

## BioDelivery Sciences (BDSI - \$ 8.52)

### KOL call highlights the real benefits of Bunavail

We recently held a KOL call with a leading Addiction Medicine specialist on the adoption curve and clinical utility of Bunavail. There has been concern following the relatively slow adoption of Bunavail (compared to the launch of Zubsolv in 2013-2014) that there is a fundamental problem with the underlying compound that is causing the slower adoption by addiction specialists. Our KOL believes that the product itself is in fact superior to both Zubsolv and standard of care Suboxone, but that the 100 patient limit and the low turnover in addiction doctors' offices is playing a large role in the rollout; as well as the insurance coverage for Bunavail relative to Suboxone & Zubsolv. Our KOL has seen good clinical success with Bunavail in the field, and all things being equal (insurance coverage mostly) he would be writing Bunavail first in the treatment algorithm for new patients. While our KOL is an "N" of one, we are heartened to hear that doctors in the field have not found any fundamental issues with the underlying drug or delivery system. While the launch of Bunavail has been a disappointment to investors to date, we believe that the slower launch ramp is more than priced in at current levels and we continue to rate BDSI a Buy with a \$20 PT based on a sum-of-the-parts with Belbuca valued at \$12/share, Bunavail valued at \$4/share, and cash (end-'16) and tech value (clonidine, IV buprenorphine) valued at \$4/share.

- **Bunavail benefits are real, insurance coverage the hurdle.** Our KOL suggested that all things being equal he prefers Bunavail but that the decision is often determined by insurance coverage. Cash-payment customers 0 admittedly a minority of patients – our KOL writes Bunavail first. Of his ~100 patient practice (as limited by law) our KOL has ~15 patients on Bunavail.
- **Low turnover for new patients a hurdle.** Our KOL estimates that only ~20% of patients turn over annually in a practice, which limits the target population for Bunavail as BDSI has been careful not to target patients who are stable on their current medication. Our KOL has successfully switched patients suffering from nausea/vomiting and oral ulcers to Bunavail with a resolution seen in their adverse events.
- **Competitor Zubsolv seen as inferior, but better coverage.** Launched in late 2013 Zubsolv has been aggressively discounting price to obtain placement on formularies. While a good strategy to drive market share it can limit product profitability. Our KOL indicates that for some insurance plans Zubsolv is the required treatment option.

### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	(0.15)	(0.07)	(0.02)	0.30	0.10	NM
<b>FY-15E</b>	(0.29)A	(0.30)	(0.26)	(0.21)	(0.92)	NM
<b>FY-14A</b>	(0.22)	(0.05)	(0.39)	(0.34)	(1.03)	NM
<b>FY-13A</b>	(0.37)	(0.36)	(0.46)	(0.33)	(1.52)	NM

Source: Company data and Laidlaw & Company estimates

### Healthcare/Biotechnology

Ticker:	<b>BDSI</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$ 20.00</b>

### Trading Data:

Last Price (05/29/2015)	\$8.52
52-Week High (09/12/2014)	\$18.48
52-Week Low (05/12/2015)	\$7.53
Market Cap. (MM)	\$446.5
Shares Out. (MM)	52.4

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**BDSI sales force seen as competent and properly positioning Bunavail.** Our KOL believes that the BDSI sales force he has interacted with and seen his colleagues interact with are focused on the right metrics with their physician customers. The BDSI sales force appears to be in general developing solid doctor relationships, and is only targeting patients who need to switch their medication rather than patients who are currently stable on their current drug. Addiction specialists treat a sensitive patient population, people who are taking action to get their lives back, and switching medicine on stable patients isn't best practice. We see it as a positive that – in our KOL's opinion – BDSI is properly delivering the Bunavail message.

**Bunavail “dissolve time” not the issue, being able to talk while taking the drug is.** Our KOL noted that while some have commented that at 10-12 minutes the Bunavail buccal strip may take longer to dissolve than Zubsolv (~5 minutes) the real key is the ability of patients to talk and interact with others while the film strip is in their mouth. Both Zubsolv & Suboxone (film & tablet) require the patient to keep one's mouth shut and chin down (to prevent drug entering the GI system) while taking the drug. Our KOL often places a placebo Bunavail in his mouth while talking to new doctors about Bunavail, just to demonstrate how much more real-world convenient Bunavail is than other options.

**Few new options for addiction medicine physicians, and an unfamiliarity with switching patients.** For a long time the only option was Suboxone and the switch from the tablet to the film strip in 2010 caused a real “uproar” in the addiction medicine community as patients & physicians are loath to alter a successful course of therapy. Our KOL believes this reluctance is also impacting the Bunavail launch as physicians are reluctant to alter their prescribing habits unnecessarily.

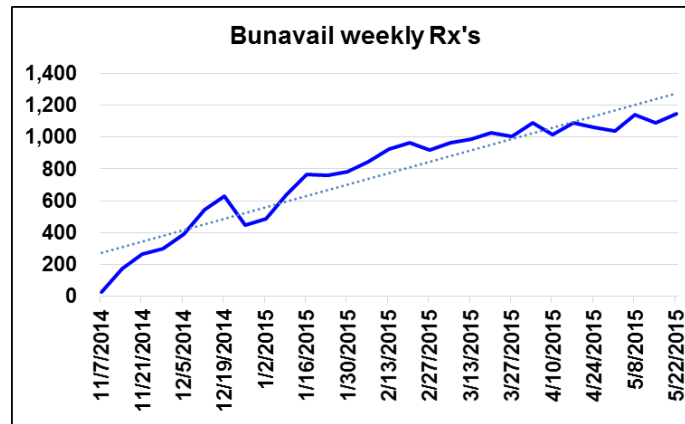
**Belbuca would be a real advantage if approved.** Our KOL was aware of BDSI's pending NDA for Belbuca (buprenorphine) for long term pain, currently at the FDA with an October 23<sup>rd</sup> PDUFA date. While our KOL realizes that Belbuca is still addictive, it is demonstrably less so than current opioid options and would be a real addition to the armamentarium for pain doctors as they deal with the ongoing epidemic of opioid abuse. Our KOL believes that Bunavail by itself (buprenorphine & naloxone) is a deterrent to diversion too, given the inherent difficulties of transporting film strips (as opposed to tablets) for resale.

Figure 1: Valuation

Sum-of-the-parts value: BDSI		
Segment	Valuation (000's)	Per share value
Belbuca (BEMA Bup.) royalty	\$777,542	\$12.0
Bunavail	\$254,820	\$4.0
Cash (end '16) & tech value	\$220,580	\$4.0
<b>SUM</b>	<b>\$1,294,445</b>	<b>\$20</b>
Shares out '16E (000)		64,034

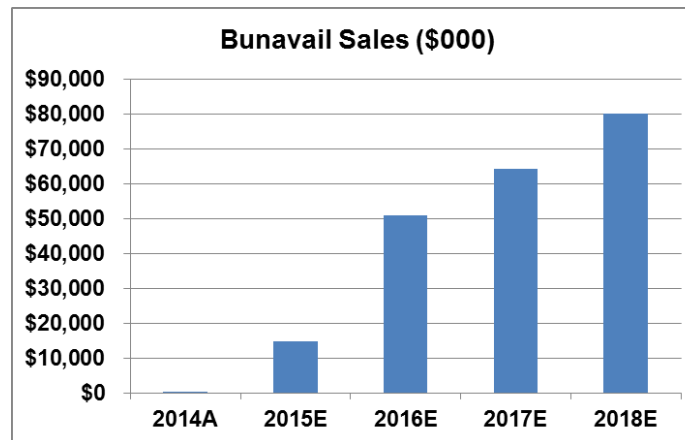
Source: Laidlaw & Company estimates.

Figure 2: Bunavail launch trajectory by week



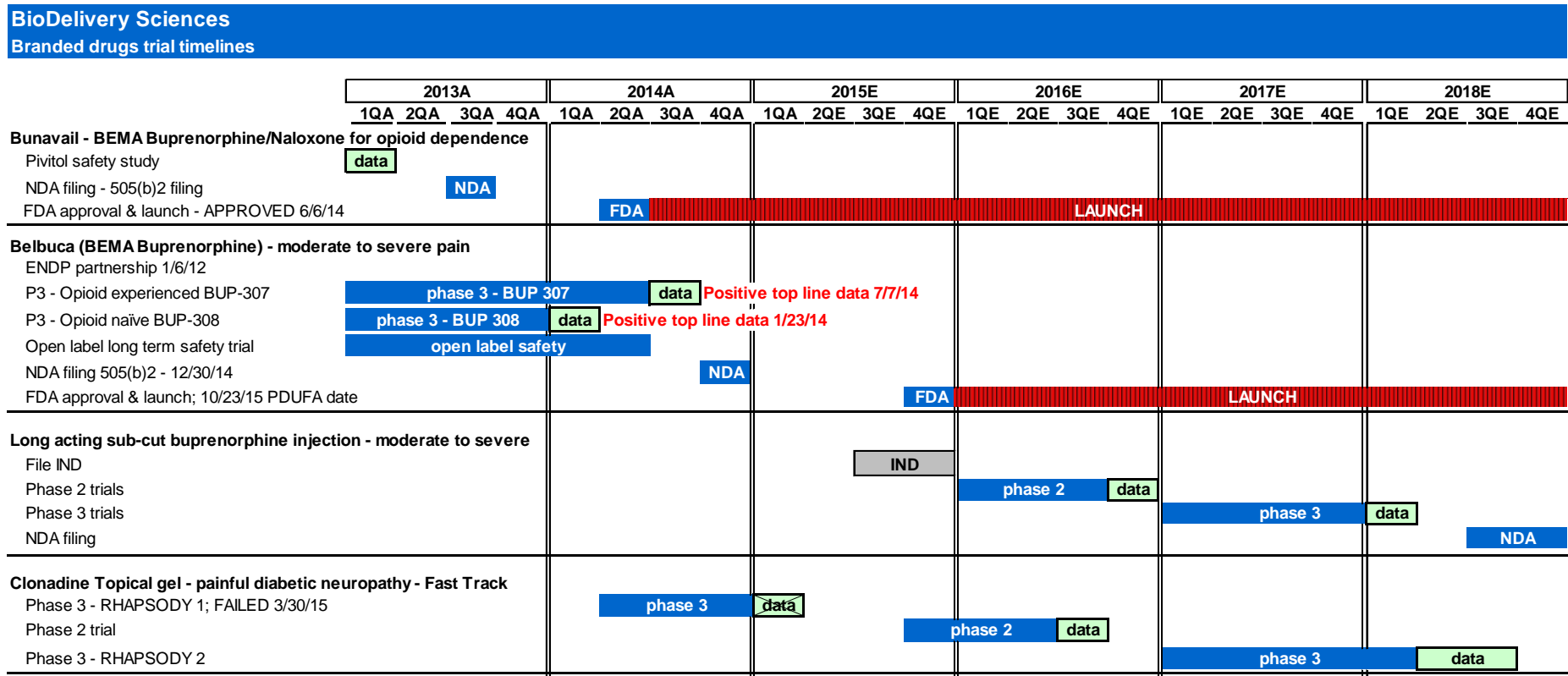
Source: Bloomberg LP.

Figure 3: Bunavail sales projections



Source: Company reports; Laidlaw & Company estimates.

Figure 1: Clinical trials timeline



Source: Company reports and SSRP estimates

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Source: Company reports; Laidlaw & Company estimates.

Figure 2: Quarterly Income Statement

BioDelivery Sciences										
Quarterly income statement										
(\$000 except per share)	2014A				2014A Year	2015E				2015E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
<b>Revenues</b>										
Bunavail sales				\$76	\$76	\$700	\$3,052	\$4,385	\$6,698	\$14,835
Royalty revenue - Onsolis	\$954	\$892	12	1,549	3,407	1,000	1,000	1,000	1,000	4,000
Contract rev / milestones	11,284	10,675	513	277	22,749	10,000	0	0	0	10,000
Research fees	8,452	2,318	1,298	645	12,712	1,354	2,000	2,000	2,000	7,354
<b>Total Revenue</b>	<b>\$20,690</b>	<b>\$13,885</b>	<b>\$1,822</b>	<b>\$2,547</b>	<b>\$38,944</b>	<b>\$13,054</b>	<b>\$6,052</b>	<b>\$7,385</b>	<b>\$9,698</b>	<b>\$36,189</b>
<b>Expenses:</b>										
Cost of Revenue (COGS)	725	687	463	3,064	4,939	1,124	1,513	1,627	1,755	6,019
<b>Gross Margin</b>	<b>19,965</b>	<b>13,198</b>	<b>1,360</b>	<b>(517)</b>	<b>34,005</b>	<b>11,930</b>	<b>4,539</b>	<b>5,758</b>	<b>7,943</b>	<b>30,170</b>
Research and development	14,623	7,983	6,770	4,909	34,285	6,549	6,250	6,000	6,000	24,799
General and administrative	4,622	7,250	13,649	12,925	38,460	13,181	13,500	13,500	13,250	53,431
Related party G&A	6	6								-
Total operating expenses	19,251	15,239	20,418	17,834	72,745	19,730	19,750	19,500	19,250	78,230
<b>Income (loss) from Operations</b>	<b>714</b>	<b>(2,041)</b>	<b>(19,059)</b>	<b>(18,351)</b>	<b>(38,740)</b>	<b>(7,800)</b>	<b>(15,211)</b>	<b>(13,742)</b>	<b>(11,307)</b>	<b>(48,060)</b>
Interest income (expense), net	(555)	(519)	(515)	(427)	(2,016)	(420)	(350)	(200)	(100)	(1,070)
Derivative (loss) gain	(4,825)	(4,120)	(5,685)	1,464	(13,167)					-
Other (exp) gain, net	23	9	25	(352)	(295)	27	25	25	25	102
<b>Income (loss) before taxes</b>	<b>(4,644)</b>	<b>(6,671)</b>	<b>(25,233)</b>	<b>(17,666)</b>	<b>(54,218)</b>	<b>(8,193)</b>	<b>(15,536)</b>	<b>(13,917)</b>	<b>(11,382)</b>	<b>(49,028)</b>
Income tax exp (benefit)										
<b>Net Income (Loss)</b>	<b>(4,644)</b>	<b>(6,671)</b>	<b>(25,233)</b>	<b>(17,666)</b>	<b>(54,215)</b>	<b>(8,193)</b>	<b>(15,536)</b>	<b>(13,917)</b>	<b>(11,382)</b>	<b>(49,028)</b>
<b>Earning per Share (EPS)</b>	<b>(\$0.11)</b>	<b>(\$0.14)</b>	<b>(\$0.51)</b>	<b>(\$0.34)</b>	<b>(\$1.12)</b>	<b>(\$0.16)</b>	<b>(\$0.30)</b>	<b>(\$0.26)</b>	<b>(\$0.21)</b>	<b>(\$0.92)</b>
<b>Adj EPS ex-1x &amp; non-cash items</b>	<b>(\$0.22)</b>	<b>(\$0.05)</b>	<b>(\$0.39)</b>	<b>(\$0.34)</b>	<b>(\$1.03)</b>	<b>(\$0.29)</b>				<b>(\$1.05)</b>
Weighted avg. shares (000)	44,035	48,521	49,556	51,308	48,355	51,909	52,659	53,409	54,159	53,034
Fully diluted shares (000)	48,166	55,321	55,556	54,505	53,387	58,909	59,659	60,409	61,159	60,034

Source: Company reports and Laidlaw estimates

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

Figure 3: Annual Income Statement

BioDelivery Sciences						
Annual income statement						
(\$000 except per share)	2014A	2015E	2016E	2017E	2018E	Comments
<b>Revenues</b>						
Bunavail sales	76	14,835	50,805	64,250	80,250	Launched 11/3/14
Royalty - Belbuca (BEMA Bup.)	-	-	11,250	47,250	81,000	10/23/15 PDUFA date
Royalty revenue - Onsolis	3,407	4,000	5,000	5,000	6,000	Smaller product
Contract revenue	22,749	10,000	50,000	-	-	ENDP milestones here
Research fees	12,712	7,354	8,000	8,000	8,000	
<b>Total Revenue</b>	<b>\$38,944</b>	<b>\$36,189</b>	<b>\$125,055</b>	<b>\$124,500</b>	<b>\$175,250</b>	
<b>Expenses:</b>						
Cost of Revenue (COGS)	4,939	6,019	7,989	9,468	11,828	
<b>Gross Margin</b>	<b>34,005</b>	<b>30,170</b>	<b>117,067</b>	<b>115,033</b>	<b>163,423</b>	
Research and development	34,285	24,799	24,000	25,000	26,000	
General and administrative	38,460	53,431	53,750	55,000	56,000	60 Bunavail reps
Related party SG&A	-	-	-	-	-	
Total operating expenses	72,745	78,230	77,750	80,000	82,000	
<b>Income (loss) from Operations</b>	<b>(38,740)</b>	<b>(48,060)</b>	<b>39,317</b>	<b>35,033</b>	<b>81,423</b>	
Interest income (expense), net	(2,016)	(1,070)	700	1,575	2,225	
Derivative (loss) gain	(13,167)	-	-	-	-	
Other expenses, net	(295)	102	100	100	100	
<b>Income (loss) before taxes</b>	<b>(54,218)</b>	<b>(49,028)</b>	<b>40,117</b>	<b>36,708</b>	<b>83,748</b>	
Income tax exp (benefit)	-	-	-	3,183	20,101	Sig. tax loss carryforwards
<b>Net Income (Loss)</b>	<b>(\$54,215)</b>	<b>(\$49,028)</b>	<b>\$40,117</b>	<b>\$33,524</b>	<b>\$63,646</b>	
<b>Adj NI less non cash &amp; 1x items</b>	<b>(\$49,584)</b>	<b>(\$55,828)</b>	<b>\$6,117</b>			
<b>Earning per Share</b>	<b>(\$1.12)</b>	<b>(\$0.92)</b>	<b>\$0.63</b>	<b>\$0.50</b>	<b>\$0.90</b>	
<b>Adj EPS ex-1x &amp; non-cash items</b>	<b>(\$1.03)</b>	<b>(\$1.05)</b>	<b>\$0.10</b>			
Weighted avg. shares (000)	48,355	53,034	56,034	59,034	62,159	
Fully diluted shares (000)	53,387	60,034	64,034	67,534	70,659	
<b>Margin &amp; Expense Analysis</b>						
COGS as % of Revenues	13%	17%	6%	8%	7%	
R&D	88%	69%	19%	20%	15%	
SG&A	99%	148%	43%	44%	32%	
Gross Profit	87%	83%	94%	92%	93%	
Op. margin cont. ops	-99%	-133%	31%	28%	46%	
Taxes	0%	0%	0%	-9%	-24%	
Net margin	-139%	-135%	32%	27%	36%	
<b>Year-over-year change</b>						
Net revenue	243%	-7%	246%	0%	41%	
R&D	64%	72%	97%	104%	104%	
SG&A	213%	39%	1%	2%	2%	
Operating income	-31%	24%	-182%	-11%	132%	

Source: Company reports and Laidlaw estimates

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

## Major risks

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**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.

**Legal risks could lead to additional liabilities and revenue loss.** In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

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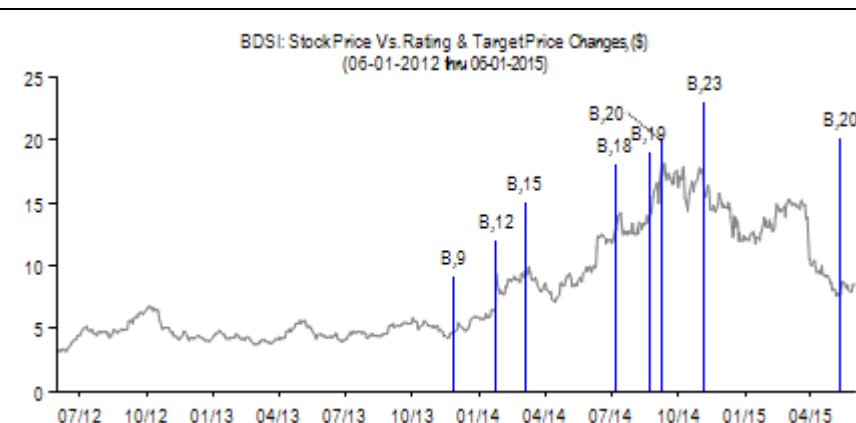
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#### Rating and Price Target Change History



Source: Laidlaw & Company

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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
11/26/2013	Buy (B)	4.81

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
11/26/2013	9.00	4.81
01/24/2014	12.00	9.41
03/05/2014	15.00	9.60
07/07/2014	18.00	13.06
08/22/2014	19.00	13.82
09/08/2014	20.00	17.98
11/06/2014	23.00	15.84
05/12/2015	20.00	7.75

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	74.07%	29.63%	7.41%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.70%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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