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EQUITY RESEARCH
Company Report

December 12, 2016

Affimed N.V. (AFMD - $ 2.00)

Healthcare/Biotechnology

Management Meetings With Investors Update After ASH

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

On the heels of the ASH meeting, our meetings with AFMD management and investors provided us some new insights on the company's leading products in development and emerging pipeline. Highlights include:

- **There is a potential opportunity for AFM13 as part of a second-line HL treatment.** While the objective of achieving a 30% or higher CR for the AFM13 combo Phase II study remains unchanged, recent developments might have provided an interesting clinical path for the drug. Management reiterated the timeline for the interim read (n~9) in 1H17 and much more matured data in 2H17. At the ASH, Merck reported robust results of Keytruda in a r/r classical HL Phase II (KEYNOTE-013) trial which includes 3 cohorts (n=210). The first 2 cohorts are post-Adcetris (3rd line) while the third is Adcetris naïve (2nd line). The ORR of the 3rd cohort (n=60) is 70% (20% CR & 50% PR). The figures of other cohorts are relatively similar. ORR, CR and PR of Adcetris in cHL are similar (70%, 32% & 40%). Keytruda exhibited a better durability of response (mainly PR) than Adcetris (15 vs. 3 months based on product insert). Should AFM13/Keytruda exhibit greater CR, the combination could be very competitive as a second-line therapy; while Keytruda is very likely to gain approval as third-line treatment in 1Q17 based on remaining KEYNOTE-013 results. Opdivo currently is approved as a third-line cHL treatment. In addition, potential of AFM13/Keytruda as a possibly more potent third-line treatment remains another option. AFMD reported at the ASH preclinical study indicating bi-engaged NK cells could proliferate and with IL-15 expand a critical cytokine.
- **Potential bispecific in NHL competitive landscape could still provide room for AFM11.** The slower progress of the AFM11 was a concern of investors despite its potential as a better CD3/CD19 T cell engager. The progress of other like-minded bispecific Abs also was not so robust, and potentially could afford more room for AFM11. For instance, Regeneron's REGN1979 (CD20/CD3) in NHL Phase I (n=25) showed only a modest 20% ORR (4% CR, 16% PR) vs. historical CD19/CD3 results (39% of Blincyto). Further, MacroGenics and JNJ's MGD011 (JNJ-64052781) in r/r NHL Phase I/II trial was suspended according to clinicaltrial.gov.
- **Action.** We are reiterating our Buy rating and our $15 target price based on peer comparable, probability adjusted m and sum-of-the-parts analyses to reflect the continued execution of pipeline advancements.

Trading Data:

Last Price (12/09/2016)	$ 2.00
52–Week High (12/18/2015)	$ 8.26
52–Week Low (11/2/2016)	$ 1.75
Market Cap. (MM)	$ 67
Shares Out. (MM)	33

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.25A	-0.24A	-0.31A	-0.31	-1.11	N.A.
FY-15A	-0.06	-0.19	-0.24	-0.19	-0.71	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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- **Emerging pipelines are promising.** AFM24 and AFM26 are the two preclinical stage pipeline compounds gaining increasing interest. AFM24 (EGFRwt/CD16a) is a NK-engaging bispecific antibody targeting wildtype EGFR with potential for treating EGFR high expressing solid tumors, such as NSCLC and H&N cancers. AFMD is scheduled to report the preclinical non-human primate toxicity study results of AFMD24 in 1H17. AFM26 (BCMA/CD16a) is an earlier (discovery) preclinical NK bi with the potential for treating multiple myeloma (MM). Management suggested that AFMD26 could potentially be used coupling with activated NK cells and carried out concurrently with transplantation in MM patients, with the objective for further enhancing the treatment efficacy. AFMD is interested in discussing with prospective partners for collaboration on the two programs.

  B-cell maturation antigen or BCMA, a member of the tumor necrosis factor family, has become very promising target for MM treatment given it is universally expressed in MM cases. BCMA is only expressed in plasma cells and very limited B cells. BCMA-targeted CAR-T, Mabs and bispecific Abs are underway and mainly in preclinical or early clinical developments.

  The CAR-T programs include: 1) **CART-BCMA** of Novartis /University of Pennsylvania in Phase I showed 45% (4/9) ORR with cytokine release syndrome (CRS) seen in 8/9; 2) **bb2121** of Bluebird Bio/Celgene showed a 100% (6/6) ORR in 2 high dose group (> $5X10^7$); 3) **BCMA CAR T** of Cellectis demonstrated promising preclinical data; 4) **KITE-585** from Kite plans to submit IND in 2017; and 5) **APRIL CAR** of Autolus targets APRIL, which is a ligand for BCMA and another tumor antigen called TACI. A Phase I trial is scheduled to start in 2Q17.

  Mabs programs include 1) **GSK2857916** of GSK is anti-BCMA antibody conjugated (ADC) to the microtubule disrupting agent monomethyl auristatin-F and exhibited 67% (6/9) ORR in high dose (3.4mg/kg) cohort; and 2) **BCMA antibody conjugated** (ADC) of Sutro Pharma and Celgene.

  Bispecific Abs programs which are all T-cell engagers include: 1) **EM901** of Celgene (acquired from EngMab in 4Q16 for $600MM) is CD3 bi with encouraging preclinical data; 2) **JNJ-957** of JNJ is another BCMA/CD3 bi in preclinical development with IND filing planned in 4Q17; and 3) **AMG 420** or BI 836909 of Amgen (acquired from Boehringer Ingelheim in 3Q16) is a BiTE and is currently being evaluated in Phase 1 studies..

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
AFM13	Hodgkin's lymphoma (r/r)	Potentially report Phase I CPI combination safety Phase I study results	**4Q16/1Q17**	***
		Potentially report Phase II CPI combination Phase II study results	**2017/2018**	****
	$CD30^+$ lymphoma	Potentially to start Phase IIa study (or in T cell lymphoma)	**2017**	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study timeline	**1H17**	****
	Acute lymphoblastic leukemia (ALL)	Potentially to report Phase I study results	**4Q17**	***
AFM24	Solid tumors	Potentially update progress	**1H17**	***
AMV564	Acute myeloid leukemia (AML)	Potentially start Phase I study	**2017**	***

***** / ***** 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 ~€67MM cash, 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	2015	1Q16	2Q16	3Q16	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	7.6	1.9	2.1	0.9	1.0	5.9	3.0	3.0	3.0	3.0	3.0	3.0
Other revenue	0.4	0.7	0.1	0.0	0.0	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Total revenue	3.8	8.2	2.0	2.1	1.0	1.1	6.2	3.2	3.2	25.0	53.1	159	484
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)	(22.0)	(7.1)	(8.6)	(8.8)	(9.2)	(33.7)	(37.7)	(41.1)	(44.8)	(48.4)	(51.8)	(55.4)
General and administrative	(2.3)	(7.5)	(2.1)	(2.0)	(2.2)	(2.3)	(8.5)	(9.4)	(9.8)	(10.3)	(10.8)	(11.4)	(11.9)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(9.2)	(10.6)	(10.9)	(11.5)	(42.2)	(47.1)	(50.9)	(76.1)	(85.4)	(93.3)	(99.0)
Operating Incomes (losses)	(8.2)	(21.3)	(7.1)	(8.5)	(10.0)	(10.4)	(36.0)	(43.8)	(47.7)	(54.3)	(39.8)	42.2	312.9
Finance income / (costs) - net	7.8	1.1	(1.3)	0.5	(0.3)	(0.3)	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)
Loss before tax	(0.4)	(20.2)	(8.5)	(8.0)	(10.3)	(10.7)	(37.5)	(45.3)	(49.2)	(55.8)	(41.3)	40.7	311.5
Tax	0.2	0.0	(0.0)	(0.0)	-	-	0.0	0.0	0.0	0.0	0.0	(15.1)	(115.2)
Net Income (Loss)	(0.3)	(20.2)	(8.5)	(8.0)	(10.3)	(10.7)	(37.5)	(45.3)	(49.2)	(55.8)	(41.3)	25.7	196.2
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(8.5)	(8.0)	(10.3)	(10.7)	(37.5)	(45.3)	(49.2)	(55.8)	(41.3)	25.7	196.2
Net Income (Loss) Applicable to Common Shareholders ($)	($0.3)	($21.8)	($9.0)	($8.9)	($11.0)	($11.3)	($39.8)	($48.2)	($52.3)	($59.4)	($43.9)	$27.3	$208.7
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.24)	(€ 0.31)	(€ 0.31)	(€ 1.11)	(€ 1.30)	(€ 1.33)	(€ 1.19)	(€ 0.83)	€ 0.49	€ 3.71
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.24)	(€ 0.31)	(€ 0.31)	(€ 1.11)	(€ 1.30)	(€ 1.33)	(€ 1.19)	(€ 0.83)	€ 0.49	€ 3.71
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.01)	($0.76)	($0.26)	($0.27)	($0.32)	($0.33)	($1.18)	($1.38)	($1.42)	($1.27)	($0.88)	$0.53	$3.95
Shares outstanding—basic	22.0	29.1	34.3	33.5	33.7	33.9	33.8	34.8	36.8	46.8	49.8	51.8	52.8
Shares outstanding—diluted	22.0	29.1	34.3	33.5	33.7	33.9	33.8	34.8	36.8	46.8	49.8	51.8	52.8
Margin Analysis (% of Sales/Revenue)													
Costs of goods										15%	15%	15%	15%
R&D	-255%	-268%	-350%	-409%	-915%	-836%	-544%	-1173%	-1278%	-179%	-91%	-33%	-11%
SG&A	-62%	-92%	-104%	-93%	-228%	-206%	-138%	-291%	-306%	-41%	-20%	-7%	-2%
Operating Income (loss)	-217%	-260%	-353%	-403%	-1043%	-942%	-582%	-1364%	-1484%	-217%	-75%	27%	65%
Pretax	-11%	-246%	-418%	-381%	-1076%	-970%	-606%	-1410%	-1530%	-223%	-78%	26%	64%
Tax Rate								0%	0%	0%	0%	37%	37%
Net Income	-7%	-246%	-418%	-381%	-1076%	-970%	-605%	-1410%	-1530%	-223%	-78%	16%	41%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-27%	-9%	-34%	-34%	-25%	-48%	0%	678%	112%	199%	205%
R&D	-33%	129%	142%	54%	36%	31%	53%	12%	9%	9%	8%	7%	7%
SG&A	-67%	222%	13%	17%	5%	16%	13%	10%	5%	5%	5%	5%	5%
Marketing and sales											25%	15%	5%
Operating Income (Losses)	-48%	161%	257%	71%	41%	42%	69%	22%	9%	14%	-27%	-206%	642%
Pretax Income	-98%	4662%	470%	55%	42%	69%	85%	21%	9%	14%	-26%	-199%	665%
Net Income	-99%	7713%	470%	55%	41%	70%	85%	21%	9%	14%	-26%	-162%	665%
EPS	-99%	5931%	299%	28%	29%	66%	56%	18%	3%	-11%	-30%	-160%	650%

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

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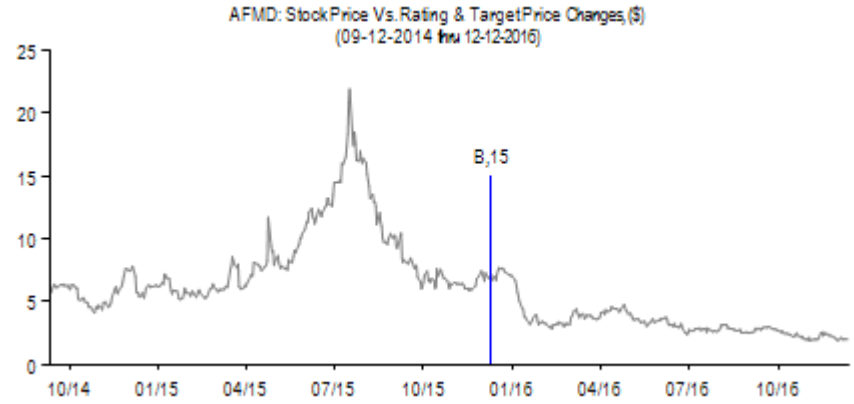
Rating and Price Target Change History



Source: Laidlaw & Company **Created by: Blue-Compass.net**

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

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.	2.56%	2.56%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Merck (MRK – Not Rated)
Regeneron Pharmaceuticals (REGN – Not Rated)
MacroGenics Inc. (MGNX – Not Rated)
Johnson & Johnson (JNJ – Not Rated)
Novartis (NVS – Not Rated)
Celgene (CELG – Not Rated)
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