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EQUITY RESEARCH
Company Report

May 23, 2018

AIT Therapeutics (AITB - $2.98)

Healthcare/Biotechnology

Incremental Update on NO-NTM Abscessus Phase II Study Results at the ATS Conference

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

AITB reported this morning the presentation of the NO-NTM Abscessus Phase II study results at the 2018 American Thoracic Society (ATS) conference with incremental updates on more matured data.

- **Details.** AITB presented most updated results from the NO-NTM Abscessus Phase II study at the American Thoracic Society (ATS) conference yesterday. The data showed NO treatment has improved 6MWD significantly during the therapy and great portion of clinical benefits still maintained at 4 and 8 weeks post treatment. As for FEV1, modest improvements were observed at day 7, 14, and 21 during NO treatment, and the benefit was dissipated at day 60 post-treatment. One patient showed complete eradication of *M. abscessus* load tested by culture, while 5 out of the 9 patients showed a >1-$\log_{10}$ reduction in *M. abscessus* load via quantitative PCR (qPCR) at week 11. For drug resistant *P. aeruginosa* reduction in four patients with this infection. two had negative cultures, one with >2-$\log_{10}$ reduction and one had no change in culture at week 11. On the safety side, no treatment related SAEs were identified. Two NO-related adverse events (hemoptysis, MetHb) were quickly resolved with minor to no effect on the patients. During the treatment, NO_2 levels remained below 2.5 ppm (safety limit is 5 ppm). MetHb levels remained below 7% except for one reading of 7.1% in one patient during one treatment with no negative effects to the patient. All patients completed all treatments in the study. As a reminder, it is an open label study enrolled 9 cystic fibrosis patients (5 ♀, 4 ♂), infected with antibiotic refractory MABSC. Patients were treated with background antibiotic therapy and 30-minute of 160 ppm NO, 5x/day for 14 days and then 3x/day for 7 days.
- **Implications.** The presentation provided incremental new information and was at a venue for more peer physicians to understand the potential of NO therapy in antibiotic refractory MABSC patients. AITB is scheduled to have a meeting with the FDA discussing the potential trial design for the next potential pivotal study in 2Q18. Further, another important AITB shares catalyst near term is to report the topline results from the NO in bronchiolitis (NO-BRO) Phase III trial in 2Q18. AITB believes differences of ≥24 hours could be clinically and economically meaningful. Should the outcome be positive, the next pivotal Phase III study could start during the 2018/2019 winter season using the proprietary NO Generator.
- **Action.** We maintain our Buy rating and 12-month $16 price target, which is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Trading Data:

Last Price (5/22/20188)	$2.98
52–Week High (11/24/2017)	$10.00
52–Week Low (3/21/20188)	$2.05
Market Cap. (MM)	$25
Shares Out. (MM)	6.1

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.28	-0.26	-0.33	-0.38	-1.25	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

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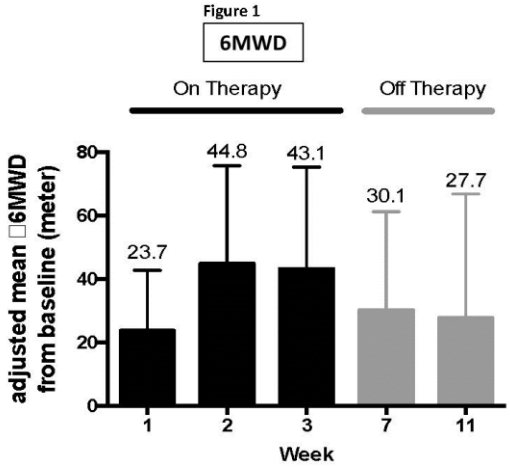
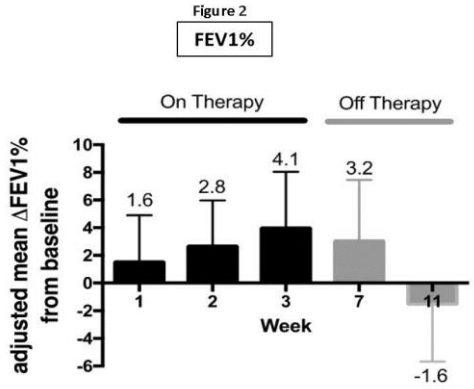
Figure 1: Adjusted mean change in 6MWD (left) and adjusted mean % change in FEV1 (right) from baseline





Source: Company report.

Figure 2: M. abscessus load reduction (left) and patient demergraphics (right)

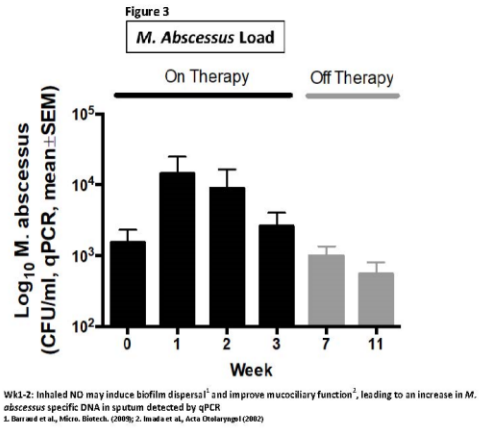


Table 1: Baseline Statistics

Baseline Parameters	mean±SD, [min, max]
MetHb* (%)	0.79 ± 0.6, [0, 1.8]
6MWD (meter)	472.2 ± 74.4, [390, 585]
*M. abscessus*** (CFU/ml)	1544 ± 2322 [100, 7000]
FEV1%	54.6 ± 22.4, [29, 99]
aPTT (sec)	33.8 ± 3.1, [28, 38.6]
WBC (x10^3/µl)	9.9 ± 1.7, [7.3, 12.6]
C-reactive Protein (mg/l)	26.86 ± 29.2, [1.7, 88.8]

*Evaluated prior to NO inhalations
**Quantitative PCR

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 report first Phase III trial data	**2Q18**	****
		Potentially start 2nd Phase III trial	**4Q18**	***
		Potentially report 2nd Phase III trial data	**2H19**	****
		Potential approval	**2019/2020**	****
AIT-NTM	NTM infection (Mycobacterium abscessus or MABSC)	Potentially FDA discussion	**2Q18**	***
		Reporting of Phase II full data at the American Thoracic Society Meeting	**May 18 - 23, 2018**	***
		Potentially start Phase III trial	**2H18**	***
AIT-PH	Pulmonary hypertension (hospital use)	Potential 510k regulatory filing	**4Q18**	****
		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 ~$11MM 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	1Q18E	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)	(1,276)	(1,505)	(1,912)	(2,524)	(7,217)	(11,907)	(12,384)	(14,489)	(15,503)	(16,123)	(15,640)	(14,076)
General and administrative	(989)	(589)	(1,660)	(6,629)	(1,180)	(1,195)	(1,231)	(1,247)	(4,852)	(5,289)	(5,712)	(6,112)	(6,418)	(6,739)	(7,076)	(7,429)
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)	(2,455)	(2,700)	(3,143)	(3,770)	(12,069)	(17,197)	(46,096)	(51,401)	(54,261)	(56,819)	(58,030)	(58,233)
Operating Incomes (losses)	(2,156)	(2,209)	(2,333)	(11,067)	(2,455)	(2,700)	(3,143)	(3,770)	(12,069)	(17,197)	(25,745)	26,094	99,492	172,648	244,401	306,507
Other Income/(Expense)																
Financial expense	411	994	1,360	6,977	140	(170)	160	100	230	253	278	306	337	370	407	448
Revaluation of warrants to purchase Convertible	2,055	152														
Total other income (expense), net	2,466	1,146	1,360	6,977	140	(170)	160	100	230	253	278	306	337	370	407	448
Pretax income	(4,622)	(3,355)	(3,693)	(18,044)	(2,595)	(2,530)	(3,303)	(3,870)	(12,299)	(16,944)	(25,466)	26,400	99,829	173,018	244,808	306,955
Tax on income	0	127	27	2	0	0	0	0	0	0	0	(9,768)	(36,937)	(64,017)	(90,579)	(113,573)
Net Income (Loss)	**(4,622)**	**(3,482)**	**(3,720)**	**(18,042)**	**(2,595)**	**(2,530)**	**(3,303)**	**(3,870)**	**(12,299)**	**(16,944)**	**(25,466)**	**16,632**	**62,892**	**109,001**	**154,229**	**193,382**
Basic and diluted net loss per share		($1.64)	($1.69)	($3.01)	($0.28)	($0.26)	($0.33)	($0.38)	($1.25)	($1.32)	($1.51)	$0.96	$3.53	$5.94	$8.19	$10.00
Shares outstanding: basic and undiluted		2,123	2,207	6,002	9,398	9,698	9,998	10,248	9,836	12,836	16,836	17,336	17,836	18,336	18,836	19,336
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	-55%	-17%	-9%	-6%	-5%	-3%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	NA	-25%	-7%	-4%	-3%	-2%	-2%
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	-114%	30%	58%	68%	73%	76%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	NA	-113%	31%	58%	68%	73%	76%
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	-113%	19%	37%	43%	46%	48%
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%	-11%	155%	60%	108%	63%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	182%	299%	-44%	102%	42%	7%	-27%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	6%	374%	-31%	-12%	53%	58%	9%	42%	168%	12%	6%	5%	2%	0%
Pretax Income		-27%	10%	389%	-59%	-12%	-54%	123%	-32%	38%	50%	-204%	278%	73%	41%	25%
Net Income		-25%	7%	385%	-59%	-12%	-54%	123%	-32%	38%	50%	-165%	278%	73%	41%	25%
EPS		NA	3%	78%	-75%	-43%	-72%	33%	-58%	6%	15%	-163%	268%	69%	38%	22%

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

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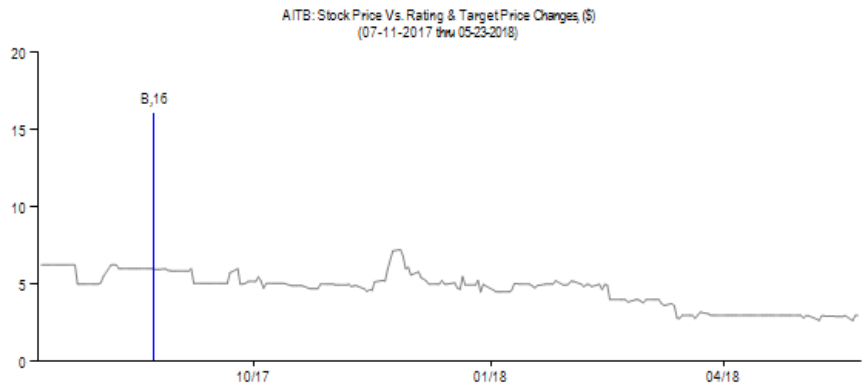
Rating and Price Target Change History



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**

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			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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