

Affimed Therapeutics (AFMD - \$2.35)

4Q16: Good Things Could Happen to Those Who are Willing to Wait

AFMD reported 4Q16 financial results yesterday with a net loss of (€5.4MM), vs. Laidlaw (€10.7MM) and the Street (€9.4MM) estimates. Net loss per share was (€0.16) vs. (€0.31) and (€0.27) for Laidlaw and the Street, respectively. AFMD ended 4Q16 with cash of ~€45MM, enough to support its operations through 4Q18, in our opinion.

- 2017 could be an eventful year for AFM13.** The combination regimen of AFM13/Keytruda in r/r HL Phase Ib trial recently completed patient recruitment of the third dose cohort. We anticipate AFMD will provide updates of incremental progress and data read-outs throughout 2017, mainly in safety and potentially signals of response. So far, patients of the first two dose cohorts have not shown dose-limiting toxicities and the overall safety profile remains similar to that of the combination of the two drugs. Once the dose finding portion (3 cohorts, n~9) of the study is established, an additional 20 patients will be treated at the active dose for safety (~6 weeks) and efficacy (3- and 6-month ORR and others). Data readout from this study is the most critical one. The study's aim is to determine whether the combination could increase the CR to possibly the 20%-30% range over CPI alone (~10%). A recent collaboration with the MD Anderson Cancer Center for NK-cell transfer and other technology with AFM13 could potentially lead to a Phase I study of HL in the future. A potential advantage of the exogenous NK-cells and AFM13 combination is that AFM13 might serve as a GPS to better guide NK-cells towards tumor cells more effectively. Other indications that might benefit from this approach could include multiple myeloma and AML. The protocol of AFM13 monotherapy in r/r HL Phase I study has been modified to include CPI-resistant patients, and AFMD expects to provide more study updates in 2H17.
- AFM11 development updates.** The AFM11 Phase I dose escalation trial in ALL of Blincyto naïve patients is ongoing and patient recruitment appears smoother than earlier and an update is expected in 1H17. The AFM11 in NHL Phase I dose escalation trial is also ongoing and we expect an update later in 1H17. Both trials are in the typical cohort escalation study (3 patient/dose) for identifying MTD and to optimizing the dose regimen.
- 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 (3/30/2017)	\$2.35
52-Week High (4/25/2016)	\$5.00
52-Week Low (12/23/2016)	\$1.65
Market Cap. (MM)	\$105
Shares Out. (MM)	33.212

Yale Jen, Ph.D.

Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

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- Emerging pipeline updates.** AFM24 (EGFRwt/CD16a), a NK-engaging bispecific antibody targeting wildtype EGFR, has the potential for treating EGFR high expressing solid tumors such as NSCLC and H&N cancers. AFMD is scheduled to report its preclinical results highlighting AFM24's promising efficacy and cytotoxic profile compared to cetuximab at the upcoming AACR meeting (April 1-5). Also, anticipated at the AACR meeting are further details of AFM26 (BCMA/CD16a), a NK-bispecific targeting BCMA/CD16a with potential for treating multiple myeloma (MM). Data to be reported include characterization of AFM26 enhanced avidity and NK-cell surface retention despite the presence of polyclonal IgG. This attribute could be attractive since it could clarify the noise signal against the background.
- Other updates.** AFMD is supporting Amphineva Therapeutics for developing AMV564, a bispecific targeting CD33/CD3 derived from AFMD's TandAb platform. Amphineva could potentially start a AMV564 in AML Phase I dose escalation trial later in 2017. Additionally, AFMD intends to provide updates at the AACR of its T-cell-recruiting HLA-A^{*02MMP1-003}/CD3 TandAbs against tumor-associated MHC/peptide complex.

Table 1: Estimated and reported 4Q16 results

4Q16 Estimates and Reported Results			
(€,MM)	Laidlaw Estimate	Actual	Consensus
Total revenue	1.1 €	1.4 €	1.8 €
Total op. profit (loss)	(10.4 €)	(6.4 €)	(9.9 €)
R&D	(9.2 €)	(5.7 €)	
SG&A	(2.3 €)	(2.1 €)	
EPS	(€ 0.31)	(€ 0.16)	(€ 0.27)
Net income (loss)	(10.7 €)	(5.4 €)	(9.4 €)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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	***
AFM24	Solid tumors	Potentially update progress	1H17	***
AFM26	Multiple myeloma	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

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	1Q16	2Q16	3Q16	4Q16	2016	1Q17E	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	1.9	2.1	0.9	1.4	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	0.0	0.0	(0.0)	0.1	-	-	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2
Total revenue	3.8	8.2	2.0	2.1	1.0	1.4	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)	(7.1)	(8.6)	(8.8)	(5.7)	(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)	(2.1)	(2.0)	(2.2)	(2.1)	(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)	(9.2)	(10.6)	(10.9)	(7.8)	(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)	(7.1)	(8.5)	(10.0)	(6.4)	(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	(1.3)	0.5	(0.3)	1.0	(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)	(8.5)	(8.0)	(10.3)	(5.5)	(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	(0.0)	(0.0)	-	0.1	0.1	-	-	-	-	0.0	0.0	0.0	0.0	(19.3)	(119.7)
Net Income (Loss)	(0.3)	(20.2)	(8.5)	(8.0)	(10.3)	(5.4)	(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)	(8.5)	(8.0)	(10.3)	(5.4)	(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)	(9.0)	(8.9)	(11.0)	(5.8)	(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)	(€ 0.25)	(€ 0.24)	(€ 0.31)	(€ 0.16)	(€ 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)	(€ 0.25)	(€ 0.24)	(€ 0.31)	(€ 0.16)	(€ 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)	(\$0.26)	(\$0.27)	(\$0.32)	(\$0.17)	(\$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	34.3	33.5	33.7	33.9	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	34.3	33.5	33.7	33.9	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%	-350%	-409%	-915%	-418%	-468%	-700%	-1033%	-444%	-783%	-669%	-729%	-140%	-73%	-27%	-9%
SG&A	-62%	-92%	-104%	-93%	-228%	-152%	-129%	-236%	-286%	-114%	-203%	-187%	-196%	-36%	-18%	-7%	-2%
Operating Income (loss)	-217%	-260%	-353%	-403%	-1043%	-470%	-496%	-836%	-1219%	-458%	-886%	-755%	-825%	-168%	-53%	33%	67%
Pretax	-11%	-246%	-418%	-381%	-1076%	-401%	-500%	-882%	-1259%	-469%	-931%	-786%	-855%	-173%	-56%	33%	67%
Tax Rate													0%	0%	0%	37%	37%
Net Income	-7%	-246%	-418%	-381%	-1076%	-396%	-499%	-882%	-1259%	-469%	-931%	-786%	-855%	-173%	-56%	20%	42%
Financial Indicator Growth Analysis (YoY%)																	
Total Revenue	-34%	118%	-27%	-9%	-34%	-18%	-21%	-55%	-64%	99%	-20%	-28%	0%	469%	106%	194%	203%
R&D	-33%	129%	142%	54%	36%	-19%	37%	-11%	-10%	-4%	50%	3%	9%	8%	7%	7%	
SG&A	-67%	222%	13%	17%	5%	7%	10%	2%	9%	-1%	7%	4%	5%	5%	5%	5%	
Marketing and sales														25%	15%	5%	
Operating Income (Losses)	-48%	161%	257%	71%	41%	-12%	50%	5%	8%	-13%	51%	10%	9%	16%	-34%	-284%	507%
Pretax Income	-98%	4662%	470%	55%	42%	-13%	59%	-6%	17%	-13%	87%	13%	9%	15%	-33%	-271%	521%
Net Income	-99%	7713%	470%	55%	41%	-14%	59%	-6%	17%	-13%	89%	13%	9%	15%	-33%	-208%	521%
EPS	-99%	5931%	299%	28%	29%	-16%	37%	-29%	-14%	-36%	39%	-18%	4%	-5%	-37%	-204%	511%

Yale Jen, Ph.D. 212-953-4978

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

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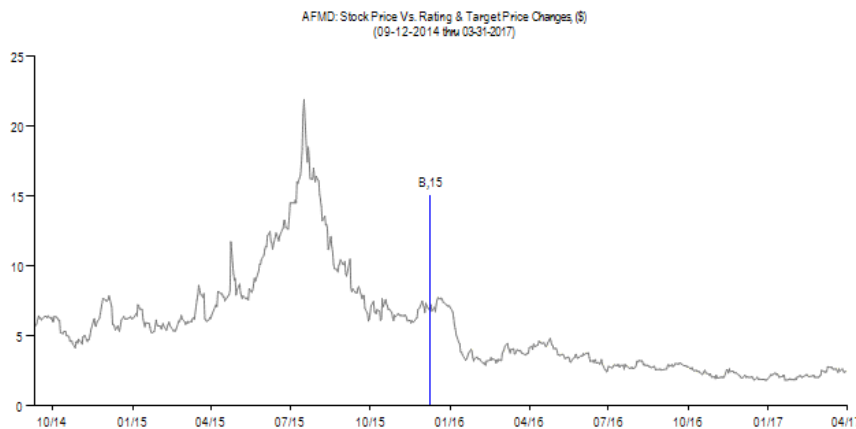
Rating and Price Target Change History

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

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			Investment Banking	Brokerage
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