

AIT Therapeutics (AITB - \$3.75)

Letter of Intent (LOI) of AIT-PH in PPHM (GeNOvent) with Partner Signed with Full Details Available in 45 Days

Last Friday after market close, AITB announced the signing of a letter of intent (LOI) for partnering GeNOvent with an unnamed company. The name of the company will be revealed upon the signing of a definitive agreement and board approvals from both companies within the next 45 days.

- Details.** Although the name of the company was not revealed, AITB provided substantial details of the deal and impact on AITB's future development. It mainly is a deal that covers the U.S. and one other country. AITB still owns the commercial rights for the EU, Asia, and ROW. Deal terms highlights include: 1) the indications include persistent pulmonary hypertension of the newborn (PPHN) and future related indications using ≤ 80 ppm NO in hospital setting; 2) AITB is entitled to a total of \$32.5MM up front and regulatory milestones payment with \$31.5MM associated with the US market. We believe the majority of the U.S. related payment could be received within the next 12 months; 3) AITB is entitled for gross profit-based royalties from GeNOvent sales. For the first \$100MM annual gross profit, royalty rate is 15%; and $> \$100$ MM, 20%. Further, 5% for the cumulative gross profit reaching the first \$50MM; 4) AITB will be responsible for the production and reimbursed by the partner for the generator systems and filters; and 5) AITB is responsible for PMA filing and system repairs; while the partner is responsible for all marketing and sales efforts, including technical support. GeNOvent PMA submission is on-track for 2Q19 with potential approval in late 2019 or early 2020. AITB also highlighted the impact from the deal: It provides cash with runway potentially to 2Q20 for pivotal bronchiolitis and pilot NTM studies (both expected to start in late 4Q19); and support AITB stock up-listing to NASDAQ.
- Implications.** We view the news an important positive catalyst for AITB shares as it is a successful first step in monetizing this asset as the company promised. Important partner-choosing criteria include a company that has a significant hospital installed base and a strong commitment and focus for commercializing GeNOvent in the U.S. We believe the partner might be a publicly listed company. The expected cash infusion could facilitate AITB advancing its two therapeutic pipeline programs, especially the advanced stage pivotal bronchiolitis study.
- 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	-0.53A	-0.24	0.88	-0.19	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 (12/28/2018)	\$3.75
52-Week High (10/17/2018)	\$5.49
52-Week Low (3/21/2018)	\$2.05
Market Cap. (MM)	\$33
Shares Out. (MM)	6.1

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- **AIT-NTM and AIT-BRO development updates.** AITB completed a positive meeting earlier with the FDA regarding the AIT-NTM development and plans to conduct a pilot study before YE19. The proposed study design could include a one-week hospital treatment, followed by a 12-week at-home use with 2x/day dosing. The projected patient size is 15. The proposed 4Q19 started NO-BRO in bronchiolitis pivotal trial could complete by 2Q20, with study design similar to that of the prior Phase II study. The study could recruit 200+ patients, in order to potentially achieve a statistically significant readout. Possible endpoints could include shortening of hospital stay. Should the study outcome be positive, and approval received, NO-BRO could potentially reach the market for the 2021 winter season.

Anticipated milestones in 2019 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 start pilot Phase II trial	1H19	***
AIT-PH	Pulmonary hypertension (hospital use)	Potential PMA regulatory filing	2Q19	****
		Potential approval	YE-19	****
		Formerly sign partnership	1Q19	****

**** / ***** 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 ended the quarter with ~\$4.9MM 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.

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	2Q19	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/MS revenues	0	0	0	0	0	0	0	10,000	10,000	13,739	11,441	20,269	31,292	40,866	50,523	56,339
Total revenue	0	0	0	0	0	0	0	10,000	10,000	13,739	34,054	106,374	202,128	295,829	386,557	461,605
COGS										0	2,261	8,611	17,084	25,496	33,603	40,527
Total gross profit	0	0	0	0	0	0	0	10,000	10,000	13,739	31,792	97,764	185,045	270,332	352,954	421,079
Research and development	(1,167)	(1,620)	(1,868)	(4,636)	(1,063)	(648)	(1,166)	(1,190)	(4,067)	(6,711)	(6,979)	(8,166)	(8,737)	(9,087)	(8,814)	(7,933)
General and administrative	(989)	(589)	(3,081)	(5,311)	(693)	(1,765)	(759)	(769)	(3,986)	(4,344)	(4,692)	(5,020)	(5,272)	(5,535)	(5,812)	(6,102)
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)	(2,413)	(1,925)	(1,959)	(8,053)	(11,055)	(39,671)	(43,986)	(46,349)	(48,579)	(49,941)	(50,763)
Operating Incomes (losses)	(2,156)	(2,209)	(4,949)	(9,947)	(1,756)	(2,413)	(1,925)	8,041	1,947	2,684	(7,879)	53,778	138,696	221,754	303,013	370,316
Other Income/(Expense)																
Financial expense	411	994	3,738	772	1,245	2,050	160	100	3,555	3,911	4,302	4,732	5,205	5,725	6,298	6,928
Revaluation of warrants to purchase Conv	2,055	152														
Total other income (expense), net	2,466	1,146	3,738	772	1,245	2,050	160	100	3,555	3,911	4,302	4,732	5,205	5,725	6,298	6,928
Pretax income	(4,622)	(3,355)	(8,687)	(10,719)	(3,001)	(4,463)	(2,085)	7,941	(1,608)	6,594	(3,577)	58,509	143,901	227,479	309,311	377,243
Tax on income	0	127	11	8	5	0	0	0	5	(2,440)	0	(21,648)	(53,243)	(84,167)	(114,445)	(139,580)
Net Income (Loss)	(4,622)	(3,482)	(8,700)	(10,711)	(2,996)	(4,460)	(2,085)	7,941	(1,603)	4,154	(3,577)	36,861	90,658	143,312	194,866	237,663
Basic and diluted net loss per share		(\$1.64)	(\$2.84)	(\$1.67)	(\$0.36)	(\$0.53)	(\$0.24)	\$0.88	(\$0.19)	\$0.36	(\$0.23)	\$2.31	\$5.50	\$8.43	\$11.14	\$13.21
Shares outstanding: basic and undiluted		2,123	3,061	6,396	8,400	8,440	8,740	8,990	8,643	11,490	15,490	15,990	16,490	16,990	17,490	17,990
Margin Analysis (% of Sales/Revenue)																
Costs of goods		NA	NA	NA	NA	NA	NA	0%	0%	10%	10%	10%	10%	10%	10%	10%
R&D		NA	NA	NA	NA	NA	NA	-12%	-41%	-49%	-20%	-8%	-4%	-3%	-2%	-2%
G&A		NA	NA	NA	NA	NA	NA	-8%	-40%	-32%	-14%	-5%	-3%	-2%	-2%	-1%
M&S		NA	NA	NA	NA	NA	NA	0%	0%	0%	-82%	10%	5%	5%	4%	4%
Operating Income (loss)		NA	NA	NA	NA	NA	NA	80%	19%	20%	-23%	51%	69%	75%	78%	80%
Pretax		NA	NA	NA	NA	NA	NA	79%	-16%	48%	-11%	55%	71%	77%	80%	82%
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	79%	-16%	30%	-11%	35%	45%	48%	50%	51%
Financial Indicator Growth Analysis (YoY%)																
Total Revenue		NA	NA	NA	NA	NA	NA	NA	NA	37%	148%	212%	90%	46%	31%	19%
Gross Profit		NA	NA	NA	NA	NA	NA	NA	NA	37%	131%	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%	-46%	-4%	-27%	-12%	65%	4%	17%	7%	4%	-3%	-10%
SG&A		-40%	423%	72%	-72%	48%	-35%	-4%	-25%	9%	8%	7%	5%	5%	5%	5%
Operating Income (Losses)		2%	124%	101%	-43%	17%	-19%	-20%	-19%	37%	259%	11%	5%	5%	3%	2%
Pretax Income		-27%	159%	23%	4%	-38%	20%	658%	-85%	-510%	-154%	-1736%	146%	58%	36%	22%
Net Income		-25%	150%	23%	4%	-38%	20%	661%	-85%	-359%	-186%	-1130%	146%	58%	36%	22%
EPS		NA	73%	-41%	-23%	-55%	-16%	509%	-89%	-295%	-164%	-1098%	138%	53%	32%	19%

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

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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.	61.67%	25.00%	3.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.67%	1.67%	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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