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EQUITY RESEARCH
Company Report

July 16, 2018

AIT Therapeutics (AITB - $3.99)

Healthcare/Biotechnology

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

Highlights from the Road: AIT-PH in Infant Pulmonary Hypertension 510(k) Filing is On-Track by YE18

We recently hosted meetings with AITB management and investors for a corporate update. We came away with strengthened confidence that the AIT-PH in persistent pulmonary hypertension of the newborn (PPHN) 510(k) filing is on track by YE18, and we believe the NO generator has the potential to be a disruptive technology in NO therapy with substantial market potential. Key takeaways include:

- **AIT-PH in PPHM development is one major focus.** AITB reiterated that the AIT-PH in PPHM 510(k) filing is on-track by year-end 2018; while potential partnering could be consummated during the same period or in early 2019. As such, potential approval could come in late 2H19 with possible launch shortly thereafter. AIT-PH connects with the in hospital ventilation system delivering lower concentrations of NO, while other AIT systems (BRO or NTM) connect to a mask delivering higher concentrations of NO and can be used in home setting. On the market side, AITB views the competition going forward could be very limited due to various contract constraints. Mallinckrodt's INOmax remains the main competitor. With cost saving and operational benefits to the hospital AIT-PH, in our opinion, could be a disruptive technology. Potentially it could gain significant hospital-based NO therapy market share despite likely material countermeasures from the current market leader, such as significant price reduction. We also view a capable marketing partner is critical for AIT-PH success. Although PPHM is the approved indication, a majority of the current NO therapy revenues (~80%) are derived from off-label indications, such as cardiac surgery and bronchopulmonary dysplasia (BPD). We believe AIT-PH can be used for those indications as well. We also believe AIT-PH use could also expand into hospitals that currently do not have the infrastructure for operating the more cumbersome INOmax system.
- **AIT-BRO and AIT-NTM updates.** AITB highlighted that the NO-BRO in bronchiolitis trial has shown a positive NO therapy benefit trend of ~20 hours shortening, even if not reaching statistical significance. This outcome could help the design of the next Phase III study, which could start in 4Q19. Further, AITB is also encouraged by the AIT-NTM in MABSC 9-patient clinical readout and is on-track for an FDA meeting to discuss the potential pivotal study design. The 6MW distance could be the primary endpoint, while bacteria eradiation and others could be the secondary. More FDA discussion updates could be available in 3Q18.
- **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 (7/11/2018)	$3.99
52–Week High (11/24/2017)	$10.00
52–Week Low (3/21/2018)	$2.05
Market Cap. (MM)	$34
Shares Out. (MM)	6.1

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.37	-0.29	-0.34	-0.32	-1.32	N.A.
FY-18A	-0.46	-1.18	-0.28	0.14	-1.67	N.A.
FY-17A	-0.44	-0.20	-0.45	-1.12	-2.84	N.A.
FY-16A	N.A.	-0.44	N.A.	N.A.	-1.64	N.A.

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

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- **AIT-NTM of current setup (generator) in MABSC clinical data presented.** Last Friday, a case study was presented at the World Bronchiectasis Conference. The study used a portable NO generator (AIT-NTM) for treating a CF patient with 8 years history of chronic *M. abscessus* infection who have been unresponsive to multiple antibiotics and with deteriorating lung function. Patient received 160 ppm NO five times a day for days 1-14 and three times a day for day 15-21 as a 21-day inpatient regimen. Patients showed improvements in FVC and 6-Minute Walk Test (6MWT) distance as well as decreased levels of inflammatory markers (CRP and ESR). There were no significant changes in *M. abscessus* stain or culture results.

Figure 1: A NIH single patient AIT-NTM in CF clinical results

Phase	Time	FEV1 (%)	FVC (%)	6MWT (m)	CRP (mg/dL)	ESR (mm/hr)	AFB Stain	AFB Culture
Pre-Trial	Baseline	39	50	410	50.7	29	Many	Heavy
Trial	Day 7	37	53	399	31.9	25	Many	Heavy
	Day 14	40	59	379	13.8	18	Many	Heavy
	Day 21	42	58	426	37	22	Many	Heavy
Post-Trial	Day 51	41	59	503	20.3	17	Many	Heavy
	Day 81	42	60	459	35.4	34	Many	Heavy
	Day 111	41	56	471	17.4	26	Many	Heavy
	Day 141	38	58	362	17.7	28	Many	Heavy

Source: Olivier, K. N. , et. al., 2018-07-13 World Bronchiectasis Conference presentation.

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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)	2015	2016	2017	2018	1Q19E	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
		Mar-16	Mar-17	Mar-18	Jun-18	Sep-18	Dec-18	Mar-19	Mar-19	Mar-20	Mar-21	Mar-22	Mar-23	Mar-24	Mar-25	Mar-26
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)	(1,868)	(4,636)	(2,095)	(1,613)	(1,710)	(1,744)	(7,163)	(11,820)	(12,292)	(14,382)	(15,389)	(16,005)	(15,524)	(13,972)
General and administrative	(989)	(589)	(3,081)	(5,311)	(813)	(838)	(846)	(857)	(3,355)	(3,657)	(3,949)	(4,226)	(4,437)	(4,659)	(4,892)	(5,136)
Marketing and sales											(28,000)	(30,800)	(32,340)	(33,957)	(35,315)	(36,728)
Total operating expenses	(2,156)	(2,209)	(4,949)	(9,947)	(2,909)	(2,451)	(2,556)	(2,602)	(10,518)	(15,476)	(44,242)	(49,408)	(52,166)	(54,620)	(55,731)	(55,836)
Operating Incomes (losses)	(2,156)	(2,209)	(4,949)	(9,947)	(2,909)	(2,451)	(2,556)	(2,602)	(10,518)	(15,476)	(23,890)	28,087	101,587	174,846	246,700	308,904
Other Income/(Expense)																
Financial expense	411	994	3,738	772	(170)	(170)	160	100	(80)	(88)	(97)	(106)	(117)	(129)	(142)	(156)
Revaluation of warrants to purchase Convertible	2,055	152														
Total other income (expense), net	2,466	1,146	3,738	772	(170)	(170)	160	100	(80)	(88)	(97)	(106)	(117)	(129)	(142)	(156)
Pretax income	(4,622)	(3,355)	(8,687)	(10,719)	(2,739)	(2,281)	(2,716)	(2,702)	(10,438)	(15,564)	(23,987)	27,980	101,470	174,717	246,558	308,748
Tax on income	0	127	11	8	0	0	0	0	0	0	0	(10,353)	(37,544)	(64,645)	(91,227)	(114,237)
Net Income (Loss)	**(4,622)**	**(3,482)**	**(8,700)**	**(10,711)**	**(2,739)**	**(2,281)**	**(2,716)**	**(2,702)**	**(10,438)**	**(15,564)**	**(23,987)**	**17,628**	**63,926**	**110,072**	**155,332**	**194,511**
Basic and diluted net loss per share		($1.64)	($2.84)	($1.67)	($0.37)	($0.29)	($0.34)	($0.32)	($1.32)	($1.42)	($1.61)	$1.14	$4.01	$6.70	$9.17	$11.16
Shares outstanding: basic and undiluted		2,123	3,061	6,396	7,496	7,796	8,096	8,346	7,934	10,934	14,934	15,434	15,934	16,434	16,934	17,434
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%	-17%	-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	-106%	33%	59%	69%	73%	76%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	NA	-106%	32%	59%	69%	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	-106%	20%	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%	15%	148%	255%	35%	41%	7%	55%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	423%	72%	-67%	-30%	-28%	7%	-37%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	124%	101%	-5%	19%	7%	7%	6%	47%	186%	12%	6%	5%	2%	0%
Pretax Income		-27%	159%	23%	-5%	-68%	56%	-358%	-3%	49%	54%	-217%	263%	72%	41%	25%
Net Income		-25%	150%	23%	-5%	-68%	57%	-359%	-3%	49%	54%	-173%	263%	72%	41%	25%
EPS		NA	73%	-41%	-21%	-75%	18%	-323%	-21%	8%	13%	-171%	251%	67%	37%	22%

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

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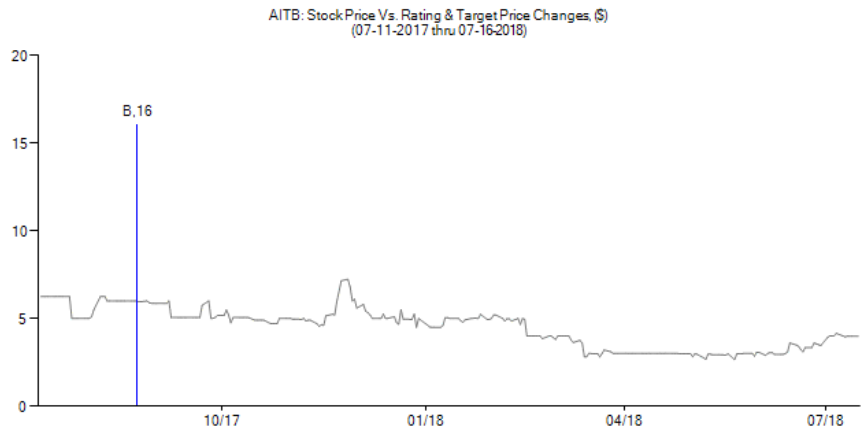
Rating and Price Target Change History



3 Year Rating Change History

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

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
08/24/...	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.	67.27%	25.45%	3.64%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Mallinckrodt (MNK – Not Rated)

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