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EQUITY RESEARCH
Company Report

August 11, 2016

Affimed N.V. (AFMD - $ 2.89)

Healthcare/Biotechnology

2Q16: Multiple Programs Are in the Middle of Development

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

Yesterday, AFMD reported 2Q16 financial results with a net loss of (€8.0MM), vs. Laidlaw (€7.6MM) and the Street (€6.8MM) estimates. Net loss per share was (€0.24) vs. (€0.22) and (€0.29) for Laidlaw and the Street, respectively. AFMD ended 2Q16 with cash of ~€59MM, enough to support its operations into 2018, in our opinion.

- **AFM13 development updates.** Patient enrollment for the AFM13/Keytruda combination in r/r HL Phase Ib is ongoing with interim data (safety and 3 month efficacy) expected in 4Q16/1Q17. The currently ongoing combo trial is a dose-escalating study starting with two lower doses, followed by an active dose of AFM13 in combination with standard Keytruda regimen. Once safety is established, an additional 20 patients will be treated at the active dose for exploring treatment efficacy, with study objectives of safety and ORR assessments at 3 and 6 months. Patients will be treated until relapse. We estimate some data update of the 20-patient study could be available possibly in 2H17. The overall objective is to demonstrate whether a combo regimen could improve the CR from single to low double-digit level of a PD-1 monotherapy to a substantially higher improvement (~20%-30%). AFMD recently has identified potential AFM13 monotherapy utility in $CD30^+$ lymphoma (both T and B cell) given PD-1 monotherapy has performed poorly in these indications. AFMD is contemplating starting clinical studies in these indications with a decision likely later in 2H16. Further, given the IND is already effective, a Columbia University physician-sponsored Phase Ib/IIa study of AFM13 in $CD30^+$ lymphoma with cutaneous manifestation might start later in 2H16. AFMD also is exploring the combination of AFM13 with adoptive NK-cell transfer to potentially enrich the effector cells for treatment, given certain cancer patients have a diminished immune system.
- **AFM11 development updates.** Patient enrollment is ongoing for the AFM11 in NHL Phase I study with first reported top-line results expected in late 4Q16. AFM11 in ALL Phase I study is underway in Blincyto treatment naïve patients in Eastern Europe (Russia, Poland and the Czech Republic). It is a dose finding study with PK and MTD as major endpoints.
- **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 (08/10/2016)	$ 2.89
52–Week High (8/10/2015)	$ 14.08
52–Week Low (6/30/2016)	$ 2.34
Market Cap. (MM)	$ 96
Shares Out. (MM)	33

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.25A	-0.24A	-0.28	-0.31	-1.08	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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- **Solid tumor development updates.** Preclinical development of AFM21 (EGFRvIII/CD3), AFM22 (EGFRvIII/CD16A) and AFM24 (EGFRwt/CD16A) are underway. AFMD indicated that AFM21 and AFM22 could potentially treat different types of tumors. AFMD targets to file an IND for one of them in 2H17 potentially as the first solid tumor-targeted TandAb. Despite that several EGFR-targeted treatments, such as Tagrisso (osimertinb) and Gilotrif (afatinib) are already available, AFMD believes the effector cell engaging antibody could potentially be more potent and possibly less drug resistant-prone. It is based on the experience that the majority of mutations that render these drugs less effective exist intracellularly, mainly in the signal transduction pathway. Extracellular mutations are less frequent, and the effector cell engaging antibody needs to only recognize the relatively unchanged extracellular receptor and bring in effector cells for cancer cell elimination. The effector cell engaging antibody, therefore, could represent a very different mode of action compared to other modalities, such as small molecular compounds or monoclonal antibodies.
- **Others.** Given Janssen recently decided not to opt-in AMV564 (CD33/CD3) from Amphivena, AFMD could potentially participate in developing this IND ready TandAb as a potential AML treatment. AFMD plans to provide more details going forward. Further, AFMD is exploring the use of a MHC-tumor antigen complex-targeted TandAb as a potential novel cancer treatment. This project is in early preclinical development.

Table 1: Estimated and reported 2Q16 results

2Q16 Estimates and Reported Results			
(€,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**1.4 €**	**2.1 €**	**2.2 €**
Total op. profit (loss)	**(8.1 €)**	**(8.5 €)**	**(7.7 €)**
R&D	(7.4 €)	(8.6 €)	
SG&A	(2.1 €)	(2.0 €)	
EPS	**(€ 0.22)**	**(€ 0.24)**	**(€ 0.20)**
Net income (loss)	(7.6 €)	(8.0 €)	(6.8 €)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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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 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**	***
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	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	2.1	1.5	1.6	7.1	7.1	7.1	7.1	7.1	7.1	7.1
Other revenue	0.4	0.7	0.1	0.0	0.1	0.1	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Total revenue	3.8	8.2	2.0	2.1	1.6	1.7	7.4	7.4	7.4	29.2	57.3	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)	(22.0)	(7.1)	(8.6)	(9.1)	(9.9)	(34.7)	(39.2)	(42.8)	(46.6)	(50.3)	(53.9)	(57.6)
General and administrative	(2.3)	(7.5)	(2.1)	(2.0)	(2.0)	(2.1)	(8.2)	(9.4)	(9.8)	(10.3)	(10.9)	(11.4)	(12.0)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(9.2)	(10.6)	(11.2)	(12.0)	(42.9)	(48.6)	(52.6)	(78.0)	(87.4)	(95.5)	(101.3)
Operating Incomes (losses)	(8.2)	(21.3)	(7.1)	(8.5)	(9.6)	(10.3)	(35.5)	(41.2)	(45.2)	(52.0)	(37.6)	44.3	314.9
Finance income / (costs) - net	7.8	1.1	(1.3)	0.5	0.2	(0.3)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Loss before tax	(0.4)	(20.2)	(8.5)	(8.0)	(9.4)	(10.6)	(36.5)	(42.2)	(46.2)	(53.0)	(38.6)	43.3	313.9
Tax	0.2	0.0	(0.0)	(0.0)	-	-	0.0	0.0	0.0	0.0	0.0	(16.0)	(116.1)
Net Income (Loss)	(0.3)	(20.2)	(8.5)	(8.0)	(9.4)	(10.6)	(36.5)	(42.2)	(46.2)	(53.0)	(38.6)	27.3	197.8
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(8.5)	(8.0)	(9.4)	(10.6)	(36.5)	(42.2)	(46.2)	(53.0)	(38.6)	27.3	197.8
Net Income (Loss) Applicable to Common Shareholders ($)	(0.3)	(21.8)	(9.0)	(8.9)	(10.0)	(11.3)	(38.8)	(44.8)	(49.1)	(56.3)	(41.0)	29.0	210.4
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.24)	(€ 0.28)	(€ 0.31)	(€ 1.08)	(€ 1.21)	(€ 1.25)	(€ 1.13)	(€ 0.77)	€ 0.53	€ 3.74
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.24)	(€ 0.28)	(€ 0.31)	(€ 1.08)	(€ 1.21)	(€ 1.25)	(€ 1.13)	(€ 0.77)	€ 0.53	€ 3.74
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.01)	($0.76)	($0.26)	($0.27)	($0.30)	($0.33)	($1.15)	($1.29)	($1.33)	($1.20)	($0.82)	$0.56	$3.98
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%	-572%	-581%	-467%	-528%	-576%	-159%	-88%	-33%	-12%
SG&A	-62%	-92%	-104%	-93%	-128%	-125%	-111%	-126%	-133%	-35%	-19%	-7%	-2%
Operating Income (loss)	-217%	-260%	-353%	-403%	-599%	-606%	-478%	-554%	-608%	-178%	-66%	27%	64%
Pretax	-11%	-246%	-418%	-381%	-587%	-624%	-491%	-567%	-621%	-181%	-67%	27%	64%
Tax Rate								0%	0%	0%	0%	37%	37%
Net Income	-7%	-246%	-418%	-381%	-587%	-624%	-491%	-567%	-621%	-181%	-67%	17%	40%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-27%	-9%	10%	1%	-10%	0%	0%	294%	96%	184%	199%
R&D	-33%	129%	142%	54%	42%	40%	58%	13%	9%	9%	8%	7%	7%
SG&A	-67%	222%	13%	17%	-1%	9%	9%	14%	5%	5%	5%	5%	5%
Marketing and sales											25%	15%	5%
Operating Income (Losses)	-48%	161%	257%	71%	36%	41%	66%	16%	10%	15%	-28%	-218%	611%
Pretax Income	-98%	4662%	470%	55%	29%	68%	80%	16%	9%	15%	-27%	-212%	625%
Net Income	-99%	7713%	470%	55%	29%	69%	80%	16%	9%	15%	-27%	-171%	625%
EPS	-99%	5931%	299%	28%	18%	65%	52%	12%	4%	-10%	-32%	-168%	611%

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

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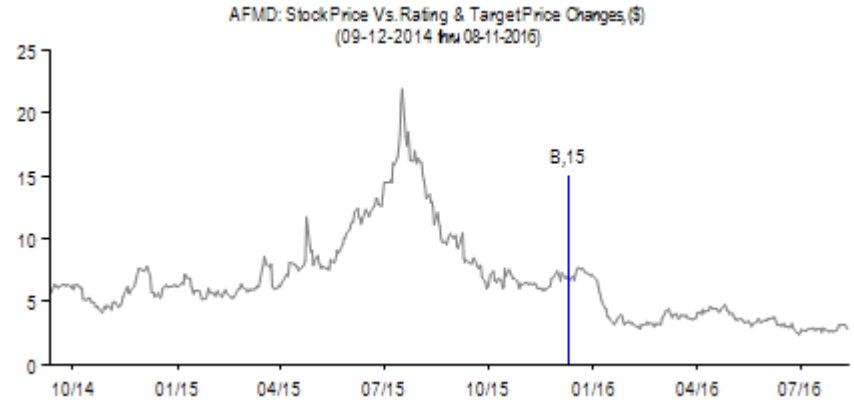
Rating and Price Target Change History



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.	62.16%	27.03%	2.70%
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Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.70%	0.00%	0.00%

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