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EQUITY RESEARCH
Company Report

May 18, 2017

Affimed Therapeutics (AFMD - $2.30)

Healthcare/Biotechnology

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

1Q17: AFM13 Demonstrated Single Agent Activity in Initially-Designed Adcetris-r/r HL Setting

Yesterday, AFMD reported 1Q17 financial results with a net loss of (€7.8MM), vs. Laidlaw (€7.9MM) and the Street (€8.3MM) estimates. Net loss per share was (€0.19) vs. (€0.17) and (€0.20) for Laidlaw and the Street, respectively. AFMD ended 1Q17 with cash of ~€54MM, enough to support its operations through YE2018, in our opinion.

- **AFM13 monotherapy updates.** Updates including data of a subset of Adcetris-r/r Hodgkin's lymphoma (HL) patients enrolled under the initial inclusion criteria showed partial responses (PRs) in 2 of 7 patients, or 1 patient from both arms (1.5mg/kg, 3x/wk and 7mg/kg, 1x/wk). Tumor shrinkage was observed in 62% of patients. Although the current study design has been modified to include mainly CPI-resistant patients; the response results from the original design remain very important given the outcome suggests single agent activity of AFM13 for treating more-difficult-to-treat r/r HL patients. We anticipate additional data from the initial AFM13 monotherapy study could be available in 2H17 with more matured study results. AFM13 monotherapy in CPI-refractory HL will begin patient recruitment, in 2Q17. If the future outcome is positive, this could provide AFM13 alone as a treatment option in different stages of HL.
- **AFM13/Keytruda combination updates.** Fewer updates for the combination regimen of AFM13/Keytruda in r/r HL Phase Ib study was available as the study is ongoing, however, an earlier report suggests that the study has advanced to the highest dose (last of 3 cohorts of dose finding portion, n~9). Updates of the ongoing data readout could be available in 2H17. The study's aim is to determine whether the combo regimen could increase the CR to the 20%-30% range compared to CPI alone (~10%).
- **AFM13 preclinical development updates.** The initial preclinical development is underway in the MD Anderson Cancer Center collaboration for NK-cell transfer with AFM13. AFMD plans to provide additional updates in 2H17. In addition, recent AFM13 combination with cytokines preclinical data was presented at the AACR meeting which suggests AFM13 could have enhanced effects on NK-cell by being more responsive to IL-2 and IL-15.
- **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 (5/17/2017)	$2.30
52–Week High (6/8/2016)	$3.82
52–Week Low (12/23/2016)	$1.65
Market Cap. (MM)	$99
Shares Out. (MM)	33.260

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.19A	-0.22	-0.20	-0.24	-0.85	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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- **AFM11 development updates.** The AFM11 in ALL study could have a rather reliable stream of patients, since it could be quite a while for Blincyto to be approved or meaningfully used in in Eastern European countries, like the Czech Republic and Russia.
- **AFM24 and AFM26 updates.** Recent data presented at the AACR demonstrated AFM24 has a better safety profile vs. Erbitux (cetuximab) as single dose of Erbitux typically can induce skin aggravations (i.e. rash) while AFM24 did not. AFM24 showed greater ADCC capability and high specificity *in vitro* as it does not bind to other members of the EGFR family. The highest investigated dose level of AFM24 animals was 93.75 mg/kg. AFM24 also showed anti-tumor efficacy in Erbitux-resistant (Ras-mutated) cells. We anticipate further AFM24 data (mainly multiple dose) to be presented at the ASCO (#e14001, June 2-6) and EACR-AACR-SIC (Session "Tumour Immunology II" Poster: #574, June 24-27). Additional details on potential AFM24 development could be provided at the 2Q17 call following the securing of additional AFM24 IP.

  For AFM26, a recent preclinical study showed the drug might be safer than other T cell engagers as it releases much less cytokines, like IL-2, 4 and 6 and TNF-a for potentially less propensity of causing cytokine release syndrome. Additional updates also will be presented at the ASCO (Session Hematologic Malignancies #8045, June 2-6) and EACR-AACR-SIC (Session "Tumour Immunology II" Poster: #575, June 24-27).

Table 1: Estimated and reported 1Q17 results

1Q17 Estimates and Reported Results			
(€,MM)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**0.9 €**	**0.4 €**	**1.8 €**
Total op. profit (loss)	**(7.5 €)**	**(7.3 €)**	**(8.2 €)**
R&D	(6.3 €)	(5.4 €)	
SG&A	(2.1 €)	(2.2 €)	
EPS	**(€ 0.17)**	**(€ 0.19)**	**(€ 0.20)**
Net income (loss)	(7.9 €)	(7.8 €)	(8.3 €)

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 Phase I CPI combination safety Phase I study results	**2017**	***
		Potentially report Phase II CPI combination Phase II study results	**2017/2018**	****
		Report more matured single agent data	**2H17**	***
		Report more NK cell transfer preclinical data	**2H17**	***
	$CD30^+$ 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	**2017/2018**	****
	Acute lymphoblastic leukemia (ALL)	Potentially to report Phase I study results	**2018**	***
AFM24	Solid tumors	Update on preclinical stufdy	**2H17**	***
AFM26	Multiple myeloma	Update on preclinical stufdy	**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	2016	1Q17	2Q17E	3Q17E	4Q17E	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	6.3	0.4	0.8	1.8	1.0	3.9	3.9	3.9	3.9	3.9	3.9
Other revenue	0.4	0.7	0.1	(0.0)	-	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2
Total revenue	3.8	8.2	6.5	0.4	0.8	1.9	1.1	4.1	4.1	25.9	54.0	160	485
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)	(30.2)	(5.4)	(7.2)	(7.8)	(8.0)	(28.4)	(31.0)	(33.8)	(36.5)	(39.0)	(41.8)
General and administrative	(2.3)	(7.5)	(8.3)	(2.2)	(2.3)	(2.3)	(2.4)	(9.2)	(9.6)	(10.1)	(10.6)	(11.1)	(11.7)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(38.5)	(7.7)	(9.5)	(10.1)	(10.3)	(37.6)	(40.6)	(64.9)	(73.4)	(80.4)	(85.2)
Operating Incomes (losses)	(8.2)	(21.3)	(32.0)	(7.3)	(8.7)	(8.2)	(9.2)	(33.5)	(36.5)	(42.2)	(26.8)	56.1	327.7
Finance income / (costs) - net	7.8	1.1	(0.2)	(0.5)	(0.3)	(0.2)	(0.5)	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)	(1.5)
Loss before tax	(0.4)	(20.2)	(32.3)	(7.8)	(9.0)	(8.4)	(9.7)	(34.9)	(37.9)	(43.7)	(28.3)	54.6	326.2
Tax	0.2	0.0	0.1	(0.0)	-	-	-	(0.0)	(0.0)	(0.0)	(0.0)	(20.2)	(120.7)
Net Income (Loss)	(0.3)	(20.2)	(32.2)	(7.8)	(9.0)	(8.4)	(9.7)	(34.9)	(37.9)	(43.7)	(28.3)	34.4	205.5
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(32.2)	(7.8)	(9.0)	(8.4)	(9.7)	(34.9)	(37.9)	(43.7)	(28.3)	34.4	205.5
Net Income (Loss) Applicable to Common Shareholders ($)	($0.3)	($21.8)	($34.3)	($8.3)	($9.6)	($9.0)	($10.4)	($37.2)	($40.4)	($46.5)	($30.1)	$36.6	$218.7
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.97)	(€ 0.19)	(€ 0.22)	(€ 0.20)	(€ 0.24)	(€ 0.85)	(€ 0.88)	(€ 0.82)	(€ 0.50)	€ 0.59	€ 3.48
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.97)	(€ 0.19)	(€ 0.22)	(€ 0.20)	(€ 0.24)	(€ 0.85)	(€ 0.88)	(€ 0.82)	(€ 0.50)	€ 0.59	€ 3.48
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.01)	($0.76)	($1.03)	($0.20)	($0.23)	($0.22)	($0.25)	($0.90)	($0.94)	($0.87)	($0.54)	$0.63	$3.70
Shares outstanding—basic	22.0	29.1	33.2	40.8	41.0	41.2	41.4	41.1	43.1	53.1	56.1	58.1	59.1
Shares outstanding—diluted	22.0	29.1	33.2	40.8	41.0	41.2	41.4	41.1	43.1	53.1	56.1	58.1	59.1
Margin Analysis (% of Sales/Revenue)													
Costs of goods										15%	15%	15%	15%
R&D	-255%	-268%	-468%	-1395%	-958%	-412%	-726%	-687%	-749%	-130%	-68%	-24%	-9%
SG&A	-62%	-92%	-129%	-576%	-302%	-121%	-215%	-221%	-232%	-39%	-20%	-7%	-2%
Operating Income (loss)	-217%	-260%	-496%	-1871%	-1160%	-433%	-841%	-808%	-881%	-163%	-50%	35%	68%
Pretax	-11%	-246%	-500%	-1988%	-1200%	-443%	-886%	-844%	-916%	-168%	-52%	34%	67%
Tax Rate									0%	0%	0%	37%	37%
Net Income	-7%	-246%	-499%	-1988%	-1200%	-443%	-886%	-844%	-916%	-168%	-52%	22%	42%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-21%	-81%	-64%	99%	-20%	-36%	0%	527%	108%	196%	204%
R&D	-33%	129%	37%	-23%	-17%	-11%	40%	-6%	9%	9%	8%	7%	7%
SG&A	-67%	222%	10%	7%	15%	5%	13%	10%	5%	5%	5%	5%	5%
Marketing and sales											25%	15%	5%
Operating Income (Losses)	-48%	161%	50%	2%	3%	-18%	44%	4%	9%	16%	-37%	-309%	485%
Pretax Income	-98%	4662%	59%	-8%	12%	-18%	78%	8%	9%	15%	-35%	-293%	497%
Net Income	-99%	7713%	59%	-8%	12%	-18%	80%	8%	9%	15%	-35%	-222%	497%
EPS	-99%	5931%	37%	-23%	-9%	-33%	47%	-12%	4%	-7%	-39%	-218%	487%

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

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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**

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			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.	63.64%	29.55%	2.27%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.27%	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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