

Kiadis

Resetting on ATIR101 Discontinuation; PT to €1.5 with NK-Cell Focus

18 November 2019

Key Takeaway

An expert event highlighted promising albeit early data for NK-cells, hinting at their potential to improve half-matched stem cell transplants and treat relapsed/refractory AML. We now include a token value for both, heavily risk-adjusted. Whilst the cash runway is now extended to perhaps 4Q20E (from 2Q20E), overhangs remain, notably a lack of data catalysts until 2021E and the dent to management credibility given numerous recent setbacks. Hold with PT to €1.5.

New Kiadis with a focus on NK cells: A presentation by Dr Dean Lee, co-founder of CytoSen, highlighted encouraging but early data with the NK cells, both in improving outcomes in half-matched haploidentical stem cell transplants (HSCT) and in treating relapsed/refractory AML. In academic studies:

- **Haplo-ID HSCT:** In 25 patients as an adjunct to the Baltimore/PTCy protocol an 8% relapse rate and 74% overall survival was observed, versus 45% for each with matched controls.
- **Relapsed/refractory AML:** A 69% complete response rate in 13 patients after a median 4 prior treatments.

A Phase I/II trial in haplo-ID HSCT, supported by the Blood and Marrow Transplant Clinical Trials Network (BMT CTN) in the US, is planned to start 2020E. A Phase I/IIa study in r/r AML is also planned to start 2020E utilising universal donor NK-cells, as opposed to a haplo donor product. Data from both could come during 2021E.

We now include placeholder NPVs for the NK cells, based on c.\$400m peak sales in HSCT, not dissimilar to our peak sales assumption for ATIR101 and c.\$325m peak sales in r/r AML. Both are heavily risk adjusted as only early academic data are currently available, assigning a 15% probability for HSCT and a lower 10% probability in r/r AML given fewer patients and a universal donor, rather than haplo donor product, will be used in future trials.

ATIR101 discontinued on diminishing likelihood of success: A higher than expected drop-out rate in the ATIR101 arm of the ongoing Phase III HATCY trial in haploidentical "half-matched" stem cell transplants (HSCT) prompted Kiadis to assess more recent real-world HSCT data. This revealed that outcomes with standard-of-care post-transplant cyclophosphamide (PTCy) have improved, therefore raising the hurdle for ATIR101 to demonstrate a benefit versus PTCy in the trial, given this was the comparator. This led Kiadis to conclude the trial should be terminated and development of ATIR101 discontinued. We have now completely removed ATIR101 from our model and valuation, previously worth €5/share (c.70%) of NPV on a pre-diluted basis.

Price Target to €1.5 per share; cash runway extended to 4Q20E: We have removed ATIR101 entirely from our forecasts and valuation but now include a placeholder valuation for the NK cells. We assume some residual Phase III costs until 2Q20E allowing time to shut down active sites, but expect a significant decrease in R&D expenses in 2020E, even allowing for the start of clinical trials with the NK-cells. Our forecasts include c.€3-4m of restructuring costs, predominantly in 4Q19E, with the

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RATING	HOLD
PRICE	€1.41 [^]
MARKET CAP	€41.8M / \$46.0M
PRICE TARGET (PT)	€1.50 (FROM €2.50)
UPSIDE SCENARIO PT	€5.00
DOWNSIDE SCENARIO PT	€0.50

[^]Prior trading day's closing price unless otherwise noted.

FY Dec

EUR	2018A	2019E	2020E	2021E
EPS	(1.46)	↑(1.90)	↑(1.19)	↑(1.26)
Prev.		(2.04)	(1.99)	(1.96)
FY P/E	NM	NM	NM	NM

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50% headcount reduction mostly in Europe. Our updated forecasts suggests cash of €47m at end September could now be sufficient to fund operations to 4Q20E.

KIADIS (KDS NA)

Estimates				
€	2018A	2019E	2020E	2021E
Rev. (MM)	0.0	0.0	0.0	0.0
<i>Previous</i>				
EBIT (MM)	(25.2)	↑ (47.7)	↑ (30.6)	↑ (32.7)
<i>Previous</i>		(51.8)	(55.0)	(53.7)
Cash Position	60.3	↓ 30.7	↓ 2.5	↓ 2.5
<i>Previous</i>		31.0	4.4	4.2
EPS	(1.46)	↑ (1.90)	↑ (1.19)	↑ (1.26)
<i>Previous</i>		(2.04)	(1.99)	(1.96)

Valuation				
	2018A	2019E	2020E	2021E
EV/EBIT	NM	NM	NM	NM
FY P/E	NM	NM	NM	NM

Market Data	
52-Week Range:	€10.70 - €1.31
Total Entprs. Value	€12.8M
Avg. Daily Value MM (USD)	0.59
Float (%)	100.0%

Financial Summary	
Long-Term Debt (MM)	€15.8
Cash & ST Invest. (MM)	€47.0

The Long View

Scenarios

Base Case

- NK cells could offer an alternative cell therapy option to treat various cancers, including solid and liquid tumours, with the potential to harness the innate immune system
- We forecast c.\$725m peak NK cell sales for haplo-ID HSCT and in treating r/r AML with conservative 15% and 10% probabilities, respectively, given the early stage of development
- Price Target €1.5/share comprising NPVs for the NK cells in HSCT and r/r AML plus Net Cash, less potential dilution to ensure sufficient funds for three years

Upside Scenario

- Positive Phase I/II HSCT data in 2021E could boost confidence in the NK cells, adding €1/share
- Positive Phase I/II r/r AML data in 2021E could boost confidence, adding c.€1.5/share
- Over a 12-month period, if the funding overhang can be addressed, reducing the potential dilution to our NPVs, this could boost our NPV derived Price Target to €5/share

Downside Scenario

- Efficacy or safety concerns with the NK cells could remove c.€2.5/share from our NPVs
- Over a 12-month period, if Kiadis can only raise limited funds at a substantial >50% discount to the current share price, this could reduce our NPV derived Price Target to €0.5/share

Investment Thesis / Where We Differ

- There is a lack of data catalysts for the next 12-18 months until initial NK cell data become available from 2021E. Our financial model suggests the c.€47m cash at end-September 2019 should be sufficient to fund cash burn to 4Q20E.

Catalysts

- Start of the Phase I/II K-NK002 trial in HSCT during 2020E
- Start of the Phase I/IIa K-NK003 r/r AML trial during 2020E
- Initial data from the NK cells during 2021E

Retain Hold with reduced €1.5 Price Target

Kiadis develops innovative cell therapies for safer and more effective bone marrow transplants and to treat cancers. Following the recent discontinuation of lead product ATIR101 the focus is now on the earlier stage NK-cells which Kiadis acquired in April in an all-share transaction. K-NK002 is due to start a Phase I/II trial in haplo-ID HSCT and K-NK003 is due to commence a Phase I/IIa trial in relapsed/refractory AML in 2020E. The NK cells could also have potential in combination with chemotherapy and antibodies, and across a range of solid and liquid tumours. Current cash is sufficient to 4Q20E, in our view. Retain Hold given the lack of near-term catalysts with a reduced NPV-based Price Target of €1.5 per share.

NK cell technology acquired through CytoSen

CytoSen's technology platform is based around natural killer cells (NK cells) a type of lymphocyte (white blood cell) that is part of the innate immune system. NK cells can potentially play a role in lowering the risk of relapse in the first few months after a haematopoietic stem cell transplant (HSCT) as they are the first white blood cells to reconstitute, in addition to preventing infections and improving mortality.

Exhibit 1 - Changes to forecasts

(EUR millions Dec YE)	2019 Old	2019 New	% Chg	2020 Old	2020 New	% Chg	2021 Old	2021 New	% Chg
Sales	0.0	0.0	n/a	0.0	0.0	n/a	0.0	0.0	n/a
Gross Profit	0.0	0.0	n/a	0.0	0.0	n/a	0.0	0.0	n/a
R&D Expenses	(35.0)	(30.9)	-12%	(37.5)	(15.1)	-60%	(35.0)	(16.1)	-54%
General & Admin. Expenses	(16.8)	(16.8)	+0%	(17.5)	(15.5)	-11%	(18.7)	(16.6)	-11%
Sales & Marketing Expenses	0.0	0.0	n/a	0.0	0.0	n/a	0.0	0.0	n/a
Operating Income	(51.8)	(50.2)	-3%	(55.0)	(31.6)	-43%	(53.7)	(32.7)	-39%
Pre-tax Profit	(57.3)	(55.7)	-3%	(60.7)	(37.3)	-39%	(61.5)	(39.6)	-36%
Net Income	(57.3)	(55.7)	-3%	(60.7)	(37.3)	-39%	(61.5)	(39.6)	-36%
Adjusted Net Income	(57.3)	(53.2)	-7%	(60.7)	(36.3)	-40%	(61.5)	(39.6)	-36%
EPS (EUR)	(2.0)	(2.0)	-3%	(2.0)	(1.2)	-39%	(2.0)	(1.3)	-36%
Adjusted EPS (EUR)	(2.0)	(1.9)	-7%	(2.0)	(1.2)	-40%	(2.0)	(1.3)	-36%
Net Cash/(Debt)	0.4	0.1	-70%	(60.8)	(34.6)	-43%	(119.1)	(70.2)	-41%

Source: Jefferies estimates

€1.5 Price Target using NPV sum-of-the-parts

Similar to other biotech stocks in our coverage universe, we believe the most appropriate valuation methodology for Kiadis is a fundamental NPV sum-of-the-parts. Hence, our Price Target comprises NPVs for the NK cells, in addition to Net Cash. We then adjust our valuation to reflect the potential dilution from a capital increase to ensure sufficient funds for at least three years. This assumes an approximate 10%-20% discount to the current share price. Data and/or potential out-licensing deals could crystallise significant value, and provide upside to our valuation, but we see limited catalysts in the next 12-18 months.

Exhibit 2 - Kiadis sum-of-the-parts valuation

	Indication	Peak Sales (\$mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	EUR per share
ATIR101	Haploidentical HSCT	385	304	0%	0	0.0
NK-cells	Haploidentical HSCT	400	329	15%	49	1.7
	r/r AML	325	267	10%	27	0.9
Net Cash/(Debt)			63	100%	63	2.1
Valuation			963		139	4.7
Potential Dilution for Funding					(89)	(3.3)
Potential Diluted Valuation						1.5

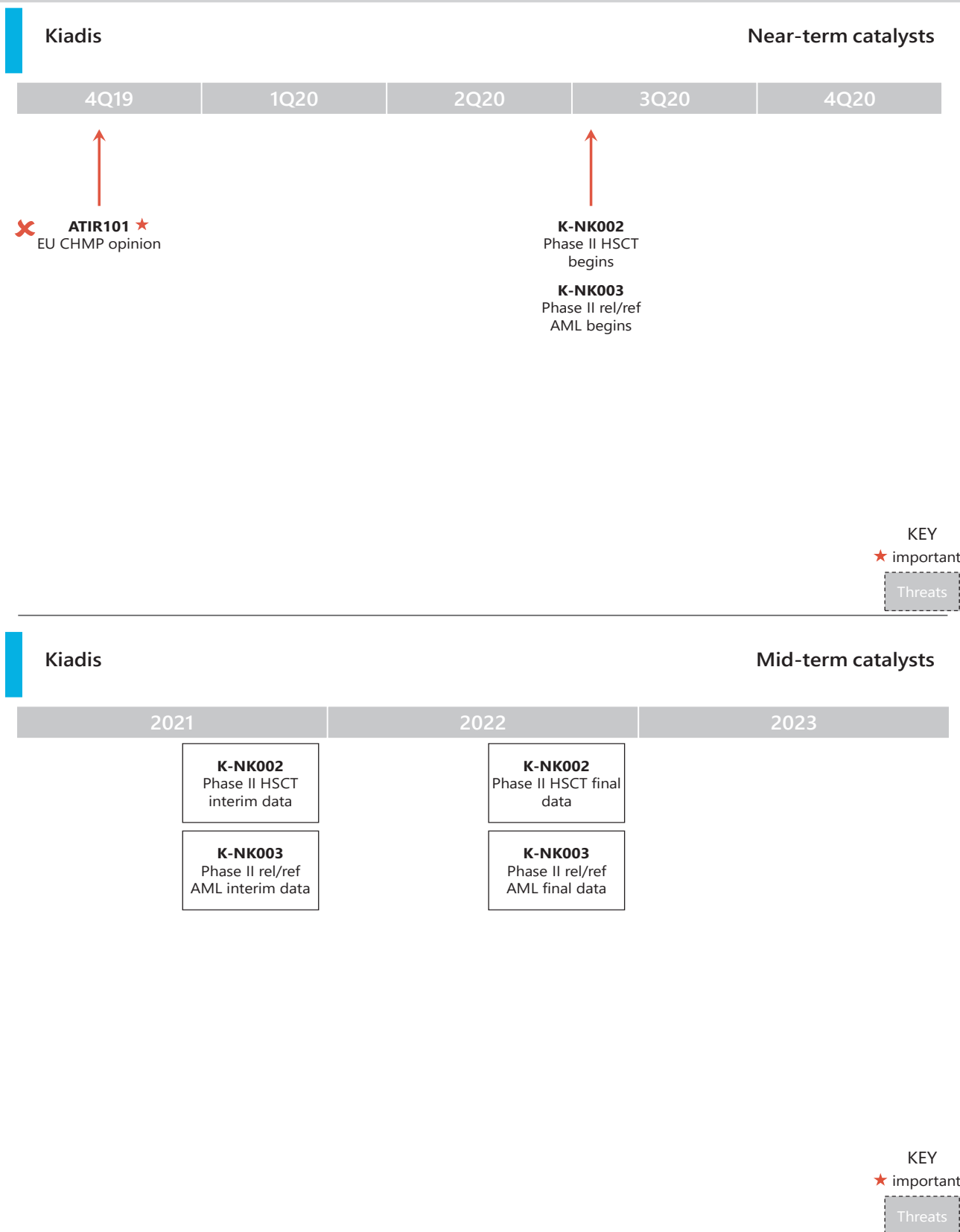
Source: Jefferies estimates

Exhibit 3 - Source of upside potential and downside risk

	Upside	EUR per share	Downside	EUR per share
NK-cells (K-NK002) Phase I/II HSCT data	Positive safety & efficacy	1.1	Efficacy and/or safety concerns	(1.7)
NK-cells (K-NK003) Phase I/II r/r AML data	Positive safety & efficacy	1.4	Efficacy and/or safety concerns	(0.9)
NK-cells additional indications	Initial encouraging clinical data	1.7	No clinical benefits	0.0
Potential Upside/(Downside)		4.1		(2.6)
Potential Valuation		8.9		2.1

Source: Jefferies estimates

Exhibit 4 - Kiadis catalysts



Source: Jefferies research

Jefferies

Exhibit 5 - Kiadis Profit and Loss Model

(EUR millions except EPS Dec YE)	2019E							
	2018A	1H19A	2H19E	2019E	2020E	2021E	2022E	2023E
NK-Cells	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
License & Other Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cost of Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Operating Expenses	(25.2)	(25.7)	(22.0)	(47.7)	(30.6)	(32.7)	(38.8)	(45.0)
R&D Expenses	(17.5)	(16.2)	(14.7)	(30.9)	(15.1)	(16.1)	(21.2)	(26.3)
General & Admin. Expenses	(7.7)	(9.5)	(7.3)	(16.8)	(15.5)	(16.6)	(17.6)	(18.6)
Sales & Marketing Expenses	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
o/w Acquisition-related Amortisation/Write-down	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Operating Income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Exceptionals	0.0	0.0	(2.5)	(2.5)	(1.0)	0.0	0.0	0.0
Operating Income	(25.2)	(25.7)	(24.5)	(50.2)	(31.6)	(32.7)	(38.8)	(45.0)
Adjusted Operating Income	(25.2)	(25.7)	(22.0)	(47.7)	(30.6)	(32.7)	(38.8)	(45.0)
Net Financial Income	(4.6)	(0.2)	(5.3)	(5.5)	(5.7)	(6.8)	(8.0)	(7.7)
Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income from Associates & JVs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pretax Profit	(29.8)	(25.9)	(29.8)	(55.7)	(37.3)	(39.6)	(46.8)	(52.7)
Adjusted Pretax Profit	(29.8)	(25.9)	(27.3)	(53.2)	(36.3)	(39.6)	(46.8)	(52.7)
Taxation	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income from Continuing Operations	(29.8)	(25.9)	(29.8)	(55.7)	(37.3)	(39.6)	(46.8)	(52.7)
Net Income from Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	(29.8)	(25.9)	(29.8)	(55.7)	(37.3)	(39.6)	(46.8)	(52.7)
Adjusted Net Income	(29.8)	(25.9)	(27.3)	(53.2)	(36.3)	(39.6)	(46.8)	(52.7)
WA Basic Shares (mn)	20.5	25.1	30.0	28.0	30.4	31.4	32.5	34.0
WA Shares Diluted (mn)	20.5	25.1	30.0	28.0	30.4	31.4	32.5	34.0
EPS (EUR)	(1.5)	(1.0)	(1.0)	(2.0)	(1.2)	(1.3)	(1.4)	(1.6)
Adjusted EPS (EUR)	(1.5)	(1.0)	(0.9)	(1.9)	(1.2)	(1.3)	(1.4)	(1.6)
Diluted EPS (EUR)	(1.5)	(1.0)	(1.0)	(2.0)	(1.2)	(1.3)	(1.4)	(1.6)
Diluted Adjusted EPS (EUR)	(1.5)	(1.0)	(0.9)	(1.9)	(1.2)	(1.3)	(1.4)	(1.6)
% Change Year over Year								
Revenue	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Cost of Sales	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Gross Profit	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Total Operating Expenses	56.3%	131.8%	55.9%	89.3%	(35.9%)	7.0%	18.6%	15.9%
R&D Expenses	55.8%	110.8%	50.3%	77.0%	(51.3%)	7.1%	31.6%	24.0%
General & Admin. Expenses	57.7%	179.6%	68.5%	117.3%	(7.7%)	7.0%	6.0%	6.0%
Sales & Marketing Expenses	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Operating Income	(56.3%)	(131.8%)	(73.6%)	(99.3%)	37.1%	(3.6%)	(18.6%)	(15.9%)
Adjusted Operating Income	(56.3%)	(131.8%)	(55.9%)	(89.3%)	35.9%	(7.0%)	(18.6%)	(15.9%)
Net Financial Income	(402.7%)	94.2%	(228.1%)	(19.7%)	(3.9%)	(19.7%)	(16.7%)	3.0%
Pretax Profit	(74.9%)	(84.1%)	(89.6%)	(87.0%)	33.1%	(6.1%)	(18.3%)	(12.6%)
Adjusted Pretax Profit	(74.9%)	(84.1%)	(73.7%)	(78.6%)	31.8%	(9.0%)	(18.3%)	(12.6%)
Net Income	(74.9%)	(84.3%)	(89.3%)	(86.9%)	33.1%	(6.1%)	(18.3%)	(12.6%)
Adjusted Net Income	(74.9%)	(84.3%)	(73.4%)	(78.6%)	31.8%	(9.0%)	(18.3%)	(12.6%)
EPS (EUR)	(27.9%)	(39.4%)	(38.2%)	(36.3%)	38.4%	(3.0%)	(14.0%)	(7.9%)
Adjusted EPS (EUR)	(27.9%)	(39.4%)	(26.6%)	(30.2%)	37.2%	(5.8%)	(14.0%)	(7.9%)

Source: Jefferies estimates; company data

Exhibit 6 - Kiadis Cash Flow Model

(EUR millions Dec YE)	2018A	2019E	2020E	2021E	2022E	2023E
Operating Income	(25.2)	(50.2)	(31.6)	(32.7)	(38.8)	(45.0)
Depreciation and Amortisation	1.0	1.4	1.7	1.9	2.1	2.2
EBITDA	(24.2)	(48.9)	(29.9)	(30.8)	(36.7)	(42.7)
Other Adjustments and Exceptionals	1.6	3.5	2.5	2.7	2.8	3.0
Decrease/(Increase) in Inventories	0.0	0.0	0.0	0.0	0.0	0.0
Decrease/(Increase) in Receivables	(0.8)	0.0	0.0	0.0	0.0	0.0
Increase/(Decrease) in Payables	1.3	0.9	(0.2)	1.0	0.7	0.7
Increase/(Decrease) in Deferred Income	0.0	0.0	0.0	0.0	0.0	0.0
Change in WC	0.5	0.9	(0.2)	1.0	0.7	0.7
Taxation Paid	(0.0)	(0.0)	0.0	0.0	0.0	0.0
Interest Paid	(2.1)	(4.4)	(4.5)	(5.5)	(6.5)	(7.5)
Net Cash Flow from Operating Activities	(24.2)	(48.8)	(32.0)	(32.7)	(39.7)	(46.5)
Purchase of Tangible Fixed Assets	(1.1)	(2.0)	(1.5)	(1.6)	(1.7)	(1.7)
Proceeds from Sale of PP&E	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of Intangible Assets	0.0	0.0	0.0	0.0	0.0	0.0
(Purchase)/Sale of Investments	0.0	0.0	0.0	0.0	0.0	0.0
(Acquisitions)/Disposals of Subsidiaries	0.0	3.1	0.0	0.0	0.0	0.0
Dividends Received from Associates	0.0	0.0	0.0	0.0	0.0	0.0
Interest Received	0.0	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Investing Activities	(1.1)	1.1	(1.5)	(1.6)	(1.7)	(1.7)
Management of Liquid Resources	0.0	0.0	0.0	0.0	0.0	0.0
Capital Changes	53.9	25.0	(0.0)	0.0	(0.0)	(0.0)
Debt Changes	2.4	(3.9)	5.3	34.4	41.9	48.7
Equity Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0
Other Financing Cash Flows	(0.6)	0.0	0.0	0.0	0.0	0.0
Net Cash Flow from Financing Activities	55.7	21.1	5.3	34.4	41.9	48.7
Effect of FX on Cash and Cash Equivalents	0.0	0.0	0.0	0.0	0.0	0.0
Increase in Cash	30.4	(26.7)	(28.3)	0.1	0.5	0.5
Change in Net Debt	(28.6)	22.8	33.5	34.3	41.4	48.2
(Cash Burn)	(25.3)	(47.8)	(33.5)	(34.3)	(41.4)	(48.2)

Source: Jefferies estimates; company data

Exhibit 7 - Kiadis Balance Sheet Model

(EUR millions Dec YE)	2018A	2019E	2020E	2021E	2022E	2023E
Non-current Assets	20.1	53.3	53.1	52.8	52.4	51.9
Intangible Assets	12.4	42.1	42.1	42.1	42.1	42.1
Property, Plant and Equipment	7.7	11.3	11.0	10.7	10.3	9.8
Investments	0.0	0.0	0.0	0.0	0.0	0.0
Other Long-term Assets	0.0	0.0	0.0	0.0	0.0	0.0
Current Assets	62.5	32.9	4.6	4.7	5.2	5.7
Inventories	0.0	0.0	0.0	0.0	0.0	0.0
Trade Accounts Receivable	0.0	0.0	0.0	0.0	0.0	0.0
Other Current Assets	2.1	2.1	2.1	2.1	2.1	2.1
Cash and Cash Equivalents	60.3	30.7	2.5	2.5	3.0	3.5
Total Assets	82.5	86.2	57.7	57.5	57.6	57.6
Current Liabilities	11.3	12.5	23.8	60.1	103.6	154.9
Trade Accounts Payable	1.8	2.7	2.5	3.4	4.0	4.7
Other Current Liabilities	2.0	2.0	2.0	2.0	2.0	2.0
Accrued Expenses	1.1	1.2	1.2	1.3	1.4	1.4
Deferred Income	0.0	0.0	0.0	0.0	0.0	0.0
Short-term Debt	5.3	5.0	17.2	52.5	95.2	144.9
Leasing Obligations	1.0	1.6	0.9	0.9	0.9	1.9
Dividends	0.0	0.0	0.0	0.0	0.0	0.0
Non-current Liabilities	27.1	24.0	19.0	19.4	19.9	18.3
Long-term Debt	21.8	17.4	13.3	14.7	16.2	16.4
Leasing Obligations	5.3	6.5	5.6	4.7	3.8	1.9
Deferred Tax Liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Income	0.0	0.0	0.0	0.0	0.0	0.0
Long-term Provisions	0.0	0.0	0.0	0.0	0.0	0.0
Total Shareholders' Equity	44.1	49.7	14.9	(22.0)	(65.9)	(115.6)
Share Capital	2.4	2.4	2.4	2.4	2.4	2.4
Share Premium Account	180.6	204.5	203.3	201.9	200.5	200.2
Other Reserves and Adjustments	0.7	33.5	33.5	33.5	33.5	33.5
Retained Earnings	(139.5)	(190.6)	(224.2)	(259.8)	(302.3)	(351.8)
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0
Total Liabilities and Shareholders' Equity	82.5	86.2	57.7	57.5	57.6	57.6

Source: Jefferies estimates; company data

Company Description

Kiadis

Kiadis develops innovative cell therapies for safer and more effective bone marrow transplants. Its NK cell platform could have potential in solid and liquid tumours with clinical trials due to start in haploidentical haematopoietic stem cell transplants (HSCT) and in patients with serious blood cancers. Kiadis is based in The Netherlands and listed on the Euronext Amsterdam in July 2015.

Company Valuation/Risks

Kiadis

Our Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for the NK cells, together with Net Cash, less potential dilution to ensure sufficient funds for three years. Risks include: (1) clinical or regulatory setbacks; (2) commercial execution risks; and (3) securing adequate funds to maximise value.

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Investment Recommendation Record

(Article 3(1)e and Article 7 of MAR)

Recommendation Published	November 15, 2019 , 14:37 ET.
Recommendation Distributed	November 17, 2019 , 19:00 ET.

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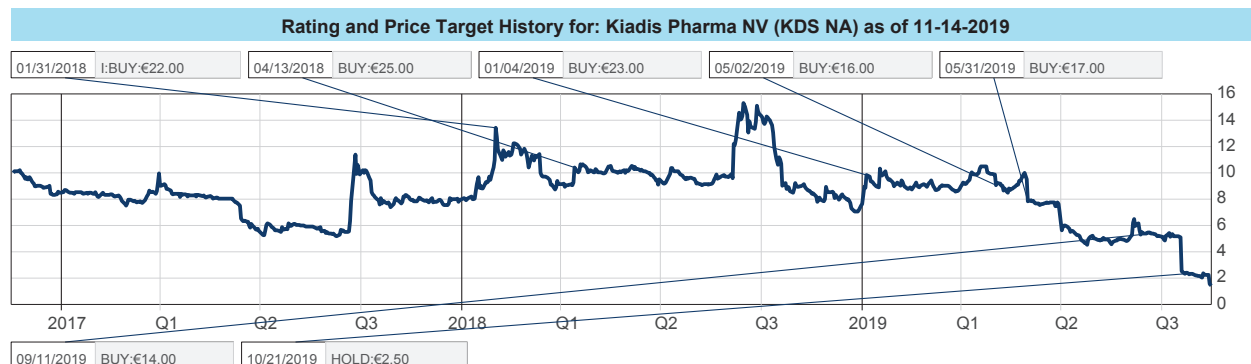
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- D: Dropped Coverage
- B: Buy
- H: Hold
- UP: Underperform

Distribution of Ratings

Distribution of Ratings						
			IB Serv./Past12 Mos.		JIL Mkt Serv./Past12 Mos.	
	Count	Percent	Count	Percent	Count	Percent
BUY	1195	53.42%	86	7.20%	13	1.09%
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