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EQUITY RESEARCH
Company Report

June 14, 2018

AIT Therapeutics (AITB - $3.00)

Healthcare/Biotechnology

NO in Bronchiolitis (NO-BRO) Pilot Study Showed Positive Trend with Phase III Study to Start in 4Q19

Ticker:	**AITB**
Rating:	**Buy**
Price Target:	**$16.00**

AITB yesterday reported nitric oxide in infant bronchiolitis pilot (NO-BRO) study topline results. The treatment exhibited positive trending in hospital length of stay (LOS) reduction vs. control but did not reach statistical significance. AITB reported this morning 1Q18 (F4Q18) financial results after changing its fiscal year end from 12/31 to 3/31 with a net gain of $1MM vs. net loss of Laidlaw and the Street ($2.6MM) estimates. On a per share basis, the figure was $0.14 vs. ($0.28) and ($0.25) for Laidlaw and the Street. Major discrepancies were due to a $3.5MM non-cash financial item. AITB ended 1Q18 with cash of ~$9MM, sufficient to support operations into 2Q19, in our opinion.

- **Details.** The study showed on an ITT basis, the mean LOS of NO treated infant (n=33) were 66.8 hours, vs. 84.2 hours of control (n=34), with benefit of 17.4 hours (p=0.20). On an adjusted ITT basis due to two patients with protocol violations (with feeding tube and with prolonged hospital stay), the mean LOS of NO treated infants (n=32) was 60.4 hours, while control (n=34) was 81.4 hours with a benefit of 21 hours (p=0.11). On the safety side, NO treatment was well tolerated and no therapy related SAEs identified. No patients discontinued treatment due to elevations in methemoglobin or nitrogen dioxide levels. Management indicated that the current focuses are on the advancement of AIT-PH for pulmonary hypertension for hospital use, and AIT-NTM in NTM infection (*Mycobacterium abscessus* or MABSC). The further development of AIT-BRO will push out to 4Q19 using the proprietary NO Generator since the trial could only be conducted during the winter season. It is noted that average LOS in Israel and the U.S. is 3.5 days and 4.5 days, respectively. In addition, AITB plans to commence an AIT-NTM in MABSC potentially pivotal trial possibly in 2019 by incorporating inputs from the FDA.
- **Implications.** Despite that the NO-BRO trial results were not statistically significant, we remain encouraged since the outcome is positively trended, and more importantly, the ~20 hours range NO therapy benefit achieved is approaching the clinically and economically meaningful $\geq$24 hours differences. Approximately one day less LOS could translate to one less overnight hospital staying and with material impact on hospital and payer costs. Although it remains too early to project, we estimate a larger study size (n=200-300) trial that properly powered could potentially achieve similar results with statistical significance.
- **Action.** We maintain our Buy rating and $16 price target, which is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Trading Data:

Last Price (6/13/2018)	$3.00
52–Week High (11/24/2017)	$10.00
52–Week Low (3/21/2018)	$2.05
Market Cap. (MM)	$26
Shares Out. (MM)	6.1

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	0.14A	-0.37	-0.33	-0.33	-0.91	N.A.
FY-17A	-1.12	-0.46	-1.18	-0.28	-3.01	N.A.
FY-16A	-0.59	-0.44	-0.20	-0.45	-1.69	N.A.
FY-15A	N.A.	-0.59	N.A.	N.A.	-1.64	N.A.

Source: Laidlaw & Company estimates- 2018 results are calendar year.

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- **Additional information.** As a reminder, the NO-BRO study is a double blind, randomized, 67-patient multi-center (6 sites all in Israel), placebo-controlled trial that evaluated NO 160ppm (30 minutes, 5x/day up to five days) therapy with SOC vs. SOC alone. The primary endpoint is hospital length-of-stay (LOS) as measured from the time of enrollment to the time of hospital discharge. The condition of a patient for being discharged from the hospital requiring to achieve an mTal score <5, have SaO2 >92% and have the physician sign the hospital discharge order. Secondary endpoints include safety, tolerability, time to mTal score <5 and time to SaO_2 >92%. The eligibilities of patients include having composite score of 7–10 using the modified Tal (mTal) score; age <12 months; gestation period of at least 28 weeks and acute bronchiolitis when admitted to the hospital, with an expected stay of at least 24 hours. The mTal score is comprised four 0-3 scale components: respiratory rate, oxygen saturation (SaO_2), accessory muscle use and wheezing.

Figure 1: Hospital length of stay (LOS) of the NO-BRO pilot study

	ITT		alTT	
study arm	NO	Control	NO	Control
Number of Patients	33	34	32	34
Mean LOS (hours)	66.8	84.2	60.4	81.4
NO Benefit (hours)	17.4		21.0	
p value (Welch's t-test)	0.2		0.11	

Source: Company report.

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
AIT-BRO	Bronchiolitis (mainly RSV infection) in infant	Potentially start Phase III trial	**4Q19**	***
		Potentially report Phase III trial data	**YE20**	****
		Potential approval	**2021/2022**	****
AIT-NTM	NTM infection (Mycobacterium abscessus or MABSC)	Potentially reporting of FDA discussion	**3Q18**	***
		Potentially start Phase III trial	**2019**	***
AIT-PH	Pulmonary hypertension (hospital use)	Potential 510k regulatory filing	**YE18**	****
		Potential approval	**2019**	****
		Potential partnership	**2018/2019**	****

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

Source: Laidlaw & Company and company presentation

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Major Risks

Clinical study failure could have a major impact on AITB share value. AITB's NO platform has demonstrated promising efficacy and a satisfactory safety profile from prior Phase II studies in three different indications, like bronchiolitis, cystic fibrosis and nontuberculous mycobacteria (NTM) infection by *Mycobacterium abscessus* complex (MABSC). However, there is no assurance that the upcoming Phase II or Phase III clinical studies can demonstrate similar efficacy and safety profiles satisfactory enough for advancing into next step or gaining clinical approval. Given that the clinical successes are the biggest near-term hurdle to be overcome before AITB's NO platform can be advanced into commercialization, clinical study failure could significantly impair the value of the company's asset and shareholder value.

NO-based products may not reach anticipated sales. Although AITB's NO platform has illustrated initial promising efficacy and safety profiles and even with possible approvals of products being developed, the sales potential could fall short of our forecasts. It is difficult to project more accurately the sales potential of the AITB's NO-based products as the culmination of sales would be shaped by each indication that it may be approved for. For bronchiolitis in infants, although there is currently no approved drug for the treatment of RSV infection, many developments on therapeutics and vaccines are underway and some or multiple successes of those endeavors could potentially change the market dynamic significantly. For other indications AITB is exploring, including NTM infection, the increasingly more challenging reimbursement environment could potentially limit AITB to price the products at a premium even if the competition landscape might be more favorable. As such, and since the anticipated sales would largely depend on which indications the NO product is approved for, the commercial outlook could be uncertain and such scenario could significantly impair the company's asset and shareholder value.

Yet-to-be-approved NO device could remain uncertain. Although several clinical study results are positive and promising, the device used for delivering NO is not approved in the U.S. AITB needs to identify and test a device that will receive FDA acceptance for conducting future clinical studies in the U.S. There are risks that the company might not find or take longer time to find such device. In addition, the performance of such device might not replicate the positive outcome demonstrated from prior studies. In any of such scenario, the development of AITB's clinical programs could be delayed or installed. However, we view such negative outcomes might have lower probability.

Additional financings could dilute shareholder value. The company currently has ~$9MM total cash. As such, AITB would most likely need more financial resources going forward if they want to expand and further develop their pipeline unless the company can successfully explore non-dilutive financial sources. Should the future operational expenses significantly increase, especially in the areas of R&D and SG&A, products not receive FDA approval, or product revenue not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

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Limited trading liquidity limits shareholder options. Given the company just went public very recently and the daily trading volume and name recognition of AITB shares are relatively modest, some investors may hesitate to own the shares as relatively illiquid trading volume could impose constraints if they want to increase or reduce their positions in a volatile stock market.

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Figure 1: Income Statement

AIT Therapeutics – Income Statement

($'000)	2014	2015	2016	2017	1Q18	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenue																
NOxBR in Bronchiolitis revenues											22,613	69,381	118,385	169,663	215,010	245,445
NOxNTM in M. abscessus NTM revenues											0	16,724	52,451	85,299	121,025	159,821
Total product revenues	0	0	0	0	0	0	0	0	0	0	22,613	86,105	170,837	254,963	336,035	405,266
Other revenues	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total revenue	0	0	0	0	0	0	0	0	0	0	22,613	86,105	170,837	254,963	336,035	405,266
COGS											2,261	8,611	17,084	25,496	33,603	40,527
Total gross profit	0	0	0	0	0	0	0	0	0	0	20,351	77,495	153,753	229,466	302,431	364,740
Research and development	(1,167)	(1,620)	(673)	(4,438)	(1,637)	(2,095)	(1,613)	(1,710)	(7,056)	(11,642)	(12,108)	(14,167)	(15,158)	(15,764)	(15,292)	(13,762)
General and administrative	(989)	(589)	(1,660)	(6,629)	(803)	(813)	(838)	(849)	(3,303)	(3,600)	(3,888)	(4,160)	(4,369)	(4,587)	(4,816)	(5,057)
Marketing and sales											(28,000)	(30,800)	(32,340)	(33,957)	(35,315)	(36,728)
Total operating expenses	(2,156)	(2,209)	(2,333)	(11,067)	(2,440)	(2,909)	(2,451)	(2,559)	(10,359)	(15,243)	(43,996)	(49,127)	(51,867)	(54,308)	(55,423)	(55,547)
Operating Incomes (losses)	(2,156)	(2,209)	(2,333)	(11,067)	(2,440)	(2,909)	(2,451)	(2,559)	(10,359)	(15,243)	(23,645)	28,368	101,886	175,158	247,008	309,192
Other Income/(Expense)																
Financial expense	411	994	1,360	6,977	(3,488)	(170)	160	100	(3,398)	(3,738)	(4,112)	(4,523)	(4,975)	(5,473)	(6,020)	(6,622)
Revaluation of warrants to purchase Convertible	2,055	152														
Total other income (expense), net	2,466	1,146	1,360	6,977	(3,488)	(170)	160	100	(3,398)	(3,738)	(4,112)	(4,523)	(4,975)	(5,473)	(6,020)	(6,622)
Pretax income	(4,622)	(3,355)	(3,693)	(18,044)	1,048	(2,739)	(2,611)	(2,659)	(6,961)	(18,981)	(27,757)	23,845	96,911	169,685	240,988	302,570
Tax on income	0	127	27	2	0	0	0	0	0	0	0	(8,823)	(35,857)	(62,784)	(89,166)	(111,951)
Net Income (Loss)	**(4,622)**	**(3,482)**	**(3,720)**	**(18,042)**	**1,043**	**(2,739)**	**(2,611)**	**(2,659)**	**(6,961)**	**(18,981)**	**(27,757)**	**15,022**	**61,054**	**106,902**	**151,823**	**190,619**
Basic and diluted net loss per share		($1.64)	($1.69)	($3.01)	$0.14	($0.37)	($0.33)	($0.33)	($0.91)	($1.78)	($1.90)	$0.99	$3.91	$6.63	$9.13	$11.13
Shares outstanding: basic and undiluted		2,123	2,207	6,002	7,196	7,496	7,796	8,046	7,634	10,634	14,634	15,134	15,634	16,134	16,634	17,134
Margin Analysis (% of Sales/Revenue)																
Costs of goods		NA	NA	NA	NA	NA	NA	NA	NA	10%	10%	10%	10%	10%	10%	10%
R&D		NA	NA	NA	NA	NA	NA	NA	NA	NA	-54%	-16%	-9%	-6%	-5%	-3%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	NA	-17%	-5%	-3%	-2%	-1%	-1%
M&S		NA	NA	NA	NA	NA	NA	NA	NA	NA	-124%	10%	5%	5%	4%	4%
Operating Income (loss)		NA	NA	NA	NA	NA	NA	NA	NA	NA	-105%	33%	60%	69%	74%	76%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	NA	-123%	28%	57%	67%	72%	75%
Tax Rate		37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
Net Income		NA	NA	NA	NA	NA	NA	NA	NA	NA	-123%	17%	36%	42%	45%	47%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
Gross Profit		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
Cost of Goods		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
R&D		39%	-58%	559%	14%	255%	35%	41%	59%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	182%	299%	-62%	38%	-3%	-27%	-50%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	6%	374%	-31%	-5%	19%	7%	-6%	47%	189%	12%	6%	5%	2%	0%
Pretax Income		-27%	10%	389%	-117%	-5%	-63%	53%	-61%	173%	46%	-186%	306%	75%	42%	26%
Net Income		-25%	7%	385%	-117%	-5%	-63%	53%	-61%	173%	46%	-154%	306%	75%	42%	26%
EPS		NA	3%	78%	-113%	-21%	-72%	16%	-70%	96%	6%	-152%	293%	70%	38%	22%

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

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Additional information available upon request.

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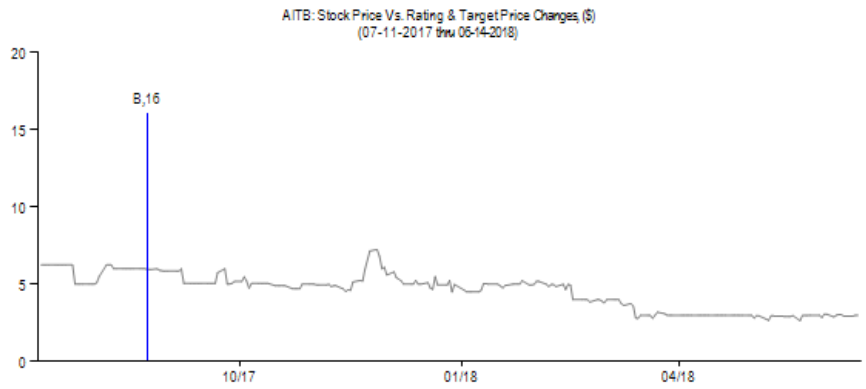
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
08/24/2017	Buy (B)	5.95

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/24/2017	16.00	5.95

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.	66.67%	25.93%	3.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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