

Medigene

Outlook

Pharma & biotech

TCR enters the clinic

Medigene has started its TCR Phase I/II clinical trial, making it one of the few clinical TCR companies globally. Combined with the completed enrolment of the Phase I/II DC vaccine trial, Medigene is positioning itself at the forefront of the next wave of cell and gene therapies. We expect initial data packages from both trials in 2019. We have updated our MDG1011 assumptions, rolled forward our model, adjusted for the sale of the US rights to Veregen, and delayed our assumed DC vaccine out-license to 2019. We value Medigene at €396m vs €316m previously.

	Revenue	PBT*	EPS*	DPS	P/E	Yield
Year end	(€m)	(€m)	(€)	(€)	(x)	(%)
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	8.5	(23.2)	(1.04)	0.0	N/A	N/A
12/19e	8.6	(23.1)	(1.04)	0.0	N/A	N/A

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

TCR trial receives regulatory approval

Medigene has started its first clinical trial (Phase I/II) with its T-cell receptor (TCR) modified T-cell (MDG1011) product candidate in patients with r/r multiple myeloma (MM), acute myeloid leukaemia (AML) or myelodysplastic syndromes (MDS). Medigene expects to enrol 92 patients and we anticipate that initial data is possible in early 2019. As evidenced by the recent clinical successes of other T-cell products ie Kymriah (Novartis) and Yescarta (Gilead), positive data could be transformational for Medigene.

Focus fully on Immuno-oncology assets

Medigene has sold the US rights to its legacy asset Veregen and while we anticipate ongoing revenues from legacy assets, the company's focus is primarily on the TCR and DC product candidates. Medigene continues to invest in the TCR platform in order to generate long-term value as demonstrated by the recent publication of Expitope 2.0 and the collaboration with RXi Pharmaceuticals.

Dentritic cell (DC) vaccine trial enrolment completed

Enrolment in the Phase I/II study of Medigene's DC vaccine is now complete and we anticipate initial data to be published towards the end of 2019. The open label trial includes 20 acute myeloid leukaemia (AML) patients who are in complete remission after chemotherapy but are not eligible for stem cell transplantation. Primary endpoints are to assess the feasibility of the dosing regimen and safety.

Valuation: €396m (€17.8/share)

We value Medigene at €396m (€17.8/share) vs €316m (€14.3/share) previously. This is based on a risk-adjusted NPV of its TCR, DC and legacy assets. We have updated our MDG1011 assumptions, rolled forward our model, adjusted for the sale of the Veregen US rights and moved back our assumed DC vaccine out-license to 2019. Initial data from the MDG1011 TCR trial, likely in early 2019, will be a significant inflection point for Medigene.

27 March 2018

Price	€13.0
Market cap	€290m

 Net cash (€m) at 31 December 2017
 51.7

 Shares in issue
 22.3m

 Free float
 80.7%

 Code
 MDG1

Primary exchange XETRA
Secondary exchange Frankfurt

Share price performance



%	1m	3m	12m
Abs	(28.9)	1.5	13.3
Rel (local)	(24.5)	12.5	16.0
52-week high/low		€18.8	€8.9

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 and its first T-cell receptor clinical trial has just initiated.

Next events Bluebird bio R&D update 2018 MDG1011 initial clinical data H119 DC vaccine initial clinical data H119

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Edison profile page

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Investment summary

Company description: Focus on immunotherapy

Medigene, an immunotherapy focused clinical company is developing its three key technologies, DC vaccines, adoptive TCR therapy and T-cell specific antibodies (TABs) for use in cancers. The purchase of privately-held Trianta Immunotherapies in January 2014 (€4m upfront, €6.0m milestones paid) was a transformational transaction, positioning Medigene as an emerging cancer immunotherapy player. 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, which is sold in 23 countries (Medigene recently sold its US rights) through partners. Medigene employs 96 staff (at end December 2017) and is headquartered in Munich, Germany.

Valuation: €396m (€17.8/share)

We value Medigene at €396m (€17.8/share) based on a risk-adjusted NPV. Our model includes the recently initiated MDG1011 trial, the enrolled DC vaccine trial in AML, deal metrics for the bluebird bio collaboration, legacy asset Veregen and Imlygic royalties. We have increased our probability of success to 15% (from 13%) for the TCR trial, and adjusted our expectations for peak patient penetration, price and development speed. With the delayed initiation of the TCR trial, we now expect data in early 2019. However, we anticipate that a licensing opportunity is still likely in 2019. We have pushed back our assumed DC vaccine out-license to 2019 and adjusted for the sale of the US rights to Veregen. Medigene is well-funded (into FY19 on current forecasts), which should enable it to execute on an expanding clinical trial programme. In addition, there is potential for further TCR R&D collaborations similar to the bluebird bio deal. Medigene is currently operating in a hot area which, as it progresses, could make the company increasingly attractive to investors.

Financials: Funded through TCR and DC readouts

Boosted by a gross €20.7m raise in May 2017, Medigene reported a 31 December 2017 cash position of €51.7m. We forecast a cash runway into FY19, which should enable initial readouts of its Phase II DC vaccine trial and TCR trial. At that point, we expect Medigene to either raise further funding and/or partner some of its programmes. We expect R&D spend to increase due to the initiation of the Phase I MDG1011 TCR study and the continuation of its DC vaccine study. For FY18, we now forecast R&D costs at €23.8m and a reduction in SG&A costs to €7.2m following the sale of the Veregen US rights.

Sensitivities: Competition intensifies

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 has become a highly competitive landscape and Medigene's technology platforms are still in relatively early stages of development. The outcomes of the investigator and company initiated trials with the DC vaccines and the preferentially expressed antigen of melanoma (PRAME) TCR are therefore key sensitivities. 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.

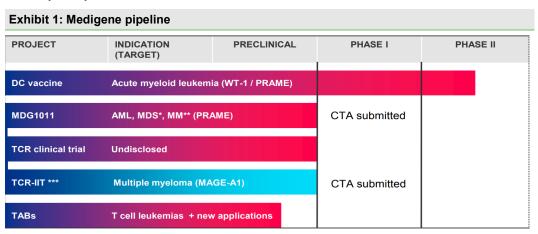


A clinical immuno-oncology player

Immuno-oncology is advancing rapidly on two core trajectories. First is the utilisation of traditional drug molecules (antibodies, small molecules) to affect the immune system, the most successful of these being immune checkpoint inhibitors (Keytruda [Merck], Opdivo [MBY] etc) which aim to block cancer cells' ability to hide from the immune system. The other field of advancement is in cell and gene therapies that look to genetically alter a patient's cells to help them to combat cancer.

Within cell and gene therapies, Medigene's most advanced technologies are its DC vaccines and adoptive TCR therapy. Its most advanced clinical candidate is its DC vaccine, which presents the WT-1 and PRAME antigens. DCs are antigen presenting cells and are a key component of the immune system. Their role is to digest and present circulating antigen material to our body's T-cells, these T-cells are then specific to the presented antigen and will search and attack it. This process is one of the key links between our innate and adaptive immune systems. DC cancer vaccines build on this idea by presenting cancer associated antigens which will then hopefully train the body's T-cells to attack cancer cells that present these antigens.

While the DC vaccines can be viewed as an indirect approach to stimulating an immune response to a cancer, Medigene's adoptive TCR therapy aims to directly attack a cancer. The approach is similar to CAR-Ts (chimeric antigen receptor T-cells) which have recently seen clinical success resulting in the first regulatory approvals of Kymriah (Novartis) and Yescarta (Kite/Gilead), which are approved to treat paediatric acute lymphoblastic leukaemia (ALL) and adult diffuse large B-cell lymphoma (DLBCL) respectively. CAR-Ts involve the extraction of T-cells from a patient, inserting antibody fragment chimeric antigen receptors (commonly by the utilisation of viral vector) into the Tcells, before expanding the cells (increasing the concentration), quality testing and then reinserting them into the patient. TCR technology in basic principles is very similar to the CAR-T approach but instead of utilising an antibody fragment to detect cancer cells, it utilises a T-cell receptor. As the name suggests, T-cell receptors are a T-cells' natural receptors, in the body these recognise and bind to antigens presented by cells. These antigens are presented on both healthy and cancerous cells by a component called the major histocompatibility complex (MHC). A theorised advantage of TCRs over CAR-Ts is that they can target a wider range of antigens, particular intracellular antigens which get presented on the surface of a cell by the MHC. The ability to target the antigens which CAR-Ts cannot could prove a major advantage, particular in solid cancers where tumour exclusive targets remain allusive. However, it should be noted that TCRs are incredibly complex and have yet to be clinically proven with the selection of the right antigen and tuning of the TCR affinity are likely to be key to any success.



^{*} Myelodysplastic syndromes

Source: Medigene

^{**} Multiple myeloma

^{***} Investigator-initiated trial (IIT) of a publicly funded collaboration between MDC, Charité and Medigene.



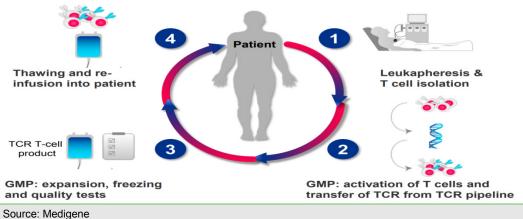
The accelerated approval of CAR-T therapies in the US (EU approval expected in 2018) following strong Phase II data demonstrates the willingness for regulators to approve these game-changing therapies. As such, the initiation of Medigene's MDG1011 Phase I/II TCR trial is a major inflection point for the company. If early signs of strong efficacy are observed, data from the Phase II component of the trial could form part of an accelerated regulatory filing. However, we note that success in two of the core indications ie AML and MM, will need to exceed past standards of care (SOCs) as new treatments both in development and recently approved are demonstrating impressive efficacy in these indications. In a fast changing field, speed of development will be the key to success.

The core inflection point remains the readout of Medigene's first internal TCR product candidate (MDG1011) which we anticipate for early 2019 (initial data). We note other potential major inflection points over the next 12-18 months in the progression of the bluebird bio collaboration, the initial readout of the DC vaccine Phase II trial and data from the investigator TCR trial (yet to be initiated).

PRAME TCR - MDG1011

Medigene's lead TCR product candidate MDG1011 is a PRAME targeting TCR. Each treatment (Exhibit 2) is personalised to a patient (autologous) by the removal and isolation of their T-cells (leukapheresis), modification of these cells to express the relevant TCR/HLA complex (HLA-A*2:01 restricted TCR specific to PRAME) by incubation with a viral vector, the expansion of these cells and then reinfusion into the patient. It should be noted that the human leukocyte antigen (HLA) system is a gene complex that encodes MHC proteins in humans and there are known to be hundreds of HLA types, which occur in different frequencies in humans. The correct identification of a patient's HLA type is needed for a TCR to work effectively. In the case of MDG1011, patients need to be HLA-A*2:01 positive.

Exhibit 2: TCR manufacturing process



Following approval of the study design from the German regulatory authority Paul-Ehrlich-Institut (PEI) and the relevant ethics committee, Medigene has initiated its first <u>TCR clinical trial</u> with its lead candidate, MDG1011. In addition, Medigene's contract manufacturer has received the required product-specific manufacturing licence to produce the study material from the local competent authority.

The company is initially targeting 92 patients with one of three relapsed or refractory blood cancers: AML, MDS and MM. Patients will be genotyped to ensure they are HLA-A*02:01 positive and they will undergo a cyclophosphamide and fludarabine preconditioning regimen. The Phase I component of the trial is designed to test up to three dose cohorts (optional fourth dose cohort may be utilised) in a 3+3 design (12 patients in total). The trial will test dose ranges from 100 thousand to 10 million transduced T-cells per kg of body weight. At each dosing level, once all patients have been treated,



a four-week safety follow up will be observed before an independent data and safety monitoring board (DSMB) will decide if the next dosing level should be done. In our view the first dose level is unlikely to prove efficacious and will instead be a safety check. However, any signs of efficacy at the lowest dose level would provide upside to our assumptions for MDG1011's efficacy. Additionally, due to numerous safety periods in the Phase I component of the trial where no new patients can be treated, we anticipate that the Phase II part of the trial is unlikely to start before the end of 2019.

Primary endpoints of the Phase I component are safety, overall response rate (ORR), maximum tolerated dose (MTD) and/or recommended Phase II dose (RPD2). In addition, the number of patients who receive the planned target dose will be assessed. These endpoints, in addition to other secondary endpoints, will be assessed at three and 12 months after dosing.

Phase II will expand the dose cohort from Phase I and include a control group, which will contain PRAME patients who are HLA-A*02:01 negative and treated according to physician's discretion. Only two of three indications will be taken forward into the Phase II part of the trial and 40 patients each will be enrolled into the treatment and control arm. Co-primary endpoints of the Phase II component include the assessment of safety and evaluation of the overall response rate (ORR) at three months (12-month total follow up). Overall survival (OS), progression free survival (PFS) and duration of response (DoR), will be also be measured at three, six and 12 months.

Medigene has chosen PRAME as its first target to test clinically as it is believed to be prevalent on tumour cells and to show limited expression on most healthy cells (except for abundance in the testis). In melanomas, PRAME expression is thought to occur in c 90% of cancerous tissue and up to c 50-65% in AML, while expression has been demonstrated to exist across other cancers including but not limited to non-small cell lung cancer (NSCLC), Hodgkin's lymphomas and breast carcinomas. Tumour exclusive targets are key drivers for an effective therapy as in theory the limit on-target off-tumour adverse events. On-target off-tumour is when a therapy binds to the correct target antigen but the antigen is presented on a healthy cell so the therapeutic attacks healthy cells instead of the cancerous ones. Focusing on tumour exclusive targets could potentially enable higher dosing regimens that are more efficacious.

Although there is no clinical data on the effectiveness of a PRAME TCR, published preclinical work to date hints at the effectiveness of a cellular-based approach for targeting PRAME in cancer. A 2006 study identified PRAME HLA-A*2:01 binding CD8+ T-cells from healthy and advanced melanoma patients. PRAME T-cell clones were demonstrated to recognise and lyse PRAME melanoma cell lines, although not in ALL cell lines. This was determined to be due to low/no levels of PRAME in ALL which were below the detection level of the PRAME T-cells. Further research has highlighted the role PRAME has as a selective target in T-cell therapies: Amir et al showed that an allogenic PRAME TCR demonstrated high reactivity to PRAME-expressing tumour cells and low reactivity to the majority of healthy cell lines. However, they did demonstrate some reactivity to mature dendritic cells and kidney epithelial cells, due to some detectable but low levels of PRAME expression in those cell types.

This research formed the basis of the only other PRAME TCR in the clinic, BPX-701 from Bellicum. BPX-701 is currently enrolling patients in a Phase I study testing it in r/r AML and MDS patients. The trial is being undertaken at the Oregon Health and Science University Hospital in Portland, Oregon and is expected to enrol 48 patients. The primary outcome is maximum tolerated dose.

BPX-701 is an autologous PRAME HLA-A*2:01 binding TCR that incorporates a Caspase 9 safety (suicide) switch in its design. The TCR is to be utilised alongside rimiducid, a commercially available dimerizer that activates the suicide switch and results in TCR cell death. While this has proved to be a successful approach in a preclinical setting and demonstrated the ability to kill the majority of T-cells in healthy patients, the effectiveness and utility of a suicide switch to reduce a serious cytokine storm or other immune response resulting from a CAR-T or TCR has not been clinically validated.



Closely behind the clinical leaders in the space, Adaptimmune and GSK are advancing a PRAME TCR through preclinical research. Adaptimmune is responsible for all preclinical work and delivery of the IND package to GSK. Approximately \$300m in development milestones are linked to the PRAME programme. Achieving all the milestones relies on the PRAME TCR being successfully developed in more than one indication and HLA type. Adaptimmune would additionally receive sales milestones and mid-single to low double-digit royalties on worldwide net sales. The current preclinical status of the PRAME TCR is unknown.

We note that manufacturing remains a key limitation in the sector, and to date only a few hundred patients have been treated with commercial cell therapies. While Novartis's lead indication for CART Kymriah is in relapsed/refractory (r/r) paediatric ALL, where eligible patient numbers are in the hundreds, Gilead's CAR-T Yescarta is approved (in the US) in r/r adult DLBCL (Kymriah approval expected shortly in DLBCL in the US and EU), where the number of eligible patients worldwide is expected to be around 15 to 20 thousand people. This will be the first major test for the industry as these highly complex personalised therapies are delivered on scale.

MAGE-A1 TCR

In addition to the internal TCR asset MDG1011, Medigene is collaborating with Charité and Max Delbrück Centre (MDC) on a MAGE-A1 (Melanoma-associated antigen 1) TCR. The collaboration aims to begin enrolment of a Phase I study in MM shortly (once it receives regulatory approval – the clinical trial application was submitted in mid-2017).

The research project is funded by the German Federal Ministry of Education and Research (BMBF) with funding directed towards Charité which will be conducting the clinical trial and MDC which will run the analytics and ensure good manufacturing practice (GMP). Medigene is supporting both organisations by managing regulatory affairs associated with trial approval in addition to providing advice on the development of the analytics and GMP production. Medigene holds the first right of negotiation for the TCR product candidate in MM once study results are available from the Phase I study. Additionally, Medigene is entitled to undisclosed profit participation if a third party subsequently acquires the rights to the MAGE-A1 TCR.

The melanoma antigen gene (MAGE) protein family is known to have limited expression on healthy tissues (is expressed in reproductive tissue) but is expressed in a range of cancer tissues. Initial clinical focus from leaders in the field appears to focus on the class A MAGE subfamily. Kite Pharma (a Gilead company) has a MAGE A3/A6 TCR (KITE-718) in Phase I trials in solid tumours. The trial is currently recruiting HLA-DPB1*04:01 positive, MAGE A3/A6 positive patients. It is expected to enrol 50 patients with data anticipated in 2019.

Some of the other most advanced MAGE TCRs are in development by Adaptimmune. The company currently has two Phase I/II trials ongoing utilising a MAGE A10 TCR. One is testing the TCR in HLA-A*02:01/ HLA-A*02:06 positive NSCLC patients and is expected to enrol 28 patients with a readout expected in 2019. The other trial is testing the same MAGE A10 TCR in HLA-A*02:01/ HLA-A*02:06 positive patients who have urothelial cancer, melanoma or head and neck cancers. The trial is expected to enrol 22 patients with readout anticipated in late 2019/early 2020. Adaptimmune also has a MAGE A4 TCR in Phase I clinical development that is currently recruiting cancer patients (expected total of 32) with different solid tumours. Patients are selected to ensure they are HLA-A*02.

DC vaccine trial completes enrolment

Medigene's most advanced clinical cancer immunotherapy technology is its autologous dendritic cell (DC) vaccines. Its lead candidate is a WT-1 and PRAME DC vaccine which is in a Phase I/II trial for maintenance of patients who are in remission from AML. The trial is open label, non-randomised and consists of 20 patients. Patients are dosed regularly for two years (if no patient



deaths) and the primary study objective is feasibility and safety, while secondary endpoints include OS, PFS and minimal residual disease (MRD). Patient enrolment is now completed and we anticipate initial trial data in early 2019.

DCs are a type of antigen-presenting cell (APC) capable of processing antigen material and presenting it on the surface to other cells in 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 should result in the activation of T-cells to recognise and attack antigen-bearing tumour cells. Historically, DC vaccines have had limited success but Medigene believes its technology overcomes previous problems. For a more detailed overview of the DC vaccine technology please see our previously published outlook note.

In addition to Medigene's own DC vaccine there are two investigator-initiated Phase I/II clinical studies underway using Medigene's technology in patients with <u>prostate cancer</u> (n=30, since 2010) and <u>acute myeloid leukaemia</u> (n=20, since 2013). Of the 30 patients to be treated in the prostate cancer study, 15 will be treated with the original (investigator-produced) DC vaccine type, with the rest dosed with Medigene's 'new generation'-designed vaccine candidates. The investigator study in AML uses DCs loaded with three antigens (WT1, PRAME and CMVpp65). Results from the CIT AML study are expected in 2019.

TABs

Medigene's TABs platform utilises its recombinant TCR technologies in order to produce, isolate and characterise monoclonal antibodies specific to TCR structures. TABs 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. 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. Medigene was recently granted a US patent (9,862,755) that covers high affinity T-cell receptors with an epitope tag, which when used in conjunction with the company's TABs, will enable the in vitro and ex vivo assessment of Medigene's T-cell therapeutics.

Competition heats up in MM

Medigene's pipeline of cellular therapies is focused on some of the most competitive disease areas currently in cancer. MM, a core indication for MDG1011 and the MAGE-A1 TCR is seeing dramatic changes in the treatment paradigm across all lines of therapy. Medigene's trials are initially focused on relapsed/refractory (often third line and above) patients, a known strategy for experimental therapies. Often, these patients have limited survival prospects and any advances, however small, are welcome. However, CAR-T treatments are shifting this paradigm and demonstrating significant survival improvements in these challenging patient populations. This improvement is highlighted by recent data from bluebird bio (in a collaboration and licence agreement with Celgene) and Legend Biotech (in a collaboration and licence agreement with Janssen). Both collaborations are developing BCMA (B-cell maturation antigen) CAR-Ts that are in Phase I/II trials. We collate the most recent data in Exhibit 3, but note that as usual, trial comparisons are done with caution due to the differences in patient characteristics, trial design and reporting methodology.

Data at ASH 2017 demonstrated that Bluebird's CAR-T bb2121 achieved an objective response in 94% (17/18) of patients, with 56% (10/18) having a complete response (Exhibit 3). Median PFS had not been reached, with PFS at nine months of 71%. Of the safety evaluable patients, 71% (15/21)



had cytokine release syndrome (CRS), mostly grade 1-2. There were two deaths in the active cohorts at weeks 22 and 69 (following infusion). The first was due to cardiac arrest and the second to MDS; both patients were complete responders at last check up.

The most recent data (Exhibit 3) from Legend Biotech on LCAR-B38M was presented at ASCO 2017. Results demonstrated a remarkable stringent complete response (sCR) rate of 74% (n=14/19). Grade 1-2 CRS occurred in 77% (n=27/35) of patients, with 5.7% (n=2/35) experiencing grade 3 CRS. There were no reported cases of neurotoxicity.

Exhibit 3: Comparison of leading CAR-T multiple myeloma treatments						
	bb2121 BCMA CAR-T (bluebird)	LCAR-B38M BCMA CAR-T (Legend)				
Partial response (PR)	N/A	5% (n=1/19)				
Very good partial response (VPGR)	89% (n=16/18)	21% (n=4/19)				
Stringent complete response (sCR)	38% (n=7/18)	74% (n=14/19)				
Complete response (CR)	56% (n=10/18)	74% (n=14/19)				
Minimum residual disease (MRD)-negative	90% (n=9/10)	N/A				
Cytokine release syndrome (Grade \geq 3) 9% (n=2/21) 5.7% (n=2/3)						
Source: bluebird bio, Legend Biotech, Edison Investment Research						

We believe the most relevant non-TCR competition for Medigene will be these and other CAR-T product candidates. However, we note it will face competition from predominately stem cell transplants along with more traditional treatments (antibodies and chemotherapy) which are approved in r/r patients either alone or in combination. Notably, these include Janssen's Darzalex (daratumumab), Takeda's Ninlaro (ixazomib), Bristol Myer's Empliciti (elotuzumab) and Celgene's Pomalyst (pomalidomide). Additionally, Celgene's first line blockbuster Revlimid (lenalidomide) and the generic steroid dexamethasone are commonly utilised across treatment lines in various combinations.

We note unlike MM where advances are coming quickly, AML remains difficult to treat, with no current cell therapy leader. Multiple TCRs and CAR-Ts are in development including from Cellectis (UCART123), Juno (JTCR016), Celyad (CYAD-01) and Bellicum (BPX-501 & BPX-701), however data thus far are very early stage. Readouts that are expected later in 2018 and early 2019 will inform these products' suitability in this cancer type. We note that stem cell transplants remain the main treatment option in AML, although recent approvals of Rydapt (Novartis) and Idhifa (Celgene) are enabling new, non-cellular approaches.

M&A activity and licensing in the sector is accelerating

M&A activity has picked up substantially in the last six months driven by weak late-stage pipelines and impending patent cliffs in top biotech/pharma companies, while the recent lowering of corporate tax in the US could encourage further activity in 2018. Cell and gene therapies, particularly those with an immune-oncology focus, have been a major beneficiary of M&A action to date, driven by the impressive results and rapid (FDA) approvals for CAR-T products Kymriah (Novartis) and Yescarta (Gilead/Kite).

Recent acquisitions of the two leaders in the field, Kite Pharma by Gilead, and Juno Therapeutics by Celgene, highlight this. In August 2017, Gilead bought Kite Pharma for \$11.9bn. Since the acquisition Kite's lead asset Yescarta (axicabtagene ciloleucel) has been approved in r/r DLBCL (diffuse large B-cell lymphoma), PMBCL (primary mediastinal large B-cell lymphoma) and TFL (transformed follicular lymphoma) by the FDA and is on track for approval in Europe in H118. Additionally, Kite has a BCMA CAR-T (KITE-585) in a Phase I trial and a MAGE A3/A6 TCR (KITE-718) also in a Phase I trial for solid tumours.

To further augment Kite's capabilities; in December 2017 Gilead acquired Cell Design Labs for \$567m. This builds on the collaboration that Kite had with Cell Design Labs over the previous 18



months. Cell Design Labs's two core technologies are synNotch Receptors (programmable T-cells) and THROTTLE switch modules (safety switch).

More recently, Celgene acquired Juno at the start of this year through the purchase of c 90% of its shares (it already owned c 10% from <u>licensing deal undertaken in 2015</u>). Juno's lead asset, JCAR017 (lisocabtagene maraleucel), like Yescarta and Kymriah, is a CD-19 targeting CAR-T focused on DLBCL as a lead indication. Celgene expects this to be on the market by 2019 with global peak sales of \$3bn. Juno has multiple T-cell products in early clinical and preclinical development, notably a BCMA targeting CAR-T (JCARH125) which is in a <u>Phase I trial</u> in MM.

Recent licensing activity includes J&J's expansion into CAR-T therapies with a worldwide collaboration and licence agreement with Chinese-based Legend Biotech (subsidiary of Genscript Biotech Corporation). The deal centres on LCAR-B38M, a BCMA targeting CAR-T for use in MM. Janssen paid \$350m upfront and entered into a 50/50 cost-sharing/profit split arrangement (December 2017). However, in China this is weighted 70/30 in favour of Legend. The drug is currently being reviewed by the Chinese FDA with plans underway for US studies.

We also note recent public and private fund-raises in the last six months from BioNtech (\$270m), Tmunity (\$100m), Eureka (\$60m), Obsidian (\$50m) and Tessa Therapeutics (\$80m) that further highlight the current investor appetite for these technologies.

Platform advancements continue to add value

In September 2016, Bluebird Bio and Medigene announced a collaboration to generate four TCR product candidates by utilising a combination of Medigene's TCR and Bluebird's lentiviral technologies. Medigene is responsible for the generation and delivery of TCRs to Bluebird and preclinical development is jointly undertaken, while Bluebird is responsible for clinical development and any potential commercialisation. Medigene received \$15m upfront and is eligible to receive over \$1bn in milestones in addition to royalties on any future net sales and R&D funding. For the first nine months of 2017, Medigene received revenue of €159k from R&D reimbursements. We anticipate an update on the progress of the partnership in 2018.

Medigene recently announced a collaboration with RXi Pharmaceuticals to further develop its T-cell platform. The collaboration is focused on early preclinical research and how RXi Pharmaceuticals' self-delivering RNAi (sd-rxRNA) technology can be utilised with Medigene's TCR technology. No deal terms were disclosed and we view this as an early stage research project only.

The company continues to advance its internal scientific capabilities. At the start of 2018, it published a paper describing Expitope 2.0, a tool for assessing cross reactivity of TCR targets between healthy and cancerous cells. The original Expitope calculated the chance of cross reactivity by looking at tissue-specific gene expression. This gave an idea of how likely it is that a protein will be abundant in a certain tissue type; however, this only indirectly predicts this as it assumes what proteins a gene expresses. Recently, human protein abundance information has become readily available due to advancements across the field. This now allows for a direct calculation of protein abundance and thus a better idea of cross reactivity between tissue types. This tool continues to be improved and utilised internally by Medigene to help predict cross reactivity of its TCRs before they enter the clinic.



Exhibit 4: Value driven across TCR development platform **TCR GMP** TCR-Clinical TCR-**TCR** generation production development modified based leads module module T cells program therapies TCR discovery TCR development TCR clinical stage collaborations collaborations partnerships Medigene's PRAME MAGE-A1 development in MM oluebird**bio** with academic partners TCR study MDG1011 Unique discovery capabilities, cGMP process potentially of Proprietary immune monitoring platform interest to other parties TCR therapies Source: Medigene

Additionally in 2017, Medigene and partners at the Max Delbruck Centre for Molecular Medicine announced the <u>publication</u> of research that demonstrated a new method for TCR identification. A key advantage of TCRs over CAR-Ts is that they can target intracellular components through the expression of epitopes (typically peptides around 10 amino acids in length that are recognised by the immune system) on the surface of a cell through the MHC (major histocompatibility complex). Most TCR technologies only focus on which peptide they target and utilise the most frequent MHC allele HLA-A*02:01 (there are 6 class I alleles). Specific MHCs only exist in certain patient groups, thus limiting any TCR to those patient groups. As such, approaches are needed which take into account both the peptide and MHC alleles of a given patient. In the paper published the team was able through the utilisation of APC (antigen presenting cells, eg dendritic cells) to reveal the best-suited epitope MHC combination. This was achieved without having previous information on the target epitope or MHC needed. The publication further highlights Medigene's ability to select the specific TCRs needed for a disease.

Legacy assets

With the acquisition of Trianta Immunotherapies in January 2014, Medigene began the transformation into an immuno-oncology company. While Medigene's strategy is now focused on its TCR and DC platforms, it still generates revenue from legacy assets. Medigene currently receives non-core revenue from four legacy assets: Veregen, EndoTag, RhuDex and Eligard, in addition to royalties from Imlygic (following Medigene's sale of its stake in Catherex to Amgen in 2015). Veregen is a topical treatment for genital warts, Medigene recently sold the US rights to Fougera Pharma (dermatology business entity of Sandoz US, part of Novartis). Fougera has acquired the IP, licences, know-how and trademark, although Medigene remains the owner of the API stock and becomes its exclusive supplier. We have adjusted our forecasts to take into account the new guidance announced by Medigene following this deal. Veregen is additionally marketed in 21 other countries by other distribution partners. Medigene's remaining assets Eligard (prostate cancer), EndoTAG-1 (breast cancer) and RhuDex (autoimmune) have been sold or out-licensed. In 2016 Medigene received a regular non-cash income of €2.493k from Cowen Healthcare Royalty Partners for Eligard. This non-cash recognition is from the \$17.68m deal that was signed in 2012, €2.493k will be recognised annually over the lifetime of Eligard's patent which was approximately 10 years



from the signing. EndoTag is now owned by SynCore Biotechnology (deal signed in December 2015). Medigene is entitled to €5m which is being paid out in five annual €1m instalments, in addition to potential milestone payments and royalties. RhuDex is owned by Dr Falk Pharma (deal signed in 2014). RhuDex is being developed in hepatology and gastroenterology. Falk Pharma is responsible for development, marketing and resultant costs.

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 has become a highly competitive landscape and Medigene's technology platforms are still in relatively early stages of development. The outcomes of the investigator and company-initiated trials with the DC vaccines and PRAME TCR are therefore key sensitivities. 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.

Valuation: €396m (€17.8/share)

We value Medigene at €396m (€17.8/share) based on a risk adjusted NPV. Our model includes the recently initiated MDG1011 trial, the enrolled DC vaccine trial in AML, deal metrics for both, the bluebird bio deal and legacy asset Veregen. Additionally, we have updated our exchange rates and value the ongoing Imlygic royalties as a result of the sale of the Catherex stake to Amgen.

We have increased our probability of success to 15% (from 13%) for the TCR trial, and adjusted our expectations for peak patient penetration, price and development speed. With the delayed initiation of the TCR trial, we now expect initial data in early 2019. However, we anticipate a licensing opportunity to still be likely in 2019 following the release of these data. We have pushed back our assumed DC vaccine out license to 2019 and adjusted for the sale of Veregen US rights. Medigene is well-funded (into FY19 on current forecasts), which should enable it to execute on an expanding clinical trial programme. Alongside this there is the potential for further TCR R&D collaborations similar to its bluebird bio deal. Medigene is operating in a hotly contested area which as it progresses, could make the company increasingly attractive to investors. For a summary of our valuation and assumptions, please see Exhibit 5.



Product	Status	Launch	NPV (€m)	Peak sales (\$m)	Probability of success	Royalty rate	rNPV (€m)	rNPV/ share (€)	Key assumptions
Veregen	Marketed	2009	2	10	100%	10%	2	0.08	10% max annual growth pa; effective 20% on sales based on revenues from royalties + product sales; 40% COGS.
Imlygic	Marketed	2015	11	230	100%	1%	11	0.47	1% royalty, Evaluate product consensus figures, peak after seven years post launch.
DC vaccine - AML	Phase I/II	2022	63	347	25%	15%	14	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)		39	1.74	\$15m upfront, total milestones \$272m split between Phase I, Phase II, Phase III, NDA filing and approval. Four products included reaching the clinic one year apart, starting in 2018. No sales-related income included at this time.
TCR	Pre-clinical	2024	1358	3,719	15%	20%	201	9.02	
DC vaccine deal metrics				200	25%		33	1.48	\$50m upfront, post Phase II (2019/50% chance); \$25m on NDA filing (2022/25% chance); \$125m on regulatory approval (2023/25% chance).
TCR deal metrics				500	15%		45	2.01	\$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			1,06 5				344	15.45	
Net cash as of	30 September	2017					51.7	2.32	
Overall valuation	on						396	17.76	

MDG1011: Adjustments to forecasts as market evolves

The key driver of our valuation is the TCR trial. Based on a variety of changes in the cell and gene therapy landscape, in addition to new information on the MDG1011 trial, we have readdressed some of our assumptions.

We have now increased the expected price to \$350k in the US and €255k in the EU. This is based on recently approved cell therapies, Yescarta and Kymriah, which were respectively priced at \$373k and \$475k (list prices before discounts) in the US. We have conservatively forecast that MDG1011 will be priced below these products, driven predominately by decreased cell and gene manufacturing costs. At this time we note that pricing remains a challenging area for these therapies, particularly in relation to the financial burden healthcare systems are willing and able to take on. The effect that the price has on our MDG1011 value can be seen in Exhibit 6.

We now assume that Medigene is able to capture at peak 20% of the relapsed/refractory AML and MM patients in the US and EU (instead of our previous assumption of 5% of the total haematological malignancy market), which equates to approximately 10,000 patients. Significant sensitivity remains around manufacturing cell therapies, a complex multi-week process that involves the removal, modification and readministration of a patient's own cells. To date, the number of patients treated with commercial cell therapies is in the hundreds. While we expect advancements across the industry, 10 thousand patients will represent a significant manufacturing achievement if reached. To achieve 20% peak penetration, we assume MDG1011 has comparable efficacy to Bluebird's in-development CAR-T bb2121 in MM, and demonstrates better efficacy than small molecule inhibitors like enasidenib (IDHIFA, Celgene) and midostaurin (Rydapt, Novartis) in AML. MDG1011's as yet unknown efficacy, in particular in relation to other in-development cell therapies, means peak penetration remains a significant sensitivity. The effect of penetration rates on our MDG1011 value can be seen in Exhibit 6.

We further note that applicable patients could be further limited, not just by the abundance of PRAME on their cancer cells, but also the abundance of the correct HLA type. The human leukocyte antigen (HLA) is a gene complex that encodes for MHC and is key to the immune



system's ability to recognise antigens. HLA types differ between patient populations and only the correctly matched HLA type will ensure that a TCR works. Patient treatment will be limited to patients who present the relevant HLA, in this case HLA-A*2:01, which is believed to be one of the most common HLA types to exist.

Exhibit 6: Effect of MDG1011 price and peak penetration on its value per share Peak penetration 10% 15% 30% 20% 25% \$200.000 2.37 3.70 5.03 6.36 7.69 \$250,000 3.04 4.70 6.36 8.02 9.68 MDG1011 price \$300,000 3.70 5.69 7.69 9.68 11.68 \$350,000 4.37 6.69 9.02 11.35 13.67 7.69 10.35 13 01 15.67 \$400,000 5.03 \$450.000 5 69 8 69 11.68 14.67 17 66 \$500,000 6.36 9.68 13.01 16.33 19.66

Source: Edison Investment Research

As per the Phase I/II MDG1011 trial design, we assume that only two of three diseases tested in the Phase I part are moved forward into the Phase II part. At this stage we have no data to accurately forecast the diseases in which MDG1011 is most likely to succeed. However, for modelling purposes we have picked AML and MM. MDS patients are typically older and it is a more heterogeneous disease then AML and MM, thus it may prove more difficult to generate consistent efficacy across patients. However, at this time it is just an assumption and we have no clinical data to back up this theory.

We forecast that MDG1011 is likely to receive accelerated approval if it demonstrates similar efficacy to that of approved cell therapies. As such we now anticipate a launch in 2021 (in the US and EU) based on positive Phase II data. To date, regulators have demonstrated a willingness to quickly advance cell therapies, as shown by the approvals of CAR-Ts Kymriah and Yescarta. Based on impressive Phase II efficacy data, Kymriah and Yescarta received accelerated approvals in r/r AML and r/r DLBCL. The FDA granted both therapies Breakthrough Therapy and Orphan Drug designation, in addition to priority review status, while in the EU both therapies are undergoing accelerated assessment through the PRIME priority medicines scheme. We believe both are likely to be approved in Europe this year based on the same, albeit more mature, Phase II data. We note that so far, while no TCR products have been commercially launched, Adaptimmune's NY-ESO Spear T-cells have breakthrough therapy and PRIME designations. We note that Medigene achieving breakthrough therapy status and subsequent accelerated approval for MDG1011 remains a significant sensitivity in our model. If data are not sufficient for accelerated approval, it would likely push any launch back by three to five years. In this fast-moving sector, speed of development will be key.

Financials: Funded to TCR and DC readouts

Boosted by a gross €20.7m raise in May 2017, Medigene reported a 31 December 2017 cash position of €51.7m. We forecast a cash runway into FY19, which should enable initial readouts of its Phase II DC vaccine trial and TCR trial. At that point, we expect Medigene to either raise further funding and/or partner some of its programmes.

In 2017, revenues increased to €7.7m (2016: €4.1m) driven predominately by a large increase in immunotherapy revenues to €4.9m (2016: €1.1m) as a result of the Bluebird collaboration. Under the terms of the partnership, Medigene received a one-off payment of \$15m (€13.4m), which will be recognised over four to five months from signing the deal in 2016.

Revenue from Veregen decreased 8% to €2.8m (2016: €3.1m). Other operating income decreased in the period to €3.7m and consisted of a non-cash item of €2.5m from Cowen Healthcare Royalty



Partners (assigned outstanding royalties from Eligard) and a one-off gain of €1.1m as a result of the sale of the US rights of Veregen.

SG&A decreased in 2017 to €8.3m (2016: €10.0m) as a result of one-off costs relating to Veregen in 2017. R&D rose to €14.9m (2016: €11.5m), which mainly related to services, personal expenses and cost of laboratory materials.

The increased revenue and costs for the period mainly offset each other, which led to an EBITDA loss of €12.1m in 2017 compared with €12.4m in 2016. Net loss for the period increased to €13.6m (2016: €9.5m), mainly as a result of one-off gains in 2016 of €4.2m from the sale of Immunocore shares.

We have made adjustments to our FY18 forecasts to reflect the sale of the Veregen US rights, updated management guidance and the delay in initiation of the MDG1011 TCR trial. We have adjusted 2018 Veregen revenues downwards by c 50% to €1.4m; this reflects an expected loss in revenue following the sale of the US rights. We have also reduced selling expenses connected to Veregen. As a result of the reduction In Veregen royalties, we now forecast a decrease in total FY18 revenues to €8.5m.

With the initiation of the TCR trial, Medigene anticipates a significant increase in R&D expenditure in 2018 and we predict this increased cost base will continue into 2019. We forecast R&D expenditure of €23.8m (increased from €18.8m previously as a result of costs shifting from 2017 to 2018 due to the delay in the TCR trial initiation) and €24.0m in 2019. In addition, we forecast a reduction in SG&A costs to €7.2m for 2018 following the sale of the Veregen US rights.

We now forecast an EBITDA loss of €22.3m in 2018, driven in core by increased R&D costs.



	€'000s 2015	2016	2017	2018e	2019
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS	0.000	0.740	44.075	0.400	0.046
Revenue	6,808	9,749 3,048	11,375 2,790	8,469 1,433	8,618
of which: Veregen revenues (royalties/milestones/supply) R&D partnering (SynCore/Falk Pharma/grants)	3,101 1,214	3,155	2,790	1,433	1,582
Non-cash income (Eligard)	2,493	2,493	3,699	3,699	3,699
Bluebird bio partnership	2,400	1,053	4,886	3,338	3,338
Cost of sales	(1,103)	(1,402)	(1,621)	(553)	(613
Gross profit	5,705	8,347	9,754	7,916	8,008
Selling, general & administrative spending	(7,615)	(10,025)	(8,266)	(7,186)	(7,395
R&D expenditure	(8,529)	(11,538)	(14,877)	(23,803)	(24,041
Other operating spending		0	0	0	(
Operating profit	(10,439)	(8,974)	(13,389)	(23,073)	(23,431
Goodwill & intangible amortisation	(526)	(525)	(524)	(523)	(522
Exceptionals	0	4,242	0	0	(
Share-based payment	(111)	0 (40.074)	0	0	(00.004
EBITDA	(9,384)	(12,371)	(12,122)	(22,325)	(22,684
Operating profit (before amort. and except.)	(9,802)	(12,691)	(12,865)	(22,550)	(22,909
Net interest Other (forex gains/losses; associate profit/loss)	(2,914)	(1,009) 263	(1,434) 1,884	(1,959) 1,278	(1,746 1,540
Other (forex gains/losses; associate profit/loss) Profit before tax (norm)	(46)	(13,437)	(12,415)	(23,231)	(23,109
Profit before tax (norm) Profit before tax (reported)	(13,399)	(9,720)	(12,413)	(23,754)	(23,631
Tax	400	228	(634)	(23,734)	(23,031
Profit/(loss) from discontinued operations	0	0	(034)	0	
Profit after tax (norm)	(12,362)	(13,209)	(13,049)	(23,231)	(23,109
Profit after tax (reported)	(12,999)	(9,492)	(13,573)	(23,754)	(23,631
Average number of shares outstanding (m)	16.8	20.0	21.6	22.3	22.3
EPS - normalised (€)	(0.74)	(0.66)	(0.60)	(1.04)	(1.04
EPS - Reported (€)	(0.77)	(0.48)	(0.63)	(1.07)	(1.04
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
•	0.0	0.0	0.0	0.0	· · · · · · · · · · · · · · · · · · ·
BALANCE SHEET					
Fixed assets	51,552	47,742	48,595	49,457	50,400
Intangible assets & goodwill	35,713	35,767	36,292	35,769	35,247
Tangible assets	2,502	3,323	4,329	5,714	7,179
Other non-current assets	13,337	8,652 63,973	7,974	7,974	7,97
Current assets Stocks	59,900 6,654	7,866	63,342 7,724	38,934 7,724	13,114 7,724
Debtors	763	1,175	1,699	1,699	1,69
Cash	46,759	52,630	51,724	27,316	1,49
Other	5,724	2,302	2,195	2,195	2,19
Current liabilities	(9,664)	(11,966)	(9,808)	(9,808)	(9,808
Trade accounts payable	(1,354)	(973)	(725)	(725)	(725
Short-term borrowings	Ó	Ó	Ó	Ó	` (
Deferred income	(226)	(3,575)	(3,575)	(3,575)	(3,575
Other	(8,084)	(7,418)	(5,508)	(5,508)	(5,508
Long-term liabilities	(13,879)	(21,157)	(15,962)	(12,625)	(9,287
Pension provisions	(359)	(408)	(405)	(405)	(405
Long-term borrowings	0	0	0	0	(
Other liabilities (Deferred taxes; Trianta milestones)	(2,915)	(2,395)	(3,672)	(3,672)	(3,672
Deferred revenues (Eligard non-cash income & bluebird bio)	(10,605)	(18,354)	(11,885)	(8,548)	(5,210
Net assets	87,909	78,592	86,167	65,958	44,419
CASH FLOW					
Operating cash flow	(10,585)	(3,611)	(20,729)	(24,006)	(23,884
Net interest	(20)	(45)	(45)	(459)	(246
Tax	0	(102)	(75)	0	//
Capex	(1,328)	(1,677)	(1,533)	(1,610)	(1,690
Expenditure on intangibles	0	10.527	0	0	
Acquisitions/disposals	0	10,537	480	0	
Equity financing	43,695	(77)	19,329	1 667	
Other	21	846 5.971	1,667	1,667	
Net cash flow Opening net debt/(cash)	31,783 (14,976)	5,871 (46,759)	(906) (52,630)	(24,408)	(25,820 (27,316
HP finance leases initiated	(14,976)	(46,759)	(52,630)	(51,724) 0	(27,310
Other (foreign exchanges differences)	0	0	0	0	



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Revenue by geography

N/A

www.medigene.com Management team

CEO and CSO: Dolores Schendel

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.

Senior VP of R&D: Dr Markus Dangl

Dr Markus Dangl has held the position as senior vice president research & preclinical development at Medigene since March 2016. Dr Dangl held positions at Roche in the past 14 years, including the establishment of the Roche Translational Medicine Hub in Singapore where he was responsible for all research and translational medicine activities. Most recently he worked as department head DTA Oncology and preclinical science leader MDM2 franchise, pharma research and early development at Roche Diagnostics. He studied biochemistry and received a PhD in biochemistry from the Leopold-Franzens university of Innsbruck, Austria.

CFO: Thomas Taapken

Dr Taapken spent more than five years at Epigenomics, 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 (now Acorda Therapeutics) and its predecessor companies for six years and spent seven years as a venture capital investor at DVC Deutsche Venture Capital and San Francisco-based US venture capital firm Burrill & Company. He 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.

CMO: Dr Kai Pinkernell

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	9.8%
Aviva	5.3%
DJSMontana	4.2%
Executive and Supervisory Board	4.0%

Companies named in this report

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