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EQUITY RESEARCH
Company Report

May 18, 2016

Affimed N.V. (AFMD - $ 3.31)

Healthcare/Biotechnology

1Q16: AFM13 Monotherapy Trial Slowed Down While PD-1 Combo Study Is Charging Forward Full Force

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

This morning, AFMD reported 1Q16 financial results with a net loss of (€8.5MM), vs. Laidlaw (€7.6MM) and the Street (€6.8MM) estimates. Net loss per share was (€0.25) vs. (€0.22) and (€0.16) for Laidlaw and the Street, respectively. AFMD ended 1Q16 with cash of ~€67MM, enough to support its operations into 2018, in our opinion.

- **AFM13 development updates.** 1) Patient enrollment of the AFM13 in relapsed/refractory Hodgkin's lymphoma (HL) monotherapy Phase IIa trial is slower than expected due to the delay in opening new sites and the availability of PD-1 treatment. Of note, PD-1 treatment Opdivo was approved on May 17 in classical HL (cHL) post transplantation and Adcetris treatment. AFMD indicated they would provide more visibility on the recruitment trend in a few months. 2) Patient enrollment for the AFM13/Keytruda combination in r/r HL Phase Ib is ongoing with interim data expected in 4Q16/1Q17, which is in-line with our projection. With the approval of Opdivo, we view this study could be the most critical for AFM13 development in HL. Opdivo achieved an ORR of 65% with CR of 7% and PR of 58% in pivotal trials. The efficacy is consistent with the pattern of the prior Phase I (Trial 9, n=23), of which the CR was also much lower (87% ORR and 22% CR). The potential critical mission of AFM13 is to improve CR (possibly ORR) under a combination setting with PD-1. Opdivo is approved ahead of the scheduled PDUFA date of Sep. 1st. Opdivo therapy median duration of response was 8.7 months and the median time to response was 2.1 months. AFMD's ongoing combo trial 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, AFM13 in CD30^{+} lymphoma (n=20-30) Phase Ib/IIa trial should start to recruit patients in 2Q16. Primary endpoint is ORR at 3 and 6 months. Biopsies (min. 3 per patient) will be assessed for all patients. We anticipate both interim data and top-line results could be available in 2017.
- **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 (05/18/2016)	$ 3.31
52–Week High (7/17/2015)	$ 24.20
52–Week Low (2/11/2016)	$ 2.76
Market Cap. (MM)	$ 110
Shares Out. (MM)	33

Earnings Estimates: (€ per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.25A	-0.22	-0.24	-0.27	-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

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- **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 commencement of AFM11 in acute lymphocytic leukemia (ALL) Phase I study is pushed out to 3Q16 from our prior projected 2Q16. AFMD will recruit patients from Russia, Poland and the Czech Republic and they will be Blincyto treatment naïve patients. As such, it is possible to compare the therapeutic profile between AFM11 and Blincyto. It will be a dose finding study determining PK and MTD as major endpoints.
- **Others.** We anticipate an IND filing for the CD33/CD3 T-cell engaging program could occur near-term. The future development direction will depend on whether Janssen will opt-in for further development. If not, Amphivena and AFMD could potentially move the program forward to clinical studies. For EGFR targeted programs (AFM21/22/24), the cell line developments are initiated. It is interesting that the T- and NK-cell engaging bispecific antibody could potentially address different solid tumors, possibly due to the different microenvironments surrounding different tumors.

Table 1: Estimated and reported 1Q16 results

1Q16 Estimates and Reported Results			
(€,000)	**Laidlaw Estimate**	**Actual**	**Consensus**
Total revenue	**1.3 €**	**2.0 €**	**2.8 €**
Total op. profit (loss)	**(8.1 €)**	**(7.1 €)**	**(6.4 €)**
R&D	(7.4 €)	(7.1 €)	
SG&A	(2.0 €)	(2.1 €)	
EPS	**(€ 0.22)**	**(€ 0.25)**	**(€ 0.16)**
Net income (loss)	(7.6 €)	(8.5 €)	(5.8 €)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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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 (n=20)	**2017**	**
		Potentially report Phase IIa study preliminlary top-line results	**2017**	***
		Potentially report Phase I CPI combination Phase I study results	**4Q16/1Q17**	****
	CD30+ lymphoma	Potentially report Phase IIa study results	**2017**	***
AFM11	Non-Hodgkin's lymphoma (NHL)	Potentially report Phase I study interium results	**4Q16**	****
	Acute lymphoblastic leukemia (ALL)	Potentially start Phase I study	**3Q16**	***
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

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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	1Q16	2Q16E	3Q16E	4Q16E	2016E	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	1.3	1.3	1.4	5.9	5.9	5.9	5.9	5.9	5.9	5.9
Other revenue	0.4	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	8.2	2.0	1.4	1.4	1.5	6.3	6.3	6.3	28.1	56.2	162	487
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)	(7.4)	(7.8)	(8.4)	(30.6)	(34.6)	(37.7)	(41.1)	(44.4)	(47.5)	(50.8)
General and administrative	(2.3)	(7.5)	(2.1)	(2.1)	(2.2)	(2.3)	(8.7)	(9.9)	(10.4)	(10.9)	(11.5)	(12.0)	(12.6)
Marketing and sales										(21.0)	(26.3)	(30.2)	(31.7)
Total Operating Expenses	(11.9)	(29.6)	(9.2)	(9.5)	(10.0)	(10.7)	(39.3)	(44.5)	(48.1)	(73.0)	(82.1)	(89.7)	(95.2)
Operating Incomes (losses)	(8.2)	(21.3)	(7.1)	(8.1)	(8.6)	(9.2)	(33.0)	(38.2)	(41.8)	(48.2)	(33.4)	48.9	319.9
Finance income / (costs) - net	7.8	1.1	(1.3)	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)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	48.0	319.0
Tax	0.2	0.0	(0.0)	-	-	-	0.0	0.0	0.0	0.0	0.0	(17.7)	(118.0)
Net Income (Loss)	(0.3)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	30.2	200.9
Net Income (Loss) Applicable to Common Shareholders	(0.3)	(20.2)	(8.5)	(7.6)	(8.4)	(9.5)	(33.9)	(39.1)	(42.7)	(49.1)	(34.3)	30.2	200.9
Net Income (Loss) Applicable to Common Shareholders ($)	($0.3)	($21.8)	($9.0)	($8.0)	($8.9)	($10.1)	($36.1)	($41.6)	($45.4)	($52.2)	($36.5)	$32.1	$213.8
Net Earnings (Losses) Per Share—Basic	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.22)	(€ 0.24)	(€ 0.27)	(€ 0.98)	(€ 1.10)	(€ 1.14)	(€ 1.03)	(€ 0.68)	€ 0.57	€ 3.75
Net Earnings (Losses) Per Share—Diluted	(€ 0.01)	(€ 0.71)	(€ 0.25)	(€ 0.22)	(€ 0.24)	(€ 0.27)	(€ 0.98)	(€ 1.10)	(€ 1.14)	(€ 1.03)	(€ 0.68)	€ 0.57	€ 3.75
Net Earnings (Losses) Per Share—Basic/diluted ($)	($0.01)	($0.76)	($0.26)	($0.23)	($0.26)	($0.29)	($1.04)	($1.17)	($1.21)	($1.10)	($0.72)	$0.61	$3.99
Shares outstanding—basic	22.0	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	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%	-268%	-350%	-525%	-557%	-561%	-484%	-547%	-597%	-146%	-79%	-29%	-10%
SG&A	-62%	-92%	-104%	-151%	-157%	-152%	-137%	-157%	-165%	-39%	-20%	-7%	-3%
Operating Income (loss)	-217%	-260%	-353%	-576%	-614%	-613%	-522%	-604%	-661%	-171%	-59%	30%	66%
Pretax	-11%	-246%	-418%	-540%	-599%	-633%	-536%	-619%	-676%	-175%	-61%	30%	65%
Tax Rate								0%	0%	0%	0%	37%	37%
Net Income	-7%	-246%	-418%	-540%	-599%	-633%	-536%	-619%	-676%	-175%	-61%	19%	41%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	-34%	118%	-27%	-39%	-4%	-11%	-23%	0%	0%	345%	100%	188%	201%
R&D	-33%	129%	142%	31%	21%	20%	39%	13%	9%	9%	8%	7%	7%
SG&A	-67%	222%	13%	26%	6%	17%	15%	14%	5%	5%	5%	5%	5%
Marketing and sales											25%	15%	5%
Operating Income (Losses)	-48%	161%	257%	62%	22%	26%	55%	16%	9%	15%	-31%	-246%	554%
Pretax Income	-98%	4662%	470%	46%	16%	50%	68%	15%	9%	15%	-30%	-240%	565%
Net Income	-99%	7713%	470%	46%	15%	51%	68%	15%	9%	15%	-30%	-188%	565%
EPS	-99%	5931%	299%	18%	2%	43%	38%	12%	3%	-9%	-34%	-185%	553%

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

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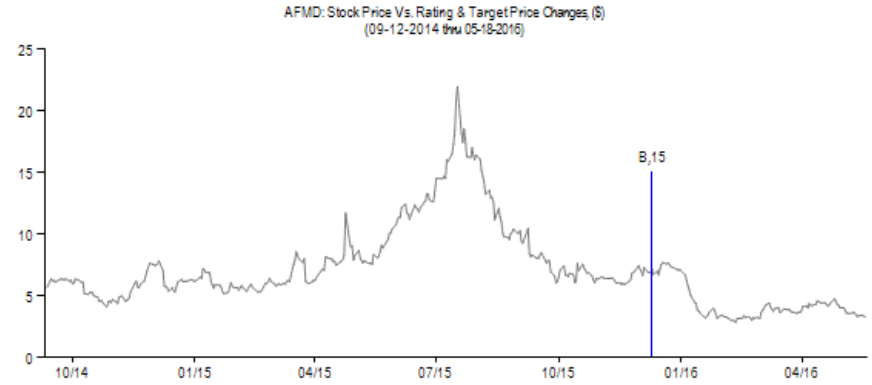
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
12/10/2015	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**

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.	66.67%	27.78%	2.78%
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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