

Affimed Therapeutics (AFMD - \$2.25)

Several Promising Early Pipeline Products Showcased at AACR

AFMD recently participated in the AACR conference with 3 posters and one oral presentation. Here is the re-cap:

- AFM26 – a novel BCMA-targeted treatment for MM.** AFM26 is a NK (via CD16a) bispecific antibody that targets BCMA as a potential treatment for multiple myeloma (MM). AFM26 showed high avidity binding to CD16a, and has a long retention on the NK-cell surface despite the presence of polyclonal IgG. This could be beneficial of its potentially higher ADCC capacity vs. mAbs and given that ~50% of MM patients have high levels of IgG M-protein in serum. The author also suggested that AFM26 could be uniquely suited for combination with adoptive NK-cell therapy as a potentially novel MM therapeutic approach. An *in vitro* study also showed that AFM26 did not induce NK-cell depletion. Although additional work is needed before the final candidate can be nominated for clinical studies, we view AFM26 as a rather unique BCMA-targeted treatment modality for potential MM treatment. Its several specific attributes could potentially have competitive advantages over other BCMA-targeted treatment options, such as CAR-T, T-engagers, or mAbs.
- AFM24 is the EGFR/CD16A-targeting NK-cell engager.** AFM24 is the EGFR-targeted candidate that could potentially advance forward to clinical studies. It recognizes a conformational epitope in the extracellular domain of EGFR differing from those targeted by other therapeutic mAbs. AFM24 showed superior ADCC cytotoxicity and reduced inhibition of EGFR-mediated phosphorylation compared to cetuximab. AFM24 demonstrated high specificity *in vitro* and does not bind to other members of the EGFR family. AFM24 appeared to be safe and a single intravenous administration was well tolerated in all animals up to the highest investigated dose level of 93.75 mg/kg. *In vivo* animal model data also suggested that AFM24 showed anti-tumor efficacy in cetuximab-resistant (Ras-mutated) cells. Together, AFM24 appears to be a promising candidate for AFMD to move forward.
- Disease-specific MHC/peptide complexes bispecific T-cell engager could be a novel ideal.** A T-cell engager targeting HLA-A*02/MMP1-003 (from matrix metalloproteinase-1) was identified and it demonstrated high target specificity and potent cytotoxicity with EC₅₀ values in the pico molar range.
- Action.** We are reiterating our Buy rating and our \$15 target price based on peer comparable, probability adjusted m and sum-of-the-parts analyses to reflect the continued execution of pipeline advancements.

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.17	-0.21	-0.19	-0.22	-0.80	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

Healthcare/Biotechnology

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

Trading Data:

Last Price (4/5/2017)	\$2.25
52-Week High (4/25/2016)	\$5.00
52-Week Low (12/23/2016)	\$1.65
Market Cap. (MM)	\$98
Shares Out. (MM)	66.425

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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	****
	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	***
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

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.

Figure 1: Income Statement

Affirmed N.V. – Income Statement													
(€'MM)	2014	2015	2016					2017E	2018E	2019E	2020E	2021E	2022E
				1Q17E	2Q17E	3Q17E	4Q17E						
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	0.9	0.8	1.8	1.0	4.5	4.5	4.5	4.5	4.5	4.5
Other revenue	0.4	0.7	0.1	-	-	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2
Total revenue	3.8	8.2	6.5	0.9	0.8	1.9	1.1	4.7	4.7	26.5	54.6	160	486
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)	(6.3)	(7.7)	(8.4)	(8.6)	(31.1)	(33.9)	(36.9)	(39.9)	(42.7)	(45.7)
General and administrative	(2.3)	(7.5)	(8.3)	(2.1)	(2.1)	(2.2)	(2.2)	(8.7)	(9.1)	(9.6)	(10.0)	(10.5)	(11.1)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(38.5)	(8.4)	(9.9)	(10.6)	(10.8)	(39.8)	(43.0)	(67.5)	(76.2)	(83.4)	(88.4)
Operating Incomes (losses)	(8.2)	(21.3)	(32.0)	(7.5)	(9.1)	(8.7)	(9.7)	(35.1)	(38.3)	(44.3)	(29.1)	53.5	324.9
Finance income / (costs) - net	7.8	1.1	(0.2)	(0.4)	(0.3)	(0.2)	(0.5)	(1.4)	(1.4)	(1.4)	(1.4)	(1.4)	(1.4)
Loss before tax	(0.4)	(20.2)	(32.3)	(7.9)	(9.4)	(8.9)	(10.2)	(36.5)	(39.8)	(45.7)	(30.5)	52.1	323.5
Tax	0.2	0.0	0.1	-	-	-	-	0.0	0.0	0.0	0.0	(19.3)	(119.7)
Net Income (Loss)	(0.3)	(20.2)	(32.2)	(7.9)	(9.4)	(8.9)	(10.2)	(36.5)	(39.8)	(45.7)	(30.5)	32.8	203.8
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(32.2)	(7.9)	(9.4)	(8.9)	(10.2)	(36.5)	(39.8)	(45.7)	(30.5)	32.8	203.8
Net Income (Loss) Applicable to Common Shareholders (\$)	(0.3)	(21.8)	(34.3)	(8.4)	(10.0)	(9.5)	(10.9)	(38.9)	(42.3)	(48.7)	(32.5)	34.9	216.8
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.97)	(€ 0.17)	(€ 0.21)	(€ 0.19)	(€ 0.22)	(€ 0.80)	(€ 0.83)	(€ 0.79)	(€ 0.50)	€ 0.52	€ 3.20
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.97)	(€ 0.17)	(€ 0.21)	(€ 0.19)	(€ 0.22)	(€ 0.80)	(€ 0.83)	(€ 0.79)	(€ 0.50)	€ 0.52	€ 3.20
Net Earnings (Losses) Per Share—Basic/diluted (\$)	(\$0.01)	(\$0.76)	(\$1.03)	(\$0.19)	(\$0.22)	(\$0.21)	(\$0.24)	(\$0.85)	(\$0.89)	(\$0.84)	(\$0.54)	\$0.56	\$3.40
Shares outstanding—basic	22.0	29.1	33.2	45.4	45.6	45.8	46.0	45.7	47.7	57.7	60.7	62.7	63.7
Shares outstanding—diluted	22.0	29.1	33.2	45.4	45.6	45.8	46.0	45.7	47.7	57.7	60.7	62.7	63.7
Margin Analysis (% of Sales/Revenue)													
Costs of goods										15%	15%	15%	15%
R&D	-255%	-268%	-468%	-700%	-1033%	-444%	-783%	-669%	-729%	-140%	-73%	-27%	-9%
SG&A	-62%	-92%	-129%	-236%	-286%	-114%	-203%	-187%	-196%	-36%	-18%	-7%	-2%
Operating Income (loss)	-217%	-260%	-496%	-836%	-1219%	-458%	-886%	-755%	-825%	-168%	-53%	33%	67%
Pretax	-11%	-246%	-500%	-882%	-1259%	-469%	-931%	-786%	-855%	-173%	-56%	33%	67%
Tax Rate										0%	0%	37%	37%
Net Income	-7%	-246%	-499%	-882%	-1259%	-469%	-931%	-786%	-855%	-173%	-56%	20%	42%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-21%	-55%	-64%	99%	-20%	-28%	0%	469%	106%	194%	203%
R&D	-33%	129%	37%	-11%	-10%	-4%	50%	3%	9%	9%	8%	7%	7%
SG&A	-67%	222%	10%	2%	9%	-1%	7%	4%	5%	5%	5%	5%	5%
Marketing and sales										25%	15%	5%	5%
Operating Income (Losses)	-48%	161%	50%	5%	8%	-13%	51%	10%	9%	16%	-34%	-284%	507%
Pretax Income	-98%	4662%	59%	-6%	17%	-13%	87%	13%	9%	15%	-33%	-271%	521%
Net Income	-99%	7713%	59%	-6%	17%	-13%	89%	13%	9%	15%	-33%	-208%	521%
EPS	-99%	5931%	37%	-29%	-14%	-36%	39%	-18%	4%	-5%	-37%	-204%	511%

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

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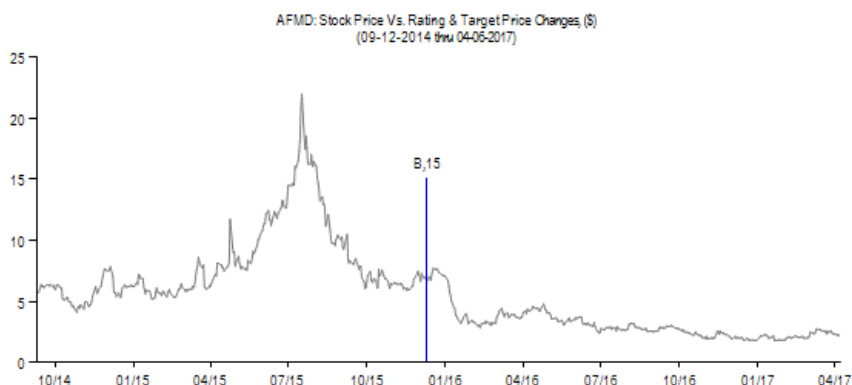
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3 Year Rating Change History

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

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.33%	2.33%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	65.12%	30.23%	2.33%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.33%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.65%	0.00%	0.00%

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