

Medigene

Data update

Promising dendritic cell data in AML

Medigene has reported top-line interim data from its Phase I/II clinical trial testing its dendritic cell (DC) vaccine in acute myeloid leukaemia (AML) patients (n=20) who were in complete remission. After a 12-month treatment period, overall survival was 89% (n=18/20) and progression-free survival was 60% (n=12/20). These early data are comparable to those of patients treated with allogeneic stem cell transplants. However, relapses are common in AML and long-term data are needed to determine the sustainability of the responses. We have increased our probability of success for the DC vaccine trial to 30% from 25% previously, in addition to rolling forward our model and updating for FX. We now value Medigene at €470m (€19.16/share) vs €457m (€18.59/share) previously.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/16	9.7	(13.4)	(0.66)	0.0	N/A	N/A
12/17	11.4	(12.4)	(0.60)	0.0	N/A	N/A
12/18e	10.4	(16.3)	(0.70)	0.0	N/A	N/A
12/19e	11.0	(17.1)	(0.70)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Interim DC data highlight potential

20 patients were treated with Medigene's autologous (made from the patient's own cells) DC vaccine. While early, the data from Medigene's TCR vaccine after the 12-month treatment period are promising. Patients had AML that was positive for the Wilms Tumour-1 (WT-1) antigen in addition to with/without PRAME positivity and were treated monthly (with a higher frequency in the first six weeks) with the DC vaccine that expressed these antigens. To be enrolled in the trial, patients had to have morphologic complete remission (CR) or complete remission with incomplete hematologic recovery (CRi) after initial therapy. While the majority of patients who are diagnosed with AML will go into CR/CRi following initial therapy, most patients will relapse within six months without further treatment. Stem cell transplant remains the gold standard for AML patients in remission. However, many patients are ineligible and are left with less effective maintenance chemotherapy treatment. No treatment related serious adverse events (AEs) were recorded.

MDG1011 TCR trial: Initial data in 2019

Screening patients is ongoing in Medigene's first TCR trial and it has manufactured the first MDG1011 TCR therapy. Although strict enrolment criteria (eg PRAME+ and HLA-A*02:01+) mean that only 10–20% of potential patients are eligible for treatment, we continue to forecast initial Phase I data in 2019.

Valuation: €470m (€19.16/share)

We value Medigene at €470m (€19.16/share) vs €457m (€18.59/share) previously. We have increased our probability of success for the DC vaccine trial to 30% from 25% previously, in addition to rolling forward our model and updating for FX. Our valuation is based on an rNPV of its TCR, DC and legacy assets in addition to deal metrics for the bluebird bio partnership and legacy asset, Veregen. For more detail on our valuation, please see our outlook note, [TCR enters the clinic](#).

Pharma & biotech

4 January 2019

Price €7.68

Market cap €189m

€/\$1.14

Net cash (€m) at 30 September 2018 (including time deposits) 76.3

Shares in issue 24.6m

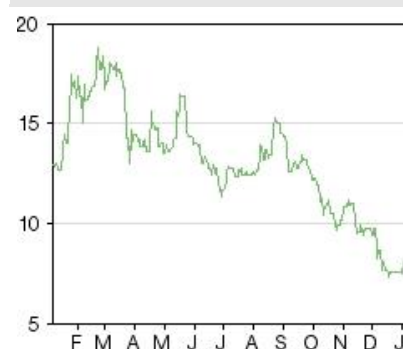
Free float 80.3

Code MDG1

Primary exchange Xetra

Secondary exchange Frankfurt

Share price performance



% 1m 3m 12m

Abs (20.9) (37.1) (40.7)

Rel (local) (13.0) (25.8) (26.2)

52-week high/low €18.8 €7.3

Business description

Medigene is a German biotech company with complementary technology platforms in cancer immunotherapy. Its dendritic cell vaccines and T-cell receptors (TCRs) are both in Phase I/II clinical studies.

Next events

FY18 results Spring 2019

MDG1011 initial clinical data 2019

DC vaccine full clinical data End 2019

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Exhibit 1: Financial summary

	€'000s	2016	2017	2018e	2019e
Year end 31 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		9,749	11,375	10,409	11,018
of which: Veregen revenues (royalties/milestones/supply)		3,048	2,790	1,433	1,582
R&D partnering (SynCore/Falk Pharma/grants)		3,155	0	0	0
Non-cash income (Eligard)		2,493	3,699	3,699	3,699
Bluebird bio partnership		1,053	4,886	5,278	5,738
Cost of sales		(1,402)	(1,621)	(553)	(613)
Gross profit		8,347	9,754	9,856	10,405
Selling, general & administrative spending		(10,025)	(8,266)	(7,186)	(7,395)
R&D expenditure		(11,538)	(14,877)	(20,084)	(21,691)
Other operating spending		0	0	0	0
Operating profit		(8,974)	(13,389)	(17,414)	(18,680)
Goodwill & intangible amortisation		(525)	(524)	(523)	(522)
Exceptionals		4,242	0	0	0
Share-based payment		0	0	0	0
EBITDA		(12,371)	(12,122)	(16,666)	(17,933)
Operating Profit (before amort. and except.)		(12,691)	(12,865)	(16,891)	(18,158)
Net interest		(1,009)	(1,434)	(691)	(478)
Other (forex gains/losses; associate profit/loss)		263	1,884	1,278	1,546
Profit Before Tax (norm)		(13,437)	(12,415)	(16,304)	(17,090)
Profit before tax (reported)		(9,720)	(12,939)	(16,827)	(17,612)
Tax		228	(634)	(101)	(101)
Profit/(loss) from discontinued operations		0	0	0	0
Profit after tax (norm)		(13,209)	(13,049)	(16,405)	(17,191)
Profit after tax (reported)		(9,492)	(13,573)	(16,928)	(17,713)
Average number of shares outstanding (m)		20.0	21.6	23.4	24.6
EPS - normalised (c)		(66.20)	(60.42)	(70.03)	(70.01)
EPS - Reported (€)		(0.48)	(0.63)	(0.72)	(0.72)
Dividend per share (c)		0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed assets		47,742	48,595	47,460	47,357
Intangible assets & goodwill		35,767	36,292	35,769	35,247
Tangible assets		3,323	4,329	4,717	5,136
Other non-current assets		8,652	7,974	6,974	6,974
Current assets		63,973	63,342	78,717	58,829
Stocks		7,866	7,724	7,724	7,724
Debtors		1,175	1,699	680	680
Cash		52,630	51,724*	68,119*	48,230*
Other		2,302	2,195	2,195	2,195
Current liabilities		(11,966)	(9,808)	(8,699)	(8,699)
Trade accounts payable		(973)	(725)	(798)	(798)
Short-term borrowings		0	0	0	0
Deferred income		(3,575)	(3,575)	(3,495)	(3,495)
Other		(7,418)	(5,508)	(4,406)	(4,406)
Long-term liabilities		(21,157)	(15,962)	(20,379)	(17,042)
Pension provisions		(408)	(405)	(405)	(405)
Long-term borrowings		0	0	0	0
Other liabilities (Deferred taxes; Trianta milestones)		(2,395)	(3,672)	(3,672)	(3,672)
Deferred revenues (Eligard non-cash income & bluebird bio)		(18,354)	(11,885)	(16,302)	(12,965)
Net assets		78,592	86,167	97,099	80,446
CASH FLOW					
Operating cash flow		(3,611)	(20,729)	(15,987)	(19,465)
Net interest		(45)	(45)	109	322
Tax		(102)	(75)	(101)	(101)
Capex		(1,677)	(1,533)	(613)	(644)
Expenditure on intangibles		0	0	0	0
Acquisitions/disposals		10,537	480	1,242	0
Equity financing		(77)	19,329	30,078	0
Other		846	1,667	1,667	0
Net cash flow		5,871	(906)	16,395	(19,888)
Opening net debt/(cash)		(46,759)	(52,630)	(51,724)	(68,119)
HP finance leases initiated		0	0	0	0
Other (foreign exchanges differences)		0	0	0	0
Closing net debt/(cash)		(52,630)	(51,724)	(68,119)	(48,230)

Source: Company accounts, Edison Investment Research. Note: *Cash consists of cash in addition to both long- and short-term time deposits.

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