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EQUITY RESEARCH
Company Report

February 23, 2015

ADMA Biologics (ADMA - $ 10.48)

Healthcare/Biotechnology

Compelling RI-002 Phase III Study 2nd Endpoint Results Suggest RI-002 Could Be an Important Commercial Product; Increase TP to $20

Ticker:	**ADMA**
Rating:	**Buy**
Price Target: ↑ raise	**$ 20.00**

This morning, ADMA reported robust 2nd endpoint results from the RI-002 in primary immune deficiency disease (PIDD) Phase III study, which was presented at the AAAAI conference.

- **Details.** ADMA announced this morning the 2nd endpoint results from the RI-002 in PIDD Phase III study. Highlights included: 1) patients experienced a total of 93 days (1.66 days/patient/year) lost from work or school due to infection; 2) a significant increase (5.3x with p=0.0001) anti-RSV neutralizing antibody titers vs. pre-treatment baseline based on PK study; and 3) safety profile of RI-002 was comparable to that of other approved IVIGs. ADMA reported earlier (see our ADMA 2015-12-03 note) that the RI-002 in PIDD Phase III (ADMA-003) study met the primary endpoint of ≤1 SBI per patient-year. ADMA expects to file a BLA in mid-2015 and we estimate product approval could slate to 2H16.
- **Implications.** In our opinion, we believe the 2nd endpoint results are very robust and potentially should alleviate concerns some investors might have regarding the commercial potential of RI-002. Specifically, we view the high titer antibodies against RSV and several other respiratory infections disease related pathogens of RI-002 provide the support that the drug is well differentiated from other IVIG for certain more severe PIDD patients during late fall to the entire winter when RSV infections could be a substantial health threat. Further, we believe the level of days lost from work or school due to infection (1.66 days/patient/year) might be substantially fewer than many other approved IVIGs (2.6 days or much more).This is a measure that could further enhance the buy-in by prescribing physicians and third party payers, given the practical real world benefits. We believe additional data from the RI-002 Phase III study also exhibited advantages over other IVIGs as well. We speculate that added benefits of RI-002 could potentially be driven by the added high titers of various antibodies.
- **Action.** We are reiterating our Buy rating and increasing our target price to $20 from $18 to reflect today's positive news and other accumulated encouraging developments. Our target price is supported by P/E, peer comparable and risk-adjusted cash flow sum-of-the-parts analyses.

Trading Data:

Last Price (02/20/2015)	$ 10.48
52–Week High (12/3/2014)	$ 14.00
52–Week Low (4/30/2014)	$ 6.76
Market Cap. (MM)	$ 97
Shares Out. (MM)	9

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.32	-0.39	-0.52	-0.61	-1.84	NM
FY-14E	-0.64A	-0.43A	-0.36A	-0.30	-1.72	NM
FY-13A	-0.55	-0.83	-0.46	-0.55	-2.38	NM
FY-12A	-0.18	-0.20	-0.70	-0.68	-1.76	NM

Source: Laidlaw & Company estimates

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- **Higher titer of anti-RSV antibodies in RI-002 is assuring.** The study demonstrated that anti-RSV neutralizing antibodies titer in patients taking RI-002 was significantly higher (5.3x with p=0.001) vs. the baseline level measured prior to treatment (Figure 1). Similar higher titers also observed in neutralizing antibodies against *H. influenza* and *S. pneumonia*. Together, we believe RI-002 would likely be the only IVIG currently available with substantial and consistent higher level of antibodies against those respiratory pathogens.

Figure 1: Maximum fold increase in antibody titers against RSV, *H. influenza* and *S. pneumoniae* in pateints receiving RI-002 vs. pre-treatment baseline

		Total (n=31)*
RSV	Mean Fold Increase (s.e)	5.3 (0.54)
	P value	.0001
H. Influenza	Mean Fold Increase (s.e)	3.2 (0.25)
	P value	.0001
S. Pneumoniae	Mean Fold Increase (s.e)	2.89 (0.30)
	P value	.006

Source: Mond, J., et. al., 2015 AAAAI presentation

- **The measure of number of days lost from work/school/day care due to infections of RI-002 treatment is superior to that of other approved IVIGs.** RI-002 treated patients experienced a total of 93 days lost from work or school due to infection or 1.66 days/patient/year (Figure 2). Analysis done by ADAM indicated such outcome is superior to all reported results from other approved IVIGs. The lowest reported data of days missed per person per year was 2.6/2.7 days while results of most other IVIGs were much higher. Figure 3 illustrates additional data from the Phase III study.

Figure 2: Number of days lost from work/school/day care due to infections of RI-002 treated patients

Statistics	Total (Subjects=59)	3-Week Cycle (Subjects=19)	4-Week Cycle (Subjects= 40)
Total days missed in the study	93	27	66
No. of days missed per person per year	1.66	1.56	1.71
1-sided 95% Upper Bound	1.97	2.14	2.09

Source: Mond, J., et. al., 2015 AAAAI presentation

Figure 3: Multiple data from the RI-002 in PIDD Phase III study

	N	Per patient per year	Median time (days)
Number of unscheduled visits to the physician or ER	54	0.967	
Time to resolution of an infection			9
Number of hospitalizations due to infection	1	0.0179 hospitalization days	
Number of days of antibiotic therapy for treatment of infection	1839	32.9 days	

Source: Company report and Laidlaw and co. equity research

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- **Safety profile is acceptable and level of RI-002 administrated is sufficient to prevent infection.** The safety profile of RI-002 indicated that the drug is well tolerated (Figure 4) and is similar to that of other approved IVIGs. Further, the current level of RI-002 administrated should be sufficient for potentially preventing infection as the trough IgG level (Figure 5), which is above what the FDA has required, did not demonstrate a linear correlation with the number of 1) infections of any kind/seriousness; 2) days lost due to infections; and 3) days on antibiotic therapy of each infusion cycle.

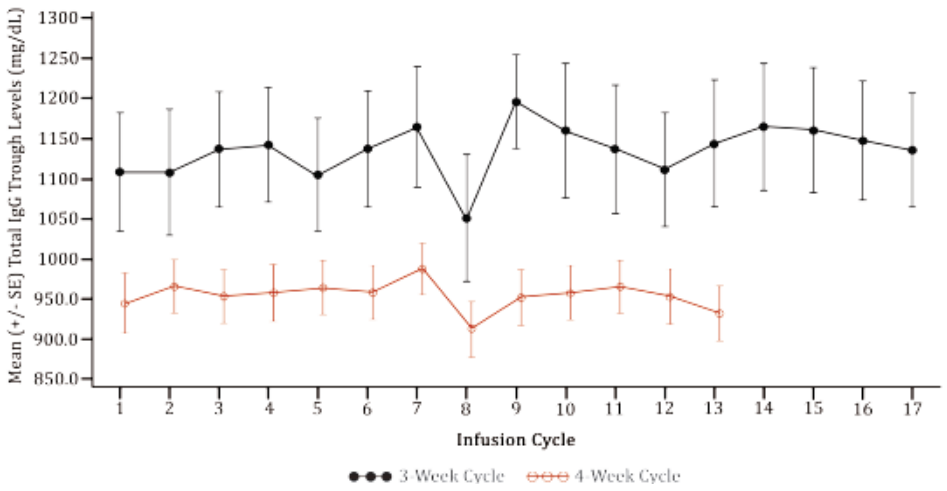
Figure 4: AE (left) and SAE (right) profile of RI-002

	Total	3 Week Cycle	4 Week Cycle
AE of Interest (AEOI) *	Subjects (N=59) n (%)	Subjects (N=19) n (%)	Subjects (N=40) n (%)
Subjects with >=1 AEOI	46 (78.0)	14 (73.7)	32 (80.0)
Bronchitis	12 (20.3)	1 (5.3)	11 (27.5)
Chronic + acute sinusitis	24 (40.7)	9 (47.4)	15 (37.5)
Otitis media	1 (1.7)	0	1 (1.7)
Influenza	5 (8.5)	2 (10.5)	3 (7.5)
Nasopharyngitis	16 (27.1)	7 (36.8)	9 (22.5)
URI	20 (33.9)	6 (31.6)	14 (35.0)

	Total			3-Week Cycle			4-Week Cycle		
SAE	Total Events [1]	Subjects (N=59) n (%) [2]	Infusions (I=793) n (%) [3]	Total Events [1]	Subjects (N=19) n (%) [2]	Infusions (I=294) n (%) [3]	Total Events [1]	Subjects (N=40) n (%) [2]	Infusions (I=499) n (%) [3]
Serious Bacterial Infection	0	0	0	0	0	0	0	0	0
Postoperative wound infection	1	1 (1.7)	1 (0.1)	0	0	0	1	1 (2.5)	1 (0.2)
Migraine	1	1 (1.7)	1 (0.1)	0	0	0	1	1 (2.5)	1 (0.2)

Source: Mond, J., et. al., 2015 AAAAI presentation

Figure 5: Mean total IgG trough level by infusion number



Source: Mond, J., et. al., 2015 AAAAI presentation

- **ADMA-003 trial recap.** ADMA-003 is a multicenter, open-label and 59-patient study. Patients received a dose between 300-800 mg/kg according to their current IVIG dose. Each patient was dosed every 21 or 28 days (527.3mg/kg and 491.1mg/kg respectively) for a total of 12 months based on the patient's requirements. Secondary endpoints include incidence of all infections (serious & non-serious), lost days of work or school, hospitalizations, emergency room visits, antibiotic use, PK profile of total IgG and specific antibody level testing for H. flu type B, CMV, measles, tetanus and RSV among others. In the study, 54 patients completed all scheduled infusions with 793 total RI-002 infusions.

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing	Importance
RI-002	RSV infection prevention in PIDD	Potential BLA filing	**1H15**	*****
		Potentially build commercialization structure	**2015**	****
		Potential U.S. approval	**4Q15 / 1Q16**	*****
		Potential U.S. product launch	**1H16**	*****
VZIG (Varitect)	Vicella Zoster virus infection	Potential commence Phase II/III study	**2015**	***
BioCenters		FDA approval of 2nd BioCenter	**2H15**	****
		FDA approval of 3rd BioCenter	**2016**	****

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major Risks

Risks of clinical study failure could have a major impact on ADMA share value. Despite a well-established path for IVIG approval, risks still exist as RI-002 might not be approved by the FDA if the pivotal study does not meet its endpoints. Given that the majority of upside for ADMA shares is currently based on the assumption that the product can be approved before its commercial potential can be realized, an unsuccessful approval application would have a significant negative impact on ADMA share value.

Commercial success of the RI-002 in PIDD and potentially in transplantation is less predictable. We believe that the potential product label for RI-002, if approved, would likely to indicate as a regular IVIG; and higher titer of anti-RSV antibodies could appear on the label if the pivotal study met the relevant secondary endpoint. As such, the company may not promote the product directly for the prevention or treatment of RSV infection, but instead, it will base on the understanding that receiving high titer RSV antibodies should reduce probability of RSV infection. With more limited sales and marketing tactics available, the sales ramp up could be slower than projected. The risk could also exists as more rapid sales expansion might only occur after the company conducting more clinical studies and demonstrating positive clinical outcome.

Developments by competitors may render RI-002 or relevant technologies obsolete or un-competitive. Although the manufacturing processes of RI-002 are protected by proprietary technology, trade secrets and know-how, it is possible that other competitors develop similar processes to produce similar or even better anti-RSV IVIG. As such, the company might not enjoy the competitive edge and potentially damage RI-002's commercial outlook

Plasma collection center operations might not perform as expected. The company currently operates one and expects to expand into three plasma collection centers over the next 12 months. Although the plasma collection operation is business with relatively sustainable positive cash inflow and ADMA management appears to have substantial experience, risks of mismanagement as well as internal and external factors could change, resulting in sub-par business performance. Although the plasma collection operation might not be the main reason for investing in ADMA shares, a less successful performance could negatively impact on the expected cash flow and strategic objective of diversifying plasma sources for RI-002 production.

Limited product diversity could increase overall risk. Given the nascent stage of the corporate development, the majority of the product pipeline value mainly resides on RI-002. The second potential pipeline product, an anti-Vicella Zoster virus immunoglobin, is in very early development stage with market potential possibly much smaller. As such, we believe the company at the current stage has very limited diversification potential in its product pipeline.

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Lack of cash could impede corporate development. Despite the company's recent successful IPO to raise $26.5MM cash, ADMA could potentially need more financial resources going forward if they want to expand and further develop its pipeline. Should the product not receive FDA approval or product revenue does not reach expectations, the company might have to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

Limited trading liquidity limits shareholder options. Given that ADMA shares only entered the public market recently; daily trading volume and name recognition are relatively low. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

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ADMA Biologics – Income Statement

($ '000)	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue																	
Product revenue	1,118	3,024	1,542	1,481	1,347	1,320	5,690	1,452	1,568	1,662	1,812	6,495	10,002	13,603	14,283	14,997	15,852
RI-002 revenue	-	-					-					-	**17,318**	**52,409**	**90,303**	**143,560**	**185,046**
License revenue	-	44	19	19	19	19	76	19	19	19	19	76	300	300	300	300	300
Total Revenue	1,118	3,068	1,561	1,500	1,366	1,339	5,766	1,471	1,587	1,681	1,831	6,571	27,620	66,312	104,886	158,857	201,197
Cost of product revenue	669	2,023	977	941	868	871	3,678	1,024	1,106	1,172	1,277	4,579	6,801	9,250	9,712	10,198	10,779
Cost of RI-002													8,659	26,205	45,151	71,780	92,523
Gross revenue (RI-002)													8,659	26,205	45,151	71,780	92,523
Gross revenue (Biocenter)	449	1,000	565	541	458	449	2,012	428	463	490	535	1,916	3,201	4,353	4,570	4,799	5,073
Total gross revenue	449	1,000	565	541	458	449	2,012	428	463	490	535	1,916	11,860	30,558	49,722	76,579	97,595
Research and development	3,469	9,303	4,330	1,784	1,483	1,083	8,680	1,039	1,060	1,749	1,994	5,842	6,076	6,319	6,635	6,967	7,315
Plasma center operating expenses	1,747	2,418	802	821	1,018	1,059	3,701	985	989	999	1,019	3,991	4,151	4,442	4,619	4,758	4,853
General and administrative	3,142	4,365	1,135	1,542	1,035	1,077	4,789	1,270	1,995	2,673	3,368	9,305	9,678	10,065	10,407	10,761	11,127
Marketing and sales													8,400	8,904	9,438	9,948	10,445
Total Operating Expenses	8,358	16,087	6,268	4,147	3,537	3,218	17,169	3,295	4,044	5,421	6,380	19,139	28,305	29,729	31,099	32,433	33,740
Operating Income (loss)	(7,909)	(15,042)	(5,684)	(3,587)	(3,038)	(2,750)	(15,059)	(2,847)	(3,562)	(4,911)	(5,827)	(17,147)	(685)	36,583	73,786	126,424	167,457
Interest income	21	8	2	4	4	10	19	6	6	6	6	24	38	61	74	88	97
Interest expense	(31)	(618)	(227)	(343)	(335)	(162)	(1,067)	(322)	(322)	(322)	(322)	(1,288)	(1,288)	(1,288)	(1,288)	(1,288)	(1,288)
Change in fair value of stock warrants	-	43	5	(35)	(15)	(40)	(84)	(40)	(40)	(40)	(40)	(160)	(100)	(100)	(100)	(100)	(100)
Other income	-	82	-	-	-	2	2	-	-	-	1	1	1	1	1	1	1
Total other expenses	(10)	(485)	(220)	(374)	(346)	(190)	(1,130)	(356)	(356)	(356)	(355)	(1,423)	(1,349)	(1,326)	(1,313)	(1,299)	(1,290)
Income (loss) before tax expense	(7,919)	(15,527)	(5,904)	(3,961)	(3,384)	(2,940)	(16,190)	(3,203)	(3,918)	(5,267)	(6,182)	(18,570)	(2,033)	35,257	72,473	125,125	166,168
Income tax expense-State income tax benefit	618	-	-	-	-	-	-	-	-	-	-	-	-	13,045	26,815	46,296	61,482
Net Incomes (Losses)	(7,301)	(15,527)	(5,904)	(3,961)	(3,384)	(2,940)	(16,190)	(3,203)	(3,918)	(5,267)	(6,182)	(18,570)	(2,033)	22,212	45,658	78,829	104,686
Net Earnings (Losses) Per Share—Basic	($1.76)	($2.38)	($0.64)	($0.43)	($0.36)	($0.30)	($1.72)	($0.32)	($0.39)	($0.52)	($0.61)	($1.84)	($0.16)	$1.72	$3.42	$5.74	$7.40
Net Earnings (Losses) Per Share—Diluted	($1.76)	($2.38)	($0.64)	($0.43)	($0.36)	($0.30)	($1.72)	($0.32)	($0.39)	($0.52)	($0.61)	($1.84)	($0.16)	$1.72	$3.42	$5.74	$7.40
Shares outstanding—basic	4,146	6,531	9,292	9,292	9,292	9,792	9,417	9,892	9,992	10,092	10,192	10,042	12,542	12,942	13,342	13,742	14,142
Shares outstanding—diluted	4,146	6,531	9,292	9,292	9,292	9,792	9,417	9,892	9,992	10,092	10,192	10,042	12,542	12,942	13,342	13,742	14,142
Margin Analysis (% of Revenue)																	
Gross	40%	33%	37%	36%	34%	34%	35%	30%	30%	30%	30%	30%	32%	32%	32%	32%	32%
Cost of RI-002													50%	50%	50%	50%	50%
R&D	310%	303%	277%	119%	109%	81%	151%	71%	67%	104%	109%	89%	22%	10%	6%	4%	4%
Plasma operation	156%	80%	52%	55%	76%	80%	65%	68%	63%	60%	56%	61%	42%	33%	32%	32%	31%
G&A	281%	142%	73%	103%	76%	80%	83%	86%	126%	159%	184%	142%	35%	15%	10%	7%	6%
M&S													30%	13%	9%	6%	5%
Operating Income (loss)	-707%	-490%	-364%	-239%	-222%	-205%	-261%	-194%	-224%	-292%	-318%	-261%	-2%	55%	70%	80%	83%
Net Income	-653%	-506%	-378%	-264%	-248%	-220%	-281%	-218%	-247%	-313%	-338%	-283%	-7%	33%	44%	50%	52%
Financial Indicator Growth Analysis (Y/Y)																	
Product (Biocenter) revenue	47%	170%	94%	101%	24%	226%	88%	-6%	6%	23%	37%	14%	54%	36%	5%	5%	6%
RI-002 revenue (projected)	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	203%	72%	59%	29%
Total Revenue	47%	174%	97%	102%	23%	216%	88%	-6%	6%	23%	37%	14%	320%	140%	58%	51%	27%
Research and development	436%	168%	195%	-49%	5%	-63%	-7%	-76%	-41%	18%	84%	-33%	4%	4%	5%	5%	5%
Plasma center operating expenses	50%	38%	56%	52%	55%	50%	53%	23%	20%	-2%	-4%	8%	4%	7%	4%	3%	2%
General and administrative	119%	39%	-21%	41%	22%	8%	10%	12%	29%	158%	213%	94%	4%	4%	3%	3%	3%
Marketing and sales														6%	6%	5%	5%
Operating incomes	71%	90%	80%	-26%	20%	-39%	0%	-50%	-1%	62%	112%	14%	-96%	-5442%	102%	71%	32%
Pretax Income	27%	96%	82%	-19%	26%	-37%	4%	-46%	-1%	56%	110%	15%	-89%	-1834%	106%	73%	33%
Net Income	24%	113%	82%	-19%	26%	-37%	4%	-46%	-1%	56%	110%	15%	-89%	-1192%	106%	73%	33%
EPS - Basic	-89%	35%	15%	-49%	-20%	-46%	-28%	-49%	-8%	43%	102%	7%	-91%	-1159%	99%	68%	29%
EPS - Diluted	-89%	35%	15%	-49%	-20%	-46%	-28%	-49%	-8%	43%	102%	7%	-91%	-1159%	99%	68%	29%
Shares outstanding—basic	1074%	58%	58%	58%	58%	15%	44%	6%	8%	9%	4%	7%	25%	3%	3%	3%	3%
Shares outstanding—diluted	1074%	58%	58%	58%	58%	15%	44%	6%	8%	9%	4%	7%	25%	3%	3%	3%	3%

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

DISCLOSURES:

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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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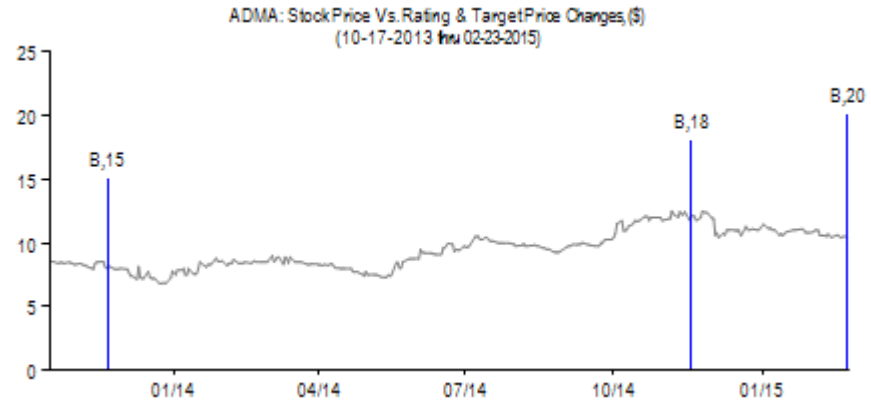
Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

RATINGS INFORMATION

Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
11/21/2013	Buy (B)	8.10

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
11/21/2013	15.00	8.10
11/18/2014	18.00	12.05
02/23/2015	20.00	10.48*

** Previous Close2/20/2015*

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.	81.82%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.55%	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

ADDITIONAL DISCLOSURES

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