

Emergent BioSolutions (EBS - \$33.78)

3Q15 beats top & bottom line on higher BioThrax sales

EBS reported 3Q15 last night after the close, beating top & bottom line on higher than expected BioThrax sales and significantly lower SG&A spend in the quarter. Management raised the lower range on FY15 total sales estimates to \$520M-\$540M (from \$510M-\$540M previously) and expects to lay out their next 5 year aspirational targets at a competitors conference in January. The one cloud on the 3Q call was the announcement that the FDA wants EBS to re-analyze an assay related to the validation of the Building 55 BioThrax sBLA. EBS is conducting 2 separate analyses of the assay: a quick analysis that will keep Building 55 on-track for 1H16 licensure and a longer analysis that may push licensure into 2H16. While not ideal to have a potential late-stage delay of potentially 6 months, we haven't modeled in significant Building 55 contributions to sales until 2017 in any event. So as long as the licensure doesn't get pushed into 2017 we are making no changes to our sales estimates at this time. And if the quick analysis is accepted by the FDA the issue becomes moot anyway. We continue to like EBS here and we are reiterating our Buy rating and our \$45 price target.

- **BioThrax German approval in 1H16.** Somewhat surprisingly, BioThrax from Bldg 55 is expected to receive German approval in 1H16, which puts Germany ahead of the US for receiving Bldg 55 product. How much EBS can actually sell ex-US remains in question, as the follow-on contract from the USG likely won't be finalized until 2H16 at the earliest. We do expect that ex-US sales will likely be at a significantly higher price point than USG sales.
- **US Bldg 55 approval still likely 2016, waiting to see if that 1H16 or 2H16.** EBS will meet with the FDA in early 2016 to determine if their quick re-analysis of a disputed validation assay will be sufficient or if a longer, 6-month re-analysis will be required. Either way we believe that Bldg 55 licensure remains a 2016 event.
- **Additional acquisitions likely a 2016 event at this point.** While EBS is still actively looking at assets we believe an accretive acquisition is likely a 2016 event at this point. We continue to expect a \$30M-\$60M pick up in 2016.
- **Reiterate Buy rating \$45 price target.** Our PT is based on a sum-of-the-parts analysis, with a base business DCF value of \$40/share, cash (net of debt) and accounts receivable at the end of 2016 of \$4/share, and a pipeline/tech value of \$1/share.

Adj-Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY16E	(0.01)	0.48	0.76	1.01	2.25	15.3x
FY15E	(0.50)A	0.36A	0.83A	0.62	1.50	23.0x
FY14A	(0.40)	0.25	0.54	0.75	1.19	28.9x
FY13A	(0.19)	0.31	0.36	0.33	0.99	34.8x

Source: Laidlaw & Company estimates

Healthcare / Biotechnology

Ticker: **EBS**
Rating: **Buy**
Price Target: **\$45.00**

Trading Data:

Last Price (11/05/2015)	\$33.78
52-Week High (08/13/2015)	\$36.20
52-Week Low (11/07/2014)	\$22.32
Market Cap. (MM)	\$1,310
Shares Out. (MM)	38.8

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Initial CDC meeting completed for the next BioThrax contract. The current \$1.25B USG contract expires in September 2016 EBS notes that they have already had a preliminary meeting with the CDC to start the process for negotiating the next contract. We expect that this is likely a 2H16 event, and will likely be in the ~\$350M/year range with an approximate \$17/dose price point (from ~\$28.50 currently).

EBS remains hopeful that ex-US sales could become reality in 2017 as they may finally have excess capacity to sell ex-US. We model in \$40M and \$78M in ex-US sales in 2017-2018 respectively. Likely ex-US sales countries include Germany (which should approve BioThrax in 1H16), Israel, UK, India, and France.

Figure 1: Variance analysis

Emergent BioSolutions					
Quarterly Variance Analysis					
<i>(\$000 except per share)</i>	3Q14A	3Q15A	3Q15E	Variance	% Y/Y
BioThrax sales	\$66,000	\$109,800	\$85,000	\$24,800	66.4%
RSDL sales		0	0	0	NM
Contracts and Grants	44,064	29,646	33,000	(3,354)	-32.7%
Total Revenue	\$137,954	\$164,987	\$152,250	\$12,737	19.6%
COGS	30,423	36,161	39,593	(3,432)	18.9%
Gross Profit	107,531	128,826	112,658	16,169	19.8%
SG&A Expense	27,692	29,806	39,585	(9,779)	7.6%
R&D ex-contracts & grants	143	12,222	3,750	8,472	8446.9%
R&D Expense	44,207	41,868	36,750	5,118	-5.3%
Operating Income	35,632	57,152	36,323	20,830	60.4%
Interest Expense	1,810	1,635	1,500	135	-9.7%
Int. & Inv. Income	59	104	150	(46)	76.3%
Other Inc./(Exp)	420	602	500	102	NA
Pretax Income	34,301	56,223	35,473	20,751	63.9%
Tax exp/(benefit)	9,269	16,434	10,287	6,147	NA
Adj-Net Income	25,032	39,789	25,185	14,604	59.0%
Shares out (000)	46,557	47,785	47,760	24	2.6%
Adj-Earnings Per Share	\$0.54	\$0.83	\$0.53	\$0.31	54.9%
Margin Analysis					
Gross Profit Margin	67.6%	73.3%	66.8%	6.5%	8.4%
SG&A Expense	29.5%	22.0%	33.2%	-11.2%	-25.3%
R&D Expense	47.1%	30.9%	30.8%	0.1%	-34.3%
Operating Income	38.0%	42.2%	30.5%	11.8%	11.3%
Tax Rate	27.0%	29.0%	29.0%	0.0%	7.3%
Adj-Net Income	18.1%	24.1%	16.5%	7.6%	32.9%

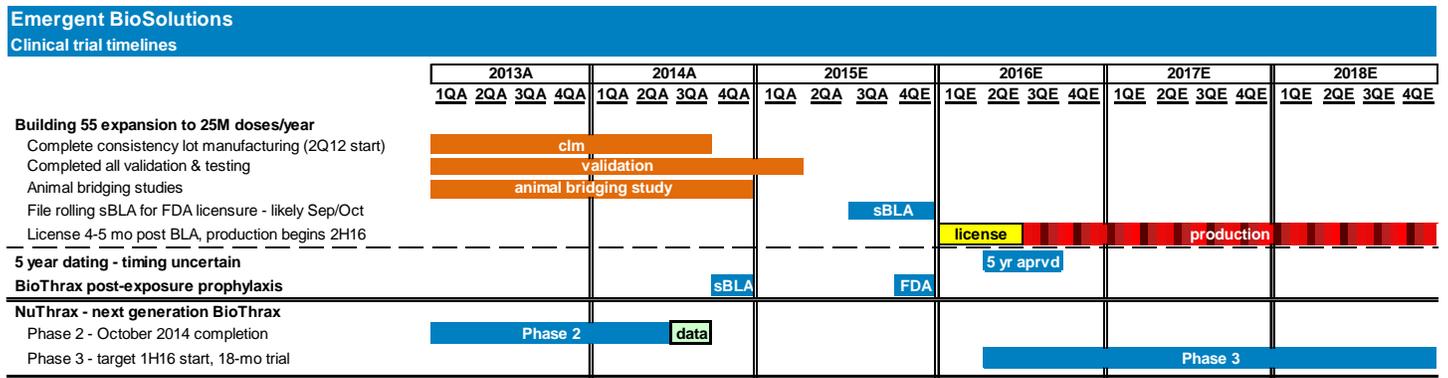
Source: Company reports; Laidlaw & Company estimates

Figure 2: Valuation

Sum-of-the-parts valuation: EBS		
Segment	Valuation (000's)	Per share value
DCF of base business	\$1,985,468	\$40
Net Cash, end '16E	\$215,020	\$4
Technology value	\$50,000	\$1
SUM	\$2,250,487	\$45
Fully diluted shares out '16E (000)		48,985

Source: Company reports; Laidlaw & Company estimates

Figure 2: Clinical Trials Timeline



Source: Company reports and Laidlaw estimates

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Emergent BioSolutions Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QA	4QE	
BioThrax - US sales	\$24,544	\$67,500	\$66,000	\$87,900	\$245,944	\$0	\$72,200	\$109,800	\$101,000	\$283,000
BioThrax - OUS sales										
Other Biodefense	2,500	7,275	11,675	10,911	32,350	11,945	2,800	7,700	7,750	30,195
Total Biodefense	27,044	74,775	77,675	98,811	278,305	11,945	75,000	117,500	108,750	313,195
Total Biosciences	8,723	3,494	6,782	11,050	30,060	6,345	7,023	6,500	15,075	34,943
Contract manufacturing	2,726	9,187	9,433	9,589	30,935	12,243	8,859	11,341	12,500	44,943
Contracts & grants	15,391	22,869	44,064	28,525	110,849	33,099	35,230	29,646	40,000	137,975
Total revenues	\$53,884	\$110,325	\$137,954	\$147,975	\$450,138	\$63,633	\$126,112	\$164,987	\$176,325	\$531,057
Expenses										
COGS	16,997	31,607	30,423	29,185	108,212	16,048	26,266	36,161	37,057	115,532
Gross margin	36,887	78,718	107,531	118,790	341,926	47,585	99,846	128,826	139,269	415,526
% product sales	56%	64%	68%	76%	68%	47%	71%	73%	73%	71%
R&D	30,256	37,401	44,207	38,965	150,829	38,702	40,941	41,868	45,750	167,261
SG&A	24,089	27,155	27,692	28,705	107,641	33,393	34,053	29,806	50,700	147,952
Operating income	(17,458)	14,162	35,632	51,120	83,456	(24,510)	24,852	57,152	42,819	100,313
Interest expense	3,535	3,621	1,810	1,174	10,140	1,661	1,628	1,635	1,500	6,424
Interest income, net	40	31	59	190	320	82	273	104	175	634
Other income/(expense)	512	1,322	420	672	2,926	100	300	602	500	1,502
Pretax income (loss)	(20,441)	11,894	34,301	50,808	76,562	(25,989)	23,797	56,223	41,994	96,025
Tax exp/(benefit)	(5,805)	2,465	9,269	16,192	22,121	(7,169)	6,800	16,434	12,178	28,243
Loss to non-ctrl interest					-					
Adjusted Net Income	(14,636)	9,429	25,032	34,616	54,441	(18,820)	16,997	39,789	29,815	67,781
Non-cash charges	(5,600)	(4,400)	(3,200)	(4,500)	(17,700)	(2,700)	(2,900)	(1,847)	(2,000)	(9,447)
GAAP net income	(20,236)	5,029	21,832	30,116	36,741	(21,520)	14,097	37,942	27,815	58,334
EPS ex non-cash items	(\$0.40)	\$0.25	\$0.54	\$0.75	\$1.19	(\$0.50)	\$0.36	\$0.83	\$0.62	\$1.50
EPS as reported	(\$0.55)	\$0.13	\$0.47	\$0.65	\$0.80	(\$0.57)	\$0.30	\$0.79	\$0.58	\$1.29
Fully diluted shares (000)	36,854	38,333	46,557	46,391	45,803	37,949	47,410	47,785	48,135	45,320
Margin & expense analysis										
Gross Margin (% prod. sales)	56%	64%	68%	76%	68%	47%	71%	73%	73%	71%
Op margin (% prod. sales)	-45%	16%	38%	43%	25%	-80%	27%	42%	31%	26%
Taxes	28%	21%	27%	32%	29%	28%	29%	29%	29%	29%
Net margin	-27%	9%	18%	23%	12%	-30%	13%	24%	17%	13%
Year-over-year change										
Net revenue	25%	34%	55%	51%	44%	18%	14%	20%	19%	18%
R&D	5%	27%	53%	30%	26%	28%	9%	-5%	17%	11%
SG&A	20%	36%	26%	59%	34%	39%	25%	8%	77%	37%
Operating income	54%	-12%	96%	83%	65%	40%	75%	60%	-16%	20%
Net income	120%	-17%	86%	90%	50%	29%	80%	59%	-14%	25%

Source: Company reports and Laidlaw estimates

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Figure 4: Annual Income Statement

Emergent BioSolutions						
Annual income statement						
(\$'000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
BioThrax - US sales	\$245,944	\$283,000	\$328,000	\$335,000	\$350,000	2015E guide: \$270M-\$285M
BioThrax - OUS sales				40,000	78,000	Excess Bldg 55 production sold OUS
Other Biodefense	<u>32,350</u>	<u>30,195</u>	<u>32,000</u>	<u>33,000</u>	<u>34,000</u>	RSDL, BAT, other Biodefense here
Total Biodefense	278,305	313,195	360,000	408,000	462,000	
Total biosciences	30,060	34,943	30,450	0	0	To be spun out mid-2016
Contract manufacturing	30,935	44,943	38,500	39,000	39,500	Acquired with Cangene 3Q13
Contracts & grants	110,849	137,975	127,000	122,000	126,000	Offset in R&D
Total revenues	\$450,138	\$531,057	\$555,950	\$569,000	\$627,500	2015E guide: \$520M-\$540M
Expenses						
COGS	108,212	115,532	127,930	112,548	117,383	
Gross margin	341,926	415,526	428,020	456,453	510,118	
% product sales	68%	71%	70%	75%	77%	Cangene impacts margins
R&D	150,829	167,261	140,500	135,000	139,000	
SG&A	107,641	147,952	128,000	103,500	110,500	
Operating income	83,456	100,313	159,520	217,953	260,618	
Interest expense	10,140	6,424	7,250	7,250	7,250	
Interest income, net	320	634	825	1,100	1,500	
Other inc/(exp)	2,926	1,502	2,000	2,000	2,000	
Pretax income	76,562	96,025	155,095	213,803	256,868	
Tax expense	22,121	28,243	44,978	62,003	74,492	
Loss to non-cont. int	0	0	0	0	0	
Adj-Net income	54,441	67,781	110,117	151,800	182,376	2015E adj-NI guide: \$60M-\$70M
Non-cash charges	(17,700)	(9,447)				
GAAP net income	36,741	58,334				2015E GAAP: \$50M-\$60M
EPS ex non-cash items	\$1.19	\$1.50	\$2.25	\$3.00	\$3.50	30% adj-EPS CAGR 2014-2018E
EPS as reported	\$0.80	\$1.29				
Fully diluted shares (000)	45,803	45,320	49,010	50,535	52,135	
Margin & expense analysis						
Gross Margin	68%	71%	70%	75%	77%	
Operating margin	25%	26%	37%	49%	52%	
Taxes	29%	29%	29%	29%	29%	Guide: high 20% range
Net margin	12%	13%	20%	27%	29%	
Year-over-year change						
Net revenue	44%	18%	5%	2%	10%	
R&D	26%	11%	-16%	-4%	3%	
SG&A	34%	37%	-13%	-19%	7%	
Operating income	65%	20%	59%	37%	20%	
Net income	50%	25%	62%	38%	20%	
EPS	21%	26%	50%	34%	16%	

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

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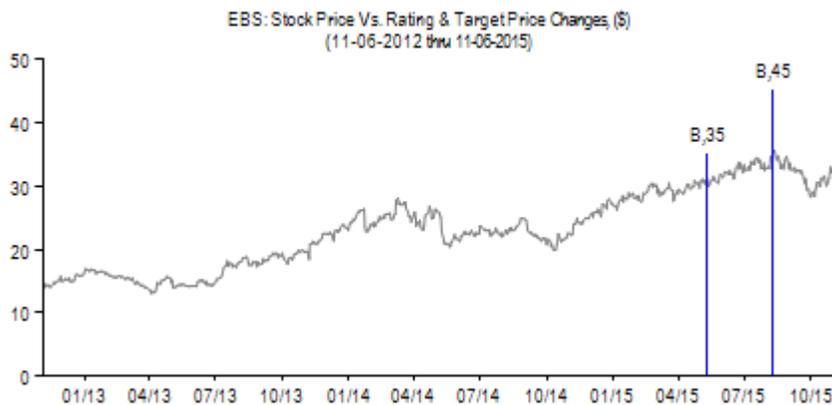
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3 Year Rating Change History		
Date	Rating	Closing Price (\$)
05/11/2015	Buy (B)	31.11

3 Year Price Change History		
Date	Target Price (\$)	Closing Price, (\$)
05/11/2015	35.00	31.11
08/10/2015	45.00	35.29

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			Investment Banking	Brokerage
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Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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