

## AIT Therapeutics (AITB - \$5.05)

### Management Updates Indicated On-track Clinical Developments and Data Readouts

After our recent meetings with AITB management and investors, we remain confident that all developments are on-track for reporting results as estimated by the company for 4Q17 and 1H18. Highlights of the meetings include:

- **Two clinical developments are on-track.** Management indicated that patient recruitment for the NOxNTM in NTM-MABSC infection Phase II study (n=10) is underway and potential topline readout should occur in 4Q17 as planned. The NOxBR in infant bronchiolitis Phase III study should continue patient recruitment for the upcoming winter season starting later in 4Q17 with topline result readout likely in 1H18. We view the reporting of these two study results highly critical for potential AITB share value appreciation. Both are also important as clinical proof-on-concept for treating each respective indication.
- **Readthrough of positive Arikayce in MAC Phase III data is encouraging for NOxNTM outlook.** Recently, Insmid (INSM – NR) reported positive Arikayce (ALIS) in NTM-MAC Phase III results that met the primary endpoint as 29% of patients taking ALIS and GBT (guideline based therapy) fully eliminated MAC infection in lung by month 6 vs. 9% of patients taking GBT alone (p <0.0001). The measurement is based on three consecutive negative sputum cultures. The NOxNTM study showed a preliminary positive outcome of 99% of bacteria reduction vs. the baseline, and improvement of 6MW distance. If the ongoing Phase II study demonstrates similar results, we believe the probability of success of NOxNTM would be substantially improved.
- **Favorable federal court ruling on generic respiratory treatment system of INOmax could also benefit AITB.** Recently, a Delaware federal court judge invalidated 11 INOmax patents (mainly the respiratory treatment system) and sided with Praxair (PX – NR) for their generic version product. INOmax is sold by Mallinckrodt (MNK – NR). It was a surprise given the previous positive IPR decisions. Given that there is some overhang that AITB's current and potential upcoming NO delivering device might have some IP conflict with MNK's, this legal ruling could eliminate such concern.
- **Action.** With a differentiated and promising NO-based treatment modality in active development for two indications, and with potentially positive multiple catalysts over the next 18 months; we believe AITB shares remain undervalued at current levels. Our 12-month \$16 price target 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	-0.56	-0.57	-2.66	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 (9/22/2017)	\$5.05
52-Week High (9/26/2016)	\$45.00
52-Week Low (7/25/2017)	\$5.00
Market Cap. (MM)	\$35
Shares Out. (MM)	0.103

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## Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
NOxBR	Bronchiolitis (mainly RSV infection) in infant	Potentially report first Phase III trial data	<b>1H18</b>	****
		Potentially start 2nd Phase III trial	<b>Late 2018</b>	***
		Potentially report 2nd Phase III trial data	<b>2H19</b>	****
NOxNTM	NTM infection (Mycobacterium abscessus or MABSC)	Report Phase II trial results	<b>4Q17</b>	****
		Potentially start Phase III trial	<b>2H18</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	3Q17E	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>	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
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)	(999)	(1,548)	(4,577)	(1,656)	(2,004)	(2,646)	(3,678)	(9,984)	(16,474)	(17,133)	(20,045)	(21,449)	(22,307)	(21,637)	(19,474)
General and administrative	(989)	(589)	(1,660)	(2,121)	(2,476)	(2,278)	(2,346)	(9,221)	(2,370)	(2,441)	(2,514)	(2,589)	(9,914)	(10,806)	(11,671)	(12,488)	(13,112)	(13,768)	(14,456)	(15,179)
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)	(3,277)	(3,894)	(13,798)	(4,026)	(4,445)	(5,160)	(6,267)	(19,898)	(27,280)	(56,804)	(63,333)	(66,901)	(70,031)	(71,409)	(71,380)
<b>Operating Incomes (losses)</b>	(2,156)	(2,209)	(2,333)	(3,560)	(3,067)	(3,277)	(3,894)	(13,798)	(4,026)	(4,445)	(5,160)	(6,267)	(19,898)	(27,280)	(36,452)	14,161	86,852	159,435	231,023	293,359
<b>Other Income/(Expense)</b>																				
Financial expense	411	994	1,360	2,717	(187)	250	(198)	2,582	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)	250	(198)	2,582	140	(170)	160	100	230	253	278	306	337	370	407	448
Pretax income	(4,622)	(3,355)	(3,693)	(6,277)	(2,880)	(3,527)	(3,696)	(16,380)	(4,166)	(4,275)	(5,320)	(6,367)	(20,128)	(27,027)	(36,174)	14,468	87,189	159,805	231,430	293,807
Tax on income	0	127	27	(6)	0	5	(1)		0	0	0	0	0	0	0	(5,353)	(32,260)	(59,128)	(85,629)	(108,709)
<b>Net Income (Loss)</b>	(4,622)	(3,482)	(3,720)	(6,283)	(2,880)	(3,522)	(3,696)	(16,381)	(4,166)	(4,275)	(5,320)	(6,367)	(20,128)	(27,027)	(36,174)	9,115	54,929	100,677	145,801	185,099
Basic and diluted net loss per share		(\$1.64)	(\$1.69)	(\$1.12)	(\$0.46)	(\$0.56)	(\$0.57)	(\$2.66)	(\$0.44)	(\$0.44)	(\$0.53)	(\$0.62)	(\$1.80)	(\$1.91)	(\$1.99)	\$0.49	\$2.87	\$5.12	\$7.23	\$8.96
Shares outstanding: basic and undiluted		2,123	2,207	5,622	6,242	6,342	6,442	6,162	9,442	9,742	10,042	10,292	11,162	14,162	18,162	18,662	19,162	19,662	20,162	20,662
<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	-76%	-23%	-13%	-9%	-6%	-5%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-52%	-15%	-8%	-5%	-4%	-4%
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	-161%	16%	51%	63%	69%	72%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-160%	17%	51%	63%	69%	72%
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	-160%	11%	32%	39%	43%	46%
<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%	1622%	1448%	580%	15%	239%	165%	138%	118%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	182%	203%	814%	2459%	355%	455%	12%	313%	10%	10%	8%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	6%	277%	390%	2129%	532%	491%	13%	45%	57%	61%	44%	37%	108%	11%	6%	5%	2%	0%
Pretax Income		-27%	10%	389%	201%	657%	275%	344%	-34%	48%	51%	72%	23%	34%	-140%	503%	83%	45%	27%	27%
Net Income		-25%	7%	386%	197%	684%	270%	340%	-34%	48%	51%	72%	23%	34%	34%	-125%	503%	83%	45%	27%
EPS		NA	3%	91%	5%	173%	27%	58%	-61%	-5%	-5%	8%	-32%	6%	4%	-125%	487%	79%	41%	24%

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

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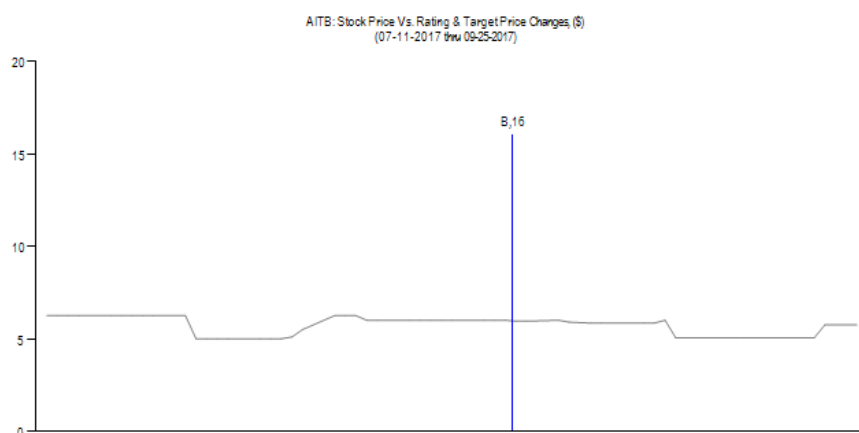
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#### 3 Year Rating Change History

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 & 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.	64.58%	31.25%	2.08%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.17%	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%

### ADDITIONAL COMPANIES MENTIONED

Insmid (INSM – Not Rated)  
Praxair (PX – Not Rated)  
Mallinckrodt (MNK – Not Rated)

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