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EQUITY RESEARCH
Company Report

January 25, 2016

Affimed N.V. (AFMD - $ 4.38)

Healthcare/Biotechnology

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

AFM13/Keytruda in Relapsed/Refractory Hodgkin Lymphoma Phase Ib Trial to Start in 1H16

AFMD reported this morning that it will start a collaboration with Merck for an AFM13/Keytruda combination Phase Ib trial in relapsed/refractory Hodgkin lymphoma and is expected to initiate the study in 1H16.

- **Details.** The Phase Ib trial is a dose finding study for establishing an optimal dosing regimen and assessing its safety and efficacy. Eligible relapsed/refractory HL patients would also include those who have failed Adcetris (conjugate anti-CD30^{+} antibody) therapy. AFMD is responsible for funding and conducting the Phase Ib clinical study and the company reiterated it will initiate the study in 1H16.
- **Implications.** We are very encouraged by the collaboration between AFMD and Merck for the commencement of the AFM13/Keytruda combination trial. To explore clinical studies of AFM13 in combination with a check point inhibitor (CPI) as cancer treatment has been one of the major emphases of AFMD's goal to establish AFM13's position in the upcoming immuno-oncology (IO) treatment paradigm. Among various IO treatments, CPI, such as anti-PD1 and/or PDL-1 is likely to become one of foundation medicines going forward, in our opinion. During last year's ASCO and ASH meetings, AFMD presented encouraging pre-clinical results demonstrating that the AFM13 and PD-1 combination afforded enhanced anti-tumor activities, while various AFM13/CPI combinations could potentially boost immunity from other effector systems, judging from the increased tumor infiltrating NK or T cells. For instance, the combination of AFM13 with either anti-CTLA-4 or anti-PD-1 antibodies augmented the number of tumor infiltrating T cells, while AFM13 alone did not achieve this goal. AFM13 and PD-1 combination also stimulated cytokine release in tumors. Together, we believe such results are consistent with the theory that an activated innate immunity could trigger the adaptive immune response, resulting in a potentially synergistic therapeutic effect. The upcoming Phase Ib study would be the first test in humans to potentially validate this hypothesis. We estimate certain clinical results could be available in late 2016 or 2017; which we view as a critical catalyst for AFMD share value.
- **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.

Trading Data:

Last Price (01/22/2016)	$ 4.38
52–Week High (7/17/2015)	$ 24.20
52–Week Low (1/20/2016)	$ 2.95
Market Cap. (MM)	$ 123
Shares Out. (MM)	33

Earnings Estimates: (€ per share)

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

Source: Laidlaw & Company estimates

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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 preliminlary 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 interium 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

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Major Risks

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.

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Figure 1: Income Statement

Affimed N.V. – Income Statement

(€'MM)	2014	1Q15	2Q15	3Q15	4Q15E	2015E	1Q16E	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Revenue																	
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
Costs of goods														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)
Total Operating Expenses	(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)
Operating Incomes (losses)	(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)
Net Income (Loss)	(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
Margin Analysis (% of Sales/Revenue)																	
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%	0%	37%	37%
Net Income	-7%	-54%	-224%	-502%	-157%	-199%	-486%	-441%	-576%	-450%	-483%	-557%	-608%	-175%	-63%	18%	41%
Financial Indicator Growth Analysis (YoY%)																	
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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Additional information available upon request.

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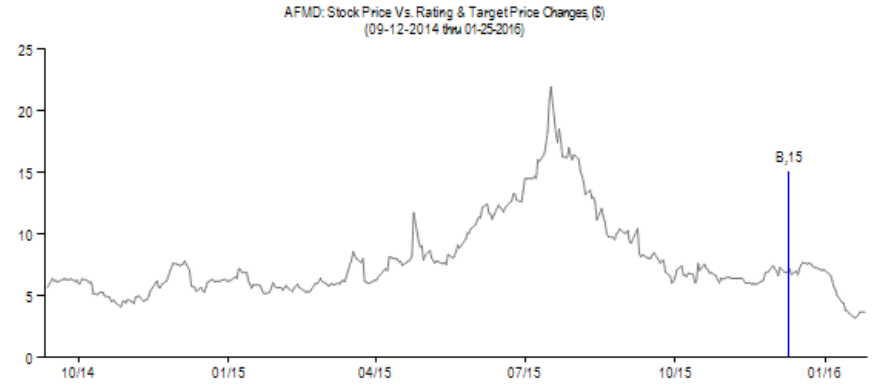
Rating and Price Target Change History



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**

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.	64.71%	26.47%	2.94%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	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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Merck (MRK – Not Rated)

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