

BioDelivery Sciences International (BDSI - \$ 15.40)

Healthcare / Biotechnology

BioDelivery's 3Q14 Results Below Our Expectations

BioDelivery Sciences announced 3Q14 results after the close on November 5, 2014. Revenue and EPS were below our expectations. We are lowering our non-GAAP EPS estimates but increasing our price target to \$23 from \$20.

Ticker: **BDSI**
Rating: **Buy**
Price Target: ↑ raise **\$ 23.00**

- 3Q14 Revenue and EPS Below Expectations.** BioDelivery Sciences reported revenue of \$1.8 million in 3Q14, \$1.6 million below our estimate and \$3.7 million below consensus. GAAP EPS for the quarter were a loss of \$0.51. Non-GAAP EPS in 3Q14 were a loss of \$0.39, \$0.14 below our estimate and \$0.16 under consensus. SG&A for the quarter was \$13.6 million, up \$10.6 million from 3Q13 and an 88.3% increase from the prior quarter. Included in SG&A were expenses related to hiring, training and deploying the Bunavail sales force as well as launch related marketing expenses totaling \$7.4 million. As a result of higher SG&A expectations, we are lowering our non-GAAP EPS estimate for 2014 and 2015 to a loss of \$0.77 and a loss of \$0.70 from a loss of \$0.60 in each year. We are also lowering our 2016 non-GAAP EPS estimate to \$0.68 from \$0.98.
- Pipeline Update.** BioDelivery, along with partner Endo, remains on track to submit an NDA for BEMA Buprenorphine by late 2014 or early 2015; we assume early 2015 in our estimates. The NDA filing will trigger a \$10 million payment from Endo, with an approval resulting in a \$50 million payment. The company expects to report top-line results from the first Phase III trial for Clonidine Topical Gel for the treatment of painful diabetic neuropathy (PDN) in 1Q15. We continue to expect an NDA filing for Clonidine Topical Gel in 2016 and potential approval in 2017.
- Bunavail Commercially Available.** On November 3, 2014, BioDelivery announced that it had shipped Bunavail to wholesalers and it expects the product to be available for prescription at retail pharmacies this week. Wholesaler demand exceeded expectations. We estimate Bunavail will generate sales of \$37.5 million in 2015. We believe the increased expenditures for sales and marketing for Bunavail bodes well for the success of the drug.
- Maintaining BUY Rating, Increasing Price Target.** We are increasing our price target to \$23 from \$20. Our price target is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Clonidine Topical Gel, and Onsolis. We believe the sell-off today is unwarranted.

Trading Data:

Last Price (11/06/2014)	\$ 15.40
52-Week High (9/12/2014)	\$ 18.48
52-Week Low (11/14/2013)	\$ 4.16
Market Cap. (MM)	\$ 790
Shares Out. (MM)	51

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_16E	NE	NE	NE	NE	0.68	22.6
FY_15E	-0.08	-0.25	-0.21	-0.16	-0.70	NM
FY_14E	0.00A	-0.05A	-0.39A	-0.30	-0.77	NM
FY_13A	-0.37	-0.36	-0.46	-0.33	-1.52	NM

Edward White

Senior Managing Director/Senior Analyst
(212) 953-4910
ewhite@laidlawltd.com

Christopher Wolpert, CFA

Associate Equity Analyst
cwolpert@laidlawltd.com

Source: Laidlaw & Company estimates

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Figure 1: Catalyst Summary

BEMA Buprenorphine Phase III Data

- Announced strong top-line data from opioid naive patient trial on January 23, 2014. Received \$10 million milestone payment from Endo as a result of database lock.
- Positive top-line experienced patient data announced July 7, 2014. Database lock resulted in \$10 million milestone payment from Endo.
- NDA filing expected by late 2014 / early 2015. NDA filing will trigger an additional \$10 million milestone payment, approval will result in \$50 million payment.

Bunavail Commercialization

- FDA approved June 6, 2014.
- Commercialization is underway with a team of approximately 60 sales representatives. Expect first weekly prescription sales data in early to mid-November.

Phase III Clonidine Topical Gel Trial (Fast Track Designation)

- Enrollment of first pivotal Phase III completed. FDA Granted Fast Track Designation for the program..
- Topline results for the first Phase III trial are projected by end of 1Q15 (study remains ahead of schedule) with the second Phase III trial to be initiated. We expect NDA filing in 2016 and potential approval in 2017.

Injectable Buprenorphine

- The product will be developed under the 505(b)(2) process with an IND filing expected in late 2014 / early 2015.

Source: Company reports; Laidlaw & Company estimates

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. In addition, 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. 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 drug Bunavail.

Figure 2: Income Statement

BioDelivery Sciences <i>Income Statement (millions, except per share data)</i>	FY 2013				FY 2014E				FY 2015E				FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E Dec	FY_16E Dec
	Q1_13	Q2_13	Q3_13	Q4_13	Q1_14	Q2_14	Q3_14	Q4_14E	Q1_15E	Q2_15E	Q3_15E	Q4_15E						
	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec						
Product sales	-	-	-	-	-	-	-	1.0	5.0	7.5	11.0	14.0	-	-	-	1.0	37.5	61.3
Product royalty revenues	-	0.9	0.9	(0.0)	1.0	0.9	0.0	0.9	0.5	1.0	1.0	6.0	2.7	1.1	1.8	2.8	8.5	14.7
Research revenues	-	-	-	-	-	-	-	-	-	-	-	-	0.2	0.0	-	-	-	-
Research and development reimbursements	-	-	-	2.8	8.5	2.3	1.3	0.8	0.8	0.6	0.3	0.3	1.2	-	2.8	12.8	2.0	-
Contract revenues	1.6	1.9	2.1	1.2	11.3	10.7	0.5	0.5	10.2	0.2	-	-	0.3	53.4	6.8	23.0	10.4	60.0
Revenue	1.6	2.8	3.0	4.0	20.7	13.9	1.8	3.2	16.5	9.3	12.3	20.3	4.5	54.5	11.4	39.6	58.4	136.0
Cost of sales	0.4	0.7	0.6	0.4	0.7	0.7	0.5	1.1	2.9	4.1	5.1	9.1	1.8	1.9	2.1	3.0	21.2	26.2
Gross Profit	1.2	2.1	2.4	3.6	20.0	13.2	1.4	2.0	13.6	5.2	7.2	11.2	2.7	52.6	9.3	36.6	37.2	109.8
<i>Operating expenses:</i>																		
Selling, general and administrative	2.9	3.1	3.0	3.2	4.6	7.2	13.6	10.0	9.7	9.4	9.2	9.7	7.6	10.1	12.3	35.6	38.0	40.0
Research and development	12.0	12.8	16.4	12.1	14.6	8.0	6.8	6.8	7.3	7.9	8.3	9.0	20.8	35.4	53.3	36.2	32.5	31.0
Related party general and administrative, net	0.0	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	15.2	20.4	16.8	17.0	17.3	17.5	18.7	28.5	45.6	65.7	71.7	70.5	71.0
Total Operating Expenses (non-GAAP, ex-COGS)	15.0	15.9	19.4	15.4	19.3	15.2	20.4	16.8	17.0	17.3	17.5	18.7	28.5	45.6	65.7	71.7	70.5	71.0
Operating Income/(loss)	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(2.0)	(19.1)	(14.8)	(3.4)	(12.2)	(10.3)	(7.5)	(25.8)	7.1	(56.4)	(35.2)	(33.4)	38.9
Operating Income/(loss) non-GAAP	(13.7)	(13.8)	(17.1)	(11.8)	0.7	(2.0)	(19.1)	(14.8)	(3.4)	(12.2)	(10.3)	(7.5)	(25.8)	7.1	(56.4)	(35.2)	(33.4)	38.9
<i>Other Income:</i>																		
Interest income	0.1	0.1	(0.5)	(0.6)	(0.6)	(0.5)	(0.5)	(0.5)	(0.5)	(0.6)	(0.6)	(0.7)	0.2	0.3	(0.9)	(2.1)	(2.5)	(2.0)
Derivative gain (loss)	1.0	0.4	(0.9)	(0.4)	(4.8)	(4.1)	(5.7)	-	-	-	-	-	3.5	(5.6)	0.1	(14.6)	-	-
Other (expense) income, net	(0.0)	(0.1)	(0.0)	(0.1)	0.0	0.0	0.0	-	-	-	-	-	0.0	0.0	(0.2)	0.0	-	-
Income (loss) before provision for income taxes (GAAP)	(12.6)	(13.4)	(18.5)	(12.9)	(4.6)	(6.7)	(25.3)	(15.3)	(3.9)	(12.8)	(10.9)	(8.3)	(22.1)	1.8	(57.4)	(51.9)	(35.8)	36.9
Income (loss) before provision for income taxes (non-GAAP)	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(2.6)	(19.6)	(15.3)	(3.9)	(12.8)	(10.9)	(8.3)	(25.6)	7.4	(57.5)	(37.2)	(35.8)	36.9
<i>Tax: (%) non-GAAP</i>	<i>NM</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>1.8%</i>	<i>NM</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>
Income tax provision GAAP	0.1	0.0	-	-	-	-	-	-	-	-	-	-	-	0.1	-	0.0	-	-
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) GAAP	(12.7)	(13.4)	(18.5)	(12.9)	(4.6)	(6.7)	(25.3)	(15.3)	(3.9)	(12.8)	(10.9)	(8.3)	(22.1)	1.7	(57.4)	(51.9)	(35.8)	36.9
Net income (loss) non-GAAP	(13.7)	(13.8)	(17.6)	(12.5)	0.2	(2.6)	(19.6)	(15.3)	(3.9)	(12.8)	(10.9)	(8.3)	(25.6)	7.2	(57.5)	(37.2)	(35.8)	36.9
EPS (GAAP)	(\$0.34)	(\$0.35)	(\$0.49)	(\$0.34)	(\$0.11)	(\$0.14)	(\$0.51)	(\$0.30)	(\$0.08)	(\$0.25)	(\$0.21)	(\$0.16)	(\$0.78)	\$0.05	(\$1.51)	(\$1.08)	(\$0.70)	\$0.68
EPS (non-GAAP)	(\$0.37)	(\$0.36)	(\$0.46)	(\$0.33)	\$0.00	(\$0.05)	(\$0.39)	(\$0.30)	(\$0.08)	(\$0.25)	(\$0.21)	(\$0.16)	(\$0.90)	\$0.24	(\$1.52)	(\$0.77)	(\$0.70)	\$0.68
Weighted Diluted Shares outstanding (millions)	37.5	38.0	38.1	38.2	44.0	48.5	49.6	50.5	51.1	51.3	51.6	51.8	28.3	30.7	37.9	48.2	51.4	54.4
Weighted Diluted Shares YOY change (%)	26.8%	22.0%	26.6%	24.4%	17.4%	27.7%	30.1%	32.4%	15.9%	5.7%	4.1%	2.5%	-	8.4%	23.6%	26.9%	6.8%	5.8%

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

Figure 3: Balance Sheet

BioDelivery Sciences <i>Balance Sheet (\$ millions, except per share data)</i>	FY 2013				FY 2014E				FY 2015E				FY_11 Dec	FY_12 Dec	FY_13 Dec	FY_14E Dec	FY_15E Dec	FY_16E Dec
	Q1_13	Q2_13	Q3_13	Q4_13	Q1_14	Q2_14	Q3_14	Q4_14E	Q1_15E	Q2_15E	Q3_15E	Q4_15E						
	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec	Mar	Jun	Sept	Dec						
Assets:																		
Cash and cash equivalents	49.7	37.4	38.3	23.2	88.2	78.4	85.8	65.9	49.9	42.9	31.2	17.1	10.8	63.2	23.2	65.9	17.1	40.1
Accounts receivable, other	0.2	0.5	0.9	2.8	2.5	12.6	0.2	2.4	10.2	9.8	9.9	14.4	0.1	0.5	2.8	2.4	14.4	23.5
Inventory	-	-	-	-	-	0.8	2.0	3.2	3.6	3.8	4.0	4.1	-	-	-	3.2	4.1	7.1
Prepaid expenses and other current assets	0.5	0.3	0.5	0.6	0.7	0.6	1.4	2.5	3.0	2.7	3.6	3.9	0.2	0.2	0.6	2.5	3.9	3.9
Total Current Assets	50.4	38.2	39.6	26.6	91.4	92.4	89.5	74.0	66.7	59.2	48.7	39.4	11.1	63.9	26.6	74.0	39.4	74.5
Equipment, net	2.7	2.6	0.2	0.2	0.2	0.2	1.5	1.5	1.7	1.9	2.1	2.3	3.3	2.8	0.2	1.5	2.3	3.1
Idle Equipment, net	-	-	-	2.8	3.3	3.5	2.7	2.7	2.7	2.7	2.7	2.7	-	-	2.8	2.7	2.7	2.7
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	2.7
Total other intangible assets	5.9	5.7	2.5	5.2	5.0	4.7	4.5	4.5	4.5	4.5	4.5	4.5	6.2	6.2	5.2	4.5	4.5	4.5
Derivative asset, warrant	0.0	-	5.4	-	-	-	-	-	-	-	-	-	0.4	0.1	-	-	-	-
Other assets	-	-	0.1	0.5	0.4	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.0	0.0	0.5	0.2	0.2	0.2
Total Assets	61.8	49.3	50.6	38.0	103.0	103.8	101.1	85.6	78.6	71.2	61.0	51.9	23.6	75.7	38.0	85.6	51.9	87.8
Liabilities & Shareholders' Equity:																		
Accounts payable and other accrued liabilities	9.5	12.0	11.1	10.4	8.8	9.5	13.1	12.8	13.9	14.2	14.3	15.3	5.1	10.8	10.4	12.8	15.3	15.4
Notes payable, current	-	-	5.3	7.3	7.3	7.3	8.0	8.0	8.0	8.0	8.0	8.0	-	-	7.3	8.0	8.0	8.0
Deferred revenue, current	7.2	5.6	4.1	2.9	1.9	1.3	0.8	1.5	7.6	4.3	5.7	9.4	12.5	8.0	2.9	1.5	9.4	21.9
Derivative liabilities	3.5	3.0	3.9	4.3	7.5	10.8	12.6	12.6	12.6	12.6	12.6	12.6	0.3	4.5	4.3	12.6	12.6	12.6
Total Current Liabilities	20.2	20.6	24.4	25.0	25.6	28.9	34.5	34.8	42.1	39.1	40.6	45.3	17.9	23.2	25.0	34.8	45.3	57.8
Note Payable, less current maturities	-	-	13.8	11.8	9.9	8.0	6.1	4.0	3.1	2.1	1.2	0.2	-	-	11.8	4.0	0.2	0.1
Deferred revenue, long-term	1.9	1.6	1.3	1.3	2.2	4.4	5.6	9.9	11.1	6.3	8.3	1.7	1.6	2.7	1.3	9.9	1.7	8.0
Other long-term liabilities	-	-	-	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	-	-	0.7	0.7	0.7	0.7
Total Liabilities	22.1	22.2	39.5	38.8	38.4	42.0	46.9	49.4	57.0	48.2	50.8	47.9	19.5	26.0	38.8	49.4	47.9	66.6
Stockholders' Equity	39.7	27.1	11.0	(0.8)	64.6	61.8	54.1	36.2	21.5	23.0	10.2	3.9	4.1	49.8	-0.8	36.2	3.9	21.2
Total Liabilities & Equity	61.8	49.3	50.6	38.0	103.0	103.8	101.1	85.6	78.6	71.2	61.0	51.9	23.6	75.7	38.0	85.6	51.9	87.8

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

Figure 4: Cash Flow Statement

BioDelivery Sciences	FY_11	FY_12	FY_13	FY_14E	FY_15E	FY_16E
<i>Non-GAAP Cash Flow Cont. Ops. (\$ millions, except per share data)</i>	Dec	Dec	Dec	Dec	Dec	Dec
Cash flows from operating activities:						
Net income	(22.1)	1.7	(57.4)	(51.9)	(35.8)	36.9
<i>Adjustments to reconcile net income to net cash provided by operating activities:</i>						
Depreciation and amortization	1.3	1.5	1.3	1.1	1.1	1.1
Debt costs	-	-	0.2	0.6	0.6	0.6
Derivative (gain) loss	(3.5)	5.6	(0.1)	14.6	-	-
Purchase of Arcion license with common stock	-	-	2.1	-	-	-
Stock-based compensation expense	1.2	1.6	3.3	7.2	9.5	10.0
<i>Changes in assets and liabilities:</i>						
Accounts receivable	0.5	(0.4)	(2.3)	0.4	(12.0)	(9.1)
Inventory	-	-	-	(3.2)	(0.9)	(3.0)
Prepaid expenses and other assets	0.0	0.0	(0.1)	(1.9)	(1.4)	-
Accounts payable and other accrued expenses	0.4	5.6	(0.7)	2.7	2.5	(0.1)
Income tax payable	-	0.1	-	-	-	-
Deferred revenue	0.0	(3.4)	(6.5)	1.7	(7.9)	(12.5)
Net cash provided by (used in) operating activities	(22.0)	12.2	(60.1)	(28.6)	(44.2)	24.0
Cash flow from investing activities:						
Purchases of property and equipment	(0.3)	(0.0)	(0.1)	(1.6)	(0.8)	(0.8)
Purchases of intangible assets	-	(1.1)	-	-	-	-
Cash provided by investing activities	(0.3)	(1.1)	(0.1)	(1.6)	(0.8)	(0.8)
Cash flows from financing activities:						
Proceeds from sale of securities	14.0	38.4	-	70.7	-	-
Proceeds from exercise of stock options	0.3	2.1	0.4	4.6	-	-
Proceeds from exercise of common stock warrants	-	-	0.1	4.9	-	-
Proceeds from notes payable and warrants	-	-	20.0	-	-	-
Deferred financing activities	-	-	(0.2)	-	-	-
Payment of notes payable	-	-	-	(7.4)	(3.8)	(0.1)
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	72.9	(3.8)	(0.1)
Effect of exchange rates on cash	-	-	-	-	-	-
Net (decrease) increase in cash and cash equivalents	(6.2)	52.4	(40.0)	42.7	(48.8)	23.0
Cash and cash equivalents at beginning of the period	18.2	10.8	63.2	23.2	65.9	17.1
Cash and cash equivalents at end of period	12.0	63.2	23.2	65.9	17.1	40.1

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

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.

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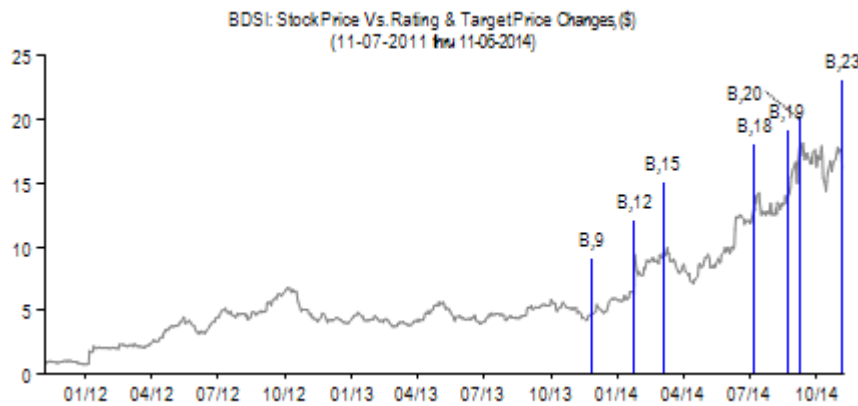
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Additional information available upon request.

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	13.06
08/22/2014	19.00	13.82
09/08/2014	20.00	17.98
11/06/2014	23.00	16.30*

Source: Laidlaw & Company

Created by: Blue-Compass.net

* Previous Close 11/5/2014

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.	95.24%	33.33%	14.29%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.76%	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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