

## Affimed N.V. (AFMD - \$ 3.86)

### KOL Hodgkin's Lymphoma Day Takeaways

AFMD hosted a KOL Hodgkin's Lymphoma (HL) Day yesterday highlighting HL treatment progressions and emerging treatment modalities. Major takeaways are:

- Despite encouraging early PD-1 mono-therapy clinical results, AFM13 combination could add value if it improves CR rate.** Given AFMD just announced it will start an AFM13/Keytruda combination Phase Ib dose-finding trial, great investor interest has been placed on the potential of this regimen. Dr. Andrew Evens from Tufts Medical School summarized Phase I clinical results of two PD-1 inhibitors in r/r HL. Opdivo (nivolumab) (n=23) demonstrated 87% ORR and 22% CR (3mg/kg Q2 wk) and with PFS not reached. Keytruda (pembrolizumab) (n=31) demonstrated 65% ORR and 16% CR (10mg/kg Q2 wk) (Figure 1). Together, PD-1 exhibited a high ORR but low CR and could potentially be suited for a combination setting, possibly with another IO therapy. Although the PD-1 in HL clinical data are preliminary; two physicians (Drs. Evens and Andreas Engert) indicated that they would use AFM13/PD-1 combo therapy if CR rates are doubled and/or with increased duration of response over PD-1 alone. AFMD is scheduled to start the study in 1H16, and we estimate certain clinical results potentially could be available in late 2016 or 2017 – a critical catalyst for AFMD share value, in our opinion. An Opdivo in r/r HL registration trial (CheckMate 205) is underway with preliminary data possibly in 2H16.
- Not all CD30 targeted therapies are the same.** Although AFM13 is not the first CD30 targeted biologics, and Adcetris is already approved for r/r HL treatment; AFM13, in our opinion, could potentially demonstrate a different treatment effect vs. Adcetris possibly due to a different cell killing mechanism. Adcetris delivers chemotherapy specifically into the cancer cell with certain chemotherapy associated pros and cons. AFM13 utilizes NK cells for cancer cell eradication. We find it encouraging that AFM13 has demonstrated efficacy in treating Adcetris failure HL patients (remain CD30<sup>+</sup>) from a prior Phase I study. Given short PFS and relatively high neuropathy is part of the shortcomings of Adcetris, AFM13 could have potential to treat earlier r/r HL patients if the safety profile is satisfactory and ORR is increased.
- Action.** We are reiterating our Buy rating and our \$15 target price based on peer comparable, probability adjusted DCF and sum-of-the-parts analyses to reflect the continued execution of pipeline advancements.

### Earnings Estimates: (€per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.24	-0.24	-0.27	-0.27	-1.02	N.A.
<b>FY-15E</b>	-0.06A	-0.19A	-0.24A	-0.11	-0.60	N.A.
<b>FY-14A</b>	-1.06	0.03	0.37	0.32	-0.01	N.A.
<b>FY-13A</b>	-57.58	-131.42	-40.36	-0.17	-1.76	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **AFMD**  
Rating: **Buy**  
Price Target: **\$ 15.00**

### Trading Data:

Last Price (01/26/2016)	\$ 3.86
52-Week High (7/17/2015)	\$ 24.20
52-Week Low (1/20/2016)	\$ 2.95
Market Cap. (MM)	\$ 128
Shares Out. (MM)	33

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- **AFM13 could repair impaired NK cells of tumor patients.** AFMD pointed out that AFM13 could repair NK cells of tumor patients and enable them in eradicating cancer cells. The specific mechanisms have not been elucidated.

**Figure 1: Efficacy of Opdivo (left) and Keytruda (right) from Phase I trials**

	Opdivo (n=23)		Keytruda (n=31)					
					Transplant ineligible/refused		Transplant failure	
n=	23		31		9		22	
ORR (n,%)	20	87%	20	65%	4	44%	16	73%
CR (n,%)	5	22%	5	16%	2	22%	3	14%
PR (n,%)	15	65%	15	48%	2	22%	13	59%
SD (n,%)	3	13%	7	23%	3	33%	4	18%
PD (n,%)	0	0%	4	13%	2	22%	2	9%

Source: Laidlaw Equity Research and 2015 ASH presentations

## Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
AFM13	Hodgkin's lymphoma (r/r)	Potentially report Phase IIa study interim results	1H16	**
		Potentially start a Phase I CPI combination Phase I study	1H16	****
		Potentially report Phase IIa study preliminary top-line results	2H16	***
		Potentially report Phase I CPI combination Phase I study results	Late 2016/2017	****
	CD30+ lymphoma	Potentially report Phase IIa study results	2017	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study interim results	2H16	****
	Acute lymphoblastic leukemia (ALL)	Potentially start Phase I study	1Q16	***
AFM21/22	Solid tumors	Potentially select clinical candidate and IND enabling study	1H16	***
		Potentially start Phase I study	2H17	***

\*\*\*\* / \*\*\*\*\* 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 AFMD share value.** Despite promising pre-clinical and Phase I trial results of the company's lead products, AFM13 and AFM11, it remains too early to predict the longer term safety and efficacy from the current ongoing clinical studies. Given clinical validation for these programs has not been fully established, it would be critical for some or all of these studies to demonstrate positive outcomes in order to increase the assets and shareholder value. Negative results of either Phase II studies could have a materially negative impact on the asset and shareholder value; especially each study could fail to illustrate proof-of-concept for AFM13 and AFM11 as potential treatment of different disease indications. Further, it remains too early to predict any potential success of clinical trials in the future should these programs further advance into next clinical stage development.

**Yet-to-be-validated NK cell platform and rapidly changing dynamic of IO platforms as cancer therapy could create more uncertainty.** Although multiple prior pre-clinical and clinical data from many investigators suggest that NK cell based therapy could have significant potential for treating cancer; currently there is no NK-cell based therapy that is approved or in late clinical stage cancer treatment development. As such, clinical risks for NK-cell based cancer therapy are higher than other treatment modalities. In addition, multiple types of immune-oncology (IO) therapy platforms (i.e. CPI and CAR-T) are all in relatively early and active development, it remains too early to predict, especially for the one that has not yet received approval, which platform could be approved and gaining market shares in the future. Bi- and tri-specific antibodies can be categorized into the IO therapy group.

**Product may not be approved or reach anticipated sales.** Although AFMD's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials; it remains too early to project whether any of these products would be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect AFMD shareholder value.

**Additional financings could dilute shareholder value.** Although the company currently has ~\$83MM (pro forma) cash after recent financing, AFMD could need more financial resources going forward if they want to expand and further develop their pipeline. Should the future operational expenses, especially from R&D, increase significantly, products not receive FDA approval, or product revenue does 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.

Figure 1: Income Statement

Affirmed N.V. – Income Statement																	
(€MM)	2014	1Q15	2Q15	3Q15	4Q15E	2015E	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<b>Revenue</b>																	
Product revenue	0.0	-	-	-	-	0.0					0.0	0.0	0.0	21.8	49.9	155.6	480.9
Research revenue	3.4	2.5	2.2	1.2	2.1	8.0	1.5	1.7	1.4	1.9	6.5	6.5	6.5	6.5	6.5	6.5	6.5
Other revenue	0.4	0.2	0.1	0.3	0.2	0.8	0.2	0.2	0.2	0.2	0.8	0.8	0.8	0.8	0.8	0.8	0.8
Total revenue	3.8	2.8	2.3	1.5	2.3	8.8	1.7	1.9	1.6	2.1	7.3	7.3	7.3	29.1	57.2	163	488
<b>Costs of goods</b>														3.3	7.5	23.3	72.1
Gross sales														18.5	42.4	132.3	408.7
Research and development	(9.6)	(2.9)	(5.6)	(6.4)	(6.9)	(21.9)	(7.2)	(7.5)	(8.0)	(8.6)	(31.4)	(35.5)	(38.7)	(42.1)	(45.5)	(48.7)	(52.1)
General and administrative	(2.3)	(1.8)	(1.7)	(2.1)	(2.2)	(7.7)	(2.2)	(2.2)	(2.3)	(2.4)	(9.2)	(10.5)	(11.0)	(11.6)	(12.1)	(12.7)	(13.4)
Marketing and sales														(21.0)	(26.3)	(30.2)	(31.7)
<b>Total Operating Expenses</b>	(11.9)	(4.8)	(7.3)	(8.5)	(9.1)	(29.6)	(9.5)	(9.8)	(10.3)	(11.0)	(40.6)	(46.0)	(49.7)	(74.7)	(83.9)	(91.6)	(97.2)
<b>Operating Incomes (losses)</b>	(8.2)	(2.0)	(5.0)	(7.1)	(6.8)	(20.8)	(7.8)	(7.9)	(8.7)	(8.9)	(33.3)	(38.7)	(42.4)	(48.9)	(34.2)	48.0	318.9
Finance income / (costs) - net	7.8	0.5	(0.2)	(0.2)	3.1	3.2	(0.5)	(0.5)	(0.5)	(0.5)	(2.0)	(2.0)	(2.0)	(2.0)	(2.0)	(2.0)	(2.0)
Loss before tax	(0.4)	(1.5)	(5.2)	(7.3)	(3.7)	(17.6)	(8.3)	(8.4)	(9.2)	(9.4)	(35.3)	(40.7)	(44.4)	(50.9)	(36.2)	46.0	316.9
Tax	0.2	-	-	(0.0)	0.0	0.0	-	-	-	-	0.0	0.0	0.0	0.0	0.0	(17.0)	(117.2)
<b>Net Income (Loss)</b>	(0.3)	(1.5)	(5.2)	(7.3)	(3.6)	(17.6)	(8.3)	(8.4)	(9.2)	(9.4)	(35.3)	(40.7)	(44.4)	(50.9)	(36.2)	29.0	199.6
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(1.5)	(5.2)	(7.3)	(3.6)	(17.6)	(8.3)	(8.4)	(9.2)	(9.4)	(35.3)	(40.7)	(44.4)	(50.9)	(36.2)	29.0	199.6
Net Income (Loss) Applicable to Common Shareholders (\$)	(0.3)	(1.6)	(5.6)	(7.9)	(3.8)	(19.0)	(8.8)	(8.9)	(9.8)	(10.0)	(37.5)	(43.2)	(47.2)	(54.1)	(38.5)	30.8	212.4
Net Earnings (Losses) Per Share—Basic	(€0.01)	(€0.06)	(€0.19)	(€0.24)	(€0.11)	(€0.60)	(€0.24)	(€0.24)	(€0.27)	(€0.27)	(€1.02)	(€1.14)	(€1.18)	(€1.07)	(€0.72)	€0.55	€3.73
Net Earnings (Losses) Per Share—Diluted	(€0.01)	(€0.06)	(€0.19)	(€0.24)	(€0.11)	(€0.60)	(€0.24)	(€0.24)	(€0.27)	(€0.27)	(€1.02)	(€1.14)	(€1.18)	(€1.07)	(€0.72)	€0.55	€3.73
Net Earnings (Losses) Per Share—Basic/diluted (\$)	(\$0.01)	(\$0.07)	(\$0.20)	(\$0.26)	(\$0.12)	(\$0.64)	(\$0.26)	(\$0.26)	(\$0.28)	(\$0.29)	(\$1.09)	(\$1.22)	(\$1.26)	(\$1.14)	(\$0.76)	\$0.59	\$3.96
Shares outstanding—basic	22.0	24.0	27.8	30.8	34.1	29.1	34.3	34.5	34.7	34.9	34.6	35.6	37.6	47.6	50.6	52.6	53.6
Shares outstanding—diluted	22.0	24.0	27.8	30.8	34.1	29.1	34.3	34.5	34.7	34.9	34.6	35.6	37.6	47.6	50.6	52.6	53.6
<b>Margin Analysis (% of Sales/Revenue)</b>																	
Costs of goods														15%	15%	15%	15%
R&D	-255%	-106%	-242%	-444%	-300%	-248%	-426%	-397%	-499%	-411%	-430%	-486%	-530%	-145%	-80%	-30%	-11%
SG&A	-62%	-67%	-72%	-142%	-94%	-88%	-130%	-118%	-145%	-115%	-126%	-144%	-151%	-40%	-21%	-8%	-3%
Operating Income (loss)	-217%	-72%	-215%	-486%	-293%	-235%	-456%	-414%	-545%	-426%	-456%	-530%	-580%	-168%	-60%	29%	65%
Pretax	-11%	-54%	-224%	-499%	-159%	-199%	-486%	-441%	-576%	-450%	-483%	-557%	-608%	-175%	-63%	28%	65%
Tax Rate													0%	0%	0%	37%	37%
Net Income	-7%	-54%	-224%	-502%	-157%	-199%	-486%	-441%	-576%	-450%	-483%	-557%	-608%	-175%	-63%	18%	41%
<b>Financial Indicator Growth Analysis (YoY%)</b>																	
Total Revenue	-34%	261%	206%	-27%	862%	135%	-39%	-18%	10%	-9%	-17%	0%	0%	299%	97%	185%	200%
R&D	-33%	-45%	172%	196%	76560%	128%	148%	34%	24%	25%	44%	13%	9%	9%	8%	7%	7%
SG&A	-67%	-61%	-62%	731%	-131%	230%	20%	33%	13%	13%	19%	14%	5%	5%	5%	5%	5%
Marketing and sales															25%	15%	5%
Operating Income (Losses)	-48%	-79%	-13%	1550%	-193%	154%	288%	58%	23%	33%	60%	16%	10%	15%	-30%	-240%	565%
Pretax Income	-98%	-91%	-1118%	-199%	-149%	4035%	457%	61%	27%	159%	101%	15%	9%	15%	-29%	-227%	589%
Net Income	-99%	-91%	-1208%	-199%	-148%	6684%	457%	61%	26%	162%	101%	15%	9%	15%	-29%	-180%	589%
EPS	-99%	-94%	-691%	-164%	-133%	5021%	290%	30%	12%	156%	69%	12%	3%	-9%	-33%	-177%	576%

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

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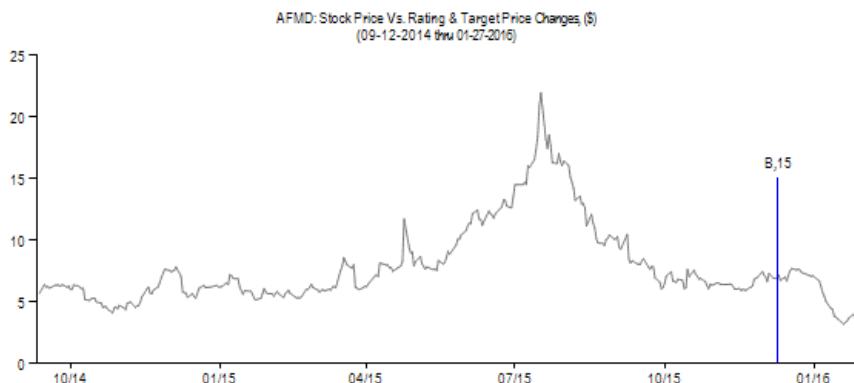
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#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
12/10/2015	Buy (B)	7.19

#### 3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
12/10/2015	15.00	7.19

Source: Laidlaw & Company

Created by: Blue-Compass.net

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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%
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<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
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