

## AIT Therapeutics (AITB - \$7.24)

### Highly Encouraging NO-NTM Abscessus Phase II Study Results with Pivotal Trial to Start in 2H18

AITB reported yesterday and hosted a meeting this morning focusing on the nitric oxide for NTM abscessus (NO-NTM abscessus) Phase II study preliminary results.

- Details.** The NTM-MABSC infection Phase II study (n=9) topline readout showed 1) one of nine patients achieved culture conversion at day 21; 2) the mean change in 6MW distance vs. baseline at various time points showed substantial improvement in day 14 and continued by day 21; and 3) continued mean percentage of improvements in forced expiratory volume (FEV1) vs. baseline at day 51. On the safety side, no NO-related SAEs reported over the 21-day treatment period. As a reminder, all enrolled patients were refractory to the standard-of-care for MABSC and had underlying cystic fibrosis. All patients received inhaled NO and background antibiotic therapies. NO was delivered at 160ppm for 30 minutes intermittently for 21 days (5x/day for 14 days and then 3x/day for a subsequent 7 days) and NO treatment terminated after day 21. AITB indicated that the full dataset for the Phase II trial could be available in late 1Q18 after 81-day follow-up. The company is scheduled to discuss with the FDA, possibly in late 1Q18 for potentially commence a Phase III trial in 2H18. Although the details remain to be determined, Phase III study would likely be a randomized controlled (vs. antibiotics alone) study with clinically meaningful measurement, such as 6MWD as primary endpoint.
- Implications.** We view the Phase II study outcome as very encouraging especially given the recent FDA guidance has suggested that the survival and measurements of symptoms and function could be the more critical primary endpoints for potential approval. Culture conversation may still be important, but might not be necessary as the only gating factor. We view the results of the 6MW distances and continued improvements of FEV1 very meaningful clinical readouts. Going forward, we believe additional details regarding these two measurements, either by comparing to historical data or from future studies, regarding the effect from antibiotic alone, would be valuable to tease out the contribution from NO. Since all patients were refractory to antibiotic therapies, we believe such background effect could be rather limited.
- Action.** With a differentiated and promising NO-based treatment modality in development for two indications, and with potentially multiple positive catalysts over the next 18 months; we believe AITB shares remain undervalued at current levels. 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.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	-1.12A	-0.46A	-1.18A	-0.34	-3.05	N.A.
<b>FY-16A</b>	-0.59	-0.44	-0.20	-0.45	-1.69	N.A.
<b>FY-15A</b>	N.A.	N.A.	N.A.	N.A.	-1.64	N.A.
<b>FY-14A</b>	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>AITB</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$16.00</b>

#### Trading Data:

Last Price (11/27/2017)	\$7.24
52-Week High (11/24/2017)	\$10.00
52-Week Low (11/16/2017)	\$4.32
Market Cap. (MM)	\$45
Shares Out. (MM)	0.103

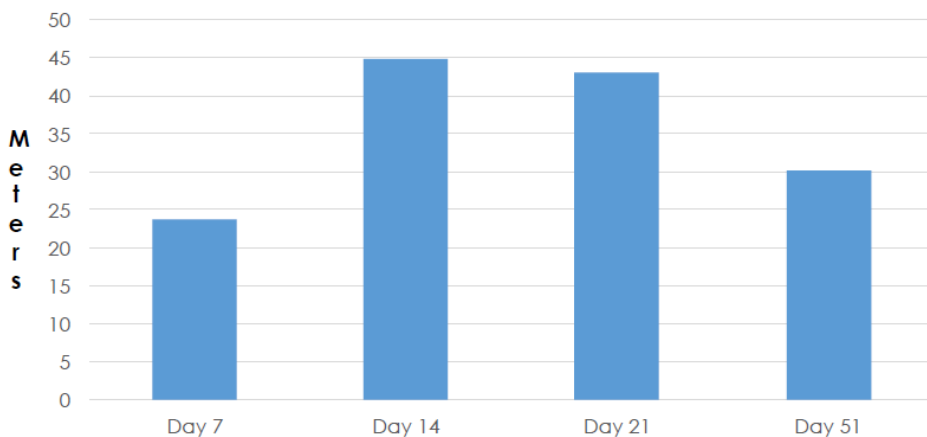
#### Yale Jen, Ph.D.

Managing Director/Senior  
Biotechnology Analyst  
(212) 953-4978  
yjen@laidlawltd.com

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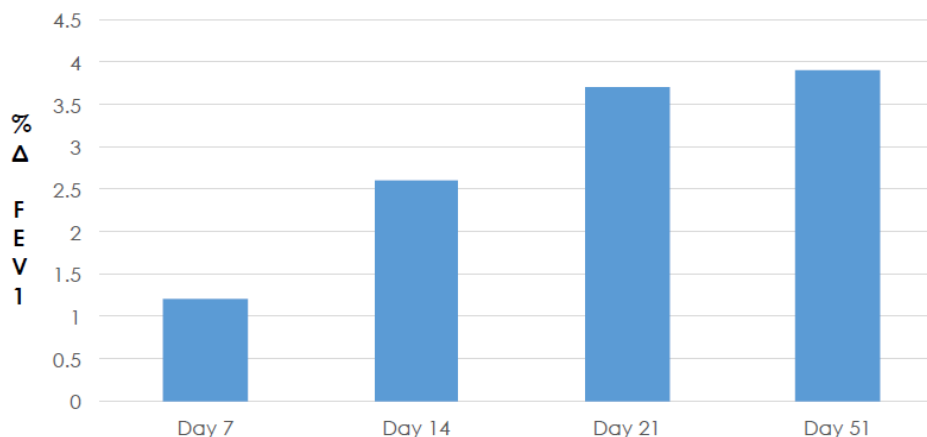
- Additional market opportunity for AIT-PH in infant pulmonary hypertension of neonatal intensive care unit (NICU) in hospital.** With the recent acquisition of the eNOGenerator from NitricGen, AITB provided more color on the commercial outlook for this device besides NABSC and bronchiolitis. AITB anticipate the eNOGenerator could be used in the neonatal intensive care unit (NICU) setting in infant pulmonary hypertension and complete with current marketed product, like INOmax from Mallinckrodt. It is potentially a several hundred million dollar opportunity and AITB plans to launch the product by 2019. AITB believes it needs to show equivalence of delivering similar level of NO compared to the currently marketed device before filing for approval. We view this to be a very nice add-on commercial opportunity for AITB. Further, we believe ultimately, AITB's revenue will be measured by the number of filters sold. The company can make 'smart filter' that can differentiate different indications and enable company to price differently based on the indication the filter to be used.

**Figure 1: Mean change in 6MW from baseline**



Source: Company report.

**Figure 2: Mean % change in FEV1 from baseline**



Source: Company report.

## Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
AIT-BRO	Bronchiolitis (mainly RSV infection) in infant	Potentially report first Phase III trial data	<b>2Q18</b>	<b>****</b>
		Potentially start 2nd Phase III trial	<b>Late 2018</b>	<b>***</b>
		Potentially report 2nd Phase III trial data	<b>2H19</b>	<b>****</b>
AIT-NTM	NTM infection (Mycobacterium abscessus or MABSC)	Report Phase II trial full dataset results	<b>1H17</b>	<b>***</b>
		Potentially start Phase III trial	<b>2H18</b>	<b>***</b>
AIT-PH	Pulmonary hypertension (hospital use)	Potential regulatory filing	<b>YE2018</b>	<b>****</b>

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

Source: Laidlaw & Company and company presentation

## Major Risks

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**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 ~\$7MM total cash as of the end of 2Q17. 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.

**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.

Figure 1: Income Statement

AIT Therapeutics – Income Statement																				
(\$'000)	2014	2015	2016	1Q17	2Q17	3Q17	4Q17E	2017E	1Q18E	2Q18E	3Q18E	4Q18E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
<b>Revenue</b>																				
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
<b>Total product revenues</b>															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	0	0	0	0
<b>Total revenue</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22,613	86,105	170,837	254,963	336,035	405,266
<b>COGS</b>																				
<b>Total gross profit</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2,261	8,611	17,084	25,496	33,603	40,527
Research and development	(1,167)	(1,620)	(673)	(1,439)	(591)	(1,193)	(1,372)	(4,595)	(1,468)	(1,776)	(2,345)	(3,259)	(8,848)	(14,599)	(15,183)	(17,764)	(19,008)	(19,768)	(19,175)	(17,258)
General and administrative	(989)	(589)	(1,660)	(2,121)	(2,476)	(864)	(890)	(6,351)	(899)	(926)	(954)	(982)	(3,760)	(4,099)	(4,427)	(4,737)	(4,973)	(5,222)	(5,483)	(5,757)
Marketing and sales															(28,000)	(30,800)	(32,340)	(33,957)	(35,315)	(36,728)
<b>Total operating expenses</b>	(2,156)	(2,209)	(2,333)	(3,560)	(3,067)	(2,057)	(2,262)	(10,946)	(2,367)	(2,702)	(3,298)	(4,241)	(12,608)	(18,698)	(47,610)	(53,301)	(56,321)	(58,947)	(59,973)	(59,743)
<b>Operating Incomes (losses)</b>	(2,156)	(2,209)	(2,333)	(3,560)	(3,067)	(2,057)	(2,262)	(10,946)	(2,367)	(2,702)	(3,298)	(4,241)	(12,608)	(18,698)	(27,259)	24,194	97,432	170,519	242,458	304,997
<b>Other Income/(Expense)</b>																				
Financial expense	411	994	1,360	2,717	(187)	5,092	(198)	7,424	140	(170)	160	100	230	253	278	306	337	370	407	448
Revaluation of warrants to purchase Convertible	2,055	152																		
<b>Total other income (expense), net</b>	2,466	1,146	1,360	2,717	(187)	5,092	(198)	7,424	140	(170)	160	100	230	253	278	306	337	370	407	448
<b>Pretax income</b>	(4,622)	(3,355)	(3,693)	(6,277)	(2,880)	(7,149)	(2,064)	(18,370)	(2,507)	(2,532)	(3,458)	(4,341)	(12,838)	(18,445)	(26,980)	24,500	97,769	170,890	242,865	305,445
Tax on income	0	127	27	(6)	0	5	0	(1)	0	0	0	0	0	0	(9,065)	(36,174)	(63,229)	(89,860)	(113,015)	(113,015)
<b>Net Income (Loss)</b>	(4,622)	(3,482)	(3,720)	(6,283)	(2,880)	(7,144)	(2,064)	(18,371)	(2,507)	(2,532)	(3,458)	(4,341)	(12,838)	(18,445)	(26,980)	15,435	61,594	107,660	153,005	192,430
Basic and diluted net loss per share		(\$1.64)	(\$1.69)	(\$1.12)	(\$0.46)	(\$1.18)	(\$0.34)	(\$3.05)	(\$0.27)	(\$0.27)	(\$0.35)	(\$0.43)	(\$1.17)	(\$1.32)	(\$1.50)	\$0.83	\$3.24	\$5.52	\$7.65	\$9.38
Shares outstanding: basic and undiluted		2,123	2,207	5,622	6,242	6,046	6,146	6,014	9,146	9,446	9,746	9,996	11,014	14,014	18,014	18,514	19,014	19,514	20,014	20,514
<b>Margin Analysis (% of Sales/Revenue)</b>																				
Costs of goods		NA	NA	NA	NA	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	NA	NA	NA	NA	-67%	-21%	-11%	-8%	-6%	-4%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-20%	-6%	-3%	-2%	-2%	-1%
M&S		NA	NA	NA	NA	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	NA	NA	NA	NA	-121%	28%	57%	67%	72%	75%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-119%	28%	57%	67%	72%	75%
Tax Rate		37%	37%	37%	37%	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	NA	NA	NA	NA	-119%	18%	36%	42%	46%	47%
<b>Financial Indicator Growth Analysis (YoY%)</b>																				
Total Revenue		NA	NA	NA	NA	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	NA	NA	NA	NA	281%	98%	49%	32%	21%
Cost of Goods		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
R&D		39%	-58%	490%	118%	1957%	1272%	583%	2%	201%	97%	138%	93%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	182%	203%	814%	871%	72%	283%	-58%	57%	10%	10%	-41%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	6%	277%	390%	1299%	267%	369%	-34%	-12%	60%	88%	15%	48%	155%	12%	6%	5%	2%	0%
Pretax Income		-27%	10%	389%	201%	1434%	109%	397%	-60%	-12%	-52%	110%	-30%	44%	46%	-191%	299%	75%	42%	26%
Net Income		-25%	7%	386%	197%	1491%	107%	394%	-60%	-12%	-52%	110%	-30%	44%	46%	-157%	299%	75%	42%	26%
EPS		NA	3%	91%	5%	481%	-26%	81%	-75%	-42%	-70%	29%	-62%	13%	14%	-156%	289%	70%	39%	23%

Yale Jen, Ph.D. 212-953-4978

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

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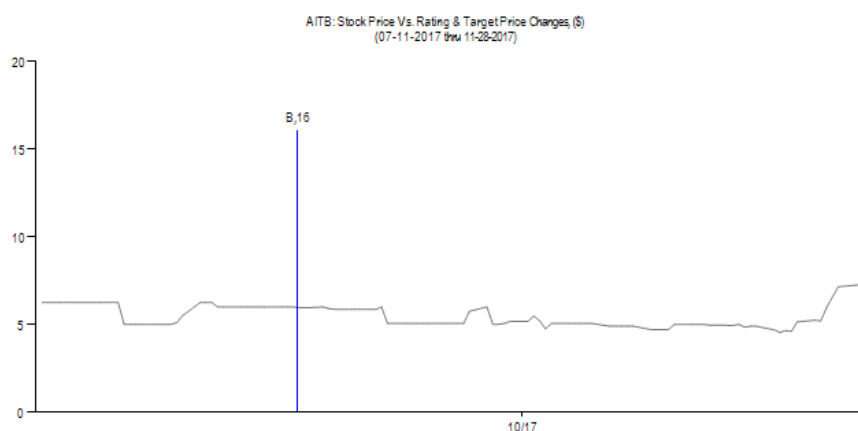
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Date	Rating	Closing Price (\$)
08/24/2...	Buy (B)	5.95

**3 Year Price Change History**

Date	Target Price (\$)	Closing Price, (\$)
08/24/2...	16.00	5.95

Source: Laidlaw &amp; Company

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			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	65.31%	30.61%	2.04%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.08%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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