EDISON

Medigene

FY16 results

Becoming an increasingly prominent player

Pharma & biotech

Medigene is well funded (FY16 cash €52.6m) to advance both its DC vaccine programmes and TCR programme. We expect a number of important milestones in 2017; specifically, we expect newsflow from its most advanced technology (DC vaccines) in Phase I/II studies for AML (complete enrolment) and the start of its first company-initiated T-cell receptor (TCR) clinical study. We have increased our rNPV-based valuation to €293m (vs €233m), to reflect the increase in the TCR programme probability to 13% (vs 5%), rolling the model forward and using FY16 cash.

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)	(0.93)	0.0	N/A	N/A
12/18e	9.3	(20.2)	(1.00)	0.0	N/A	N/A

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

FY16 results demonstrated good progress

Medigene made good progress in 2016 by realising value from a number of its non-core assets (sale of its Catherex subsidiary, AAVLP deal, final transference of EndoTAG-1 to SynCore and sale of 50% of its stake in Immunocore shares), alongside expansion of its TCR technology platform with the grant of a US patent. Underpinning this was the development of its senior management team, which Medigene believes is now in place to move the company forward. Of particular significance was the announcement of its TCR development deal with bluebird bio, a prominent T-cell immunology company. This was Medigene's first commercial partnering agreement based on its proprietary TCR technology platform and is important as it validates Medigene's technology and offers potentially new immuno-oncology products, while retaining all rights for its TCR programme and pipeline.

2017: TCR progression into the clinic

We expect Medigene to take significant steps in 2017, with the initiation of its own TCR clinical study alongside an investigator-initiated TCR study. Advancing its TCR programme into the clinic will be a positive milestone for the company, moving it further into the spotlight as a promising immunotherapy player. This is important as cell-based therapies continue to garner significant interest, particularly around CAR-T candidates and technology. We note that Medigene's TCRs could offer efficacy/safety advantages which, if demonstrated, could attract investment interest.

Valuation: Increased to €293m, with upside potential

We have increased our rNPV-based valuation to €293m (vs €233m) or €13.98 per share (vs €11.8 per share), primarily due to increasing the TCR programme probability to 12% (vs 5%), adding in the bluebird bio deal, rolling the model forward three months and using the FY16 cash position of €52.6m. Medigene is well funded and focused on executing its clinical development strategy which, if delivered could create a number of inflection points to the stock.

24 April 2017

Price	**€11.08**
Market cap	**€223m**

Net cash (€m) at 31 December 2016	52.6m
Shares in issue	20.1m
Free float	62.6%
Code	MDG1
Primary exchange	XETRA
Secondary exchange	Frankfurt

Share price performance

%	1m	3m	12m
Abs	(1.1)	(17.5)	40.1
Rel (local)	(1.8)	(20.3)	21.4
52-week high/low		€14.83	€6.25

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

Q1 results	11 May 2017
TCR (IIT) clinical trial initiation	H217
First TCR (CIT) clinical trial initiation	H217

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Edison profile page

Investment summary

Company description: Increasingly prominent player

The purchase of privately-held Trianta Immunotherapies in January 2014 (€4m upfront, €3.9m milestones paid and potential future milestone of €2.1m) was a transformational transaction, positioning Medigene as an emerging cancer immunotherapy player. Trianta had three key technology platforms – DC (dendritic cell) vaccines, adoptive T-cell therapy (TCR) and T-cell specific antibodies (TABs) – and Medigene is focused on advancing these starting in haematological malignancies. Originally founded in 1994 as a spin-out of the Munich Gene Center, Medigene raised €125m in its Frankfurt Stock Exchange IPO in 2000, and its legacy assets – Eligard (prostate cancer), EndoTAG-1 (breast cancer) and RhuDex (autoimmune) – have now been sold or out-licensed. It has also sold 100% of its stake in Catherex to Amgen and 50% of its stake in Immunocore. Supply chain revenues, royalties and milestones are received on Veregen, a topical ointment for genital warts, sold in 23 countries through partners. Medigene now employs 88 staff (end 2016) and is headquartered in Munich, Germany.

Valuation: Increased to €293m

We have raised our rNPV to €293m (vs €233m), as we have increased the probability of the TCR programme to 13% (vs 5%), rolled the model forward by three months and now use the reported FY16 cash position of €52.6m. We have also included the bluebird bio deal and removed the IIT DC vaccine trial as this is incorporated into the DC vaccine deal metrics. Medigene is well-funded (into FY19 on current forecasts), which should enable it to execute on an expanding clinical trial programme. There are a number of potential inflection points, including the start of its own TCR study (expected 2017), complete enrolment in its own DC trial in AML (expected 2017) and the start of a TCR-IIT trial in multiple myeloma (expected 2017). Alongside this there is the potential of further TCR R&D collaborations similar to its recent bluebird bio deal. Medigene is operating in a hot area which as it progresses could make it increasingly attractive to investors.

Financials: Well-funded to make good progress

Medigene reported a FY16 cash position of €52.6m. We forecast a cash runway into FY19, which should enable completion of its Phase II DC vaccine trial, significant advancement of its company-initiated TCR trial (starting H217) and the start of a second company-initiated TCR trial (H218). At that point, we expect Medigene to either raise further funding and/or partner some of its programmes. We expect an increase in R&D spend due to the initiation of a Phase I study in TCR and the continuation of its DC vaccine study. We now forecast R&D in FY17 of £17.9m (vs £10.8m) and £19.7m in FY18 and SG&A costs of €8.3m (vs €8.1m) in 2017 and €8.5m in 2018.

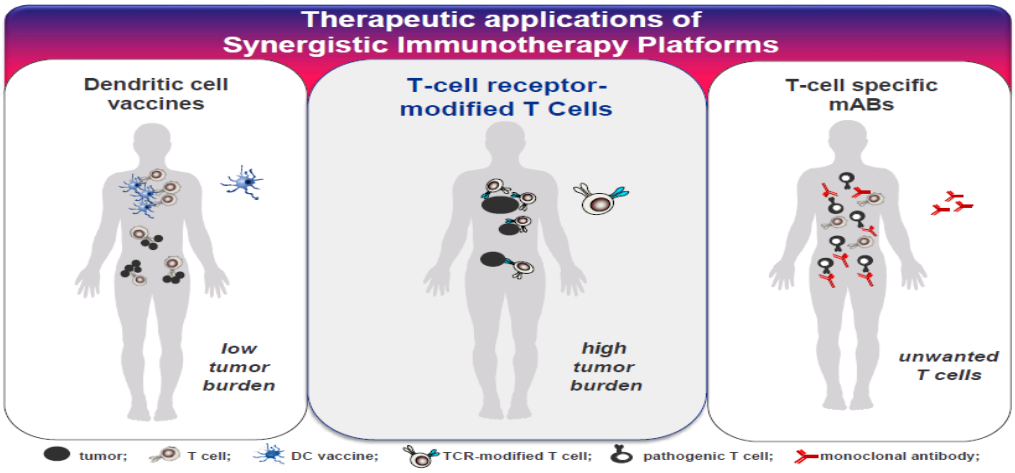
Sensitivities: Reducing as it progresses

Medigene is subject to the risks typically associated with biotech company drug development, including the possibility of unfavourable outcomes in clinical trials, success of competitors and commercial decisions by partners or potential partners. Cancer immunotherapy is a highly-promising and rapidly evolving field, yet Medigene's technology platforms are still in relatively early stages of development. The outcomes of the investigator-initiated trials with the DC vaccines and the TCR CIT and IIT trials are therefore key sensitivities. Equally, while the TCR CIT and IIT trial are expected to start in 2017 there is still work to be done on the GMP manufacturing and the submission of the clinical trial applications. Equally, multiple companies have more advanced DC vaccines and TCRs in development, which could limit the market opportunity for Medigene's candidates and restrict the cancer targets that may be pursued.

Immuno-oncology focus

Medigene is an immuno-oncology company focused on T-cell directed therapies. It has a proprietary pipeline and partnered clinical development programmes in oncology. Its technology platforms are synergistic with one another and therefore able to potentially address different types and stages of cancer (see Exhibit 1). The technology platforms are Dendritic cell vaccines (Phase I/II in AML), T-cell receptor-modified T cells (TCRs) (late preclinical stage, moving into clinical in 2017) and T-cell-specific antibodies (TABs) (preclinical development). These are underpinned by its immune monitoring facility, which detects cellular immune responses at preclinical and clinical stages.

Exhibit 1: Medigene's immunotherapies tailored to different types and stages of cancer



Source: Medigene presentation

An autologous (patient-derived) dendritic cell-based vaccine technology is the most advanced programme, with a company-initiated trial ongoing in AML (currently in Phase II of a Phase I/II study) and two investigator-initiated Phase I/II studies, in acute myeloid leukaemia (AML) and prostate cancer (ongoing). The TCR programme, similar in mechanism to CAR-T therapies and currently attracting industry interest, is at the pre-clinical stage with a GMP-compliant manufacturing process being developed and a Phase I/II study expected to start late 2017. Medigene's overall product portfolio is summarised in Exhibit 2.

Exhibit 2: Medigene pipeline overview

Product	Indication	Status	Description	Notes
DC vaccines	AML, prostate cancer	Phase I/II	Autologous (patient-derived) dendritic cell-based vaccine	Two investigator-initiated (IIT) Phase I/II studies ongoing in AML and prostate cancer, Company-initiated (CIT) Phase II study AML
TCRs	Haematological malignancies	Pre-clinical	Autologous T-cells primed with tumour-specific T-cell receptors	Establishment of GMP process ongoing, CIT trial expected to start 2017 (undisclosed indication), IIT trial expected to start 2017 (multiple myeloma)
TABs	Haematological malignancies	Pre-clinical	Anti-T-cell antibodies	Potential to treat T-cell mediated diseases, such as T-cell leukaemia (and auto-immune diseases)
Veregen (remaining legacy product)	Genital warts	Marketed (WW)	Polyphenon E (defined composition of tea catechins)	Marketed in 23 countries around the world, sold exclusively through global network of various distributors

Source: Edison Investment Research and Medigene

Medigene has progressed over recent years to become an immunotherapy-focused company. Importantly, it has a track record of gaining value from non-core assets which it has executed over the past 24 months. Exhibit 3 provides an overview of these deals. Veregen is the remaining legacy product which we expect Medigene will also look to exit in order to complete the move into its core focus of immunotherapy.

Exhibit 3: Legacy product pipeline overview

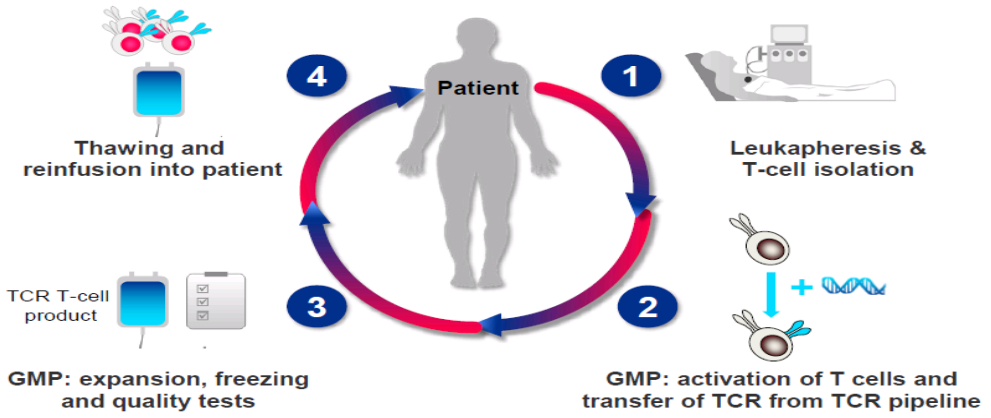
Legacy product pipeline	Overview
EndoTAG	Medigene to receive €5m from SynCore in five annual instalments and is eligible for milestone payments and royalties for EndoTAG-1
	First payment of €1m received in Q116
Catherex, Inc (spin-off)	Sold to Amgen
	Medigene receives c 40% of all upfront payments and milestones and an undisclosed amount of royalties on net sales for Amgen's drug Imlygic
	Q116 received upfront payment and a milestone payment totalling €4.5m
Rhudex	Phase I compound, developed in Primary Biliary Cirrhosis (PBC)
	Out-licensed to Dr Falk Pharma - eligible for clinical milestones and royalties
AAVLP	Granted an exclusive worldwide licence for the development and commercialisation of its preclinical-stage adeno-associated virus-like particles (AAVLP) technology to 2A Pharma, a Swedish biotech company

Source: Edison Investment Research and Medigene

T-cell receptor (TCR) technology

T-cells are distinguished from other lymphocytes by the presence of T-cell receptors (TCRs) on the cell surface. TCRs allow T-cells to identify cancer targets eg tumour-targeted antigens presented on the surface of the tumour cells. Medigene's TCR technology aims to arm the patient's own T-cells with tumour-specific T-cell receptors. The binding of naturally occurring TCRs to cancer cells is typically poor (low affinity) because cancer proteins (TAAs) are often unmutated self-proteins and TCRs that have a high affinity for these self-proteins are rapidly deleted during early lymphocyte development. In general, TCRs therefore need to be modified and engineered in some way to enhance their ability to target and bind to cancer antigens. The process of treating a patient (which Medigene has yet to do) is outlined in Exhibit 4. For more detail please see here.

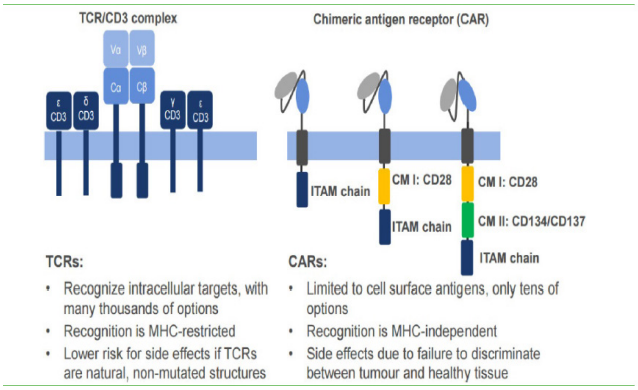
Exhibit 4: Personalised cancer treatment based on Medigene's TCR technologies



Source: Medigene presentation

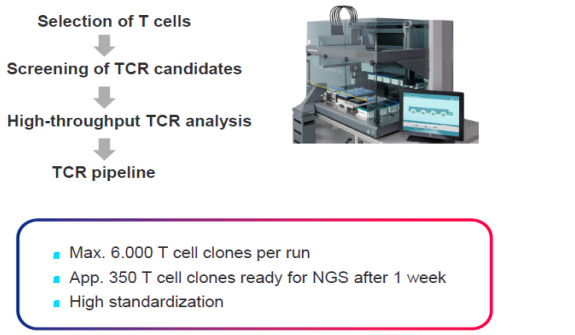
Cancer immunotherapy, stimulating/modifying a patient's immune system to target tumour cells, is currently an area of high interest. At the forefront has been the chimeric antigen receptor (CAR) T-cell technology (CAR-T). CAR-T uses an engineered antibody fragment to recognise the target cell and link this to a number of signalling domain proteins within the T-cell, designed to activate the T-cell once the antibody recognition fragment (eg CD19) has bound to a target cell. This has the potential to initiate a powerful immune response to destroy the cancer cells, but it comes with the possible cost of also stimulating cytokine-release syndrome (CRS). There is no evidence that Medigene's TCR technology causes CRS, which along with the potential ability to target a broader spectrum of intracellular proteins (more addressable targets) and more specificity (recognition is MHC-restricted) indicates that TCRs may become the immunotherapy of choice. Exhibit 5 provides an overview of the key distinctions between Medigene's TCRs and CAR-Ts.

Exhibit 5: Medigene's TCRs vs CAR-Ts



Source: Medigene presentation

Exhibit 6: Robotic platform for high-throughput generation of TCR lead candidates



Source: Medigene presentation

Medigene has been developing a comprehensive pipeline of recombinant TCRs for which it has established a robotic platform for high throughput generation of TCR lead candidates (see Exhibit 6), while establishing a GMP (good manufacturing practice) compliant process for the final step of combining the TCRs with the patient-derived T-cells. We expect the GMP-process development to complete this year along with the application for its Phase I/II clinical study, planned to initiate in late 2017. An overview of the study design is outlined in Exhibit 7.

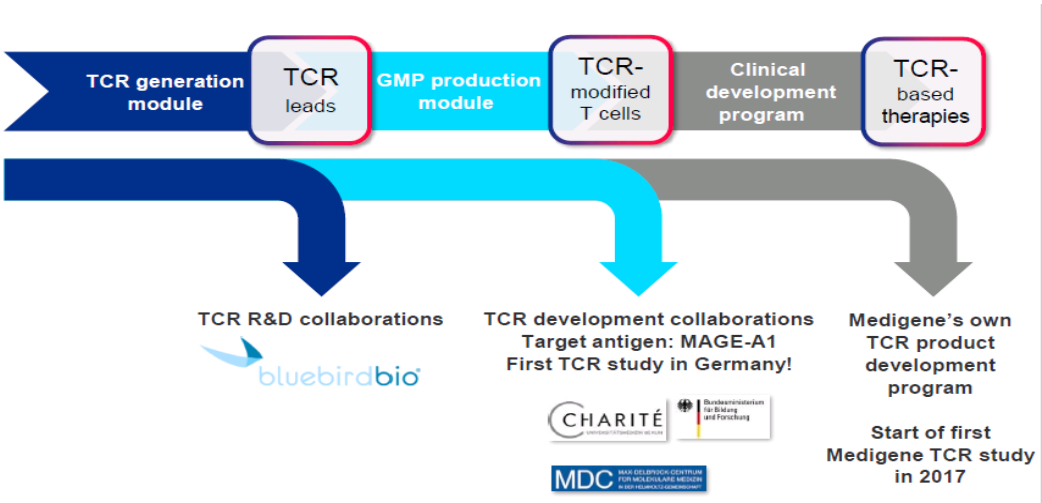
Exhibit 7: Company-initiated clinical study design

Clinical design	Phase I/II safety and feasibility study
Overview	Target: PRAME, T-cells expressing a HLA-A2:01 restricted TCR specific for PRAME
Indications	Advanced stages of Acute Myeloid Leukaemia, myelodysplastic syndrome, multiple myeloma
Phase I overview	Dose escalation, testing up to four dose cohorts in a 3+3 design
Phase II overview	Dose cohort will expand and include a prospective control group, potential to expand in size and into further malignancies

Source: Edison Investment Research

While the initiation of its first company-initiated TCR clinical study is important, it is worth noting that Medigene is creating value along the TCR development chain (see Exhibit 8). This has been demonstrated by a R&D collaboration with bluebird bio to generate TCR candidates against four targets (see here for more detail) and TCR development collaborations (see here for more detail).

Exhibit 8: Medigene's value creation along the TCR development chain



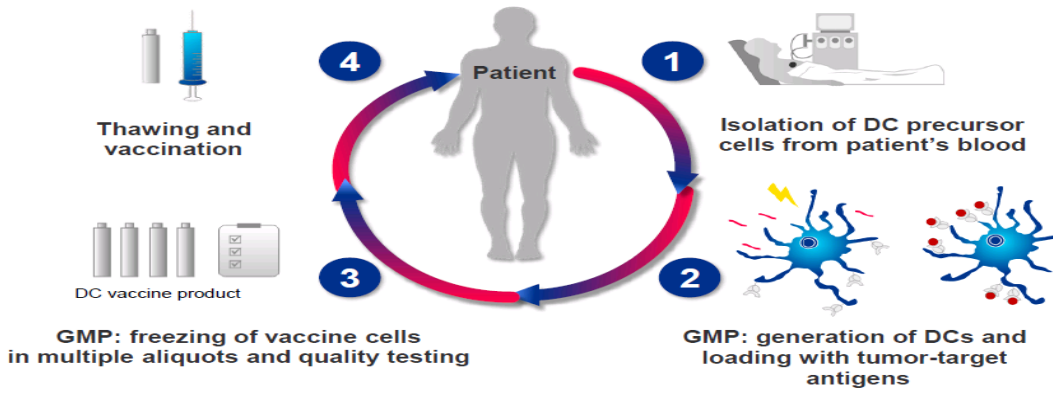
Source: Medigene presentation

Dendritic cell (DC) vaccine

Medigene's most advanced cancer immunotherapy technology is its new generation autologous dendritic cell (DC) vaccines. DCs are a type of antigen-presenting cell (APC) capable of processing antigen material and presenting it on the surface to other cells of the immune system. DC-based therapy involves isolating mononuclear cells from a patient, maturing them to DCs and loading them with cancer antigen(s), before injecting them back into the patient. This results in the activation of T-cells to recognise and attack antigen-bearing tumour cells, while also inducing natural killer (NK) cells to help target tumour cells (see Exhibit 9). Medigene has indicated that its 'new generation' vaccines overcome the weakness of other DC vaccines as they are high quality and fully characterised with >85% mature polarised DCs. For more details of the technology please see here. Equally, the manufacturing process has a number of important advantages which makes it efficient such as:

- No tumour tissue from patient needed
- Only one leukapheresis per patient
- Manufacturing time just three days
- High quantity yield of dendritic cells for more than 20 vaccinations
- Over two years' shelf-life of frozen cells
- Can be administered to the patient as required

Exhibit 9: Personalised cancer treatment with DC vaccines



Source: Medigene presentation

Medigene's DC vaccine programme is the most clinically advanced. There are two investigator-initiated Phase I/II clinical studies underway with DC vaccines, using Medigene's technology, in patients with prostate cancer (n=30) and acute myeloid leukaemia (AML, n=20), since 2010 and 2013 respectively. Of the 30 patients to be treated in the prostate cancer study, 15 will be treated with the original (investigator-produced) DC vaccine type, and the rest dosed with Medigene's 'new generation' designed vaccine candidates. Importantly, Medigene has also initiated its own Phase I/II trial with its DC vaccine for AML, tailored to present two leukaemia-associated antigens (WT1 and PRAME); the investigator study in AML uses DCs loaded with three antigens (WT1, PRAME and CMVpp65). An overview of both the CIT and IIT studies are given in Exhibit 10 and Exhibit 11. Results are expected in 2019 from the CIT study.

Exhibit 10: Investigator-initiated clinical trial overview – DC vaccine

DC vaccine trials – IIT	Sponsor	Data
AML, intermediate and high risk patients	Professor M. Subklewe	Abstract presented at CIMT see here
Phase I/IIa	Ludwig-Maximilians-University Munich	Abstract presented at ASH see here
Opened: Q1/2014		
Enrolment completed		
Treatment/observation ongoing		
AML, Compassionate use	Professor G. Kvalheim	Abstract presented at CIMT see here
Enrolment completed	Department. of Cellular Therapy	Abstract presented at AACR see here
Treatment/observation ongoing	Oslo University Hospital	

Source: Edison Investment Research and Medigene

Exhibit 11: Company-initiated clinical trial overview – DC vaccine

DC vaccine trial – CIT	
Clinical design	Phase I/II: open-label, prospective, non-randomised trial, 20 AML patients (6 Phase I & 14 Phase II)
Inclusion criteria	Patients selected with AML expressing the vaccine antigens: WT-1 with or without PRAME expressed on LIC/LSC, complete remission after chemotherapy, not eligible for allotransplantation
Primary objective	Feasibility and safety
Secondary objective	Overall survival (OS), progression free survival (PFS), induction of immune responses, control of minimal residual disease (MRD), clinical response: time to progression (TTP)

Source: Edison Investment Research and Medigene. Note: PRAME = preferentially expressed antigen of melanoma, LIC = leukaemia initiating cells, LSC = leukaemia stem cells.

T-cell specific antibodies (TABs)

Medigene's TABS (T-cell-specific antibodies) platform utilises its recombinant TCR technologies in order to produce, isolate and characterise monoclonal antibodies specific for TCR structures. T-cell-specific antibodies (TABS antibodies) recognise T-cells based on their unique T-cell receptors and can therefore distinguish between different T-cells expressing different TCRs. TABS antibodies are highly complementary to Medigene's TCR technology platform as they can be used to track its TCR-modified T-cells both in vitro and in vivo. In the future, TABs could potentially be applied to precisely control the production of genetically-modified T-cells or to remove them after adoptive transfer in patients if adverse effects appear. This would indicate potential in diseases such as T-cell leukaemia. For more details please click here. It is Medigene's earliest stage programme and studies are ongoing to establish proof-of-concept.

Sensitivities

Medigene is subject to the risks typically associated with biotech company drug development, including the possibility of unfavourable outcomes in clinical trials, success of competitors and commercial decisions by partners or potential partners. Cancer immunotherapy is a highly-promising and rapidly evolving field, yet Medigene's technology platforms are still in relatively early stages of development. The outcomes of the investigator-initiated trials with the DC vaccines and the TCR CIT and IIT trials are therefore key sensitivities. Equally, while the TCR CIT and IIT trials are expected to start in 2017 there is still work to be done on the GMP manufacturing and the submission of the clinical trial applications. Also, multiple companies have more advanced DC vaccines and TCRs in development, which could limit the market opportunity for Medigene's candidates and restrict the cancer targets that may be pursued. Securing the appropriate intellectual property rights is also likely to be an important issue for T-cell-based therapies.

Valuation

We have reviewed our rNPV model and updated it to reflect the more streamlined focus on immuno-oncology and updated our assumptions. We have raised our rNPV to €293m (vs €233m) as we have increased the probability of success of the TCR programmes to 13% (vs 5%) due to the announcement of it entering the clinical stage in 2017 and included the bluebird bio TCR deal. We have also removed the DC vaccine trial in prostate cancer as this is an IIT trial and its potential is incorporated as part of the DC vaccine deal metrics and in light of a lower sales growth in Veregen (its non-core asset), we have lowered the peak sales to €19m vs c €40m and royalty rate to 10% vs 20%. Finally, we have rolled the model forward by three months and incorporated the reported FY16 cash position of €52.6m into our model. We believe there is further upside here as and when the TCR programme actually enters the clinic. Our valuation model, which applies a standard 12.5% cost of capital, and key assumptions are summarised in Exhibit 12.

Exhibit 12: rNPV Valuation and assumptions

Product	Status	Launch	NPV (€m)	Peak sales ($m)	Probability of success	Royalty rate	rNPV (€m)	rNPV/ share (€)	Key assumptions
Veregen	Marketed	2009	4	19	100%	10%	4	0.21	10% max annual growth pa; effective 20% on sales based on revenues from royalties+product sales; 40% COGS
Imlygic	Marketed	2015	17	455	100%	1%	17	0.86	1% royalty, bloomberg product consensus figures, peak after 7 years post launch
DC vaccine - AML	Phase I/II	2022	60	347	25%	15%	13	0.65	50% AML patients eligible (~19,500 in US/EU); 15% peak penetration; $7,500 per dose, 10 doses/patient
bluebird bio TCR deal	Pre-clinical	2026 onwards			10% (product 1 & 2), 7% product (3 & 4)		34	0.84	$15m upfront, total milestones $272m split between Phase I, Phase II, Phase III, NDA filing and approval, based on milestone weighting research*. 4 products included reaching the clinic 1 year apart, starting in 2018. No sales related income included at this time
TCR	Pre-clinical	2024	840	4,214	13%	20%	106	5.39	5% penetration across all haematological malignancies; $150,000 effective annual price; $4bn illustrative peak sales potential
DC vaccine deal metrics				200	25%		33	1.67	$50m upfront, post Phase II (2018/50% chance); $25m on NDA filing (2022/25% chance); $125m on regulatory approval (2023/25% chance)
TCR deal metrics				500	13%		34	1.72	$100m upfront, post Phase II (2019/25% chance); $50m on NDA filing (2023/5% chance); $150m on regulatory approval (2024/5% chance); 2x products included
Portfolio total			921				240	11.34	
Net cash (FY16)							53	2.64	
Overall valuation							293	13.98	

Source: Edison Investment Research. Note: *Based on Avance milestone weightings.

Medigene is well-funded (into FY19 on current forecasts), which should enable it to execute on an expanding clinical trial programme. There are a number of potential inflection points over the next 24 months, including:

- Start of first Medigene-instigated TCR study in 2017 (including finalisation of its GMP process development at a CMO, Clinical trial application and approval)
- Complete enrolment in its DC trial in AML (expected 2017)
- Start of TCR-IIT in 2017 (collaboration with Charite and Max D) in multiple myeloma patients (including submission of clinical trial application (CTA) including the IMPD and approval)
- Additional TCR R&D collaborations (see overview of recent deals below)

A sector with potential to deliver high premiums

Cancer immunotherapy, stimulating/modifying a patient's immune system to target tumour cells, is one of the hottest areas of research and investor interest today. This has been driven by

increasingly compelling efficacy data in cancers with historically bleak outcomes, with the potential to achieve a cure or functional cure for some patients. It is clear from recent licensing activity in the cancer immunotherapy field that big pharma's appetite for these technologies, even at early stages of development, is high and can reasonably be expected to continue for some time. Coupling this with the significant inherent potential of these products to put certain cancers into effective remission has resulted in very high market capitalisations for a number of (mainly US-based) cancer immunotherapy companies. We highlight this peer group in Exhibit 13, which shows an average market cap of approximately $1.4bn (median of $810m). We also include companies working more exclusively on DC vaccine technologies, which shows relatively more modest valuations and highlights the differing levels of current investor interest between the two technologies.

Exhibit 13: Cancer immunotherapy companies - peer group analysis

Company	Ticker	Market cap ($m)	Lead T-cell product status	Technology
T-cell based companies				
Kite Pharma	KITE	4,463	Phase II/BLA submitted	CAR-T/TCR
bluebird bio	BLUE	3,951	Phase I	CAR-T/Lentivirus
Juno Therapeutics	JUNO	2,580	Phase II	CAR-T
Cellectis	CLLS	831	Phase I	CAR-T
Ziopharm	ZIOP	810	Phase II	CAR-T/TCR/NK Cells
Atara Biotherapeutics	ATRA	511	Phase II	T-Cell
Lion Biotechnologies	LBIO	446	Phase II	Tumour infiltrating lymphocytes
Bellicum Pharmaceuticals	BLCM	354	Phase I	CAR-T/TCR/Stem cell
Nantkwest	NK	272	Phase I	NK Cells
Celyad	CYAD	190	Phase I	CAR-T/NKR
	Average	1,441		
	Median	**810**		
DC vaccine based companies				
Northwest Biotherapeutics	NWBO	53	Phase III	DC vaccines
Argos Therapeutics	ARGS	48	Phase III	DC vaccines and cell therapies
Immunocelluar Therapeutics	IMUC	8	Phase III	DC vaccines
	Average	36		
	Median	**48**		

Source: Edison Investment Research and EvaluatePharma

While it is clear that investors are prepared to pay a premium for stocks in the immunotherapy area it is difficult to quantify an appropriate level for Medigene at this stage. However, we note its recent deal with bluebird bio (a large player in this area) as an important indicator of its potential. The deal was Medigene's first commercial partnering agreement based on its proprietary TCR technology platform. The deal is to produce TCR therapeutic candidates against four targets using Medigene's TCR technology platform and bluebird bio's lentiviral vector, gene editing, synthetic biology and manufacturing capabilities. The partnership will be executed with Medigene having responsibility for generating and delivering the relevant TCRs to bluebird bio, as well as joint development of preclinical product candidates. bluebird bio will take responsibility for clinical development and any resulting commercialisation. The deal offers validation of Medigene's TCR technology and also has wide-ranging potential as the four targets could be utilised across a number of indications.

Medigene will receive an upfront payment of $15m R&D funding (specific to the collaboration) and potential milestones resulting from preclinical and clinical development, along with any resulting commercialisation (company guidance indicates royalty payments could range from single to double digits). While there are few TCR-related deals a useful indicator of the potential of future deals in this area can be seen by looking at recent CAR-T deal activity (see Exhibit 14 below).

Exhibit 14: Licensing activity

Licensor/Licensee	Technology	Date	Deal type	Deal value ($m)	Upfront fee ($m)	Milestones ($m)
Pfizer/Cellectis	CAR-T	Jun-14	Research collaboration	2,886	80	2,775
Shire (Baxalta)/Precision Biosciences	CAR-T	Feb-16	Research collaboration	1,705	105	1,600
Celgene/Juno Therapeutics	CAR-T/TCR	Jun-15	Research collaboration	Unknown	1,000	Unknown
Merck KGaA/Intrexon	CAR-T	Mar-15	License agreement	941	115	826
Amgen/Kite Pharma	CAR-T	Jan-15	Research collaboration	585	60	525

Source: Edison Investment Research and EvaluatePharma

Financials

Medigene reported a FY16 cash position of €52.6m, which the company has stated is sufficient to fund current operations beyond its forecast horizon of two years. We forecast a cash runway into FY19, which should enable completion of its Phase II DC vaccine trial, significant advancement of its company-initiated TCR trial (starting late 2017) and the start of a second company-initiated TCR trial (H218). At that point, we expect Medigene to either raise further funding and/or partner some of its programmes.

We have reviewed our FY17 forecasts and now include forecasts to FY18. We expect a sharper increase in R&D spend due to the initiation of a Phase I study in TCR and the continuation of its DC vaccine study. We now forecast R&D in FY17 of €17.9m (vs €10.8m) and €19.7m in FY18. We forecast SG&A costs of €8.3m (vs €8.1m) in 2017 and €8.5m in 2018. Finally, we expect capex to increase in FY17 and FY18 as a result of investment into increasing the capacity to generate TCRs along with an expanded team. We forecast €3m of capex in FY17 and FY18.

The main source of revenues for Medigene is its non-core asset Veregen. We currently forecast revenues of €3.1m and €3.4m in FY17 and FY18, respectively. We also include revenue from the bluebird bio agreement which we expect to be recognised over the four years of the deal. We do not include any potential milestones resulting from this deal at this time.

Exhibit 15: 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
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	20.1	20.2
EPS - normalised (€)	(0.42)	(0.74)	(0.56)	(0.93)	(1.00)
EPS - FRS 3 (€)	(0.47)	(0.77)	(0.37)	(0.96)	(1.03)
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	41,490	17,067
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	30,147	5,724
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	61,716	42,901
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)	0	0
Other	(62)	21	846	0	0
Net cash flow	4,811	31,783	5,871	(22,483)	(24,424)
Opening net debt/(cash)	(10,166)	(14,976)	(46,759)	(52,630)	(30,147)
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)	(30,147)	(5,724)

Source: Edison Investment Research and Medigene

Contact details	Revenue by geography
Lochhamer Str. 11 82152 Planegg/Martinsried Germany +49 (0)89 2000 330 www.medigene.com	N/A

Management team

CEO and CSO: Dolores Schendel	CFO: Thomas Taapken
Professor Dr Dolores Schendel joined Medigene as Chief Scientific Officer in 2014 with the acquisition of Trianta Immunotherapies (now Medigene Immunotherapies) where she was a majority founding member and has been Managing Director since 2013. She was appointed CEO with effect from April 2016. From 1998-2013, Professor Schendel was director of the Institute of Molecular Immunology of the German Research Center for Environmental Health at the Helmholtz Center in Munich. Previously she served as a university professor for Immunology at the Ludwig-Maximilian-University, focusing on human cellular immunology and T-cell responses within the field of oncology. Professor Schendel is the author of more than 200 scientific publications, has spent several decades as a scientific review board member in various research organisations such as the German Research Foundation, German Cancer Aid and the European Research Council.	Dr Taapken spent more than five years at Epigenomics AG, initially as CFO and subsequently, from October 2012, as its CEO/CFO. He led the company's efforts in gaining regulatory approval for the first blood-based molecular diagnostic cancer screening test by the FDA and oversaw its subsequent introduction into the US market. Prior to this he served as CFO at Biotie Therapies Corp (now Acorda Therapeutics) and its predecessor companies for six years, spent seven years as a venture capital investor at DVC Deutsche Venture Capital and San Francisco-based US venture capital firm Burrill & Company and worked for several years at Sanofi (originally Hoechst AG) in the US and Germany, managing corporate venture capital activities, as well as in the areas of corporate & business development and research.
COO: Dave Lemus	**CMO: Dr Kai Pinkernell**
Dave Lemus has been vice chairman of the Supervisory Board of Medigene from 2013 until end 2015 when he joined the management board in January 2016 as COO. Prior to this, he served as CEO of Sigma Tau Pharmaceuticals, where he played a pivotal role in the turnaround of the company's operations. During his time as CEO at Sigma Tau, Mr. Lemus presided over the FDA approval and subsequent successful commercial product launch of a rare disease therapeutic, in addition to the commercial revival of the company's lead oncology product which resulted in its successful sale for US$900m to Baxalta (Shire) in July 2015. From 1998 to 2011, Mr Lemus was the CFO and executive vice president of MorphoSys, where he launched Germany's first biotech IPO in 1999.	Dr Kai Pinkernell has been responsible for the clinical advancement of Medigene's immunotherapy platforms since February 2016. Prior to joining Medigene, he held leading positions at Miltenyi Biotech GmbH, Bergisch Gladbach, Germany, most recently as global head of clinical business and head of clinical development. Previously, Dr Pinkernell was with Cytori Therapeutics, San Diego, US, as senior director of regenerative cell technology. He studied medicine and received his MD from the Westfaelische-Wilhems University in Muenster, Germany.

Principal shareholders	(%)
QVT	15
Aviva	7
DJS Montana	4
Ridgeback	3

Companies named in this report

Amgen, Pfizer, Cellectis, Shire, Precision Biosciences, Celgene, June Therapeutics, Kite Pharma, bluebird bio, Ziopharm, Atara Biotherapeutics, Lion Biotechnologies, Bellicum Pharmaceuticals, Nantkwest, Celyad, Northwest Biotherapeutics, Argos Therapeutics, Immunocellular Therapeutics, Catherex, Immunocore, Syngentis

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