

Affimed N.V. (AFMD - \$ 3.69)

4Q15: Uneventful Quarter with Multiple Clinical Studies Ongoing to Explore Drug Activities and NK Immune Responses

Yesterday, AFMD reported 4Q15 financial results with a net loss of (€6.3MM), vs. Laidlaw (€3.6MM) and the Street (€5.8MM) estimates. Net loss per share was (€0.19) vs. (€0.11) and (€0.17) for Laidlaw and the Street, respectively. AFMD ended 2015 with cash of ~€67MM, enough to support its operations into 2018, in our opinion.

- AFM13 development updates.** AFMD updated investors on the three AFM13 in relapsed/refractory Hodgkin's lymphoma (HL) and CD30⁺ lymphoma Phase II studies. 1) Patient enrollment for the r/r HL Phase IIa trial is ongoing with interim data expected in mid-16, and efficacy (ORR) data potentially by year end 2016. 2) The AFM13/Keytruda combination in r/r HL Phase Ib trial is slated to start in 2Q16 with interim data (3 month safety and efficacy results) potentially available in 4Q16. It is a dose-escalating study starting with two lower doses, followed by an active dose of AFM13 in combination with standard Keytruda regimen. Once safety is established, an additional 20 patients will be treated at the active dose for exploring treatment efficacy. Study objectives are safety and ORR assessments at 3 and 6 months. 3) In collaboration with Columbia University, an IND for AFM13 in CD30⁺ lymphoma (n=20-30) Phase Ib/IIa trial was filed recently, and we anticipate the trial will start to recruit patients in 2Q16. All patients will be treated under active dose (i.e. 1.5mg/kg, 3x/wk, under which NK cells are permanently activated) but with the drug to be administered at different times or levels (i.e. 1.5mg/kg, 1x/wk or 7mg/kg, 1x/wk, under which NK cell were activated and then recovered). The study objective is to assess treatment efficacy and its impact on NK-cell-induced immunity. Primary endpoint also is ORR at 3 and 6 months. Biopsies (min. 3 per patient) will be assessed for all patients. Interim data reporting could be available and we anticipate top-line results could be available in 2017.
- AFM11 development updates.** For the AFM11 in non-Hodgkin's Lymphoma (NHL) Phase I study, patient enrollment is ongoing and top-line results could be available by year end 2016. The AFM11 in acute lymphocytic leukemia (ALL) Phase I study is expected to start in 2Q16.
- 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.

Earnings Estimates: (€per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.22	-0.23	-0.25	-0.28	-0.98	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

Healthcare/Biotechnology

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

Trading Data:

Last Price (03/30/2016)	\$ 3.69
52-Week High (7/17/2015)	\$ 24.20
52-Week Low (2/11/2016)	\$ 2.76
Market Cap. (MM)	\$ 123
Shares Out. (MM)	33

Yale Jen, Ph.D.

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

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
AFM13	Hodgkin's lymphoma (r/r)	Potentially report Phase IIa study interim results	Mid-16	**
		Potentially start a Phase I CPI combination Phase I study	2Q16	****
		Potentially report Phase IIa study preliminary top-line results	4Q16	***
		Potentially report Phase I CPI combination Phase I study results	YE-2016	****
	CD30+ lymphoma	Potentially report Phase IIa study results	2017	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study interim results	4Q16	****
	Acute lymphoblastic leukemia (ALL)	Potentially start Phase I study	Mid-16	***
AFM21/22	Solid tumors	Potentially select clinical candidate and IND enabling study	2H16	***
		Potentially start Phase I study	2H17	***

**** / ***** 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 ~\$83MM (pro forma) cash after recent financing, 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	1Q15	2Q15	3Q15	4Q15	2015					2016E	2017E	2018E	2019E	2020E	2021E	2022E
							1Q16E	2Q16E	3Q16E	4Q16E							
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	2.5	2.2	1.2	1.7	7.6	1.2	1.3	1.3	1.4	5.2	5.2	5.2	5.2	5.2	5.2	5.2
Other revenue	0.4	0.2	0.1	0.3	0.0	0.7	0.1	0.1	0.1	0.1	0.4	0.4	0.4	0.4	0.4	0.4	0.4
Total revenue	3.8	2.8	2.3	1.5	1.7	8.2	1.3	1.4	1.4	1.5	5.6	5.6	5.6	27.4	55.5	161	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)	(2.9)	(5.6)	(6.4)	(7.0)	(22.0)	(7.4)	(7.7)	(8.1)	(8.8)	(32.0)	(36.2)	(39.4)	(43.0)	(46.4)	(49.6)	(53.1)
General and administrative	(2.3)	(1.8)	(1.7)	(2.1)	(2.0)	(7.5)	(2.0)	(2.0)	(2.1)	(2.2)	(8.4)	(9.5)	(10.0)	(10.5)	(11.0)	(11.6)	(12.2)
Marketing and sales														(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(4.8)	(7.3)	(8.5)	(9.0)	(29.6)	(9.4)	(9.7)	(10.3)	(11.0)	(40.4)	(45.7)	(49.4)	(74.5)	(83.7)	(91.4)	(97.0)
Operating Incomes (losses)	(8.2)	(2.0)	(5.0)	(7.1)	(7.3)	(21.3)	(8.1)	(8.3)	(8.9)	(9.5)	(34.8)	(40.1)	(43.8)	(50.3)	(35.7)	46.5	317.3
Finance income / (costs) - net	7.8	0.5	(0.2)	(0.2)	1.0	1.1	0.5	0.5	0.2	(0.3)	0.9	0.9	0.9	0.9	0.9	0.9	0.9
Loss before tax	(0.4)	(1.5)	(5.2)	(7.3)	(6.3)	(20.2)	(7.6)	(7.8)	(8.7)	(9.8)	(33.9)	(39.2)	(42.9)	(49.4)	(34.8)	47.4	318.2
Tax	0.2	-	-	(0.0)	0.0	0.0	-	-	-	-	0.0	0.0	0.0	0.0	0.0	(17.5)	(117.8)
Net Income (Loss)	(0.3)	(1.5)	(5.2)	(7.3)	(6.3)	(20.2)	(7.6)	(7.8)	(8.7)	(9.8)	(33.9)	(39.2)	(42.9)	(49.4)	(34.8)	29.8	200.5
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(1.5)	(5.2)	(7.3)	(6.3)	(20.2)	(7.6)	(7.8)	(8.7)	(9.8)	(33.9)	(39.2)	(42.9)	(49.4)	(34.8)	29.8	200.5
Net Income (Loss) Applicable to Common Shareholders (\$)	(0.3)	(1.6)	(5.6)	(7.9)	(6.7)	(21.8)	(8.1)	(8.3)	(9.2)	(10.4)	(36.0)	(41.7)	(45.7)	(52.6)	(37.0)	31.7	213.3
Net Earnings (Losses) Per Share—Basic	(€0.01)	(€0.06)	(€0.19)	(€0.24)	(€0.19)	(€0.71)	(€0.22)	(€0.23)	(€0.25)	(€0.28)	(€0.98)	(€1.10)	(€1.14)	(€1.04)	(€0.69)	€0.57	€3.74
Net Earnings (Losses) Per Share—Diluted	(€0.01)	(€0.06)	(€0.19)	(€0.24)	(€0.19)	(€0.71)	(€0.22)	(€0.23)	(€0.25)	(€0.28)	(€0.98)	(€1.10)	(€1.14)	(€1.04)	(€0.69)	€0.57	€3.74
Net Earnings (Losses) Per Share—Basic/diluted (\$)	(\$0.01)	(\$0.07)	(\$0.20)	(\$0.26)	(\$0.21)	(\$0.76)	(\$0.24)	(\$0.24)	(\$0.27)	(\$0.30)	(\$1.04)	(\$1.17)	(\$1.22)	(\$1.11)	(\$0.73)	\$0.60	\$3.98
Shares outstanding—basic	22.0	24.0	27.8	30.8	34.1	29.1	34.3	34.5	34.7	34.9	34.6	35.6	37.6	47.6	50.6	52.6	53.6
Shares outstanding—diluted	22.0	24.0	27.8	30.8	34.1	29.1	34.3	34.5	34.7	34.9	34.6	35.6	37.6	47.6	50.6	52.6	53.6
Margin Analysis (% of Sales/Revenue)																	
Costs of goods														15%	15%	15%	15%
R&D	-255%	-106%	-242%	-444%	-419%	-268%	-568%	-549%	-582%	-586%	-571%	-646%	-704%	-157%	-84%	-31%	-11%
SG&A	-62%	-67%	-72%	-142%	-116%	-92%	-155%	-145%	-151%	-147%	-149%	-170%	-179%	-38%	-20%	-7%	-3%
Operating Income (loss)	-217%	-72%	-215%	-486%	-435%	-260%	-623%	-594%	-633%	-633%	-621%	-716%	-783%	-184%	-64%	29%	65%
Pretax	-11%	-54%	-224%	-499%	-376%	-246%	-585%	-558%	-618%	-653%	-605%	-700%	-767%	-180%	-63%	29%	65%
Tax Rate												0%	0%	0%	0%	37%	37%
Net Income	-7%	-54%	-224%	-502%	-374%	-246%	-585%	-558%	-618%	-653%	-605%	-700%	-767%	-180%	-63%	19%	41%
Financial Indicator Growth Analysis (YoY%)																	
Total Revenue	-34%	261%	206%	-27%	603%	118%	-53%	-39%	-4%	-11%	-32%	0%	0%	389%	103%	191%	202%
R&D	-33%	-45%	172%	196%	78056%	129%	153%	37%	26%	25%	45%	13%	9%	9%	8%	7%	7%
SG&A	-67%	-61%	-62%	731%	-128%	222%	9%	21%	2%	13%	11%	14%	5%	5%	5%	5%	5%
Marketing and sales														25%	15%	5%	5%
Operating Income (Losses)	-48%	-79%	-13%	1550%	-201%	161%	305%	67%	25%	30%	63%	15%	9%	15%	-29%	-230%	583%
Pretax Income	-98%	-91%	-1118%	-199%	-185%	4662%	412%	51%	19%	55%	67%	16%	10%	15%	-30%	-236%	572%
Net Income	-99%	-91%	-1208%	-199%	-183%	7713%	412%	51%	19%	56%	67%	16%	10%	15%	-30%	-186%	572%
EPS	-99%	-94%	-691%	-164%	-160%	5931%	259%	21%	5%	48%	38%	12%	4%	-9%	-34%	-183%	559%

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

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

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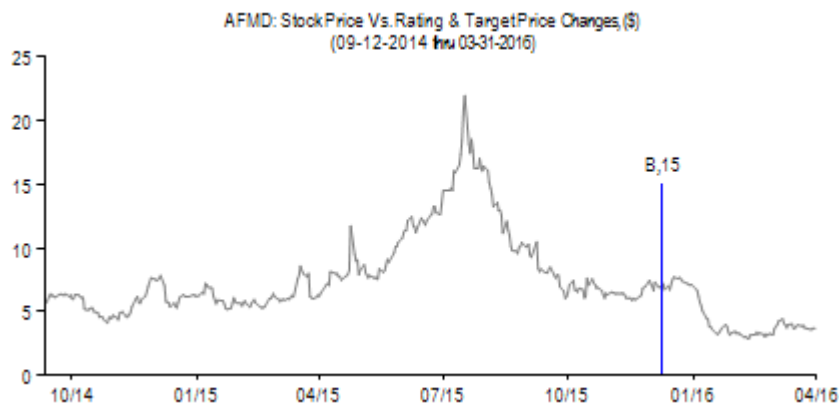
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3 Year Rating Change History		
Date	Rating	Closing Price (\$)
12/10/2015	Buy (B)	7.19

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	65.71%	25.71%	2.86%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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