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EQUITY RESEARCH
Company Report

July 14, 2016

Affimed N.V. (AFMD - $ 2.75)

Healthcare/Biotechnology

Management Updates with Focus on Possible Clinical Utility of AFM13 and AFM11

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

After our recent meeting with AFMD management, we are impressed by management's timely response in identifying therapeutic opportunities of its lead compounds AFM13 and AFM11 in various hematological cancers under a rapidly changing treatment landscape due to the recent and upcoming entries of different immune-oncological therapies.

- **AFM13/Keytruda combination key focus in r/r HL.** AFMD reaffirmed the difficulty of patient recruitment of its AFM13 monotherapy in r/r Hodgkin's Lymphoma (HL) Phase IIa study after the availability of PD-1 treatment. They view the HL monotherapy development could be very challenging near term. Instead, the AFM13/Keytruda combination regimen remains promising if it can improve the CR from 7% (PD-1 treatment alone) to the 20% - 30% range. Patient recruitment could be smoother as well. The ongoing combination trial remains on track to potentially report dose-finding Phase I (n=9) top-line results in 4Q16/1Q17. A Phase II portion (n=18) would start shortly thereafter with data potentially available in 2H17. AFMD recently has identified potential AFM13 monotherapy utility in T cell lymphoma and $CD30^+$ lymphoma based on the treatment landscape and unmet needs. AFMD is contemplating starting clinical studies in these indications with a decision likely in late 3Q16. A Columbia University physician sponsored AFM13 in $CD30^+$ lymphoma Phase Ia/IIb study might start later in 2H16. Together, we view the focusing on a combination regimen in r/r HL and monotherapy in the other two indications to be a more optimal path forward.
- **AFM11 development updates.** The AFM11 in non-Hodgkin's Lymphoma (NHL) Phase I study remains on track to report results by late 4Q16. An ALL (acute lymphoblastic leukemia) dose-finding Phase I study (Blincyto-naïve) is underway with top-line results potentially in late 4Q17. We view the safety readout as equally important as the efficacy signal. Given the recent events in the CAR-T arena (CD19 in ALL) and possible implication that severity of AE could be correlated with the treatment potency, it will be dually important to demonstrate AFM11's efficacy (more potent based on preclinical data) and that the drug has a well acceptable safety profile.
- **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 (07/14/2016)	$ 2.75
52–Week High (7/17/2015)	$ 24.20
52–Week Low (6/30/2016)	$ 2.34
Market Cap. (MM)	$ 91
Shares Out. (MM)	33

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.25A	-0.22	-0.24	-0.27	-0.98	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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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
AFM13	Hodgkin's lymphoma (r/r)	Potentially report Phase I CPI combination Phase I study results	**4Q16/1Q17**	***
		Potentially start Phase II CPI combination Phase II study	**1H17**	***
		Potentially report Phase II CPI combination Phase II study results	**2H17**	****
	$CD30^+$ lymphoma	Potentially to start Phase IIa study (or in T cell lymphoma)	**4Q16**	***
		Potentially to report Phase IIa study (Columbia) results	**2017**	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study interium results	**4Q16**	****
	Acute lymphoblastic leukemia (ALL)	Potentially to report Phase I study results	**4Q17**	***
AFM21/22	Solid tumors	Potentially select clinical candidate and IND enabling study	**2H16**	***
		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 ~€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	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	7.6	1.9	1.3	1.3	1.4	5.9	5.9	5.9	5.9	5.9	5.9	5.9
Other revenue	0.4	0.7	0.1	0.1	0.1	0.1	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Total revenue	3.8	8.2	2.0	1.4	1.4	1.5	6.3	6.3	6.3	28.1	56.2	162	487
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)	(7.4)	(7.8)	(8.4)	(30.6)	(34.6)	(37.7)	(41.1)	(44.4)	(47.5)	(50.8)
General and administrative	(2.3)	(7.5)	(2.1)	(2.1)	(2.2)	(2.3)	(8.7)	(9.9)	(10.4)	(10.9)	(11.5)	(12.0)	(12.6)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(9.2)	(9.5)	(10.0)	(10.7)	(39.3)	(44.5)	(48.1)	(73.0)	(82.1)	(89.7)	(95.2)
Operating Incomes (losses)	(8.2)	(21.3)	(7.1)	(8.1)	(8.6)	(9.2)	(33.0)	(38.2)	(41.8)	(48.2)	(33.4)	48.9	319.9
Finance income / (costs) - net	7.8	1.1	(1.3)	0.5	0.2	(0.3)	(0.9)	(0.9)	(0.9)	(0.9)	(0.9)	(0.9)	(0.9)
Loss before tax	(0.4)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	48.0	319.0
Tax	0.2	0.0	(0.0)	-	-	-	0.0	0.0	0.0	0.0	0.0	(17.7)	(118.0)
Net Income (Loss)	(0.3)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	30.2	200.9
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	30.2	200.9
Net Income (Loss) Applicable to Common Shareholders ($)	($0.3)	($21.8)	($9.0)	($8.0)	($8.9)	($10.1)	($36.1)	($41.6)	($45.4)	($52.2)	($36.5)	$32.1	$213.8
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.22)	(€ 0.24)	(€ 0.27)	(€ 0.98)	(€ 1.10)	(€ 1.14)	(€ 1.03)	(€ 0.68)	€ 0.57	€ 3.75
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.22)	(€ 0.24)	(€ 0.27)	(€ 0.98)	(€ 1.10)	(€ 1.14)	(€ 1.03)	(€ 0.68)	€ 0.57	€ 3.75
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.01)	($0.76)	($0.26)	($0.23)	($0.26)	($0.29)	($1.04)	($1.17)	($1.21)	($1.10)	($0.72)	$0.61	$3.99
Shares outstanding—basic	22.0	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	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%	-268%	-350%	-525%	-557%	-561%	-484%	-547%	-597%	-146%	-79%	-29%	-10%
SG&A	-62%	-92%	-104%	-151%	-157%	-152%	-137%	-157%	-165%	-39%	-20%	-7%	-3%
Operating Income (loss)	-217%	-260%	-353%	-576%	-614%	-613%	-522%	-604%	-661%	-171%	-59%	30%	66%
Pretax	-11%	-246%	-418%	-540%	-599%	-633%	-536%	-619%	-676%	-175%	-61%	30%	65%
Tax Rate								0%	0%	0%	0%	37%	37%
Net Income	-7%	-246%	-418%	-540%	-599%	-633%	-536%	-619%	-676%	-175%	-61%	19%	41%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-27%	-39%	-4%	-11%	-23%	0%	0%	345%	100%	188%	201%
R&D	-33%	129%	142%	31%	21%	20%	39%	13%	9%	9%	8%	7%	7%
SG&A	-67%	222%	13%	26%	6%	17%	15%	14%	5%	5%	5%	5%	5%
Marketing and sales											25%	15%	5%
Operating Income (Losses)	-48%	161%	257%	62%	22%	26%	55%	16%	9%	15%	-31%	-246%	554%
Pretax Income	-98%	4662%	470%	46%	16%	50%	68%	15%	9%	15%	-30%	-240%	565%
Net Income	-99%	7713%	470%	46%	15%	51%	68%	15%	9%	15%	-30%	-188%	565%
EPS	-99%	5931%	299%	18%	2%	43%	38%	12%	3%	-9%	-34%	-185%	553%

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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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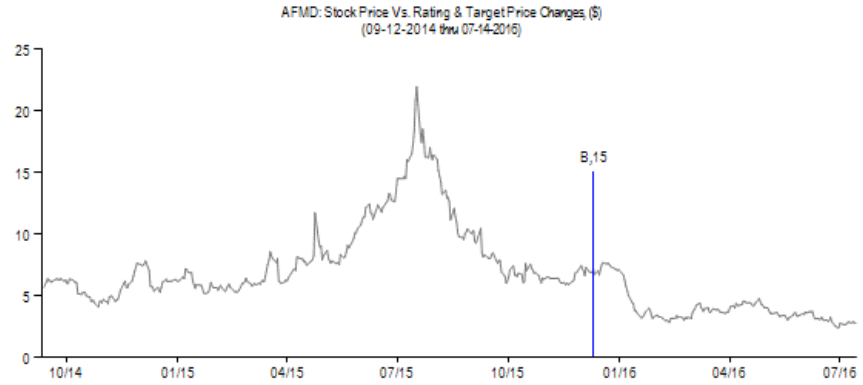
Rating and Price Target Change History



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.	67.57%	27.03%	2.70%
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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