

Medigene

CTA submitted

Next step taken toward its first TCR clinical trial

Medigene has announced that it has submitted a clinical trial authorisation application (CTA) to begin its first clinical trial with its proprietary T-cell receptor (TCR) modified T cells. If approved, the trial will evaluate it as an immunotherapy to treat a range of blood cancer indications and will be one of the first in Germany of TCR-modified cells. The trial is expected to start by the end of 2017. This submission triggers a final milestone payment of €2m for the Trianta acquisition (January 2014). We maintain our valuation of €315m but note the company is well-funded to deliver important milestones from progressing its clinical programme.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/15	6.8	(12.8)	(0.74)	0.0	N/A	N/A
12/16	9.7	(11.3)	(0.56)	0.0	N/A	N/A
12/17e	9.0	(18.6)	(0.89)	0.0	N/A	N/A
12/18e	9.3	(20.2)	(0.91)	0.0	N/A	N/A

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

Clinical trial application submitted for its TCR CIT

In 2017 we expect Medigene to take significant steps with its TCR programme, primarily with the initiation of its own TCR clinical study. The announcement on 10 July indicates that the company's plans are on track and, subject to regulatory approval, a combined Phase I/II safety and feasibility clinical trial will start in H217. This is a significant milestone as the company's first clinical study for its proprietary modified T cells and one of the first TCR trials in Germany. The TCR therapy targets PRAME (preferentially expressed antigen in melanoma) and will be evaluated in patients with advanced haematological diseases. For an overview of the company-initiated trial (CIT) design and Medigene's TCR technology please see our recent note [here](#).

Completion of the transformative Trianta acquisition

In 2014 Medigene completed an all-share purchase of privately-held Trianta Immunotherapies, for a total value of €10m (€4m upfront and the remainder linked to milestones). The CTA submission triggers a final milestone payment of €2m to the former shareholders of Trianta Immunotherapies, to be made within the next five months. This is intended to be settled through the issuance of new shares from authorised capital. This milestone payment will be the third and final payment from the Trianta acquisition. This deal has proved transformational to Medigene, in our opinion, as it has given it access to three types of immunotherapy assets (DC vaccine, T-cell receptor-based adoptive cell therapy, and T-cell-directed antibodies) and enabled it to progress to be a promising immunotherapy player.

Valuation: Maintained but continuing to progress

We maintain our rNPV-based valuation at €315m or €14.23/share. Medigene is well funded and we expect a number of important milestones in 2017; specifically, completed enrolment in Phase I/II studies for its DC vaccines in AML, start of its first company-initiated T-cell receptor (TCR) clinical study and potential newsflow relating to the progression of TCR leads resulting from its bluebird bio deal.

Pharma & biotech

11 July 2017

Price **€10.85**

Market cap **€240m**

Net cash (£m) at 31 March 2017 (pro forma, adjusted for net equity raise) 67.7

Shares in issue 22.1m

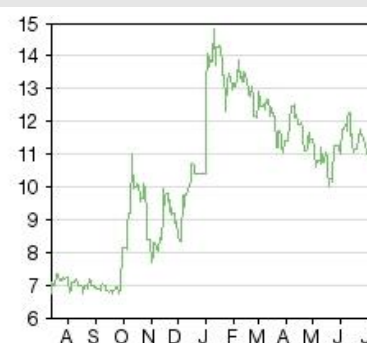
Free float 70.7%

Code MDG1

Primary exchange XETRA

Secondary exchange Frankfurt

Share price performance



% 1m 3m 12m

Abs (11.5) (13.4) 65.6

Rel (local) (8.9) (15.1) 28.1

52-week high/low €14.8 €6.7

Business description

Medigene is a German biotech company with complementary technology platforms in cancer immunotherapy. Dendritic cell vaccines are in Phase I/II clinical studies, while a T-cell receptor candidate should enter the clinic in 2017.

Next events

Interim results 3 August 2017

TCR (IIT) clinical trial initiation H217

First TCR (CIT) clinical trial initiation H217

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[Edison profile page](#)

Medigene is a research client of Edison Investment Research Limited

Exhibit 1: Financial summary

	€'000s	2014	2015	2016	2017e	2018e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		13,784	6,808	9,749	8,959	9,263
of which: Veregen revenues (royalties/milestones/supply)		5,195	3,101	3,048	3,128	3,433
R&D partnering (SynCore/Falk Pharma/grants)		6,096	1,214	3,155	0	0
Non-cash income (Eligard)		2,493	2,493	2,493	2,493	2,493
Bluebird bio partnership				1,053	3,338	3,338
Cost of sales		(2,086)	(1,103)	(1,402)	(1,231)	(1,353)
Gross profit		11,698	5,705	8,347	7,728	7,910
Selling, general & administrative spending		(7,081)	(7,615)	(7,942)	(8,286)	(8,524)
R&D expenditure		(7,498)	(8,529)	(11,538)	(17,884)	(19,672)
Other operating spending		0	0	0	0	0
Operating profit		(2,881)	(10,439)	(6,891)	(18,443)	(20,286)
Goodwill & intangible amortisation		(527)	(526)	(525)	(524)	(523)
Exceptionals		0	0	4,242	0	0
Share-based payment		(66)	(111)	(50)	(50)	(50)
EBITDA		(2,005)	(9,384)	(10,238)	(17,644)	(19,488)
Operating profit (before GW and except.)		(2,288)	(9,802)	(10,558)	(17,869)	(19,713)
Net interest		(1,774)	(2,914)	(1,009)	(1,495)	(1,928)
Other (forex gains/losses; associate profit/loss)		(1,257)	(46)	263	720	1,489
Profit before tax (norm)		(5,319)	(12,762)	(11,304)	(18,644)	(20,152)
Profit before tax (FRS 3)		(5,912)	(13,399)	(7,637)	(19,218)	(20,725)
Tax		155	400	228	0	0
Profit/(loss) from discontinued operations		0	0	0	0	0
Profit after tax (norm)		(5,164)	(12,362)	(11,076)	(18,644)	(20,152)
Profit after tax (FRS 3)		(5,757)	(12,999)	(7,409)	(19,218)	(20,725)
Average number of shares outstanding (m)		12.2	16.8	20.0	21.0	22.1
EPS - normalised (€)		(0.42)	(0.74)	(0.56)	(0.89)	(0.91)
EPS - FRS 3 (€)		(0.47)	(0.77)	(0.37)	(0.91)	(0.94)
Dividend per share (€)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed assets		46,617	51,552	47,742	50,012	52,282
Intangible assets & goodwill		38,377	35,713	35,767	35,243	34,720
Tangible assets		951	2,502	3,323	6,117	8,910
Other non-current assets		7,289	13,337	8,652	8,652	8,652
Current assets		24,666	59,900	63,973	61,190	36,767
Stocks		4,406	6,654	7,866	7,866	7,866
Debtors		1,733	763	1,175	1,175	1,175
Cash		14,976	46,759	52,630	49,847	25,424
Other		3,551	5,724	2,302	2,302	2,302
Current liabilities		(7,755)	(9,664)	(11,966)	(11,966)	(11,966)
Trade accounts payable		(1,785)	(1,354)	(973)	(973)	(973)
Short-term borrowings		0	0	0	0	0
Deferred income		(57)	(226)	(3,575)	(3,575)	(3,575)
Other		(5,913)	(8,084)	(7,418)	(7,418)	(7,418)
Long-term liabilities		(14,457)	(13,879)	(21,157)	(17,820)	(14,482)
Pension provisions		(413)	(359)	(408)	(408)	(408)
Long-term borrowings		0	0	0	0	0
Other liabilities (Deferred taxes; Trianta milestones)		(3,221)	(2,915)	(2,395)	(2,395)	(2,395)
Deferred revenues (Eligard non-cash income & bluebird bio)		(10,823)	(10,605)	(18,354)	(15,017)	(11,679)
Net assets		49,071	87,909	78,592	81,416	62,601
CASH FLOW						
Operating cash flow		(8,765)	(10,585)	(3,611)	(19,469)	(20,977)
Net interest		9	(20)	(45)	5	(428)
Tax		0	0	(102)	0	0
Capex		(873)	(1,328)	(1,677)	(3,019)	(3,019)
Expenditure on intangibles		0	0	0	0	0
Acquisitions/disposals		0	0	10,537	0	0
Equity financing		14,502	43,695	(77)	19,700	0
Other		(62)	21	846	0	0
Net cash flow		4,811	31,783	5,871	(2,783)	(24,424)
Opening net debt/(cash)		(10,166)	(14,976)	(46,759)	(52,630)	(49,847)
HP finance leases initiated		0	0	0	0	0
Other (foreign exchanges differences)		(1)	0	0	0	0
Closing net debt/(cash)		(14,976)	(46,759)	(52,630)	(49,847)	(25,424)

Source: Medigene and Edison Investment Research

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