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EQUITY RESEARCH
Company Report

August 2, 2017

Affimed Therapeutics (AFMD - $2.20)

Healthcare/Biotechnology

2Q17: AFM13/Keytruda Combo DLT Dose Identified, Extended Study Ongoing and 12-Patient Data Readout in 2H17

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

Yesterday, AFMD reported 2Q17 financial results with a net loss of (€7.9MM), vs. Laidlaw (€9.0MM) and the Street (€8.1MM) estimates. Net loss per share was (€0.18) vs. (€0.22) and (€0.19) for Laidlaw and the Street, respectively. AFMD ended 2Q17 with cash of ~€49MM, enough to support its operations through 2H18, in our opinion.

- **AFM13/Keytruda updates.** AFMD indicated that the dose associated with dose-limiting toxicity (DLT) has been identified for the AFM13/Keytruda combo in HL Phase Ia study. The DLT dose was 3mg/Kg 3x/week, followed by 7mg/Kg once weekly and later 7mg/Kg once every three weeks. Patients of the extended portion of the combo study will also be treated with this regimen since five more patients (3+3) during escalating phase also took the same regimen and did not show DLT. Other escalating doses have been tested include 0.15 mg/Kg 3x/week → 0.5 mg/Kg/weekly and /3 weeks; and 0.5 mg/Kg 3x/week → 1.5 mg/Kg/weekly and every 3 weeks. AFMD is also scheduled to report the dose escalating portion (n~12) of the combo study results at a medical conference in 2H17. We anticipate more matured data, including the extended phase, to be available in late 2017 and 2018 (such as 3- and 6-month ORR, and later the duration of response) to provide the basis for potentially advancing this program forward.
- **AFM13 monotherapy trial updates.** The German Hodgkin Study Group (GHSG) has modified the patient eligibility criteria of the AFM13 in HL Phase IIa monotherapy study as those being pre-treated with both Adcetris and anti-PD1. AFMD plans to report the full data (including ORR) after the completion of the study, which is anticipated in 2019.
- **AFM11 development updates.** Patient recruitment for the AFM11 in ALL (12 sites) and in NHL (10 sites) study have completed 3 and 2 dose cohorts, respectively. The studies on the subsequent dose cohort is ongoing. All clinical sites are located at Eastern European countries, like the Czech Republic and Russia, where the approval and use of Blincyto have not yet occurred. AFMD has not yet provides a timeline as to when initial topline readout might happen.
- **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 (8/1/2017)	$2.20
52–Week High (8/4/2016)	$3.25
52–Week Low (12/23/2016)	$1.65
Market Cap. (MM)	$97
Shares Out. (MM)	33.260

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.19A	-0.18A	-0.16	-0.18	-0.71	N.A.
FY-16A	-0.25	-0.24	-0.31	-0.16	-0.97	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

Source: Laidlaw & Company estimates

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- **AFM24 and AFM26 updates.** For AFM24, earlier reported preclinical data suggested the drug showed anti-tumor activities in Erbitux-resistant (Ras-mutated) cells. AFMD has developed several candidates of EGFR/CD16A NK cell engager with the assessment for determining the final IND-enabling-study-ready candidate ongoing. Management expects to provide more updates later in 2017.

  For AFM26, AFMD is in the process of evaluating which candidate the company will move forward through IND-enabling studies. With higher avidity vs. mAbs, management also suggested that AFM26 could potentially demonstrate activities at concentration higher than 1mg/Kg by avoiding the interference from abundant BCMA antigens presented at serum.

Table 1: Estimated and reported 2Q17 results

2Q17 Estimates and Reported Results			
(€,MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**0.8 €**	**0.6 €**	**1.3 €**
Total op. profit (loss)	**(8.7 €)**	**(6.8 €)**	**(8.0 €)**
R&D	(7.2 €)	(5.4 €)	
SG&A	(2.3 €)	(2.0 €)	
EPS	**(€ 0.22)**	**(€ 0.18)**	**(€ 0.19)**
Net income (loss)	(9.0 €)	(7.9 €)	(8.1 €)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
AFM13	Hodgkin's lymphoma (r/r)	Potentially report dose escalation results of Keytruda combination Phase II study	**2H17**	***
		Potentially report interium results of Keytruda combination Phase II study	**Late 2017**	****
		Potentially report topline results of Keytruda combination Phase II study	**2018**	****
		Report matured single agent data	**2019**	***
		Report more NK cell transfer preclinical data	**2H17**	***
	$CD30^+$ lymphoma with cutaneous manifestation	Potentially to report Phase Ib/IIa study	**2018**	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study timeline	**2018**	***
	Acute lymphoblastic leukemia (ALL)	Potentially to report Phase I study results	**2018**	***
AFM24	Solid tumors	Update on preclinical stufdy	**2H17**	***
		Potential to start Phase I study	**2018**	***
AFM26	Multiple myeloma	Update on preclinical stufdy	**2H17**	***
		Potential to start Phase I study	**2018**	***

***** / ***** 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)	2015	2016	1Q17	2Q17	3Q17E	4Q17E	2017E	2018E	2019E	2020E	2021E	2022E
Revenue												
Product revenue	0.0	0.0	-	-	-	-	0.0	0.0	21.8	49.9	155.6	480.9
Research revenue	7.6	6.3	0.4	0.5	0.8	0.6	2.3	2.3	2.3	2.3	2.3	2.3
Other revenue	0.7	0.1	(0.0)	0.1	0.1	0.1	0.3	0.3	0.3	0.3	0.3	0.3
Total revenue	8.2	6.5	0.4	0.6	0.9	0.7	2.6	2.6	24.4	52.5	158	483
Costs of goods									3.3	7.5	23.3	72.1
Gross sales									18.5	42.4	132.3	408.7
Research and development	(22.0)	(30.2)	(5.4)	(5.4)	(5.9)	(6.0)	(22.8)	(24.9)	(27.1)	(29.3)	(31.3)	(33.5)
General and administrative	(7.5)	(8.3)	(2.2)	(2.0)	(2.0)	(2.0)	(8.3)	(8.7)	(9.1)	(9.6)	(10.0)	(10.5)
Marketing and sales									(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(29.6)	(38.5)	(7.7)	(7.4)	(7.9)	(8.1)	(31.1)	(33.6)	(57.2)	(65.1)	(71.6)	(75.8)
Operating Incomes (losses)	(21.3)	(32.0)	(7.3)	(6.8)	(7.0)	(7.4)	(28.5)	(31.0)	(36.1)	(20.1)	63.3	335.6
Finance income / (costs) - net	1.1	(0.2)	(0.5)	(1.2)	(0.2)	(0.5)	(2.3)	(2.3)	(2.3)	(2.3)	(2.3)	(2.3)
Loss before tax	(20.2)	(32.3)	(7.8)	(8.0)	(7.2)	(7.9)	(30.8)	(33.3)	(38.4)	(22.4)	61.0	333.2
Tax	0.0	0.1	(0.0)	0.0	-	-	0.0	0.0	0.0	0.0	(22.6)	(123.3)
Net Income (Loss)	(20.2)	(32.2)	(7.8)	(7.9)	(7.2)	(7.9)	(30.8)	(33.3)	(38.4)	(22.4)	38.4	209.9
Net Income (Loss) Applicable to Common Shareholders	(20.2)	(32.2)	(7.8)	(7.9)	(7.2)	(7.9)	(30.8)	(33.3)	(38.4)	(22.4)	38.4	209.9
Net Income (Loss) Applicable to Common Shareholders ($)	(21.8)	(34.3)	(8.3)	(8.5)	(7.7)	(8.4)	(32.8)	(35.4)	(40.9)	(23.8)	40.9	223.3
Net Earnings (Losses) Per Share—Basic	(€ 0.71)	(€ 0.97)	(€ 0.19)	(€ 0.18)	(€ 0.16)	(€ 0.18)	(€ 0.71)	(€ 0.73)	(€ 0.69)	(€ 0.38)	€ 0.64	€ 3.42
Net Earnings (Losses) Per Share—Diluted	(€ 0.71)	(€ 0.97)	(€ 0.19)	(€ 0.18)	(€ 0.16)	(€ 0.18)	(€ 0.71)	(€ 0.73)	(€ 0.69)	(€ 0.38)	€ 0.64	€ 3.42
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.76)	($1.03)	($0.20)	($0.19)	($0.17)	($0.19)	($0.75)	($0.78)	($0.74)	($0.41)	$0.68	$3.63
Shares outstanding—basic	29.1	33.2	40.8	44.2	44.4	44.6	43.5	45.5	55.5	58.5	60.5	61.5
Shares outstanding—diluted	29.1	33.2	40.8	44.2	44.4	44.6	43.5	45.5	55.5	58.5	60.5	61.5
Margin Analysis (% of Sales/Revenue)												
Costs of goods									15%	15%	15%	15%
R&D	-268%	-468%	-1395%	-904%	-658%	-863%	-881%	-960%	-111%	-56%	-20%	-7%
SG&A	-92%	-129%	-576%	-328%	-221%	-293%	-318%	-334%	-37%	-18%	-6%	-2%
Operating Income (loss)	-260%	-496%	-1871%	-1131%	-779%	-1055%	-1100%	-1195%	-148%	-38%	40%	69%
Pretax	-246%	-500%	-1988%	-1326%	-801%	-1127%	-1189%	-1285%	-157%	-43%	39%	69%
Tax Rate								0%	0%	0%	37%	37%
Net Income	-246%	-499%	-1988%	-1322%	-801%	-1127%	-1189%	-1284%	-157%	-43%	24%	43%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	118%	-21%	-81%	-71%	-6%	-49%	-60%	0%	842%	115%	201%	206%
R&D	129%	37%	-23%	-37%	-32%	5%	-24%	9%	9%	8%	7%	7%
SG&A	222%	10%	7%	0%	-9%	-2%	-1%	5%	5%	5%	5%	5%
Marketing and sales										25%	15%	5%
Operating Income (Losses)	161%	50%	2%	-20%	-30%	15%	-11%	9%	17%	-44%	-415%	430%
Pretax Income	4662%	59%	-8%	-1%	-30%	44%	-5%	8%	15%	-42%	-372%	446%
Net Income	7713%	59%	-8%	-1%	-30%	45%	-4%	8%	15%	-42%	-272%	446%
EPS	5931%	37%	-23%	-25%	-47%	11%	-27%	3%	-5%	-45%	-266%	437%

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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 ($)
12/10/2...	Buy (B)	7.19

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
12/10/2...	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.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	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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