

AIT Therapeutics (AITB - \$5.00)

Healthcare/Biotechnology

eNOGenerator Acquisition Provides an FDA Designated NO Delivery System for Future Clinical Developments

AITB yesterday announced the intent to license a novel inhaled nitric oxide (NO) delivery system, eNOGenerator, from NitricGen. Two senior managers also joined AITB as part of the senior management team focusing on technology.

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

- Details.** AITB announced yesterday that the company entered into a letter of intent to acquire exclusive global rights for eNOGenerator and its associated critical assets, like IP and others, from NitricGen. It is a novel NO delivery system with an FDA designation as a medical device that can deliver NO to the lungs at concentrations ranging from 1 - 400 ppm. In addition, the device can deliver NO via either intermittent or continuous dosing. eNOGenerator's setup for in home use will not require coupling with large high-pressure NO cylinders. Inventory, storage requirements, or external oxygen are not needed for use in a hospital setting. The NO generator system weighs ~7lbs for high concentration delivery and can be scaled down for lower concentration use at home. Terms of the deal include a total of \$2MM in up-front and milestone payments, which we believe are mostly back-end loaded. NitricGen is also entitled to a sales-based low single-digit royalty and rights for purchasing AITB warrants (100K shares).

Trading Data:

Last Price (11/1/2017)	\$5.00
52-Week High (8/7/2017)	\$7.50
52-Week Low (10/23/2017)	\$4.71
Market Cap. (MM)	\$30
Shares Out. (MM)	0.103

- Implications.** We view this news as an important positive development for AITB shareholders. First, the acquired eNOGenerator will provide AITB a novel and patented NO delivery system with an FDA designation that could facilitate future clinical developments, like MABSC (NOxNTM) and infant bronchiolitis (NOxBR). In addition, AITB will have the option for developing both therapies via a medical device regulatory path (via PMA) instead of a drug (via NDA). Such a possibility could potentially shorten the development time. We believe the two newly hired managers have extensive experience in developing some of the major NO delivery systems for the current market leader (INOmax by Mallinckrodt) and in more advanced clinical development (INOpulse in PAH at Phase III by Bellerophon). As such, AITB could gain enhanced technical capabilities for their future development.

- 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. 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
FY-17E	-1.12A	-0.46A	-0.56	-0.57	-2.66	N.A.
FY-16A	-0.59	-0.44	-0.20	-0.45	-1.69	N.A.
FY-15A	N.A.	N.A.	N.A.	N.A.	-1.64	N.A.
FY-14A	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.

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Source: Laidlaw & Company estimates

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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	1H18	****
		Potentially start 2nd Phase III trial	Late 2018	***
		Potentially report 2nd Phase III trial data	2H19	****
NOxNTM	NTM infection (Mycobacterium abscessus or MABSC)	Report Phase II trial results	4Q17	****
		Potentially start Phase III trial	2H18	***

**** / ***** 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 ~\$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
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	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
Total revenue	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
COGS																				
Total gross profit	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)
Total operating expenses	(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)
Operating Incomes (losses)	(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
Other Income/(Expense)																				
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																		
Total other income (expense), net	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)
Net Income (Loss)	(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
Margin Analysis (% of Sales/Revenue)																				
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%
Financial Indicator Growth Analysis (YoY%)																				
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 & Company estimates

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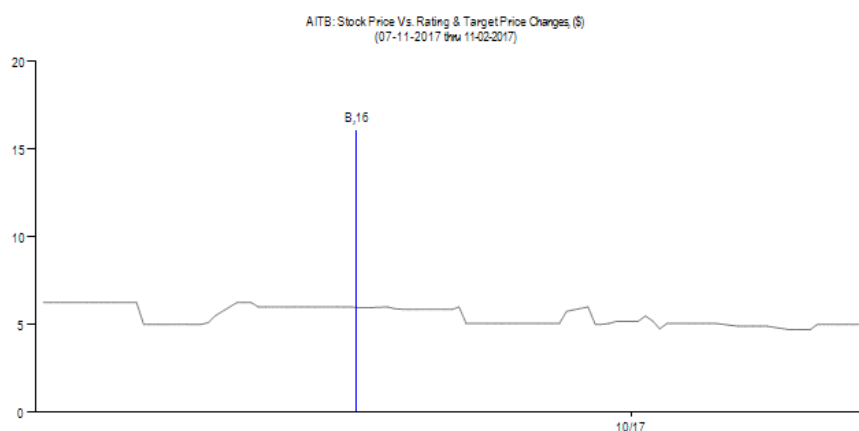
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Date	Rating	Closing Price (\$)
08/24/2...	Buy (B)	5.95

3 Year Price Change History

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

Source: Laidlaw & Company

Created by: Blue-Compass.net

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			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.	64.58%	31.25%	2.08%
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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)
Bellerophon (BLPH – Not Rated)

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