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EQUITY RESEARCH
Company Report

November 2, 2016

Affimed N.V. (AFMD - $ 2.13)

Healthcare/Biotechnology

3Q16: Multiple Programs Are in the Midst of Development and AFM24 Has Moved Up as the Lead for Solid Tumors

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

AFMD reported 3Q16 financial results this morning with a net loss of (€10.3MM), vs. Laidlaw (€9.4MM) and the Street (€8.3MM) estimates. Net loss per share was (€0.31) vs. (€0.28) and (€0.24) for Laidlaw and the Street, respectively. AFMD ended 3Q16 with cash of ~€49MM, enough to support its operations into 2018, in our opinion.

- **AFM13 development updates.** Patient enrollment of the first dose cohort is completed and the second dose cohort is underway for the AFM13/Keytruda combination in r/r HL Phase Ib trial. An interim data update (mainly safety) is expected in 4Q16/1Q17. The combo trial is a dose-finding study starting with a lower dose, followed by escalating active doses of AFM13 in combination with standard Keytruda regimen. After the establishment of safety, three and six month ORR assessments (n~20) would be the critical measurement, with potential increase of CR over CPI alone (<10%) to the 20%-30% range as major objective. We estimate an update for the 20-patient study portion results later; the company did not provide further guidance on the timeline. AFMD is planning to start its own AFM13 monotherapy in $CD30^+$ lymphoma (possibilities include T-cell lymphoma or anaplastic large cell lymphoma) trial by incorporating the ongoing Columbia University physician-sponsored Phase Ib/IIa study. The timeline has not been determined. One of AFMD's rationale for pursuing this is due to PD-1 monotherapy performing poorly in these $CD30^+$ indications. AFMD also is exploring the combination of AFM13 with adoptive NK-cell transfer to potentially enrich the effector cells as a treatment; given certain cancer patients have an impaired immune system.
- **AFM11 development updates.** Patient enrollment is slower than expected for the AFM11 in NHL Phase I study and AFMD guided to provide a study timeline update in 1H17 from an earlier projected top-line result of late 4Q16. AFM11 in ALL Phase I study is underway in Blincyto treatment naïve patients in Eastern Europe (Russia, Poland and the Czech Republic) with first patient already enrolled. 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 (11/02/2016)	$ 2.13
52–Week High (12/18/2015)	$ 8.26
52–Week Low (11/2/2016)	$ 1.75
Market Cap. (MM)	$ 71
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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- **Solid tumor development updates.** AFMD indicated that the preclinical AFM24 (EGFRwt/CD16A) has moved up as the lead program for treating solid tumors while AFM21 (EGFRvIII/CD3) and AFM22 (EGFRvIII/CD16A) are as backups. AFMD indicated that preclinical toxicity evaluation is ongoing and intends to provide an update in 1H17. The rationale for choosing AFM24 over AFM21/AFM22 is the target (wild-type EGFR) is more of tumor associated, instead of tumor-specific, and therefore potentially could be used for treating some larger indications, such as lung cancer, possibly under a combination regimen setting (i.e. CPIs). It is known that 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.
- **Others.** AFMD is developing AFM26 (BCMA/CD16) as a potential treatment for multiple myeloma (MM). AFMD envisions this drug could potentially be used in stem cell transplantation setting for MM patients. In addition, AFMD will participate in the development of Amphivena's AMV564 (CD33/CD3) as a potential acute myeloid leukemia (AML) treatment with Phase I trial potentially to start in the future. 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 3Q16 results

3Q16 Estimates and Reported Results			
(€,MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**1.6 €**	**1.0 €**	**2.4 €**
Total op. profit (loss)	**(9.6 €)**	**(10.0 €)**	**(8.7 €)**
R&D	(9.1 €)	(8.8 €)	
SG&A	(2.0 €)	(2.2 €)	
EPS	**(€ 0.28)**	**(€ 0.31)**	**(€ 0.24)**
Net income (loss)	(9.4 €)	(10.3 €)	(8.3 €)

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 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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Additional information available upon request.

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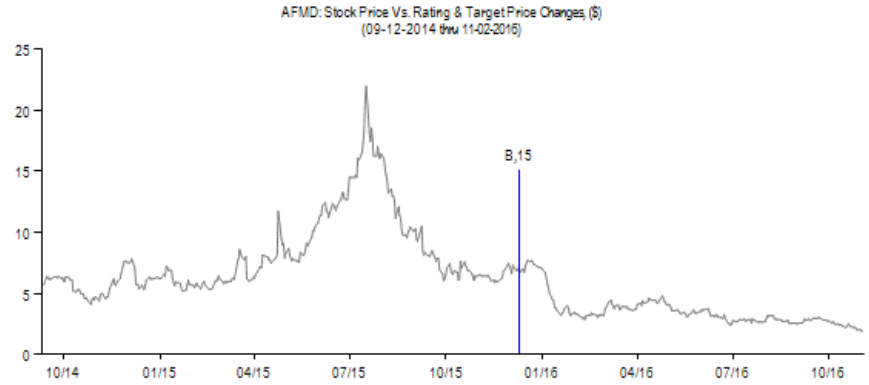
Rating and Price Target Change History



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.	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%

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