.01**
Weighted Average Shares Outstanding - Basic and Diluted	0.5	19.1	23.0	28.2	28.3	28.5	28.6	28.7	28.9	29.0

Source: Cowen and Company

Positives

1. Cempra has two programs that are strong differentiators from other antibiotics that are currently in development. We believe both programs have strong partnering ability and believe that partnerships will be obtained while in Phase III development. We believe the FDA is highly motivated to approve a safe and well tolerated macrolide that has IV to oral step-down potential.
2. Taksta for PJI offers Cempra a fast approval pathway with the FDA. The company has the ability to use historical safety from other countries to support an NDA filing. The pivotal trial can be a small, open-label trial. PJI is a second problem for many patients and a dilemma for physicians who must cycle antibiotics at the risk of causing resistance.
3. Historically, many antibiotic companies have partnered or been acquired while in Phase III testing. We believe Cempra has a high likelihood of being acquired once they move into Phase III testing. This space tends to have many new biotech entrants and then there is strong M&A that occurs with big pharma being the instigators. We believe this trend has a high likelihood of continuing given that the market is beginning to look similar to the last M&A sweep. Also there is a great need for new antibiotics and the big pharma companies feel the need as well.

Negatives

1. Cempra did not garner the amount of cash they were looking for in their IPO and as such will need to come back to the Street for additional financing before CEM-101 finishes clinical development. The only other option is a partnership, but this cannot be guaranteed.
2. There are multiple antibiotics now in development and other biotechs with programs are looking to go public as well. Cempra's program could be overshadowed by other entrants into the marketplace and this would have a negative impact on the company's share price.
3. While Cempra has a library of macrolides they can develop, they have already chosen the most promising for development as an antibiotic. The company's expertise lies in antibiotic drug development and if CEM-101 and Taksta fail, then the company does not have an antibiotic pipeline to fall back on.

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
CEMP	Cempra

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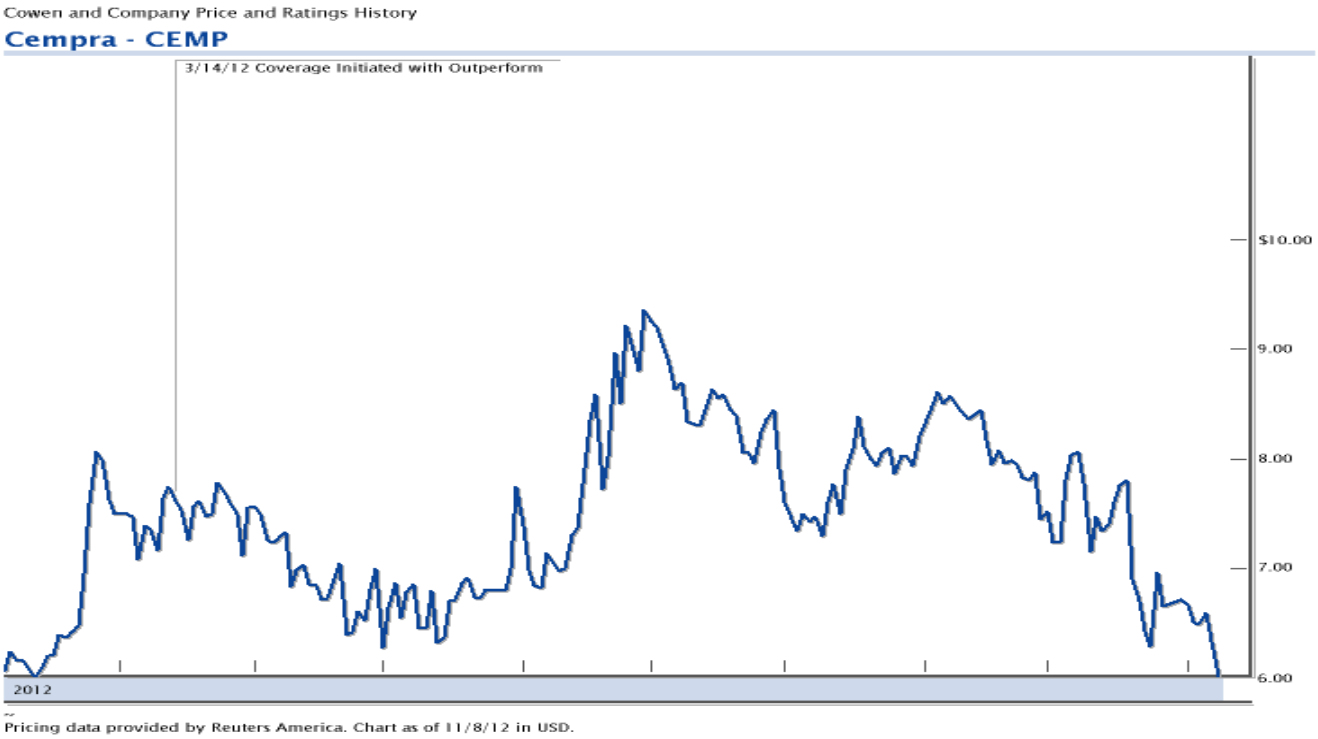
Rating	Definition
Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

COWEN AND COMPANY RATING ALLOCATION (a)

Rating	Pct of companies under coverage with this rating	Pct for which Investment Banking services have been provided within the past 12 months
Buy (b)	55.7%	9.2%
Hold (c)	41.9%	1.7%
Sell (d)	2.4%	0.0%

(a) As of 09/30/2012. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above). Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.


Cowen and Company Price and Ratings History
Cempra - CEMP
3/14/12 Coverage Initiated with Outperform
$10.00
9.00
8.00
7.00
6.00
2012
Pricing data provided by Reuters America. Chart as of 11/8/12 in USD.