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EQUITY RESEARCH
Company Report

July 10, 2014

BioDelivery Sciences International (BDSI - $ 13.94)

Management Meeting Highlights

Healthcare / Biotechnology

Ticker:	**BDSI**
Rating:	**Buy**
Price Target:	**$ 18.00**

We hosted Dr. Mark Sirgo in our office for a presentation and conference call on Wednesday (7/9). We continue to believe that the company will deliver on its outlined plans and create shareholder value.

- **Milestone Overview, Pipeline Outlined**. BioDelivery CEO Dr. Mark Sirgo gave an update on both achieved and expected milestones for the company which remain steady and often in 2014. The company continues to execute on its pipeline that utilizes its core BEMA technology as well as expands its pain expertise to Clonidine Topical Gel. While we do not expect the company to license out the BEMA technology, we believe with $88.2 million in cash as of the end of 1Q14 the company is a strong position to expand its pipeline by acquiring or in-licensing additional product candidates. We continue to believe that the company has sufficient cash to successfully launch Bunavail.

- **Potential Rescheduling of Hydrocodone Combination Products Creates Additional Market Opportunity.** Following the signing of the Food and Drug Administration Safety and Innovation Act on July 9, 2012, the FDA began soliciting advice and recommendations pertaining to the rescheduling of hydrocodone combination products (HCPs) to Schedule II controlled substance under Controlled Substances Act (CSA). HCPs are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are Schedule III drugs approved for marketing for the treatment of pain and for cough suppression. The Drug Enforcement Administration (DEA) has submitted an official proposal for the rescheduling and is expected to make a ruling on the suggested changes in the next 24 months. If rescheduled, HCPs will become less available and could limit direct competitors for Bunavail once it is commercialized. While we have not factored this proposed change into our models, we view this decision as a potential substantial value driver for BioDelivery that could result in significantly higher peak sales than our current expectation of $225 million. Please see additional details on the proposed rescheduling on page 2.

- **Maintaining BUY Rating, Price Target.** We are maintaining our BUY rating and price target of $18. Our price target is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis.

Trading Data:

Last Price (07/09/2014)	$ 13.94
52–Week High (7/7/2014)	$ 14.38
52–Week Low (7/31/2013)	$ 4.15
Market Cap. (MM)	$ 675
Shares Out. (MM)	48

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.29	NM
FY_14E	0.00A	-0.15	-0.07	-0.24	-0.47	NM
FY_13A	-0.37	-0.36	-0.46	-0.33	-1.52	NM
FY_12A	0.29	0.23	-0.46	0.17	0.24	NM

Source: Laidlaw & Company estimates

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Summary of Rescheduling of Hydrocodone Combination Products

Following the signing of the Food and Drug Administration Safety and Innovation Act on July 9, 2012, the FDA began soliciting advice and recommendations pertaining to the scheduling of drugs containing hydrocodone combined with other analgesics or as cough suppressants under the Controlled Substances Act (CSA). As part of the effort, stakeholder input was solicited regarding the health benefits and risks, including the potential for abuse of hydrocodone combination products (HCPs) and the impact of moving these products from Schedule III to Schedule II narcotics. On January 24-25, 2013, the U.S. Drug Enforcement Administration (DEA) presented to an Advisory Committee composed of science and medical professionals with opioid abuse expertise as well as a patient representative. Following the presentation, the Advisory Committee voted 19 to 10 in favor of recommending that hydrocodone combination products be placed into Schedule II. On December 16, 2013, the Department of Health and Human Services (HHS) submitted to the Administrator of the DEA its scientific and medical evaluation entitled, "Basis for the Recommendation to Place Hydrocodone Combination Products in Schedule II of the Controlled Substances Act." The recommendation included an eight-factor analysis of the abuse potential of HCPs, along with the HHS's recommendation to control HCPs under Schedule II of the CSA. On February 27, 2014, The DEA submitted a formal proposal to reschedule HCPs to schedule II, labeled Docket No. DEA-389 “Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II.” The response period was open until April 28, 2014. Of note, The American Academy of Pain Medicine (AAPM) responded on April 24, 2014. While the AAPM neither supported nor opposed to the rescheduling, they highlighted the need to accompany any change to by policies to meet higher costs to insurers/patients, a potential reduction in patient access to necessary pain medications, and the possibility of requirement to use sub-optimal pain prescription alternatives that may result. Other institutions, such as the American Society of Addiction Medicine, have strongly advocated the proposal.

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Figure 1: Catalyst Summary

Source: Company reports; Laidlaw & Company estimates

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Risks to Owning the Stock

There are many standard risks for development stage specialty pharmaceutical companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with relying on third parties to formulate and manufacture products and the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include: patent infringement risk, financing risk, currency risk, product liability (both clinical and non-clinical), patent protection risk and potential governmental price controls. The stock of small cap specialty pharmaceutical companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. BioDelivery is susceptible to all of these risks.

The value of the stock is hinged on binary events, including the FDA approval of BEMA Buprenorphine. Longer-term value for the company is based on the ultimate market potential and expectations for the company's drugs, and the successful commercialization of BEMA Buprenorphine and the FDA approved Bunavail.

BioDelivery is exposed to litigation by third parties based on claims that its technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that it has misappropriated the trade secrets of others. On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol RX, LLC filed an action against BioDelivery relating to Bunavail the United States District Court for the Eastern District of North Carolina for alleged patent infringement. The plaintiffs claim that the formulation for Bunavail, which has never been disclosed publicly, infringes its patent (U.S. Patent No. 8,475,832). This action could be in response to a recent decision in which the FDA ruled in favor of BioDelivery's position in two Citizen Petitions filed by the plaintiffs that sought to prevent the FDA from accepting and filing BioDelivery's NDA for Bunavail. The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505(b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as Bunavail), unless such application references the NDA for Suboxone (buprenorphine/naloxone) sublingual film (and not the Suboxone sublingual tablet NDA).

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Figure 2: Income Statement

BioDelivery Sciences *Income Statement (millions, except per share data)*	FY 2013 Q1_13 Mar	Q2_13 Jun	Q3_13 Sept	Q4_13 Dec	FY 2014E Q1_14 Mar	Q2_14E Jun	Q3_14E Sept	Q4_14E Dec	FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E Dec	FY_16E Dec
Product sales	-	-	-	-	-	-	2.0	7.5	-	-	-	9.5	28.1	42.2
Product royalty revenues	-	0.9	0.9	(0.0)	1.0	1.0	0.9	0.9	2.7	1.1	1.8	3.7	8.5	13.0
Research revenues	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-	-
Research and development reimbursements	-	-	-	2.8	8.5	4.2	3.4	1.7	1.2	-	2.8	17.7	2.0	-
Contract revenues	1.6	1.9	2.1	1.2	11.3	2.5	11.8	1.7	0.3	53.4	6.8	27.3	37.3	50.0
Revenue	**1.6**	**2.8**	**3.0**	**4.0**	**20.7**	**7.7**	**18.1**	**11.8**	**4.5**	**54.5**	**11.4**	**58.3**	**76.0**	**105.1**
Cost of product royalties	0.4	0.7	0.6	0.4	0.7	0.7	0.7	0.7	1.8	1.9	2.1	2.8	6.0	9.1
Cost of sales	-	-	-	-	-	-	1.4	3.4	-	-	-	4.8	8.4	10.5
Gross Profit	**1.2**	**2.1**	**2.4**	**3.6**	**20.0**	**7.0**	**16.1**	**7.8**	**2.7**	**52.6**	**9.3**	**50.8**	**61.6**	**94.6**
Operating expenses:														
Selling, general and administrative	2.9	3.1	3.0	3.2	4.6	6.2	13.0	13.1	7.6	10.1	12.3	36.8	52.3	54.9
Research and development	12.0	12.8	16.4	12.1	14.6	7.3	6.2	5.8	20.8	35.4	53.3	33.9	22.4	20.0
Related party general and administrative, net	0.0	0.0	0.0	0.0	0.0	-	-	-	0.1	0.1	0.0	0.0	-	-
Other non-GAAP adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses (ex-COGS)	**15.0**	**15.9**	**19.4**	**15.4**	**19.3**	**13.5**	**19.2**	**18.9**	**28.5**	**45.6**	**65.7**	**70.8**	**74.7**	**74.9**
Total Operating Expenses (non-GAAP, ex-COGS)	**15.0**	**15.9**	**19.4**	**15.4**	**19.3**	**13.5**	**19.2**	**18.9**	**28.5**	**45.6**	**65.7**	**70.8**	**74.7**	**74.9**
Operating Income/(loss)	**(13.7)**	**(13.8)**	**(17.1)**	**(11.8)**	**0.7**	**(6.5)**	**(3.1)**	**(11.1)**	**(25.8)**	**7.1**	**(56.4)**	**(20.0)**	**(13.1)**	**19.7**
Operating Income/(loss) non-GAAP	**(13.7)**	**(13.8)**	**(17.1)**	**(11.8)**	**0.7**	**(6.5)**	**(3.1)**	**(11.1)**	**(25.8)**	**7.1**	**(56.4)**	**(20.0)**	**(13.1)**	**19.7**
Other Income:														
Interest income	0.1	0.1	(0.5)	(0.6)	(0.6)	(0.3)	(0.2)	(0.1)	0.2	0.3	(0.9)	(1.2)	(0.7)	(0.2)
Derivative gain (loss)	1.0	0.4	(0.9)	(0.4)	(4.8)	0.0	0.0	0.0	3.5	(5.6)	0.1	(4.8)	0.0	0.0
Other (expense) income, net	(0.0)	(0.1)	(0.0)	(0.1)	0.0	0.0	0.0	0.0	0.0	0.0	(0.2)	0.0	0.0	0.0
Income (loss) before provision for income taxes (GAAP)	**(12.6)**	**(13.4)**	**(18.5)**	**(12.9)**	**(4.6)**	**(6.8)**	**(3.3)**	**(11.2)**	**(22.1)**	**1.8**	**(57.4)**	**(26.0)**	**(13.7)**	**19.5**
Income (loss) before provision for income taxes (non-GAAP)	**(13.7)**	**(13.8)**	**(17.6)**	**(12.5)**	**0.2**	**(6.8)**	**(3.3)**	**(11.2)**	**(25.6)**	**7.4**	**(57.5)**	**(21.1)**	**(13.7)**	**19.5**
Tax: (%) non-GAAP	*NM*	*NM*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*1.8%*	*NM*	*0.0%*	*0.0%*	*0.0%*
Income tax provision GAAP	0.1	0.0	-	-	-	-	-	-	-	0.1	0.1	0.0	-	-
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	**(12.7)**	**(13.4)**	**(18.5)**	**(12.9)**	**(4.6)**	**(6.8)**	**(3.3)**	**(11.2)**	**(22.1)**	**1.7**	**(57.5)**	**(26.0)**	**(13.7)**	**19.5**
Net income (loss) non-GAAP	**(13.7)**	**(13.8)**	**(17.6)**	**(12.5)**	**0.2**	**(6.8)**	**(3.3)**	**(11.2)**	**(25.6)**	**7.2**	**(57.6)**	**(21.1)**	**(13.7)**	**19.5**
EPS (GAAP)	**($0.34)**	**($0.35)**	**($0.49)**	**($0.34)**	**($0.11)**	**($0.15)**	**($0.07)**	**($0.24)**	**($0.78)**	**$0.05**	**($1.51)**	**($0.57)**	**($0.29)**	**$0.39**
EPS (non-GAAP)	**($0.37)**	**($0.36)**	**($0.46)**	**($0.33)**	**$0.00**	**($0.15)**	**($0.07)**	**($0.24)**	**($0.90)**	**$0.24**	**($1.52)**	**($0.47)**	**($0.29)**	**$0.39**
Weighted Diluted Shares outstanding (millions)	37.5	38.0	38.1	38.2	44.0	44.9	45.8	46.7	28.3	30.7	37.9	45.4	47.6	50.6
Weighted Diluted Shares YOY change (%)	*26.8%*	*22.0%*	*26.6%*	*24.4%*	*17.4%*	*18.2%*	*20.3%*	*22.4%*		*8.4%*	*23.6%*	*19.6%*	*5.0%*	*6.1%*

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

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Figure 3: Balance Sheet

BioDelivery Sciences *Balance Sheet ($ millions, except per share data)*	FY 2012 Q1_12 Mar	 Q2_12 Jun	 Q3_12 Sept	 Q4_12 Dec	FY 2013 Q1_13 Mar	 Q2_13 Jun	 Q3_13 Sept	 Q4_13 Dec	FY 2014E Q1_14 Mar	 Q2_14E Jun	 Q3_14E Sept	 Q4_14E Dec	 FY_11 Dec	 FY_12 Dec	 FY_13 Dec	 FY_14E Dec	 FY_15E Dec
Assets:																	
Cash and cash equivalents	32.1	43.0	31.3	63.2	49.7	37.4	38.3	23.2	88.2	81.9	77.7	67.7	10.8	63.2	23.2	67.7	51.8
Accounts receivable, other	0.2	0.0	0.0	0.5	0.2	0.5	0.9	2.8	2.5	0.9	2.2	1.4	0.1	0.5	2.8	1.4	4.3
Prepaid expenses and other current assets	0.6	0.1	0.2	0.2	0.5	0.3	0.5	0.6	0.7	0.3	0.6	0.4	0.2	0.2	0.6	0.4	0.4
Total Current Assets	**32.9**	**43.2**	**31.6**	**63.9**	**50.4**	**38.2**	**39.6**	**26.6**	**91.4**	**83.1**	**80.6**	**69.5**	**11.1**	**63.9**	**26.6**	**69.5**	**56.5**
Equipment, net	3.2	3.1	2.9	2.8	2.7	2.6	0.2	0.2	0.2	0.3	0.3	0.3	3.3	2.8	0.2	0.3	1.2
Idle Equipment, net	-	-	-	-	-	-	-	2.8	3.3	3.3	3.3	3.3	-	-	2.8	3.3	3.3
Goodwill	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7
Total other intangible assets	6.9	6.7	6.4	6.2	5.9	5.7	2.5	5.2	5.0	5.0	5.0	5.0	6.2	6.2	5.2	5.2	5.2
Derivative asset, warrant	0.7	0.4	0.2	0.1	0.0	-	5.4	-	-	-	-	-	0.4	0.1	-	-	-
Other assets	0.0	0.0	0.0	0.0	-	-	0.1	0.5	0.4	0.4	0.4	0.4	0.0	0.0	0.5	0.5	0.5
Total Assets	**46.4**	**56.1**	**43.9**	**75.7**	**61.8**	**49.3**	**50.6**	**38.0**	**103.0**	**94.7**	**92.2**	**81.2**	**23.6**	**75.7**	**38.0**	**81.5**	**69.4**
Liabilities & Shareholders' Equity:																	
Accounts payable and other accured liabilities	5.0	5.8	7.4	10.8	9.5	12.0	11.1	10.4	8.8	6.2	8.8	8.7	5.1	10.8	10.4	8.7	9.1
Notes payable, current	-	-	-	-	-	-	5.3	7.3	7.3	7.3	7.3	7.3	-	-	7.3	7.3	7.3
Deferred revenue, current	12.5	15.1	22.7	8.0	7.2	5.6	4.1	2.9	1.9	0.7	1.7	1.1	12.5	8.0	2.9	1.1	1.4
Derivative liabilities	2.4	5.6	8.9	4.5	3.5	3.0	3.9	4.3	7.5	7.5	7.5	7.5	0.3	4.5	4.3	7.5	7.5
Total Current Liabilities	**20.0**	**26.5**	**39.1**	**23.2**	**20.2**	**20.6**	**24.4**	**25.0**	**25.6**	**21.7**	**25.3**	**24.6**	**17.9**	**23.2**	**25.0**	**24.6**	**25.4**
Note Payable, less current maturities	-	-	-	-	-	-	13.8	11.8	9.9	7.9	5.8	3.8	-	-	11.8	3.8	0.0
Deferred revenue, long-term	1.6	1.5	4.3	2.7	1.9	1.6	1.3	1.3	2.2	0.8	2.9	1.9	1.6	2.7	1.3	1.9	2.5
Other long-term liabilities	-	-	-	-	-	-	-	0.7	0.7	0.7	0.7	0.7	-	-	0.7	0.7	0.7
Total Liabilities	**21.5**	**28.0**	**43.3**	**26.0**	**22.1**	**22.2**	**39.5**	**38.8**	**38.4**	**31.1**	**34.8**	**31.0**	**19.5**	**26.0**	**38.8**	**31.0**	**28.6**
Stockholders' Equity	**24.9**	**28.1**	**0.6**	**49.8**	**39.7**	**27.1**	**11.0**	**(0.8)**	**64.6**	**27.1**	**57.4**	**50.2**	**4.1**	**49.8**	**-0.8**	**50.6**	**40.9**
Total Liabilities & Equity	**46.4**	**56.1**	**43.9**	**75.7**	**61.8**	**49.3**	**50.6**	**38.0**	**103.0**	**58.2**	**92.2**	**81.2**	**23.6**	**75.7**	**38.0**	**81.5**	**69.4**

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

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Figure 4: Cash flow Statement

BioDelivery Sciences *Non-GAAP Cash Flow Cont. Ops.($ millions, except per share data)*	**FY_11** Dec	**FY_12** Dec	**FY_13** Dec	**FY_14E** Dec	**FY_15E** Dec
Cash flows from operating activities:					
Net income	(22.1)	1.7	(57.4)	(26.0)	(13.7)
Adjustments to reconcile net income to net cash provided by operating activities:					
Depreciation and amortization	1.3	1.5	1.3	1.3	1.3
Accretion of Discount	-	-	0.2	0.3	0.3
Derivative (gain) loss	(3.5)	5.6	(0.1)	4.8	-
Purchase of Arcion license with common stock		-	2.1	-	-
Stock-based compensation expense	1.2	1.6	3.3	4.6	4.6
Changes in assets and liabilities:					
Accounts receivable	0.5	(0.4)	(2.3)	1.4	(2.8)
Prepaid expenses and other assets	0.0	0.0	(0.1)	0.2	-
Accounts payable and other accrued expenses	0.4	5.6	(0.7)	(1.0)	(0.5)
Income tax payable	-	0.1	-	(0.2)	-
Deferred revenue	0.0	(3.4)	(6.5)	0.8	(0.3)
Net cash provided by (used in) operating activities	(22.0)	12.2	**(60.1)**	**(13.7)**	**(11.1)**
Cash flow from investing activities:					
Purchases of property and equipment	(0.3)	(0.0)	(0.1)	(0.9)	(1.0)
Purchases of intangible assets	-	(1.1)	-	-	-
Cash provided by investing activities	**(0.3)**	**(1.1)**	**(0.1)**	**(0.9)**	**(1.0)**
Cash flows from financing activities:					
Proceeds from sale of securities	14.0	38.4	-	62.0	-
Proceeds from exercise of stock options	0.3	2.1	0.4	2.6	-
Proceeds from exercise of common stock warrants	-	-	0.1	2.6	-
Proceeds from notes payable and warrants	-	-	20.0	-	-
Deferred financing activities	-	-	(0.2)	-	-
Repayment of note	-	-	-	(8.2)	(3.8)
Return of short swing profits	-	-	-	0.1	-
Change in amounts due to related parties	0.0	(0.0)	-	-	-
Other	1.7	0.9	-	-	-
Cash (used in) provided by financing activities	**16.1**	**41.3**	**20.2**	**59.1**	**(3.8)**
Effect of exchange rates on cash	-	-	-	-	-
Net (decrease) increase in cash and cash equivalents	(6.2)	52.4	(40.0)	44.5	(15.8)
Cash and cash equivalents at beginning of the period	18.2	10.8	63.2	23.2	67.7
Cash and cash equivanlents at end of period -	**12.0**	**63.2**	**23.2**	**67.7**	**51.8**

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

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DISCLOSURES:

ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

EQUITY DISCLOSURES

For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

Additional information available upon request.

Laidlaw & Co (UK) Ltd. has not provided any investment banking services for the company (ies) mentioned in this report over the last 12 months.

RATINGS INFORMATION

Rating and Price Target Change History

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	13.05

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	94.12%	35.29%	11.76%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.88%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Endo Health Solutions Inc. (ENDP, Not Rated)

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