

AIT Therapeutics (AITB - \$3.95)

2Q18: AIT-PH in PPHN 510(k) Filing the Near-term Major Objective with Submission Scheduled in 1Q19

Yesterday, AITB reported 2Q18 financial results with a net loss of (\$3.0MM) vs. Laidlaw (\$2.7MM) and the Street (\$4.9MM) estimates. Net loss/share was (\$0.36) vs. (\$0.37) and (\$0.78) for Laidlaw and the Street. AITB ended 2Q18 with cash of ~\$6.7MM, plus a \$20MM equity line closed recently.

- **AIT-PH in PPHM development is major focus.** AITB reiterated that the AIT-PH in PPHM 510(k) filing is on-track by 1Q19. Potential partnering could be consummated during the same period or in early 2019. AITB is collaborating with Sparton corporation for the production of ventilator-comparable AIT-PH system delivering lower concentrations of NO. Potential approval could come in before YE19 or early 1Q20 with possible launch shortly thereafter. We believe AIT-PH could be a disruptive technology based on potential cost saving and operational benefits to the hospital.

F1Q19 Estimates and Reported Results			
(\$,000)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$0	\$0	\$0
Total op. profit (loss)	(\$2,909)	(\$1,756)	(\$2,200)
R&D	(\$2,095)	(\$1,063)	
SG&A	(\$813)	(\$693)	
EPS	(\$0.37)	(\$0.36)	(\$0.78)
Net income (loss)	(\$2,739)	(\$2,996)	(\$4,900)

Source: Bloomberg and Laidlaw and Co.

- **AIT-BRO and AIT-NTM updates.** The final version of the mask comparable NO generator is near completion. AITB recently completed a positive meeting with the FDA regarding the AIT-NTM development. AITB plans to conduct a pilot study possibly starting in 1H19 to explore 1) real-world home use experience, 2) the possibility of delivering NO higher than 160 ppm, and 3) potentially including MAC patients. The knowledge gained from this study would be used for designing a pivotal study, which might start in late 2019 or 2020. AITB reiterated that the NO-BRO in bronchiolitis pivotal trial is scheduled to start in 4Q19 with study design similar to that of the prior Phase II study, except with more patients for potentially achieving a statistically significant readout.
- **Action.** With a differentiated and promising NO-based treatment modality development in place, we believe AITB shares remain undervalued at current levels. We maintain our Buy rating and \$16 price target, which is based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses.

Earnings Estimates: (per share)

(March)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.36A	-0.16	-0.20	-0.19	-0.90	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.

Healthcare/Biotechnology

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

Trading Data:

Last Price (8/14/2018)	\$3.95
52-Week High (11/24/2017)	\$10.00
52-Week Low (3/21/2018)	\$2.05
Market Cap. (MM)	\$32
Shares Out. (MM)	6.1

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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 pilot Phase II trial	1H19	***
AIT-PH	Pulmonary hypertension (hospital use)	Potential 510k regulatory filing	1Q19	****
		Potential approval	YE-19	****
		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

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 ~\$6.7MM 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.

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)	2015	2016	2017	2018	1Q19	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
Royalty revenues	0	0	0	0	0	0	0	0	0	5,739	11,441	20,269	31,292	40,866	50,523	56,339
Total revenue	0	0	0	0	0	0	0	0	0	5,739	34,054	106,374	202,128	295,829	386,557	461,605
COGS																
Total gross profit	0	0	0	0	0	0	0	0	0	5,739	2,261	8,611	17,084	25,496	33,603	40,527
Research and development	(1,167)	(1,620)	(1,868)	(4,636)	(1,063)	(850)	(901)	(919)	(3,734)	(6,162)	(6,408)	(7,497)	(8,022)	(8,343)	(8,093)	(7,284)
General and administrative	(989)	(589)	(3,081)	(5,311)	(693)	(714)	(721)	(730)	(2,858)	(3,115)	(3,364)	(3,600)	(3,780)	(3,969)	(4,167)	(4,376)
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)	(1,756)	(1,564)	(1,622)	(1,650)	(6,592)	(9,277)	(37,772)	(41,897)	(44,142)	(46,269)	(47,575)	(48,387)
Operating Incomes (losses)	(2,156)	(2,209)	(4,949)	(9,947)	(1,756)	(1,564)	(1,622)	(1,650)	(6,592)	(3,537)	(5,980)	55,867	140,903	224,063	305,378	372,691
Other Income/(Expense)																
Financial expense	411	994	3,738	772	1,245	(170)	160	100	1,335	1,469	1,615	1,777	1,955	2,150	2,365	2,602
Revaluation of warrants to purchase Conve	2,055	152														
Total other income (expense), net	2,466	1,146	3,738	772	1,245	(170)	160	100	1,335	1,469	1,615	1,777	1,955	2,150	2,365	2,602
Pretax income	(4,622)	(3,355)	(8,687)	(10,719)	(3,001)	(1,394)	(1,782)	(1,750)	(7,927)	(2,069)	(4,365)	57,643	142,857	226,213	307,744	375,293
Tax on income	0	127	11	8	5	0	0	0	5	0	0	(21,328)	(52,857)	(83,699)	(113,865)	(138,858)
Net Income (Loss)	(4,622)	(3,482)	(8,700)	(10,711)	(2,996)	(1,394)	(1,782)	(1,750)	(7,922)	(2,069)	(4,365)	36,315	90,000	142,514	193,878	236,435
Basic and diluted net loss per share		(\$1.64)	(\$2.84)	(\$1.67)	(\$0.36)	(\$0.16)	(\$0.20)	(\$0.19)	(\$0.90)	(\$0.17)	(\$0.28)	\$2.22	\$5.35	\$8.22	\$10.87	\$12.89
Shares outstanding: basic and undiluted		2,123	3,061	6,396	8,400	8,700	9,000	9,250	8,838	11,838	15,838	16,338	16,838	17,338	17,838	18,338
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	-107%	-19%	-7%	-4%	-3%	-2%	-2%
G&A		NA	NA	NA	NA	NA	NA	NA	NA	-54%	-10%	-3%	-2%	-1%	-1%	-1%
M&S		NA	NA	NA	NA	NA	NA	NA	NA	0%	-82%	10%	5%	5%	4%	4%
Operating Income (loss)		NA	NA	NA	NA	NA	NA	NA	NA	-62%	-18%	53%	70%	76%	79%	81%
Pretax		NA	NA	NA	NA	NA	NA	NA	NA	-36%	-13%	54%	71%	76%	80%	81%
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	-36%	-13%	34%	45%	48%	50%	51%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue		NA	NA	NA	NA	NA	NA	NA	NA	NA	493%	212%	90%	46%	31%	19%
Gross Profit		NA	NA	NA	NA	NA	NA	NA	NA	NA	454%	208%	89%	46%	31%	19%
Cost of Goods		NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	281%	98%	49%	32%	21%
R&D		39%	15%	148%	80%	-29%	-26%	-44%	-19%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	423%	72%	-72%	-40%	-38%	-9%	-46%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	124%	101%	-43%	-24%	-32%	-32%	-34%	41%	307%	11%	5%	5%	3%	2%
Pretax Income		-27%	159%	23%	4%	-80%	3%	-267%	-26%	-74%	111%	-1421%	148%	58%	36%	22%
Net Income		-25%	150%	23%	4%	-80%	3%	-268%	-26%	-74%	111%	-932%	148%	58%	36%	22%
EPS		NA	73%	-41%	-23%	-86%	-30%	-231%	-46%	-81%	58%	-907%	140%	54%	32%	19%

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

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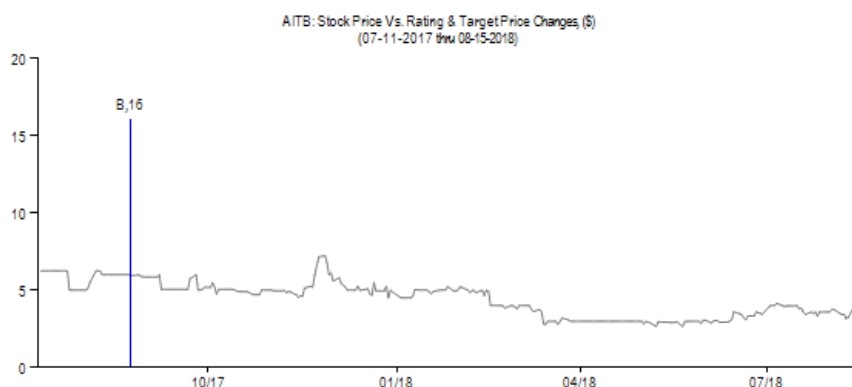
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Rating and Price Target Change History



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.	61.82%	21.82%	3.64%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.64%	1.82%	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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Sparton Corp. (SPA – Not Rated)

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