Medigene AG

Germany / Biotech
Primary Exchange: XETRA, Frankfurt
Bloomberg: MDG1 GR
ISIN: DE000A40ESG2

Initiating Coverage

RATING	**BUY**
PRICE TARGET	**€ 3.80**
Return Potential	265.4%
Risk Rating	High

DEVELOPING NOVEL TCR-GUIDED CANCER THERAPIES

Medigene AG is an immuno-oncology platform company dedicated to developing T cell receptor (TCR)-guided therapies that specifically target tumour cells to effectively eliminate cancer without harming healthy tissues. TCRs are special proteins on the surface of T cells (a type of immune cell) that function like "scanners", recognising and binding to certain markers (antigens) on cancer cells. The company utilises its state-of-the-art end-to-end technology platform to generate optimal 3S (sensitive, specific and safe) TCRs with unique and distinctive attributes. These can be utilised in multiple therapeutic modalities such as off-the-shelf TCR-guided T cell engager therapies (TCR-TCEs), off-the-shelf TCR natural killer cell therapies and autologous T cell receptor engineered T cell (TCR-T) therapies, for both Medigene's in-house product pipeline and external partnering. Strong strategic partnerships with high-calibre players including BioNTech, Regeneron and WuXi Biologics (WuXi), validate Medigene's technology, expand the pipeline and provide access to additional financial resources. The recent partnership with WuXi led to the joint development of MDG 3010, a new off-the-shelf TCR-TCE therapy for solid tumours targeting the well-validated KRAS G12V neoantigen. TCR-TCE programmes are attracting great interest from large pharmaceutical companies, leading to lucrative early-stage licensing agreements (e.g. Candid, GSK or Almirall). Medigene aims to demonstrate proof-of-principle for MDG 3010 by the end of 2025, which could potentially lead to a licence agreement shortly thereafter. We initiate coverage of Medigene with a Buy rating and a €3.80 price target.

Although it is a challenge, we see a good chance that the lead drug candidate MDG1015 will be out-licensed in 2025 Medigene's autologous lead third generation (3G) TCR-T candidate, MDG1015, received IND clearance from the FDA in Q3/24 and a European CTA was submitted to the EMA in Q4/24 which could pave the way for the start of phase 1 clinical trials in a broad range of solid cancers. However, due to funding constraints in the current difficult capital market environment, the company reformulated its strategy and is now focusing on licensing the programme rather than raising capital to fund the trial.

(p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2021	2022	2023	2024E	2025E	2026E
Revenue (€ m)	10.5	31.2	6.0	8.0	10.0	35.0
Y-o-y growth	n.a.	198.6%	-80.7%	32.6%	25.0%	250.0%
EBIT (€ m)	-10.0	-8.7	-16.1	-14.9	-6.5	2.9
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	8.3%
Net income (€ m)	-10.0	-8.3	-16.2	-15.0	-6.5	2.9
EPS (diluted) (€)	-0.41	-0.34	-0.66	-1.13	-0.44	-0.96
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€ m)	-10.8	11.0	-15.7	-13.4	-5.4	3.6
Net gearing	-49.6%	-59.6%	-41.2%	-20.8%	-49.2%	-25.5%
Liquid assets (€ m)	22.4	33.2	16.7	8.5	2.7	6.2

RISKS

Risks include, but are not limited to development, regulatory, competition and financial risks.

COMPANY PROFILE

Medigene AG is a leading German-based immuno-oncology biotech platform company focused on the development of T cell receptor (TCR)-guided therapies for the treatment of solid tumours. The company's cutting-edge technology platform allows the generation of optimal 3S TCRs for the development of TCR-guided therapies. The IND-approved lead drug candidate MDG1015 is looking for a strategic partner to finance ist clinical development.

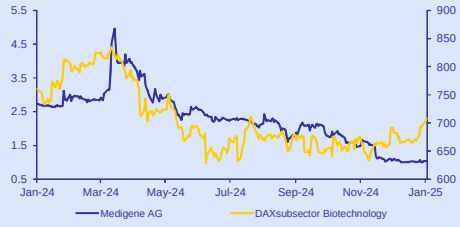
MARKET DATA

As of 15 Jan 2025

Closing Price	€ 1.04
Shares outstanding	14.74m
Market Capitalisation	€ 15.33m
52-week Range	€ 1.00 / 4.96
Avg. Volume (12 Months)	17,664

Multiples	2024	2025	2026
P/E	n.a.	n.a.	n.a.
EV/Sales	1.6	1.3	0.4
EV/EBIT	n.a.	n.a.	4.3
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 30 Jun 2024

Liquid Assets	€ 14.02m
Current Assets	€ 15.63m
Intangible Assets	€ 9.84m
Total Assets	€ 28.81m
Current Liabilities	€ 6.53m
Shareholders' Equity	€ 19.66m

SHAREHOLDERS

Management and Directors	4.0%
Freefloat & others	96.0%

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INVESTMENT CASE

Medigene has a proprietary technology platform capable of generating novel TCR-guided therapies for the treatment of solid tumours Medigene's T-cell receptor (TCR) technology platform is a cutting-edge immunotherapy approach designed to develop best-in-class TCR-guided therapies. The company only uses tumour-specific antigens that have been extensively validated in the academic and research space. The platform isolates naturally occurring TCRs with high affinity and specificity from young healthy donors. These TCRs are therefore highly specific, sensitive and safe (3S) and can target tumour cells with high specificity so that cancer is effectively eliminated without harming healthy tissues. The company is pursuing three TCR-guided therapeutic approaches with a focus on off-the-shelf modalities: (1) T cell engagers such as antibody (TCR-TCE) therapies, and (2) natural killer cell (TCR-NK) therapies as well as (3) autologous third generation TCR-engineered T cell (3G TCR-T) therapies with armouring capabilities that increase immunotherapeutic efficacy, safety and durability.

TCR-TCE off-the-shelf products developed through cooperations – WuXi Biologics (WuXi) is a top partner Medigene is pursuing the development of off-the-shelf therapies through a combination of proprietary and external technologies. To this end, Medigene has recently entered into a strategic partnership with the contract research and manufacturing organisation (CRMO) WuXi to leverage Medigene's TCR technology platform with WuXi's global R&D and manufacturing capabilities, which include the following industry-leading capabilities (1) WuXiBody™ bispecific antibody platform (2) T Cell Engager (TCE) platform and (3) expertise in anti-CD3 monoclonal antibodies, which are critical for T cell engagement in immunotherapy strategies. WuXi is therefore an ideal partner for Medigene in the development of innovative TCR-TCEs immunotherapies.

First off-the-shelf programme, MDG3010, targeting KRAS G12V could show proof of principle by YE25 / H1/26 The first early preclinical joint TCR-TCE programme, MDG3010, will target the well-validated KRAS G12V neoantigen in patients with HLA-A*11 type. This target is particularly relevant in difficult-to-treat cancers such as pancreatic, colorectal, and lung cancers, where KRAS mutations are a major driver of disease progression and poor prognosis. MDG3010 could reach proof of principle by YE25 / H1/26.

TCR-TCEs are a validated approach that can generate attractive value – strong Big Pharma appetite for bispecific approaches The novel TCR-TCE approach was validated by FDA approval in January 2022 of Immunocore's allogeneic T cell engager Kimmtrak (tebentafusp) for the treatment of unresectable or metastatic uveal melanoma (eye cancer). Kimmtrak has been successfully adopted and reported sales of USD226m for 9M 2024 (+32% growth YoY). Recent licensing/co-development agreements in the T-cell engager (TCE) space such as (1) Candid Therapeutics with WuXi (license of up to USD925m in upfront and performance-based milestone payments for a preclinical trispecific TCE), (2) Candid with EpimAb Biotherapeutics (license of over USD1bn in upfront and milestone payments for novel TCEs for various autoimmune indications), (3) GSK with WuXi (license of USD40m upfront and up to USD1.5bn in success-based milestone payments for up to four preclinical TCEs) – these deals underscore the value of WuXi's bi-specific platform –, (4) GSK with Chimagen (acquisition of a clinical stage TCE for up to USD850m) or (5) Almirall with EpimAb (licensing up to three TCEs for up to USD250m), highlight strong appetite for this powerful approach. Based on these deals, we estimate that MDG3010 could be out-licensed to Big Pharma in 2026 after proof-of-principle. Medigene expects further collaborations with other partners (e.g. specialists in NK cells) in the next few months.

Strategic shift to align the company's focus with market trends and optimise resource allocation In the light of the difficulty of securing sufficient funds to finance the phase 1 study of its lead autologous drug candidate MDG1015 in a difficult capital market environment, management decided to implement a strategic and organisational realignment,

including a streamlined R&D focus, a 40% workforce reduction and other cost-saving measures. These measures involve prioritising R&D of off-the-shelf therapies, particularly TCR-TCEs (including MDG3010) and TCR-NKs, which are anticipated to offer significant therapeutic advantages and market opportunities, and deprioritising the autologous proprietary pipeline. Medigene remains committed to fulfilling its obligations to existing partnerships for autologous TCR-T programmes (e.g. Regeneron and BioNTech) and ensuring continued innovation in its End-to-End Platform for generating optimal TCRs. The company aims to balance immediate market opportunities with long-term growth potential while exploring partnerships and financing opportunities to extend its cash runway beyond July 2025 and support future development.

Medigene's lead IND-approved autologous third generation (3G) TCR-T therapy MDG1015 to be deprioritised – potential phase 1 trial postponed until the company finds a licensing partner to fund it MDG1015 is a first-in-class, 3G TCR-T cell therapy targeting the well-validated cancer testis antigens NY-ESO-1/LAGE-1a, armoured and enhanced by the costimulatory switch protein PD1-41BB in HLA-A*02 cancer patients. The incorporation of PD1-41BB in MDG1015 is a significant technological advancement, specifically designed to counteract the tumour microenvironment (TME) by turning inhibitory signals (from PD-1 interactions) into stimulatory ones (through 41BB activation), thereby maintaining T-cell activity and persistence in the immunosuppressive TME. The TCR-T candidate received IND clearance from the FDA in September 2024 and a European clinical trial application (CTA) was submitted to the EMA in December 2024. We note that the TCR-T therapy approach has recently been validated through the approval of Adaptimmune's first generation (1G) TCR-T therapy Tecelra® (afami-cel). Given that the 3G programme MDG1015 addresses efficacy, safety and durability limitations present in first generation (1G) therapies such as Tecelra®, we believe it is an attractive programme. The company will be fully focused on out-licensing to a partner that can fund the international phase 1 clinical study. We consider a potential deal closing and trial initiation in late 2025 to be likely. The other autologous cell therapy programmes will be paused and the company will seek partners to advance them through the preclinical stage into the clinic.

TCR-T therapy targeting the well-validated MAGE-A4 target for various solid tumours in collaboration with Regeneron is recruiting patients for the ongoing phase 1 study in China Medigene's development partnership with Regeneron Pharmaceuticals to develop TCR-T cell therapies targeting the melanoma-associated antigen A4 (MAGE-A4) is progressing as planned. In January 2024, Regeneron initiated patient enrolment in an investigator-initiated trial in Beijing, China, which triggered an anticipated €1m milestone payment. This collaboration reflects Medigene's strategy of validating Medigene's superior TCR technology, expands the pipeline and provides Medigene with access to additional financial resources. The key partners in autologous approaches, Regeneron and BioNTech, have each made upfront payments of >USD20m.

Medigene shares are significantly undervalued, presenting an attractive investment opportunity With its innovative TCR-guided programmes and a broad application in solid tumours, Medigene is well-positioned for growth in the evolving cancer immunotherapy landscape. Using our proprietary risk-adjusted valuation model, we estimate fair value for Medigene's immune-oncology pipeline at €3.80 per share. This valuation is driven by (1) partnered programmes such as off-the-shelf MDG3010 (WuXi) and autologous TCR-T therapies targeting MAGE-A4 (Regeneron) and PRAME (BioNTech) through potential upfront and milestone payments; and (2) Medigene's own lead preclinical candidate, MDG1015, which is also expected to be developed in collaboration with partners. Despite the company's limited cash runway until July 2025, we see good prospects for the success of the new partnership-orientated strategy given Medigene's positive track record in attracting high-calibre partners. We expect positive developments in the partnership endeavours to catalyse upward momentum in the company's share price and initiate coverage with a Buy recommendation.

SWOT ANALYSIS

STRENGTHS

- **Experienced management team** Dr Selwyn Ho (CEO), and Prof Dolores J. Schendel (CSO), accompanied by Mr James Cornicelli (Senior VP & Head of Corporate Development and Strategy) are highly qualified executives with over 90 years of combined experience in the pharmaceutical and biotech industries as well as in academia with a particular focus on cancer and immune-oncology.
- **Cutting-edge technology platform to generate TCR-guided immunotherapies** Medigene's End-to-End Platform is designed to create best-in-class 3S TCRs that can be combined to guide multiple off-the-shelf and autologous therapeutic modalities to tumour cells. These optimal 3S (sensitive, specific and safe) TCRs have unique and distinctive attributes and can target a broad range of solid tumours whose targets are inaccessible to other binders (antibodies, CAR-Ts, etc.).
- **High-calibre partnerships validate the technology** Medigene is currently partnered with three leading players in the field of immunotherapy: Regeneron (US, previously 2seventy bio / bluebird bio), BioNTech (Germany), and most recently WuXi Biologics (China), to leverage their collective expertise in developing and commercialising TCR-guided therapies. They also provide Medigene with access to additional financial resources (Regeneron and BioNTech have each made upfront payments of >USD20m) to develop its pipeline.
- **Validated TCR-guided therapy approach for solid tumours** The recent FDA approval of the first TCR-T soft tissue cancer therapy Tecelra® (afami-cel) from Adaptimmune and the FDA approval in January 2022 of Immunocore's allogeneic TCR-TCE therapy Kimmtrak (tebentafusp) for the treatment of eye cancer validated TCR-T and TCR-TCE therapies including Medigene's TCR-guided approach. These regulatory milestones demonstrate that these therapies can be both safe and effective, opening the door for further acceptance and development of such treatments.

WEAKNESSES

- **Limited financial latitude – streamlining process underway** The company had cash resources of €9.5m at the end of September 2024 which will finance ongoing operations into ~July 2025. In October 2024, the company secured a financing option through a SEPA equity commitment of up to €15m with a fund managed by Yorkville Advisors. These funds still fall short of the total amount needed to complete MDG1015's phase 1 study and fund further work on the other pipeline programmes. For this reason, the company has implemented downsizing and refocusing measures, accompanied by an intensified search for partnerships to finance pipeline development.
- **Early-stage proprietary pipeline in late preclinical phase** The lead proprietary programme, MDG1015, a third-generation TCR-T therapy targeting various solid tumours has convincing preclinical efficacy data. However, the response rate still has to be demonstrated in patients in a phase 1 clinical trial, which received FDA IND clearance in September 2024. A European CTA was submitted to the EMA in December 2024. If a licensing partner can be found, a phase 1 study could begin later in 2025.
- **Small size compared with large dominant competitors** With a market cap of ~€16m, Medigene is small compared to the big immuno-oncology players such as Bristol Myers (Juno Theraputics), Roche (Spark Therapeutics), Merck & Co, Astra Zeneca, Novartis, Gilead Sciences (Kite Pharma) and Iovance Biotherapeutics.

OPPORTUNITIES

- **Progress in MDG1015's phase 1 clinical trials in solid tumours may create significant shareholder value** Assuming a partner is found, we expect that phase 1 trials could begin in 2025 and headline results, including initial efficacy data, could be published in 2026, demonstrating proof-of-concept of Medigene's third generation TCR-T therapy in humans.
- **Additional value upside from further preclinical TCR-T pipeline programmes** The company has further attractive earlier-stage TCR-T programmes for various solid tumour indications with substantial value-generation potential. If the company finds partners for MDG2011 and MDG2021, their development could be continued.
- **Leveraging high-calibre partnerships for accelerated development** Medigene's strategic collaborations with leading companies like Regeneron and BioNTech offer opportunities to leverage shared resources, expertise, and complementary technologies to accelerate pipeline development. The clinical-stage MAGE A4 programme in partnership with Regeneron is currently recruiting for phase 1 in China and the partner could publish the results towards YE25/H1/26.
- **Expansion into allogeneic products through TCR-guided partnerships** Medigene is pursuing the development of off-the-shelf cell therapies by leveraging its in-house proprietary technologies. These have the potential to offer scalable and readily available treatment options, as opposed to autologous therapies which need to be custom manufactured for each patient. The early preclinical TCR-guided programme MDG3010 in collaboration with WuXi Biologics could provide proof of principle by YE25 / H1/26, which could trigger strong Big Pharma partnering interest in this asset. Further partnerships (e.g. with natural killer cell specialists) are expected.

THREATS

- **Financing risks** In view of the company's short cash runway (July 2025), the company needs to find strategic partners or investors willing to finance the further development of its R&D portfolio. A difficult financing environment or negative results from clinical trials in the immune-oncology space (particularly TCEs) could hinder the acquisition of non-dilutive funds and lead to possible insolvency.
- **Clinical development and regulatory risks** Medigene's proprietary pipeline of TCR-guided therapies is still in preclinical development. There is a significant risk that the programmes, particularly the value-driving lead drug candidates MDG1015 (autologous) and MDG3010 (off-the-shelf), may fail to show efficacy in preclinical development or in the clinical trials. Negative or inconclusive clinical trial results could lead to delays, additional costs, or even the discontinuation of a development programme. Moreover, even if Medigene achieves good results in clinical trials, there is still a risk that they do not meet the expectations of the regulatory agencies (FDA and EMA), who may not approve the products or may request further trials.
- **Competitive risks** Medigene's pipeline may face competitive pressure. Several companies, including GSK, Bristol Myers, Roche, Merck & Co, Astra Zeneca, Novartis, Gilead Sciences, Iovance Biotherapeutics, Immatics and Adaptaimmune are developing innovative immune therapies in solid tumours and blood cancers. Despite Medigene's world-class level of innovation in its TCR-guided approach, any unexpected breakthrough by one or more of these competitors could significantly hit the company's potential revenues.

VALUATION

Biotechnology valuation is notoriously difficult since there is high risk in R&D pipeline development, which leads to uncertainty in projecting cash flows. We have assessed Medigene's fair value based on a sum-of-the-parts methodology. We believe this is the most appropriate valuation method for Medigene because it reflects the implicit risk-adjusted value of every drug candidate in the R&D pipeline. Development risks, including clinical and regulatory risks, are taken into account as are market size and the expected timing of cash flows post-approval for each project.

We have used a risk-adjusted NPV model for the following proprietary preclinical R&D programmes: (1) MDG1015, in the four lead cancer indications of gastric cancer, ovarian cancer and two types of soft tissue sarcomas; (2) MDG3010, in partnership with WuXi for off-the-shelf use, targeting the KRAS neoantigen in patients with HLA-A*11 type; and (3) the partnered TCR-T programmes with Regeneron and BioNTech. We believe that other preclinical programmes are also promising, in particular MDG2011 and MDG2021 in different cancer indications with mutations of the neoantigen KRAS, which are currently paused due to funding constraints. However, due to their earlier preclinical stage and significant development risk, as well as the uncertainty as to whether the company will be able to secure the appropriate funding to conduct the trials, we consider them to have upside potential for our valuation.

During the forecasting process, we adjusted our sales estimates and resulting cash flows for success probabilities to obtain risk-adjusted expected values. We base our probability coefficients on statistical sector studies, such as the Tufts CSDD, and on our own estimates.

Additionally, using First Berlin methodology, which takes into account company-specific risk factors, we have derived a cost of equity (COE) of 16% for Medigene. Based on a debt ratio of 0%, we arrive at a WACC of 16%, which we have used to discount projected cash flows. Including projected proforma net cash of USD18.0m, we value Medigene at USD62.0m, which implies a fair value of USD4.00 (€3.80) per share on a proforma fully diluted basis. Using our ten-factor risk analysis, we set a High risk rating for Medigene. The main risk factors that we have identified are financing, development, regulatory and competition.

Figure 1: "Sum-of-the-parts" valuation model

Compound	Project[1]	Present Value		Patient Pop (K)	Treatment Cost (USD)	Market Size (USDM)	Market Share (%)	Peak Sales (USDM)	PACME Margin[2] (%)	Discount Factor (%)	Patent Life[3] (years)	Time to Market (years)
MDG 1015	Cancer - US	USD	19.6M	7K	420,000	2,940.0M	20%	813.9M	7%	16.0%	12	7
MDG 1015	Cancer - Europe	USD	12.1M	20K	210,000	4,200.0M	10%	590.2M	7%	16.0%	12	7
PACME PV autologous pipeline		USD	31.7M			7,140.0M		1,404.1M				
MDG3010	Milestones risk adj. PV	USD	34.1M	(Partnership with WuXi / ~50% ownership)								
Partnered TCR-Ts	Milestones risk adj. PV	USD	19.5M	(Regeneron & BioNTech)								
- Costs PV[4]		USD	-42.2M									
NPV		USD	43.1M									
Net cash (proforma)		USD	17.7M									
Fair Value		USD	60.8M									
Share Count (proforma)		15,339K										
Price Target		USD	4.00									
Price Target		EUR	3.80	(based on EUR-USD exchange rate of 1.03)								

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining market exclusivity after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

ESTIMATED PRICE AND SALES POTENTIAL FOR MDG1015 IN THE US

Peer drugs pricing We have identified two recently approved comparable cell therapy drugs: (1) Iovance Biotherapeutics' autologous tumour-infiltrating lymphocyte – TIL – therapy Amtagvi (Lifileucel), which collects the TILs directly from the patient's tumour sample and fortifies them in a laboratory to better fight cancer. It received an accelerated approval based on phase 2 data from the FDA in February 2024 and launched the product immediately at a price of USD515k; and (2) Adaptimmune's autologous TCR-T therapy Tecelra® (afami-cel) received accelerated approval in August 2024 and set a price of USD727k.

MDG1015 pricing We conservatively assume a list price of USD600k per treatment course for MDG1015, coupled with ~30% discounts to insurance providers, equating to an average ex-factory therapy price of USD420k p.a. in the US. Our conservative price estimate implies a discount to the 1G TCR-T drug Tecelra® despite the superiority of MDG1015, which will in our view promote the achievement of faster reimbursement and market penetration.

Target patient population We assume that Medigene can achieve a market share of ~20% in the targeted US market. We believe this is a conservative assumption considering that these are the patients that benefit most from the treatment. Plus, there is no treatment alternative in the market capable of improving patient survival beyond standard of care. Based on statistical data on the incidence for Medigene's following four selected indications: (1) gastric (including gastroesophageal) cancer; (2) ovarian cancer and two subtypes of soft tissue sarcoma, (3) myxoid/round cell liposarcoma; and (4) synovial sarcoma, we estimate a potential patient population in the US of ~71k patients; of which ~8%-14% of patients may belong to the target population that meets the target profile (NY-ESO-1 and LAGE-1a) and inclusion criteria of HLA-A*02+ subtype, we conservatively project a target population of 10% or ~7k in the US. HLA subtypes play a critical role in the effectiveness of therapies that involve the immune system, particularly T-cell-based therapies.

Licensing, time to market and peak sales We assume that the company will be able to license the product to a pharmaceutical or biotech partner in 2025, who will fund clinical development. We estimate a PACME royalty rate of 7% upon commercialisation. Medigene's royalties will roughly equate to its profit on the product. The partner will organise the manufacturing of the product by Medigene's CRMO, take over development phases 1 to 3, carry out commercialisation and bear the costs of marketing and distribution. Assuming positive results and accelerated approval, we project a potential US market launch in 2031. We think that the selected cancer indications will grow at a CAGR of 3% by 2040. We project total peak sales potential of ~USD814m five years after launch for MDG1015 in the core US market.

ESTIMATED PRICE AND SALES POTENTIAL FOR MDG1015 IN EUROPE

Pricing and target population in the EU In Europe, where prices are typically substantially below the US level, we assumed an average ex-factory therapy price of USD210k. Further, we estimate a prevalence of ~200k people with the four selected cancer indications in Europe, of which ~10% of patients or ~20k may belong to the target population who have the NY-ESO-1 and LAGE-1a mutations and meet the inclusion criteria of HLA-A*02+.

Licensing, time to market and peak sales in the EU We expect Medigene to conduct an international study in the US and Europe, and MDG1015 would be licensed to one partner for both main US and European regions. As a result, licensing and timing assumptions are the same for both regions. Given the decentralised European healthcare system, we assume a more conservative 10% market penetration for MDG1015, which would lead to peak sales of ~USD590m.

ESTIMATED MILESTONE POTENTIAL FOR MDG3010 AND THE PARTNERED TCR-TS

Partnership environment for bispecific TCE therapies – outlicensing of MDG3010 is likely following proof-of-principle Recent licensing/co-development agreements in the T-cell engager (TCE) space highlight strong appetite for this promising approach. Given the momentum in the bispecific TCE space, MDG3010 could become very attractive for Big Pharma once proof-of-principle is achieved. We give an overview of recent deals in table 1.

Table 1: Selected bi-specific antibody deals in 2019-2025

Licensee / licensor Year	Drug candidates	Description	Development stage	Total deal value USD	Upfront payment USD
Candid / WuXi January 2025	trispecific antibody for immune-oncology	trispecific TCE	Preclinical	Up to USD925m	undisclosed
Candid / EpimAb December 2024	multi-specific antibodies for autoimmune indications	multi-specific TCEs	Preclinical	Over USD1bn	undisclosed
GSK / Chimagen October 2024	CMG1A46 for autoimmune diseases (lupus)	dual CD19 and CD20 targeted TCE	Phase 1 ready	USD850m	USD300m
Almirall / EpimAb October 2023	bispecific antibodies for immune-oncology	access to Fabs-In-Tandem Immunoglobulin platform	Preclinical	USD 211m plus royalties	undisclosed
GSK/ WuXi January 2023	up to 4 bispecific antibodies for immune-oncology	bispecific TCEs designed to bind to CD3	Preclinical	USD1.5bn	USD40m
GSK / Merck KGaA February 2019	bintrafusp alfa for immune-oncology	bispecific fusion protein	Phase 1	Up to €3.7bn	€300m

Source: First Berlin Equity Research, Companies

Product profile The programme targets a novel tumour-associated antigen mutation of the KRAS gene in patients with the HLA-A*02+ subtype, which is among the most common mutations found in various solid tumours, particularly pancreatic, small bowel, colorectal, lung (NSCLC) and endometrial cancers. These indications have larger incidence and patient populations than MDG1015 (worldwide ~50% larger according to Medigene) which could attract potential licensing partners. However, at this early stage it is difficult to predict which indications Medigene or a partner will explore in clinical trials.

MDG3010 – assumptions on potential milestones and royalties For MDG3010, we have assumed a total value of milestone payments up to the potential approval and market launch of the product of USD150m and a licence fee of 2.5% on sales. These figures are conservative and are below the values shown in table 1 and in other deals in the industry.

Partnered TCR-T programmes – assumptions on potential milestones Given that Medigene has received upfront payments totalling USD 49m from Regeneron (target: MAGE-A4) and BioNTech (target: PRAME) for the development of the agreed TCRs with novel neoantigens and that management has confirmed that the partners are satisfied with the work done so far, we have made the conservative assumption that Medigene will receive a further USD80m in milestones.

COMPANY PROFILE

OVERVIEW

Medigene AG (Medigene) – a leading player using T-cell receptor (TCR)-guided technologies for the treatment of solid tumours Medigene is a biotechnology company based in Planegg/Martinsried, near Munich, Germany, that focuses on the development of cutting-edge immunotherapies for cancer treatment. Founded in 1994, Medigene has become a leading player in the field of cancer immunotherapy, with a particular focus on TCR guided therapies. In a TCR-guided therapeutic approach, the TCR acts like a "radar" or "scanner" that helps the patient's immune cells (e.g. T cells, NK cells) to recognize cancer cells by binding to specific markers (antigens) that are present on the surface of these harmful cells and not in healthy cells, triggering an immune response. The company's core expertise lies in generating optimal 3S (highly specific, sensitive and safe) TCRs for the development of TCR-guided therapies that harness the power of the immune system to recognise and eliminate cancer cells.

The firm's TCR expertise can be applied to autologous (patient's own cells) and allogeneic (donor cells) therapies TCR-guided therapies can be either autologous TCR-T cell therapies (using the patient's own T cells) or off-the-shelf such as TCR-TCE therapies (using T cell engagers) and TCR-NK therapies (using natural killer cells). Medigene, similarly to other immune-oncology players, has initially focused on developing autologous T-cell therapies because these minimise the risk of immune rejection and have been technically more feasible in the early stages of T-cell therapy development. This individualised approach ensures a highly specific immune response tailored to each patient's unique tumour profile. Based on the rapid advance of technologies in recent years, off-the-shelf therapies are gaining traction in the field as technical feasibility has been validated (e.g. TCR-TCE), triggering Big Pharma's strong appetite for this type of programme. Off-the-shelf therapies can be produced in bulk and stored for on-demand use. Their main advantages over autologous therapies are: (1) they are faster to deploy because they eliminate the need for patient-specific cell collection and processing. This is especially critical for patients with rapidly progressing cancers; (2) they have the potential for large-scale manufacturing, reducing production costs and increasing accessibility for a broader patient population; and (3) they can be standardised, offering consistency in dosing and quality across patients. These advantages make off-the-shelf therapies a promising evolution in the field of cancer immunotherapy, addressing some of the logistical and scalability limitations of autologous approaches.

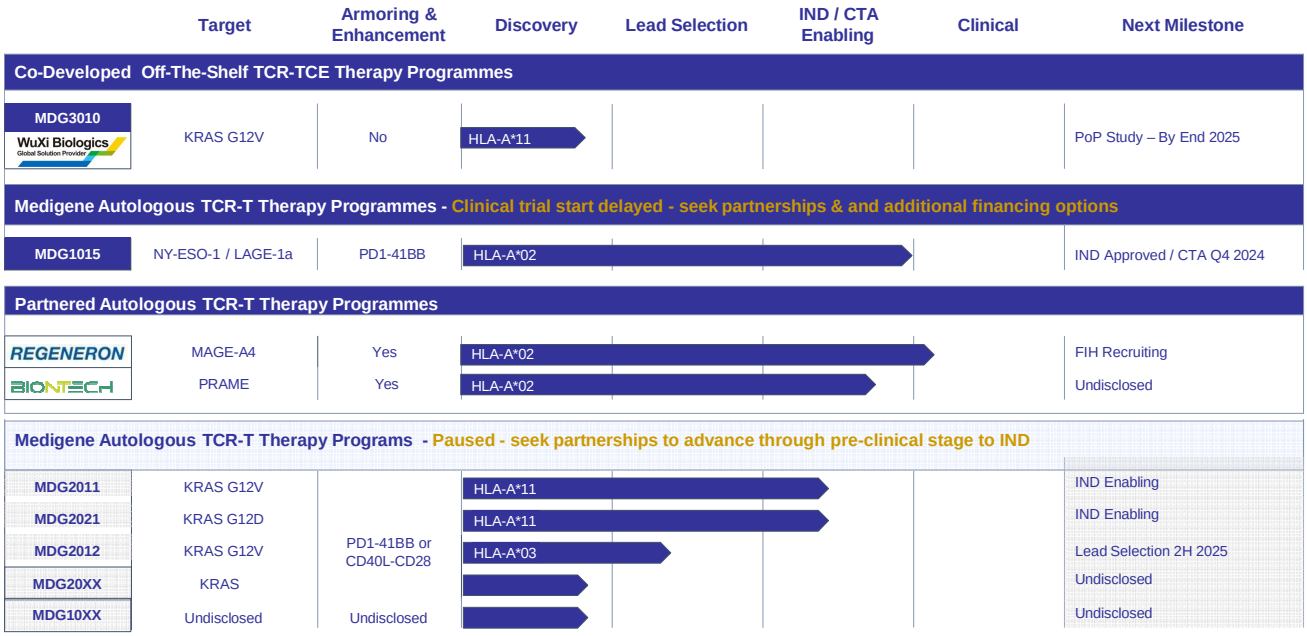
STRATEGIC REALIGNMENT

First wave of strategic realignment was completed in 2023 Over the years, Medigene has shifted its strategic focus for TCR-guided therapies toward solid tumours, departing from its earlier work on blood cancers such as leukaemia (see History section). This strategic realignment is driven by the broader market potential and the critical need for effective treatments in solid tumour oncology. In 2023, the company decided to put its clinical-stage, first generation TCR-T programme MDG1011 for blood cancers on hold and focus all efforts on 1) working on developing other preclinical TCR-T therapy candidates directed at novel well-validated antigens for solid tumour applications, 2) expanding its TCR-T platform with technologies such as its proprietary costimulatory switch proteins PD1-41BB (reverses immune suppression and optimises T cell persistence) or CD40L-CD28L (enhances T-cell activation and supports the long term persistence of activity), allowing the creation of third generation (3G) TCR-T cell therapies with improved efficacy and safety, and 3) exploring opportunities in both autologous and allogeneic TCR-guided products. The knowledge and data gained from the first generation MDG1011 programme contributed to the development of these next-generation therapies. The company's most advanced proprietary preclinical programmes focusing on solid tumours currently under development are: 1) lead programme

MDG1015 (IND-approved and clinic-ready), followed by MDG2011, MDG2021 and MDG2012 for autologous administration and 2) MDG3010 for potential allogeneic administration in collaboration with WuXi Biologics (WuXi). Our report focuses on MDG1015 and MDG3010. In partnership with high-calibre players BioNTech and Regeneron, Medigene has expanded its pipeline with the autologous TCR-T programmes against the well-validated neoantigens MAGE-A4 (in phase 1) and PRAME (preclinical), respectively.

Strategic shift in November 2024 to align the company's focus with market trends and optimised resource allocation In light of the company's difficulties in securing sufficient funds to finance the phase 1 study of its lead autologous drug candidate MDG1015 in a difficult capital market environment, management decided to implement strategic and organisational realignment, including a streamlined R&D focus, a 40% workforce reduction and other cost-saving measures. These measures involve prioritising R&D of off-the-shelf therapies, particularly TCR-TCEs (including MDG3010) and TCR-NKs, which are anticipated to offer significant therapeutic advantages and market opportunities, and deprioritising the autologous proprietary pipeline. Medigene remains committed to fulfilling its obligations to existing partnerships for autologous TCR-T programmes (Regeneron and BioNTech) and ensuring the continued innovation of its End-to-End Platform for generating optimal TCRs. The company aims to balance immediate market realities with long-term growth potential while exploring partnerships and financing opportunities to extend its cash runway beyond July 2025 and support future development. We give an overview of proprietary and partnered pipeline in figure 2 below.

Figure 2: Snapshot of the immuno-oncology R&D pipeline following strategic refocus



Source: First Berlin Equity Research, Medigene AG

R&D PIPELINE FOLLOWING STRATEGIC CHANGES

MDG3010 is Medigene's earliest-stage programme but at the same time the one with the most attractive profile within the immuno-oncology landscape. It comprises a TCR-guided T cell engager (TCE) therapy (TCR-TCE) being developed in partnership with the Chinese CRMO and antibody specialist WuXi Biologics. This programme would be the first off-the-shelf candidate.

MDG1015 is Medigene's lead autologous, proprietary preclinical programme, which combines a high-affinity TCR targeting the well-validated cancer antigens NY-ESO-1/LAGE-1a, with the PD1-41BB costimulatory switch protein technology. The NY-ESO-1/LAGE-1a antigens are expressed in various solid tumours, including melanoma, ovarian cancer, and sarcomas. The PD1-41BB switch receptor aims to enhance T cell activity by converting inhibitory signals from the tumour microenvironment (TME) into activating signals, potentially increasing the therapy's efficacy and durability while reducing T cell exhaustion. In addition, the manufacturing process developed for MDG1015 significantly shortens vein-to-vein time in which this product can be administered to patients (an advantage in itself) and provides a differentiated drug product composition with less expanded cells, offering the potential for increased clinical efficacy, durability and safety. The TCR-T candidate received FDA IND clearance in September 2024. European clinical trial application (CTA) was submitted to the EMA in December 2024. While the dose-escalation phase 1 clinical trial could begin as soon as possible, funding constraints have led the company to postpone a potential clinical study until a strategic partner is found to fund it.

MDG2011 and **MDG2021** are preclinical TCR-T programmes targeting two tumour-associated antigen mutations of the KRAS gene which are among the most common mutations found in various solid tumours, including pancreatic, colorectal, and lung cancers. Both programmes are armoured with the PD1-41BB costimulatory switch protein and they have both achieved promising in-vitro results and started the IND enabling process.

MDG2012 is designed to create a TCR-T therapy with strong selectivity and effectiveness against tumour cells, armoured with one of the costimulatory switch proteins, PD1-41BB or CD40L-CD28L. The earlier stage MDG2012 programme is focused on identifying, optimising and evaluating potential TCR-T candidates (leads) with a view to selecting the best one for further development.

Autologous R&D pipeline programmes partnered with high calibre immune-oncology players The company is also collaborating with industry leaders to expedite its autologous TCR-T therapeutic programmes. Medigene entered into significant partnerships together with the immunotherapeutic specialists Regeneron (US, since 2016, previously 2seventy bio / bluebird bio) and BioNTech (Germany, since 2022) to develop TCR-based therapies targeting solid tumours. These partnerships are fully funded by the partners. Regeneron and BioNTech have made upfront payments of €23m and €26m respectively, and Medigene is eligible for further milestone and royalties payments in the future which may reach a triple digit EUR million sum per programme.

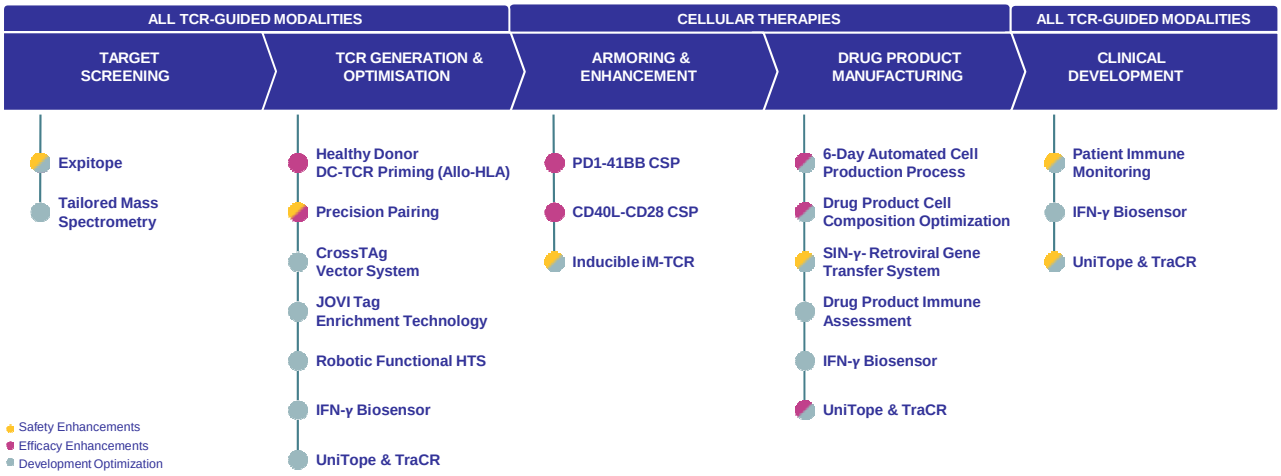
Lead TCR-T therapy targeting MAGE-A4 for various solid tumours in collaboration with Regeneron – patient recruitment for the phase 1 study in China is underway Medigene's partnership with Regeneron to develop TCR-T cell therapies targeting the well validated melanoma-associated antigen A4 (MAGE-A4) has reached a key milestone. In January 2024, Regeneron initiated patient enrolment in the investigator-initiated phase 1 trial at Beijing University in China, which triggered an anticipated €1m milestone payment. The partner could publish results towards YE25 / H1/26. We note that Regeneron obtained this programme as part of its acquisition of 2seventy bio's pipeline, which was completed in April 2024. The Chinese trial is being led by Regeneron's local partner JW Therapeutics. Further details of the study can be found at https://clinicaltrials.gov/study/NCT06170294?tab=table.

CUTTING-EDGE END-TO-END TECHNOLOGY

Medigene's End-to-End technology platform is a comprehensive system designed to develop personalised, highly specific, potent T-cell receptor (TCR)-based immunotherapies for cancer treatment. Medigene only uses tumour-specific antigens that have been extensively validated in the academic and research space, ensuring that the selected targets are exclusive to cancer cells and not expressed in healthy tissues. Medigene's platform focuses on discovering and engineering TCRs that can recognise these targets. This involves screening, identifying and isolating naturally occurring TCRs from young healthy

donors with the highest affinity and specificity to ensure they can effectively target and destroy cancer cells while minimising potential off-target effects. These TCRs are therefore highly specific, sensitive and safe (3S). Medigene's platform includes a diverse library of TCRs against various antigens, providing flexibility in developing therapies for different cancer types. For autologous cell therapy applications, the company has developed innovative TCR-T armouring capabilities designed to enhance the efficacy and durability of its TCR-T cell therapies by counteracting immune evasion. Together with an external CRO, the company has developed an optimised, automated, scalable manufacturing process capable of producing highly specific and potent TCR-T cells.

Figure 3: Medigene's end-to-end technology platform



Source: First Berlin Equity Research, Medigene AG

INNOVATION BACKED BY EXTENSIVE IP WORLDWIDE

Broad IP portfolio Medigene AG has developed a robust intellectual property (IP) portfolio centred around its innovative T cell receptor (TCR)-guided immunotherapies for cancer treatment. The company's patents cover various aspects of its proprietary technologies, such as TCR-T therapies and the End-to-End platform, including:

I. multiple TCR generation technologies such as (1) allogeneic-HLA (Allo-HLA) TCR Priming which enables the identification and development of TCRs that recognise HLA-restricted tumour antigens in a way that isn't limited by patient-specific HLA types, (2) UniTope for the identification of unique tumour-specific antigens, (3) TraCR for screening of cross-reactivity to ensure that selected TCRs are specific to cancer antigens, (4) IFN-Biosensor capable of detecting the key immune response marker interferon-gamma (IFN-γ) in real time, ensuring therapy is actively targeting cancer cells and supporting fine-tuning of TCR-T cell programmes to maintain efficacy and safety, and

II. specific immune response enhancement technologies for TCR-T cell therapies such as (1) PD1-41BB and CD40L-CD28 costimulatory switch proteins, and (2) the inducible Medigene TCR (iM-TCR), which enables the generation of advanced T cell receptors engineered to respond to specific activation signals (e.g. selective activation only within the tumour environment, minimising potential off-target effects).

As of 30 September 2024, the company held a portfolio of 29 different patent families globally which included 104 issued patents and 124 pending applications. These patents are primarily filed under Medigene Immunotherapies GmbH (MeIT), with some in collaboration with partners including Helmholtz Munich (HM) and Regeneron (formerly 2seventy bio, Inc.). Specifically, Medigene holds 22 patent families under its name, while four are in-licensed from HM, one is jointly filed with HM, and two are jointly filed with Regeneron. The company is continuously expanding its IP in new technologies and geographical regions.

COMPANY HISTORY

The most important events in the history of Medigene are summarised below:

Table 2: Key milestones on the company's history

Time	Corporate events
1994	Medigene was founded as a spin-off from the Gene Center at the Ludwig-Maximilian University in Munich, Germany. The company initially focused on the development of gene therapies and was one of the pioneers in this field in Europe.
June 2000	IPO: Medigene became one of the first German biotech companies to go public, listing on the Frankfurt Stock Exchange during the biotech boom. The company raised about €125m (3.0m shares at €42p/s) for the expansion of its R&D activities.
2001-2005	The company developed a pipeline of cancer drug candidates, including EndoTAG-1, a cytotoxic and anti-angiogenic breast cancer therapy, and the tumour cell vaccine programme, aimed at treating various types of cancer (e.g. melanoma), and Veregen, a topical treatment for genital wards embedding lower R&D risk.
2006	Acquisition of the British biotech company Avidex, which added cutting-edge expertise in T-cell receptor (TCR) technology.
2007-2009	Approval and market lunch of the first product, Veregen, in the US and Europe. The company licensed the marketing rights to partners.
2014	Following the setback in phase 3 clinical trials suffered by its lead drug candidate EndoTAG-1 which did not meet the primary endpoints for pancreatic cancer, Medigene made a strategic decision to focus exclusively on immunotherapies, particularly T-cell TCR therapies and dendritic cell vaccines. Medigene acquired the T cell TCR and DC vaccine biotech Trianta GmbH (renamed Medigene Immunotherapies), which boosted Medigene's immunotherapy expertise and pipeline. Trianta's founder and CEO, Dolores Schendel, joined Medigene as CSO.
2015	Entered into a collaboration with Bluebird bio / 2seventy bio (later acquired by Regeneron Pharmaceuticals), a leading gene therapy company, to develop TCR immunotherapy candidates, reinforcing Medigene's focus on T-cell-based cancer therapies. The company started a phase 1/2 clinical trial with its DC vaccine FDC101 for the treatment of AML.
2016	In February, Dolores Schendel became CEO of Medigene. In June, Medigene launched strategic realignment measures including the decision to divest non-core assets.
2017	The company sold Veregen's US rights to its US licensor Fougera Pharmaceuticals (subsidiary of Novartis) for an undisclosed amount. While the non-core asset generated some revenue it was not a substantial marketing success.
2018	The Bluebird bio (2seventy bio/Regeneron) collaboration was expanded. Medigene also closed a strategic partnership with Roivant Sciences to develop and commercialise TCR therapies. This second partnership provided Medigene with significant funding and expanded its pipeline of immunotherapies. The company also started a phase 1 study of its first generation (1G) TCR-programme MDG1011 in the blood cancers AML and MDS.
2019	Disposal of Veregen's remaining rights to Aresus Pharma GmbH for €7.75m.
2022	Comprehensive R&D partnership with BioNTech concluded. In addition, the final results for its DC vaccine FDC101 phase 1/2 study in AML were published. These did not conclusively prove its efficacy in preventing relapse. In addition, the highly experienced pharmaceutical manager Dr Selwyn Ho joined Medigene AG as CEO on 25 July.
2023	According to the published final results, the 1G TCR-programme MDG1011 was well tolerated and showed first signs of efficacy in AML and MDS although not conclusively. The company decided to shift its focus from haematologic cancers (like leukemia) to solid tumours.
2024	The company received IND clearance to initiate the phase 1 dose-finding clinical study for the lead candidate MDG1015. Medigene entered into a partnership with the Chinese CRMO and antibody specialist Wuxi Biologics to co-develop a first-in-class cancer candidate for allogeneic delivery. Management also launched a process of strategic realignment.

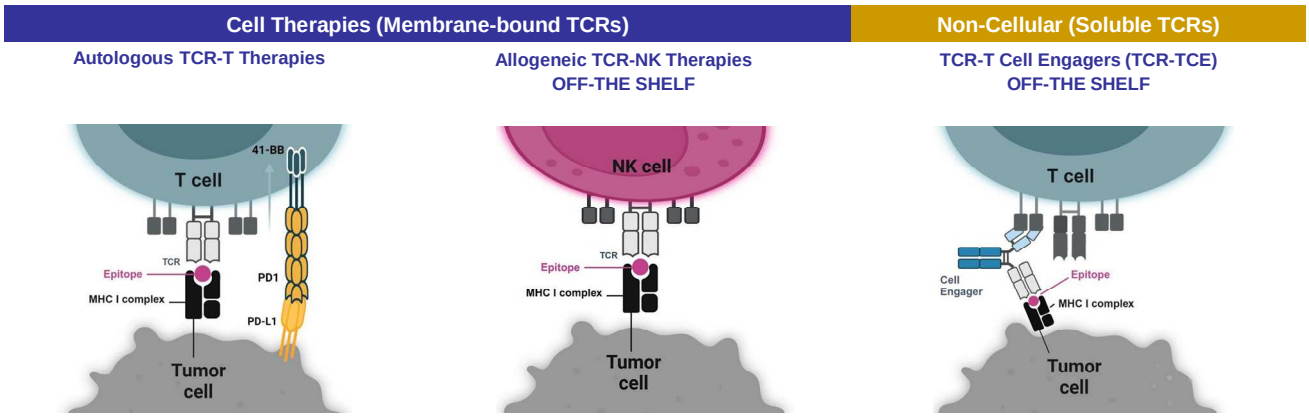
Source: First Berlin Equity Research, Medigene AG

TCR-GUIDED THERAPIES FOR ALLOGENEIC APPLICATIONS & MDG3010

THE ALLOGENEIC TCR-GUIDED APPROACH

Off-the shelf- therapies As we have already mentioned, the development of allogeneic therapies — derived from donor cells — is very attractive, as these could improve scalability, reduce costs, and make treatments more accessible and faster to administer. Medigene is therefore exploring strategies to create allogeneic TCR-guided therapies based on its unique TCR-expertise. Two key "off-the-shelf" approaches being explored by the company are using T cell engagers (TCEs) such as antibodies (see the WuXi Biologics deal below) or using engineered natural killer (NK) cells. NK cells have the advantage over T cells that they do not rely on HLA (Human Leukocyte Antigen) compatibility requirements. T cells depend on specific matching of HLA types to ensure proper recognition of target antigens and avoid rejection by the immune system. NK cells are an excellent option to target cancer cells that downregulate HLA to evade T cell detection. Medigene's TCR-guided off-the-shelf applications are promising, although they are at an earlier development stage and there are still considerable hurdles to overcome (see figure 4).

Figure 4: Medigene's three TCR-guided modalities



Source: First Berlin Equity Research, Medigene AG

The TCR-TCE approach In a TCR-TCE approach, bispecific molecules are engineered to link tumour cells and T cells. TCR-TCE combinations have complementary functions as with one arm (the TCR) they bind to a tumour-associated intracellular or extracellular antigen and with a second arm (the antibody) to the CD3 receptor protein on T cells, thereby recruiting and activating T cells by bringing them close to the tumour cells. This interaction activates the T cell, triggering a cascade of intracellular signals that result in T cell proliferation, cytokine release, and the killing of the target tumour cell (see figure 5 overleaf). This dual binding is highly effective in redirecting T cells to attack the cancer, even if the patient's natural immune system has not recognised the tumour as a threat.

Partnership with Chinese CRMO and antibody specialist WuXi Biologics to discover superior cancer candidates using antibody-based TCR-TCEs Medigene recently entered into a three-year strategic partnership with the contract research and manufacturing organisation (CRMO) WuXi Biologics (WuXi). The partnership will leverage Medigene's cutting-edge TCR technology platform with WuXi's outstanding global R&D and manufacturing capabilities. WuXi's WuXiBody™ platform offers high flexibility in designing bispecific antibodies and enables rapid development timelines, cutting development time by 6 to 18 months compared to traditional approaches, while manufacturing costs could be reduced by up to 90%. WuXi's industry-leading T Cell Engager (TCE) platform and its world-class expertise in anti-CD3 monoclonal antibodies are critical for T cell engagement in

immunotherapy strategies and enable the development of novel off-the-shelf TCR-TCE therapies for solid tumours. These sophisticated TCE competences make WuXi a partner of choice for Medigene in the development of innovative TCR-TCE immunotherapies.

Figure 5: Medigene's TCR-TCE approach together with WuXi

Optimal 3S TCR – from Medigene

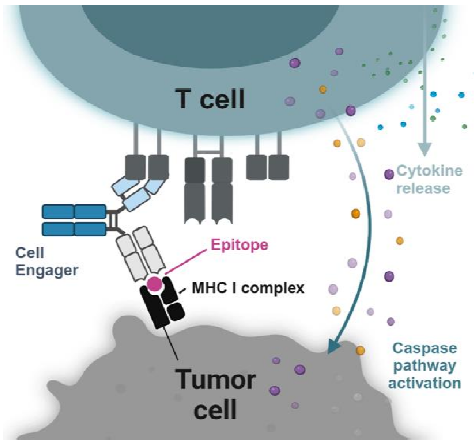
- ✓ **Specificity:** Exclusive recognition of target epitope ; No off-target reactivity
- ✓ **Sensitivity:** High functional avidity (picomolar)
- ✓ **Safety:** No cytotoxicity towards a panel of healthy cells ; No HLA allo-cross-reactivity

WuXiBody™ – from WuXi

- ✓ **Flexibility:** Accommodates various half-life extended bispecific formats, enhancing targeting options and efficacy[1]
- ✓ **Optimised:** Potential best-in-class, humanised, medium affinity CD3-engaging antibody; distinct fast-on, fast-off binding mode ⟶ better efficacy and safety profile
- ✓ **Speed:** Saves 6-18 months of development time vs. 24 to 36 months for Bispecifics

Drug Product Manufacturing – from WuXi

- ✓ **Efficient Process**
  - ✓ Reduces manufacturing costs by as much as 90%
  - ✓ Can be used in both fed-batch and concentrated fed-batch production
  - ✓ High protein expression in CHO cells (5 g/L in fed-batch, 35 g/L in concentrated fed-batch)
- ✓ **Drug Product**
  - ✓ No aggregation issues; No solubility issues > 30 mg/mL
  - ✓ Very stable: >2 weeks in serum at 37 °C



Source: First Berlin Equity Research, Medigene AG

MDG3010 – A PROMISING ASSET

MDG3010, a TCR-TCE therapy targeting KRAS G12V – proof of principle expected by YE25 / H1/26 Medigene's early preclinical TCR-guided antibody programme MDG3010 in collaboration with WuXi will be targeting the well-recognised oncogenic mutation KRAS G12V in patients with the HLA*A11 subtype. This target is particularly relevant in difficult-to-treat cancers such as pancreatic, colorectal, and lung cancers, where KRAS mutations are a major driver of disease progression and poor prognosis. For instance, pancreatic cancer, one of the deadliest cancer types globally, shows KRAS mutations in over 95% of cases. Medigene is guiding that MDG3010 could provide proof of principle by YE25 / H1/26.

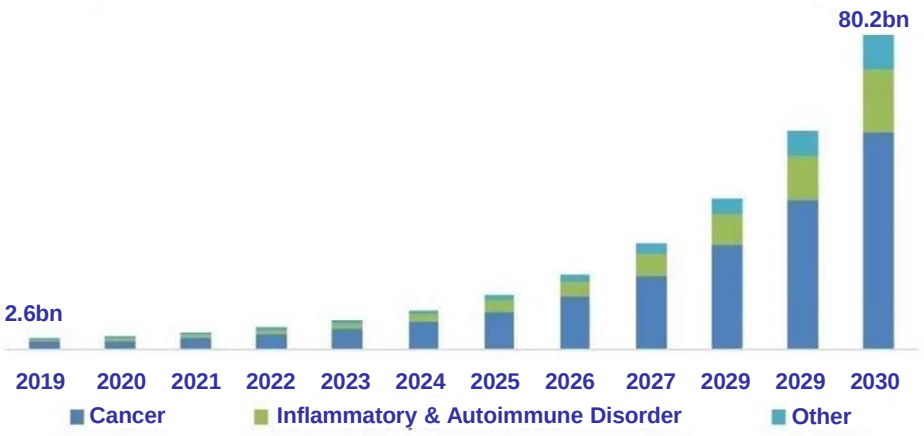
WuXi's optimised anti-CD3 enables T cells to kill without exhaustion – platform clinical readiness and commercial value underlined by four TCEs currently in phase 1 Current TCEs face challenges such as suboptimal CD3 affinity which can either overactivate T cells, causing exhaustion and cytokine release syndrome, or fail to activate them adequately, reducing efficacy. Moreover, existing therapies often lack control over CD3 engagement kinetics and have short half-lives, necessitating frequent dosing. WuXi's anti-CD3 technology introduces a unique epitope with intermediate affinity (exactly as needed), ensuring optimal engagement kinetics for effective T-cell activation without overactivation. It also features fast-on, fast-off binding which enhances the therapeutic window and tumour cell killing while minimising cytokine release and exhaustion, improving safety. Preclinical and clinical trials demonstrate WuXi's CD3 potency, as the platform is being used in several phase 1 trials. WuXi's strategic collaborations, such as (1) the license agreement with respect to a preclinical trispecific TCE with Candid Therapeutics (Candid) for up to USD925m in upfront and performance-based milestone payments and (2) the USD40m upfront agreement with GSK and up to USD1.5bn in success-based milestone payments for up to four programmes, further validate the platform's value.

TCR-TCE bispecific approach validated in 2022 The most significant advance in the treatment of solid tumours with TCR-TCEs comes from Immunocore's allogeneic TCR-TCE therapy Kimmtrak (tebentafusp), which was approved by the FDA in January 2022 for the treatment of unresectable or metastatic uveal melanoma (eye cancer) after showing unprecedented median overall survival (OS) benefit (median OS: 21.7 months) as a first-line treatment against standard of care (SOC median OS. 16 months). Kimmtrak is being successfully adopted and recently reported sales of USD226m at the 9M 2024 stage (+32% growth YoY).

Strong Big Pharma appetite for bispecific TCE therapies – we believe proof-of-principle will be followed by outlicensing of MDG3010 Given the momentum in the TCE space, this programme could become very attractive for Big Pharma once proof-of-principle is achieved. Recent licensing/co-development agreements in the T-cell engager (TCE) space such as (1) Candid with WuXi, (2) GSK with WuXi, (3) Candid with EpimAb Biotherapeutics (license of over USD1bn in upfront and milestone payments for novel TCEs for various autoimmune indications), (4) GSK with Chimagen (payment of up to USD850m for a clinical stage TCE) or (5) Almirall with EpimAb (licensing up to three TCEs for up to USD250m), highlight strong appetite for this promising approach. Further collaborations between Medigene and other partners (e.g. specialists in NK cells) are expected in the next few months.

Bispecific antibodies are a rapidly growing market The bispecific antibodies market is set to experience significant growth from 2019 to 2030. In 2019, the market was valued at approximately USD2.6bn. By 2022, it had grown to around USD5.4bn and is projected to reach USD80.2bn by 2030, equating to a CAGR of 40.9% for the period 2023-2030. This substantial expansion is driven by the increasing prevalence of chronic diseases and particularly cancer, an increase in R&D spending in this area, advancements in antibody engineering technologies, and a growing demand for targeted therapies.

Figure 6: Bispecific antibodies market size by indication (2019 – 2030) in USD



Source: First Berlin Equity Research, Medigene AG & KBV Research

MDG 1015 – IN SEARCH OF A FINANCING PARTNER FOR THE LEAD DRUG CANDIDATE

THE TCR-T THERAPY APPROACH WAS RECENTLY VALIDATED

Tecelra®'s approval validated the TCRT-approach The approval of Adaptimmune's TCR-T therapy Tecelra® (afami-cel) was a major milestone that validated the TCR-T therapy space. Tecelra®, which targets MAGE-A4 (an antigen overexpressed in many solid tumours and the same target as Medigene's programme in partnership with Regeneron), showed clinical benefits in solid tumours that have historically been challenging for immunotherapies such as chimeric antigen receptor CAR-T cell therapies. Solid cancers are more heterogeneous and have a complex microenvironment, making it difficult for therapies to target them effectively. The efficacy seen in trials with Tecelra® provided evidence that TCR-T therapies could overcome these challenges. Unlike CAR-T cell therapies that target surface proteins (e.g. CD19 in blood cancers), TCR-T therapies can target a broader range of antigens, including proteins on the inside of a cancer cell. The success of Tecelra® validated this approach, proving that TCR-T therapies could potentially target a wide variety of tumour types, expanding the therapeutic possibilities beyond haematological cancers. Moreover, regulatory approval of Tecelra® by the FDA not only provided clinical proof-of-concept but also set a benchmark for safety, efficacy, and manufacturing processes for future TCR-T therapies, helping to de-risk the pathway for other companies such as Medigene developing similar treatments.

Tecelra® was granted priority review and accelerated approval by the FDA for patients with advanced synovial sarcoma (SS) The FDA approval of Tecelra® is based on the results of the open-label phase 2 SPEARHEAD-1 clinical trial involving 44 HLA-A*02–positive, metastatic patients with unresectable SS. Tecelra® achieved an overall response rate (ORR) in SS patients of 39% (n=17/44), with all responses consisting of partial responses (PRs), and the median duration of response (DOR) was 11.6 months (95% CI, 4.4-18.0). Tecelra®'s label carries a black box warning for cytokine release syndrome (CRS). Adaptimmune set a list price of USD727k for Tecelra®**.**

While Tecelra®'s results were promising and led to its FDA approval, shortcomings show room for improvement in the therapy's performance Tecelra® showed a meaningful impact in patients with limited options. However, the therapy faced shortcomings in terms of a still modest ORR, limited duration of response in some patients, and the occurrence of side effects such as CRS and haematological toxicities. This performance suggests areas where further improvement could enhance the efficacy and safety of this first generation (1G) therapy.

Medigene's 3G TCR-T therapy addresses efficacy, safety and duration limitations present in 1G therapies To overcome 1G TCRs' moderate affinity, Medigene's 3G TCR-T approach generates a drug product (DP) containing TCRs from young healthy donors with optimal affinity which allows for improved tumour recognition and safety. Medigene's armouring with the costimulatory switch protein PD1-41BB reduces T cell exhaustion and promotes their better proliferation and efficacy. In addition, Medigene's DP involves a shorter production process using younger T cells with a pure CD8+ population and fewer expansion cycles, leading to a higher quality, very potent drug composition with a high fraction of stem cell memory (T_{SCM}) and central memory T cells (T_{CM}) of ~85%+ that can be administered at lower doses. In a T cell therapy, high T cell T_{SCM} + T_{CM} content indicates a product with enhanced proliferative potential, versatility, and longevity. T_{SCM} have stem cell-like properties and are highly valuable because of their longevity, resistance to exhaustion, and ability to maintain a robust and sustained immune response, and T_{CM} can help to generate a potent immune attack while maintaining a capacity for repeated activation. This cell therapy can elicit a sustained immune response against the tumour, increasing the chances of achieving long-term disease control (see table 3 overleaf).

Table 3: Medigene's 3G TCR-T approach addresses shortcomings of recently approved 1G therapy

	Current FDA Approved 1st Generation TCR-T Therapy	Medigene's 3rd Generation TCR-T Therapies e.g., MDG1015 / MDG2011	Potential benefits of Medigene's Approach
TCR Target Interaction	➢ Transgenic TCR ➢ **Mutation** of natural TCR to enhance affinity ➢ Cross reactive to HLA- A*02:05 (contraindicated)	➢ Transgenic 3S TCR; young healthy donors, broad TCR repertoires ➢ Optimal affinity TCR with **no mutation** to enhance affinity	Improved efficacy & safety
Armor and Enhance against TME Immunosuppression	➢ **No armouring or enhancement applied** ➢ TME may limit T cell penetration, persistence and proliferation	➢ **PD1-41BB Co-Stimulatory Switch Protein (CSP)** mitigates TME immunosuppression, with improved T cell persistence and proliferation	Improved efficacy & durability
Drug Product (DP) Composition, Manufacturing and Administration	➢ 14-day production process, multiple expansion cycles yield older cells; drug product (DP) with many cells required (**2.68 x 10^9**) ➢ **Long** vein-to-vein time of **~ 42 days** ➢ **Mixed CD4+ / CD8+** populations give sub-optimal DP composition ➢ Low T_{SCM} / T_{CM} fraction **(~18%)** 1; CD4+ in DP may upregulate Treg in vivo and reduce efficacy and safety	➢ 6-day production process, fewer expansion rounds yield younger, fitter cells; DP with expectation of fewer cells required (**10^6 - 10^7**) ➢ **Short** vein-to-vein time of **~ 20 days** ➢ **Virtually pure CD8+** population for cell composition ➢ Very high T cell T_{SCM} / T_{CM} fraction **(~85%+)** with stemness & cell durability; **Low CD4+ (<5%)** in DP limits risk in vivo	Improved efficacy, safety & durability

Source: First Berlin Equity Research, Medigene AG

MDG1015 – AN ARMOURED & ENHANCED IMMUNOTHERAPY

Drug profile – a highly innovative immunotherapy targeting two well validated antigens Medigene's lead late-preclinical drug candidate MDG1015, is a first-in-class, third generation (3G) autologous T cell receptor (TCR)-based immunotherapy designed to target the two well validated cancer antigens NY-ESO-1/LAGE-1a, armoured with the PD1-41BB switch receptor technology. The TCR used in MDG1015 have been meticulously selected and engineered to recognise the specific peptide-HLA-A*02 alleles presented on the surface of tumour cells with a high degree of specificity. Medigene employed its cutting-edge screening and optimisation technology to ensure that these TCRs have a high affinity for their targets while maintaining specificity, thereby minimising the risk of off-target effects that could harm healthy tissues. MDG1015's dual-antigen targeting approach (NY-ESO-1 and LAGE-1a) reduces the likelihood of tumour escape by ensuring that even if one antigen is downregulated or mutated (typical tumour strategy to escape the immune system), the T cells can still recognise and target the tumour via the other antigen. This approach enhances the robustness of the therapy and could lead to better long-term outcomes. In addition, NY-ESO-1 and LAGE-1a belong to a group of well-validated tumour-specific antigens typically expressed in various solid tumours, including melanoma, ovarian cancer, and sarcomas but not in normal tissues which makes them attractive targets for TCR-based immunotherapy (sources: Eleftheriadou et al., 2019; Odunsi, K., et al., 2003; D'Angelo, S.P., et al., 2018; Chen, Y.T., et al., 1997; Jungbluth, A.A., et al., 2001)

The tumour microenvironment (TME) in solid tumours Solid tumours usually create a cellular environment around them that is favourable to tumour growth, the so-called tumour microenvironment (TME). This includes the surrounding blood vessels, immune cells, fibroblasts, signalling molecules, such as cytokines and chemokines, and the extracellular matrix. Substantial evidence indicates that the TME plays a critical role in all aspects of cancer biology, including the tumour's ability to escape from being eliminated by the immune system through several mechanisms such as physical blockade of immune cell infiltration, dysregulation of cytokines, perturbation of immune checkpoints (e.g. PD-1 which can downregulate immune response) and recruitment of inhibitory cell populations, ultimately creating a permissive environment for tumour growth (source: Schaaf et al., 2018: Peng et al., 2018 and 2020).

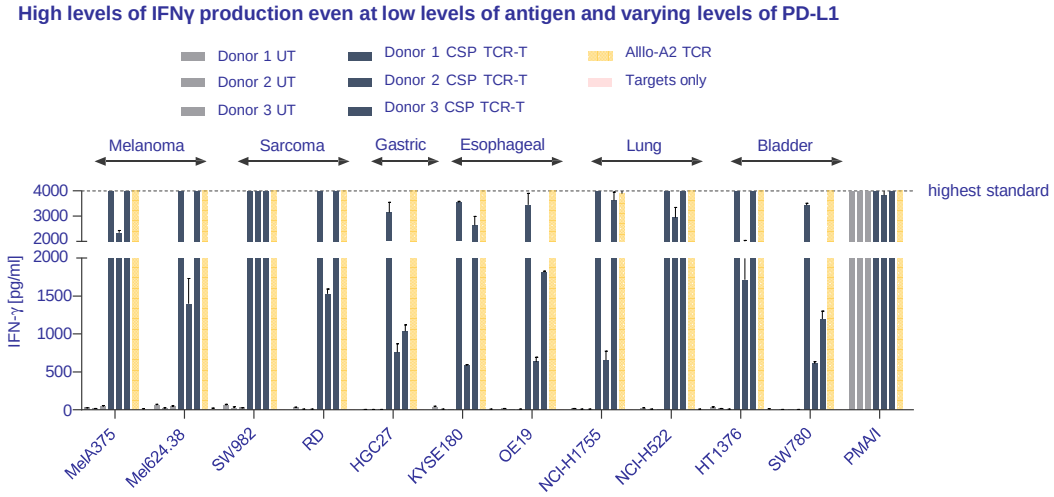
PD1-41BB costimulatory switch protein (CSP) to enhance T-cell activation, persistence and functionality The incorporation of the PD1-41BB CSP in MDG1015 is a significant technological advancement. This feature is specifically designed to counteract T-cell exhaustion by turning inhibitory signals (from PD-1 interactions) into stimulatory ones (through 41BB activation), thereby maintaining T-cell activity and persistence in the immunosuppressive TME. This could potentially result in a longer-lasting and more effective immune anti-tumour response, reducing the risk of relapse. We note that PD-1 inhibiting drugs have been successfully used in various cancer types. However, resistance or non-response to this therapy, as well as various significant side effects including autoimmune reactions when given systemically, represent major obstacles. While therapies combining other cancer agents with PD-1/PD-L1 checkpoint inhibitors such as Keytruda, Opdivo and Libtayo could be a treatment option, this strategy has the potential to increase the above-mentioned side effects and the overall cost of therapy. We therefore see Medigene's cell therapy with the PD1-41BB CSP, which acts locally on the tumour, as the most efficient approach.

Improved drug product (DP) DP composition Medigene's innovative approach not only enhances TCR-T cell functionality by combining 3S TCRs with the PD1-41BB costimulatory switch protein but also places a significant emphasis on the DP manufacturing process. This process is vital for producing effective, safe, and durable TCR-T therapies. With a focus on the DP composition, the company aims to reduce the time required to manufacture DP ex-vivo and hence reduce the overall vein-to-vein timeframe for patients, while maintaining the highest standards of safety, efficacy and durability. The company has developed a streamlined 6-day manufacturing process that focuses on the enrichment of CD8+ T cells whilst simultaneously maintaining a high degree of stemness. This allows for the creation of highly effective DPs, as the field has shown that more stem-like DPs exhibit greater potency and durability of response. The inclusion of the PD1-41BB CSP eliminates the need for CD4+ T cells within the DP, as CD8+ T cells are empowered to autonomously produce supporting cytokines. By doing so, the potential risks posed by CD4+ T cells can be circumvented and therefore potentially enhance both clinical safety and therapeutic efficacy.

PRECLINICAL IN-VITRO DATA

In vitro studies demonstrate high affinity and specificity of MDG1015 to a wide range of solid tumours In TCR therapy, the production of IFN-γ is a key indicator of T cell activation. IFN-γ is a cytokine critical for immune response, promoting inflammation and enhancing the anti-tumour activities of other immune cells. High levels, such as those exceeding 3,000 pg/ml (4,000 pg/ml represents the highest standard), indicate that the T cells are strongly engaged with the target cells, suggesting effective recognition and subsequent activation. According to an in-vitro study (source: Crame Presentation at CHI 2024), the results, which are summarised in figure 7 overleaf, MDG1015 (CSP TCR-T – bars in blue) targeting the antigens NY-ESO-1/LAGE-1a was tested against a range of solid tumour samples from different donors which included melanoma, sarcoma, gastric, oesophageal, lung and bladder cancer, compared to untreated samples (UT – grey bars). MDG1015 TCRs triggered consistently high IFN-γ levels (often reaching or exceeding 3,000 pg/ml) in multiple tumour samples, indicating a strong and broad recognition of solid tumours, which is promising for the potential use of this TCR therapy in cancer treatment. It is noteworthy that IFN-γ production was high in some of the samples even at low antigen concentrations (even zero in some tumour types), as shown in the table at the bottom of figure 7.

Figure 7: MDG1015 specific & sensitive recognition of multiple tumour cell lines



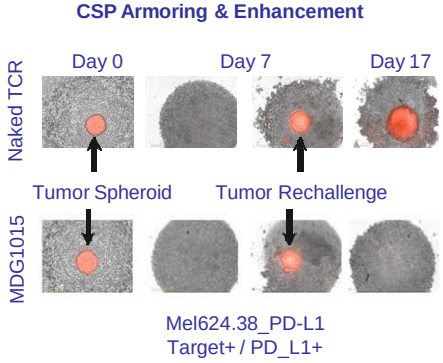
Expression	MelA375	Mel624.38	SW982	RD	HGC27	KYSE 180	OE19	NCI-H1755	NCI-H5222	HT1376	SW780
NY-ESO-1 mRNA [1]	101.72	2.75	15.7	16.67	82.61	0.02	0.00	121.11	0.00	15.72	0.06
LAGE-1a mRNA [1]	0.04	56.95	0.00	24.41	46.50	16.23	28.30	56.12	36.77	39.85	1.72
Cell surface PD-L1 [2]	616	456	4587	2585	965	1075	1022	4037	3148	226	6453

1. Copies x 10^3/25 ng RNA, 2. Δ MFI, PD-L1 was overexpressed in all cell lines except HT1367 that naturally expresses PD-L1

Source: First Berlin Equity Research, Medigene AG

MDG1015 armoured with PD1-41BB CSP switch clearly outperforms naked TCR,...
Based on in-vitro test results presented by Crame at the Innovations for Cell and Gene Therapies (ICGT) Congress in May 2024, MDG1015 demonstrated superior performance over the naked TCR in terms of rapid and sustained tumour cell killing, even after multiple exposures to the tumour, making it a promising therapeutic strategy. The test was conducted in tumour spheroids (three-dimensional clusters of cancer cells used in laboratory research) targeting the human melanoma Mel624.38 tumour cell line expressing PD-L1. The test compared the performance of the "naked TCRs" (no armouring) with that of the armoured TCR T cells (MDG1015) in terms of their ability to kill tumour cells over time and upon re-challenge. The tumour was not able to regrow in the MDG1015 cell line despite tumour rechallenge (TCR exposure to a new set of tumour cells), as opposed to the naked one (see figure 8 below). Interestingly, control testing in additional tumour cell lines showed that MDG1015 had a comparable performance to naked TCRs in PD-L1 negative cells (Non-small cell lung cancer cell line), as well as in NY-ESO negative cells (bladder cancer cell line). The PD1-41BB CSP switch is safe as it is only activated when the T cell's TCR successfully binds to the intended target antigen on the tumour cell.

Figure 8: MDG1015 armoured capabilities demonstrated through rapid & sustained tumour cell killing upon serial rechallenge

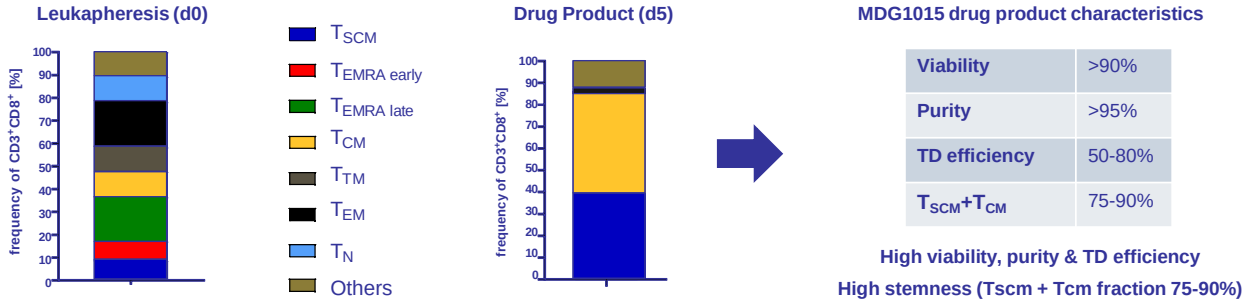


Source: First Berlin Equity Research, Medigene AG

…showing a 3-fold increase of Interferon-gamma (IFN-γ) release and 5-fold increase in polyfunctional T cells which reflects the stronger anti-tumour response The modified cells showed a 3-fold increase in IFN-γ cytokine release, indicating a stronger immune response, and a 1.5-fold increase in proliferation after encountering the NY-ESO-1 antigen, which is important for sustaining the immune response over time. When exposed repeatedly to antigens in a tumour-like environment, these TCR-T cells with PD1-41BB exhibited better functional performance. Single-cell secretome analysis further revealed a 5-fold increase in polyfunctional T cells, with a 6-to-8-fold higher polyfunctional strength index which measures how robust and versatile these T cells are, compared to the unmodified TCR-T cells. These findings highlight that the co-expression of PD1-41BB boosts both the efficacy and versatility of the engineered TCR-T cells, making them more resilient and effective in targeting tumour cells.

High quality drug product with high stemness reflected in a ~80% T_{SCM} + T_{CM} Following leukapheresis, a medical procedure used to separate white blood cells – leukocytes – from the blood, Medigene's fast 6-day manufacturing process achieves a desired drug composition with high purity of >95% and high stemness with T_{SCM} + T_{CM} proportion of 75%-90%, which suggests a robust and long-lasting therapeutic response. As explained on page 14, Medigene's 3G TCR-T programmes, including MDG1015, have superior properties compared to 1G products, which include T_{SCM} + T_{CM} content. T_{SCM} and T_{CM} are two subsets of memory T-cells that lead to superior proliferative capacity and persistence, which are crucial for effective cancer immunotherapy. Therefore, a high degree of stemness in drug products usually leads to more potent cell therapies.

Figure 9: MDG1015 manufacturing yields an optimal, tailored drug product



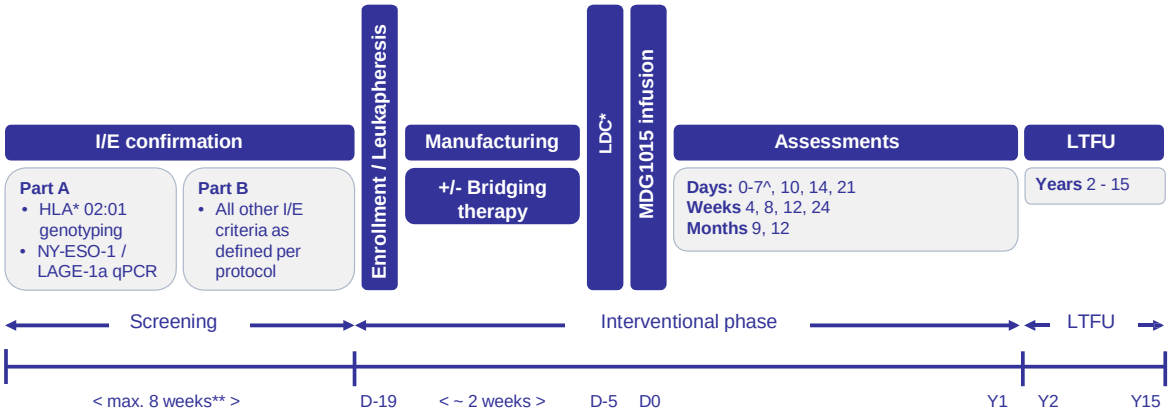
Source: First Berlin Equity Research, Medigene AG

PLANNED PHASE 1 CLINICAL STUDY

EPITOME-1015-I dose-escalating phase 1 trial Medigene intends to conduct an open-label dose-escalating phase 1 safety study of MDG1015 in the four selected advanced solid tumours: GAC, OC, MRCLS and SS. The clinical trial is designed to assess the safety, feasibility, and preliminary efficacy of the therapy in patients with the selected advanced solid tumours. The trial is structured into two key phases: a dose escalation phase followed by an expansion phase. In the dose escalation phase, the investigators will aim to determine the maximum tolerated dose (MTD) and observe dose-limiting toxicities (DLTs). This phase is crucial for finding a safe and effective dose level. The phase 1 trial will include a total of ~50 patients. Phase 1a will see 1-2 patients treated for each indication, ~10-12 patients in total. Once the optimal dose is established, the expansion phase will enrol ~30-40 patients, to further evaluate the efficacy of the treatment at this dose. Both phases will monitor the therapy's safety profile, and will also assess its anti-tumour activity, including objective response rates (ORR), progression-free survival (PFS), and overall survival (OS).

The patients are screened to determine whether they meet the inclusion criteria, i.e. essentially the HLA*02:01 type and tumour expression of the NY-ESO-1/LAGE-1a antigens. Following leukapheresis and production of the autologous product, patients will receive lymphodepleting chemotherapy (LDC), a preparatory treatment that temporarily reduces the number of lymphocytes in the patient's body and creates a more favourable environment for the infused immune cells (TCR-T cells) to expand and work more effectively. We anticipate that recruitment will take approximately 3 months and key assessments will take place at 9 and 12 months (see figure 10 below).

Figure 10: Overview of the planned phase 1 trial



Source: First Berlin Equity Research, Medigene AG

MDG1015 has received FDA IND approval, but a potential phase 1 trial will be postponed until the company finds a licensing partner to fund it The TCR-T candidate has received IND clearance from the FDA in September 2024. European submission to the EMA took place in December 2024, while the international dose-escalation phase 1 clinical trial has been postponed until the company has secured the necessary funding from a strategic partner (licence agreement). Given the programme's attractive profile, we expect that Medigene will be able to find a partner in the next 6-9 months, allowing the trial to start in H2/25. Given that the company expects that it will take about 12-15 months after initiation of the study to publish headline results including 9-month data, we assume that this data could be available in 2026.

IMMUNO-THERAPY IN SOLID TUMOURS – MEDICAL NEED AND MARKET

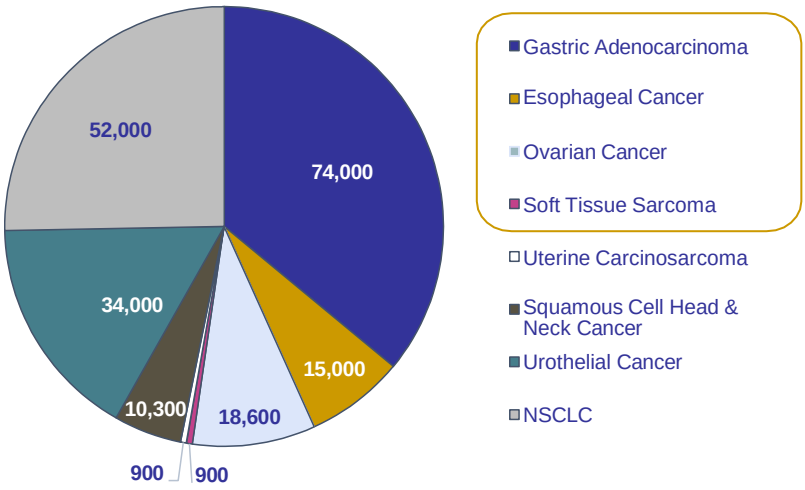
High unmet medical need in advanced solid tumours Cancer is a leading cause of death and generates among the highest costs to healthcare systems around the globe. Due to low specificity, traditional chemotherapy usually applied to treat cancer also kills healthy cells, is poorly tolerated and has therapeutic and safety limitations. Tumour resistance is a further obstacle to effective treatment. Current research is therefore focusing on treatment approaches that limit damage to healthy cells and more specifically target cancerous cells such as growth factor inhibitors, anti-angiogenesis factors and immune therapy. However, the unmet medical need in solid tumours remains very high. When the cancer is not detected before it spreads outside of the location in which it arises, this greatly increases the risk for patients that treatment will not be successful. The five-year survival statistics for advanced solid cancers can be as low as 1-10% for many solid tumours (e.g. lung, brain, colorectal or pancreatic cancer), highlighting a clear need for better treatments for these patient groups.

Solid tumour market to grow at a CAGR of 7.45% until 2034 The solid tumour market was valued at USD170.3bn in 2023 and the market is expected to hit USD375.4bn by 2034, rising at a CAGR of 7.45% during the forecasting period. The market is driven by advancements in targeted therapies, immunotherapies such as checkpoint inhibitors, CAR-T therapies, combinations with other cancer therapies as well as personalised medicine (source: Biospace).

TARGETED TUMOUR TYPES

Cancer selection Medigene selected the tumour types to be studied in the planned MDG1015 clinical trials based on the expression of the NY-ESO-1/LAGE-1a antigen and the immunosuppressive PD-L1 protein as well as the unmet medical need associated with these cancer types. The universe of solid tumours that express the NY-ESO-1/LAGE-1a antigen and the PD-L1 protein and thus represent a potential strategic focus for therapy development is shown in figure 11 overleaf. Medigene selected the following four indications: 1) gastric cancer, 2) ovarian cancer and two subtypes of soft tissue sarcoma, 3) myxoid/round cell liposarcoma and 4) synovial sarcoma; they are present in 34-60%, 35-55% and 75-80% of expressing NY-ESO-1/LAGE-1a cases, respectively. Medigene estimates that over 100k patients in the world's top eight economies could be eligible for treatment with MDG1015 based on yearly incidence, target expression and HLA-A*02 positivity. These cancers are also marked by a clear need for new treatment modalities, with estimated five-year survivals for the four selected cancer types as low as 5%-31%.

Figure 11: Global patient population expressing NY-ESO-1/LAGE-1a and HLA-A*02



Global patient population of **~200,000 annually**

Source: First Berlin Equity Research, Medigene AG

Gastric cancer (GC), also known as stomach cancer, is the fifth most common cancer worldwide. It is estimated that ~90% of all gastric cancers are gastric adenocarcinomas (GACs). Overall, ~60% of people with GAC are not eligible for curative treatment owing to late presentation or comorbidities. GC often goes undetected in its early stages because symptoms can be vague, leading to a late diagnosis when the disease has advanced. This contributes to its high mortality rate, making it the third leading cause of cancer-related deaths globally. The 5-year survival rate for advanced GC remains low, often less than 30%, and in US patients diagnosed with metastases, this figure is as low as 6.6% (Lordick et al., 2022; American Cancer Society – Cancer Statistics Center, SEER database, 2024).

Ovarian cancer (OC) is the eighth most common cancer in women, and in 55% of US patients distant metastases are present at the time of diagnosis. Its mortality rate is high, largely because it is often diagnosed at an advanced stage. Symptoms are typically

nonspecific, such as abdominal discomfort, bloating, and changes in bowel habits, which leads to delayed detection. The overall 5-year survival rate for OC varies, ranging from 90% for localised cases to ~30% for those with metastasis. A key characteristic of OC is its frequent recurrence after initial treatment, making it challenging to manage. Despite advances in surgery and chemotherapy, the disease often develops resistance to treatment, necessitating new therapeutic strategies (American Cancer Society – Cancer Statistics Center, SEER database, 2024).

Myxoid/round cell liposarcoma (MRCLS) is a rare subtype of soft tissue sarcoma originating from the fat cells and typically affects younger patients between 30–50 years of age. MRCLS usually grows in the arms and legs. These tumours grow slowly, and they can spread to other parts of the body. Treatment typically involves surgery, sometimes combined with radiation therapy and chemotherapy, but the high recurrence rate, even after aggressive treatment, poses a significant challenge. This disease occurs in up to ~1,350 patients in the US, making it an orphan indication. In patients with advanced disease, the disease-specific 5-year survival rate is ~8% (Hoffman et al., 2013).

Synovial sarcoma (SS) is another rare soft tissue sarcoma, primarily affecting younger adults, with ~1,300 new cases diagnosed annually in the US, making it an orphan indication. It often develops near joints, such as the knee, and tendons, and is known for its aggressive nature. Synovial sarcoma is marked by its potential to spread to the lungs and other organs. Treatment typically involves surgery, radiation, and sometimes chemotherapy, but the overall prognosis remains guarded. For patients with advanced stage disease, the median overall survival at or after second line therapy is under a year and the 5-year overall survival is ~10% (Carroll C et al., 2022).

FINANCIAL HISTORY AND OUTLOOK

Financial statement in accordance with IFRS Medigene has published its audited 2023 annual report and its unaudited 9M 2024 results in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union (EU).

Revenue 2021-2023 Medigene's financial statement is typical of an early-stage R&D biotech company. The company generates initial revenues from upfront, milestone and R&D payments from TCR-T cell programmes developed in collaboration with its strategic partners. The group's sales performance over the last three years has therefore shown significant fluctuations depending on progress of its partnered R&D programmes. In 2022, the company's revenues peaked at €31.3m, a substantial 200% increase from €10.5m in 2021. This sharp rise was largely due to a major upfront payment from the partnership concluded with BioNTech (€25.1m) and milestone payments from 2seventy bio (€5.2m). In 2023 revenue dropped to €6m.

OPEX 2021-2023 R&D expenses were unusually high in 2022, chiefly due to a one-off impairment of €20.4m (2021: €1.5m) for the drug candidate RhuDex®, which had been out-licensed to Dr Falk Pharma GmbH since 2014 and failed to show efficacy in a clinical trial. The higher R&D expenses seen in 2023 chiefly reflect the increase of R&D employees and salaries adjustments to progress the R&D pipeline. G&A expenses show a growing trend in 2021-2023 mainly due to higher personnel and consulting expenses. In accordance with the stage of the firm, it is loss-making. See the main KPIs on ´table 3 below.

P&L KPI outlook 2024 In December 2024, Medigene lowered its financial guidance for 2024 to projected revenues between €7m and €9m (FBe: €8m; 9M/24: €5.9m) from previously between €9m and €11m, as a milestone payment of €2m planned for 2024 is no longer expected before the end of 2024. In 2024, revenue was driven by the ongoing BioNTech partnership. R&D expenses are expected to range from €11.5m to €13.5m (FBe: €13.2m; 9M/24: €8.9m), which reflects increased investment in advancing key programmes, particularly MDG1015, towards clinical trials.

Our 2024 projections are the baseline for our projections going forward. In 2025, we have taken into account the intended financing of programme development by partners (recognised as revenue) and the cost reduction measures of ~40% decided by management. We see 2025 and 2026 as transition years in which Medigene will enter into licensing partnerships to advance the proprietary preclinical programmes that could enter clinical trials in the coming years. We therefore expect revenues from partnerships and OPEX to increase in 2026 (see table 4 below).

Table 4: Income statement 2021-2026E (KPIs)

in EUR'000	2021	2022	2023	2024E	2025E	2026E
Revenue	10,463	31,247	6,034	8,000	10,000	35,000
Research & Development Expenses	-12,797	-28,499	-11,545	-13,200	-9,000	-16,000
General & Administrative Expenses	-6,150	-7,692	-9,316	-8,300	-5,100	-7,000
Seling Expenses	-667	-2,193	-20	0	0	0
Other Operating Income	526	393	341	12	15	20
TOTAL OPEX	-19,088	-37,991	-20,540	-21,488	-14,085	-22,980
EBIT	**-9,985**	**-8,727**	**-16,149**	**-14,928**	**-6,485**	**2,920**
Net financial result	-298	-647	-443	-560	-540	-540
Other financial income/expenses	62	0	0	0	0	0
Net income	**-9,983**	**-8,330**	**-16,177**	**-14,988**	**-6,525**	**2,880**
Expenses as % of OPEX						
Research & Development Expenses	*67%*	*75%*	*56%*	*61%*	*64%*	*70%*
General & Administrative Expenses	32%	20%	45%	39%	36%	30%

Source: First Berlin Equity Research, Medigene AG

Balance sheet, stock 2:1 reverse split and financing measures Medigene's cash & cash equivalents (including time deposits) declined to €16.7m at YE 2023 (2022: €33.2m), due to funding of ongoing operations. Based on the company's planned burn rate, management expect that the cash runway will reach until July 2025. This guidance included the gross proceeds of €5.9m from the oversubscribed capital increase completed in May 2024 through the placement of 4.9m shares at €1.20 p/s, which resulted in cash & cash equivalents of €9.5m at the end of September 2024. In October 2024 Medigene secured a financing option through a Standby Equity Purchase Agreement (SEPA) with Yorkville Advisors Global. The agreement allows Medigene to issue new shares to Yorkville for up to €15m, over a period of 36 months, without requiring existing shareholders' approval. Medigene can issue up to 400k shares in each tranche, with Yorkville purchasing these shares at 95% of their average trading price. This financing measure can only be utilised if the company obtains further funding via a capital increase from other investors, which has proven to be difficult. Management has therefore decided to pursue non-dilutive partnership financing in the future. We have not included any further capital increase in our financial forecasts. In addition, Medigene reduced its share capital through a 2:1 reverse split, decreasing the number of shares from about 29.5m to 14.7m in August 2024. This move was designed to raise the share price on the stock market well above the €1 p/s level.

Table 5: Balance sheet 2021-2026E (KPIs)

in EUR'000	2021	2022	2023	2024E	2025E	2026E
Cash and cash equivalents	22,417	22,224	8,674	2,486	2,729	2,157
Short-term investments	0	11,000	8,000	6,000	0	4,000
Accounts receivables	1,039	3,240	416	500	550	600
Other current assets	708	788	1,047	1,110	1,176	1,247
Current Assets, Total	**24,164**	**37,252**	**18,137**	**10,096**	**4,456**	**8,004**
Property plant and equipment	4,904	4,392	3,438	2,143	1,293	793
Intangible assets	30,115	9,747	9,853	9,917	9,981	10,045
Goodwill	287	287	287	288	288	288
Non-Current Assets, Total	**35,306**	**14,426**	**13,579**	**12,348**	**11,562**	**11,126**
Accounts payable	498	634	340	323	297	300
Provisions & other liabilities (ST)	1,980	2,821	2,087	2,191	2,301	2,416
Other current liabilities	5,555	3,960	4,752	4,942	5,140	5,345
Lease liabilities (LT)	2,965	2,746	2,036	1,629	1,303	1,173
Provision, contract & other liabilities (LT)	3,656	4,490	1,434	1,434	1,434	1,434
Total Liabilities	**14,654**	**14,651**	**10,650**	**10,519**	**10,475**	**10,668**
Equity	44,816	37,027	21,066	11,925	5,543	8,462
Equity ratio	75%	72%	66%	53%	35%	44%

Source: First Berlin Equity Research, Medigene AG

Cash flow statement We expect that increased partnered-financed pipeline development, will lead to a positive operating cash flow by 2026. For 2024, we forecast a negative operating cash flow of €-13.3m, which will decline to €-5.1m in 2025 and rise to €4.0m in 2026. We expect Medigene to continue outsourcing the clinical development of its lead programmes to Clinical Research Organisations (CROs) and therefore see minimal CAPEX investment in the forecasting period. We provide an overview of our cash flow projections in table 6 below.

Table 6: Cash flow statement 2021-2026E (KPIs)

in EUR'000	2021	2022	2023	2024E	2025E	2026E
Operating cash flow	-10,754	11,976	-15,119	-13,267	-5,144	3,999
Cash flow from investing	4,026	-12,005	2,384	1,840	5,770	-4,380
Cash flow from financing	-1,033	-282	-776	5,239	-383	-191
Impact of exchange rates on cash	144	118	-39	0	0	0
Net cash flow	-7,617	-193	-13,550	-6,188	243	-572

Source: First Berlin Equity Research, Medigene AG

NEWSFLOW

In our view, Medigene's stock price will be driven by news about its pipeline as well as by the achievement of financial milestones. We expect the company to make a number of announcements during the coming 12-18 months which will act as catalysts for the stock. These include:

Pipeline

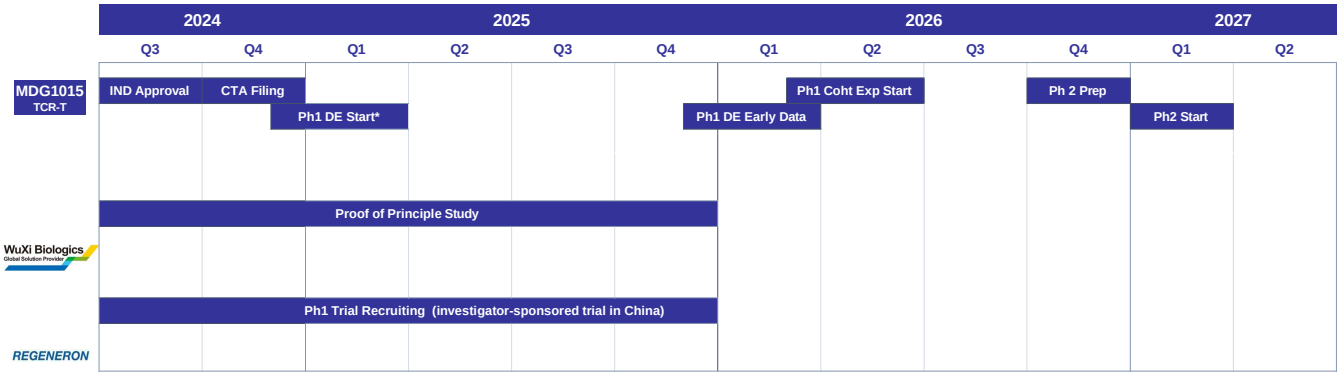
- Approval of the European clinical trial of lead drug candidate MDG1015 is expected in H1/25;
- We expect a partnership for MDG1015 in H1 2025, the international phase 1 study could start later in 2025;
- The proof-of-principle preclinical study of the TCR-TCE programme MDG3010 in cooperation with WuXi Biologics is expected to be completed by YE 2025;
- The ongoing phase 1 study of the TCR-programme targeting MAGE A4 in collaboration with Regeneron is expected to be completed by YE 2025 / H1 2026.

Financial results

The company publishes financial results and a business update on a quarterly basis. We expect the publication of financial results, including detailed updates on the business development and the R&D pipeline, as follows:

- FY 2024 results including business update is due in March 2025;
- Q1 2025 results including business update is due in May 2025;
- Q2 2025 results including business update is due in August 2025;
- Q3 2025 results including business update is due in October 2025.

Figure 12: Key pipeline catalysts anticipated through Q2 2027



**MDG1015: Clinical trial start delayed - seek partnerships & and additional financing options*

Source: First Berlin Equity Research, Medigene AG

MANAGEMENT

MANAGEMENT BOARD

Dr Selwyn Ho, Chief Executive Officer (CEO)

Dr Ho joined Medigene as CEO in July 2022, bringing with him over 25 years of international experience across Europe, US and Asia in executive and senior management positions in both privately held and publicly traded biotech and pharma companies with a focus on inflammation and immunology, with various responsibilities in the areas of Product Development, Medical Affairs, Strategic Marketing and Market Access, Business Development and Licensing as well as Corporate Strategy and Financing. He also serves as an Executive-In-Residence at New Rhein Healthcare Investors, a venture capital and growth stage fund focused on healthcare therapeutics and medical devices and is a Non-Executive Director for Immodulon Therapeutics Ltd., a clinical stage company developing novel therapies for cancer based on bacterial derived immunomodulators. Prior to Medigene, he worked for Connect Biopharma (NASDAQ: CNTB) where he held the position of Chief Business Officer and, amongst other responsibilities, jointly led the execution of the company initial public offering (IPO) which closed in March 2021. Before that, Dr Ho served in multiple leadership roles across several prominent biopharmaceutical companies including UCB and Allergan and the big pharma companies Novartis and Astra Zeneca.

Dr Ho received his medical degree (MB BS) and Bachelor of Science (BSc) in Pharmacology from Imperial College, University of London, UK, and post-graduate qualifications (Dip Pharm Med) in Pharmaceutical Medicine from the Faculty of Pharmaceutical Physicians, Royal College of Physicians, UK.

Prof Dolores J. Schendel, Chief Scientific Officer (CSO)

Prof Dolores J. Schendel has been the CSO of Medigene since April 2014 and in this role she has been instrumental in building the company's TCR technology platform. Prof Schendel is a recognised leader with over 35 years of experience in the field of immunology and cancer immunotherapy and has a remarkable academic background. She is a recipient of the German federal Order of Merit and the Bavarian Order of Merit and received the "Deutsche Krebshilfe Preis", the award of the German Cancer Aid. Her scientific leadership as CSO drives the innovative approach behind Medigene's T cell-based therapies, ensuring they are rooted in cutting-edge immunological research. From 2016 to 2020, she was also CEO of Medigene until Dr Ho took over this position. During her tenure as CEO, she led the company through a strategic transformation, focusing Medigene's resources on its core competencies in T cell immunotherapy. Prof Schendel's journey with Medigene began in 2014 when Medigene acquired Trianta Immunotherapies GmbH, a spin-off of her research group, which she co-founded in 2013.

Before moving to industry, Prof Schendel served as Director of the Institute of Molecular Immunology at the Helmholtz Zentrum München (German Research Centre for Environmental Health), where she conducted pioneering research on adoptive T cell therapy from 1998 to 2013. During this time, she became a leading figure in the immunology community. She is the author of more than 200 scientific publications and has contributed to the understanding of immune responses to cancer. Before that she had a distinguished academic career as a Professor of Immunology at the Ludwig Maximilian University (LMU) in Munich. Her work focused on understanding how T cells recognise and attack cancer cells. Prof Schendel began her academic journey in the United States, where she earned her PhD in Genetics from the University of Wisconsin-Madison. She conducted postdoctoral research at the German Cancer Research Centre (DKFZ) in Heidelberg, Germany, focusing on tumour immunology, which set the stage for her lifelong commitment to cancer research.

SUPERVISORY BOARD

Dr Gerd Zettlmeissl, Chairman and Board member

He is the former CEO of the Austrian-based biotechnology company Valneva SE (formerly Intercell AG) and is an accomplished vaccine expert and biopharmaceutical business executive. Dr Zettlmeissl has more than 30 years of scientific and leadership experience in the biopharmaceutical industry. Since early 2015, he serves as representative of the Supervisory Boards of several NGOs and biotech companies such as Themise Bioscience (Austria), GlycoVaxyn (Switzerland). He is the former CEO of the Austrian-based biotech company Intercell (now Valneva). While at Intercell AG from 2001 to 2011, he built the company from a private start-up venture to a publicly listed international organisation with more than 400 employees. Prior to joining Intercell, Dr. Zettlmeissl held senior management roles at Chiron Corp and Behringwerke AG. In 2010, he was named Vaccine Biotech CEO of the Year at the World Vaccine Congress.

Antoinette Hiebeler-Hasner, Deputy Chairman and Board member

She brings extensive expertise in finance, auditing, risk management and corporate governance. She has over 25 years of experience in finance and accounting, having held various senior roles in leading multinational companies. Her career includes significant positions in auditing and consulting firms such as KPMG and her own tax consulting company which after various mergers resulted in the Optegra Consulting Group, integrated later into the global company Vistra Group. Until June 2022 she was the Country Director for all Vistra companies in Germany. Also, together with her family, she is the founder of H3 AEROSPACE GmbH & Co. KG (2009).

Dr Anthony Man, Board member

Dr Man is an executive with over 30 years of experience in the pharmaceutical and biotechnology industries, specialising in oncology and immunology. He is currently an independent drug development consultant to the pharmaceutical industry. He has held several senior leadership positions in global pharmaceutical and biotechnology companies such as Novartis, Roche, Lederle Laboratories and Basilea Pharmaceutica, where he was responsible for the development of innovative therapies. During his career, he led the development and approval of more than 30 drugs. At Novartis, he served as the Senior Vice President and Global Head of Clinical Development, where he played a pivotal role in shaping the company’s oncology strategy and development programs.

Dr Frank Mathias, Board member

Dr Mathias is a seasoned executive with over 30 years of experience in the pharmaceutical and biotechnology industries. He has been the CEO of several biotech companies, including Oxford Biomedica, Rentschler Biopharma SE, and Medigene, where he was the CEO from 2009 to 2016. Before that he was COO of Medigene and held significant roles in sales, marketing, and management at major pharmaceutical companies such as Amgen, Servier and Hoechst. In 2019, he was awarded the title of “EY Entrepreneur of the Year” in Germany. Dr Mathias is a pharmacist by training and completed his Doctorate in Pharmacy at Paris VI University.

Ronald Scott, Board member

Mr Scott brings over 30 years of experience in the pharmaceutical and biotechnology industries. He is best known for his long-standing career at Basilea Pharmaceutical International, Basel, Switzerland, where he served as CEO from 2013 to 2018. He was Basilea's COO in 2012 and Basilea's CFO from the company's foundation in 2000 until January 2012. Prior to joining Basilea, Mr Scott worked in senior finance, licensing and corporate finance M&A roles at pharmaceutical giant Roche. Previously, Mr Scott worked for Prudential Investment Corporation in the US as Director of Finance and International Business Development, where he was responsible for divestitures and joint venture transactions. Mr Scott holds a Bachelor's degree from Utah State University and a Master's degree from Harvard University, both in the US.

SHAREHOLDERS & STOCK INFORMATION

Stock Information	
ISIN	DE000A40ESG2
WKN	A40ESG
Bloomberg ticker	MDG1 GR
No. of issued shares	14,737,594
Transparency Standard	Prime Standard
Country	Germany
Sector	Healthcare
Subsector	Biotechnology

Source: Börse Frankfurt, First Berlin Equity Research

Shareholder Structure	
Management and Directors	4.0%
Freefloat & others	96.0%

Source: Medigene AG

INCOME STATEMENT

All figures in € '000	2021	2022	2023	2024E	2025E	2026E
Revenue	**10,463**	**31,247**	**6,034**	**8,000**	**10,000**	**35,000**
Cost of goods sold	-1,360	-1,983	-1,643	-1,440	-2,400	-9,100
Gross profit	**9,103**	**29,264**	**4,391**	**6,560**	**7,600**	**25,900**
Research & Development Expenses	-12,797	-28,499	-11,545	-13,200	-9,000	-16,000
General & Administrative Expenses	-6,150	-7,692	-9,316	-8,300	-5,100	-7,000
Seling Expenses	-667	-2,193	-20	0	0	0
Other Operating Income	526	393	341	12	15	20
Total operating expenses (OPEX)	**-19,088**	**-37,991**	**-20,540**	**-21,488**	**-14,085**	**-22,980**
Operating income (EBIT)	**-9,985**	**-8,727**	**-16,149**	**-14,928**	**-6,485**	**2,920**
Net financial result	-298	-647	-443	-560	-540	-540
Other financial income/expenses	62	0	0	0	0	0
Pre-tax income (EBT)	**-10,283**	**-9,374**	**-16,592**	**-15,488**	**-7,025**	**2,380**
Income taxes	300	1,044	415	500	500	500
Net income / loss	**-9,983**	**-8,330**	**-16,177**	**-14,988**	**-6,525**	**2,880**
Diluted EPS (€)	**-0.41**	**-0.34**	**-0.66**	**-1.13**	**-0.44**	**-0.96**
Ratios						
Gross Margin on Revenue	87.0%	93.7%	72.8%	82.0%	76.0%	74.0%
EBIT Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on Revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of OPEX						
Seling Expenses	3.5%	5.8%	0.1%	0.0%	0.0%	0.0%
General & Administrative Expenses	32.2%	20.2%	45.4%	38.6%	36.2%	30.5%
Research & Development Expenses	67.0%	75.0%	56.2%	61.4%	63.9%	69.6%
Y-Y Growth						
Revenue	n.a.	198.6%	-80.7%	32.6%	25.0%	250.0%
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in € '000	2021	2022	2023	2024E	2025E	2026E
Assets						
Current Assets, Total	**24,164**	**37,252**	**18,137**	**10,096**	**4,456**	**8,004**
Cash and cash equivalents	22,417	22,224	8,674	2,486	2,729	2,157
Short-term investments	0	11,000	8,000	6,000	0	4,000
Accounts receivables	1,039	3,240	416	500	550	600
Other current assets	708	788	1,047	1,110	1,176	1,247
Non-Current Assets, Total	**35,306**	**14,426**	**13,579**	**12,348**	**11,562**	**11,126**
Property plant and equipment	4,904	4,392	3,438	2,143	1,293	793
Intangible assets	30,115	9,747	9,853	9,917	9,981	10,045
Goodwill	287	287	287	288	288	288
Total Assets	**59,470**	**51,678**	**31,716**	**22,444**	**16,018**	**19,131**
Shareholders' Equity & Debt						
Current Liabilities, Total	**8,033**	**7,415**	**7,179**	**7,456**	**7,738**	**8,061**
Short-term debt	188	171	0	0	0	0
Accounts payable	498	634	340	323	297	300
Provisions & other liabilities	1,980	2,821	2,087	2,191	2,301	2,416
Other current liabilities	5,367	3,789	4,752	4,942	5,140	5,345
Longterm Liabilities, Total	**6,621**	**7,236**	**3,471**	**3,063**	**2,737**	**2,607**
Provision, contract & other liabilities	3,656	4,490	1,434	1,434	1,434	1,434
Lease liabilities	2,965	2,746	2,036	1,629	1,303	1,173
Shareholders Equity	**44,816**	**37,027**	**21,066**	**11,925**	**5,543**	**8,462**
Total Consolidated Equity and Debt	**59,470**	**51,678**	**31,716**	**22,444**	**16,018**	**19,131**
Ratios						
Current ratio (x)	3.01	5.02	2.53	1.35	0.58	0.99
Quick ratio (x)	3.01	5.02	2.53	1.35	0.58	0.99
Net gearing	-49.6%	-59.6%	-41.2%	-20.8%	-49.2%	-25.5%
Book value per share (€)	1.82	1.51	0.86	0.90	0.38	0.57
Net debt	-22,229	-22,053	-8,674	-2,486	-2,729	-2,157
Equity ratio	75.4%	71.6%	66.4%	53.1%	34.6%	44.2%

CASH FLOW STATEMENT

All figures in € '000	2021	2022	2023	2024E	2025E	2026E
Net income	**-9,983**	**-8,330**	**-16,177**	**-14,988**	**-6,525**	**2,880**
Interest, net	298	647	443	560	540	540
Tax provision	-300	-1,044	-415	-500	-500	-500
EBIT	**-9,985**	**-8,727**	**-16,149**	**-14,928**	**-6,485**	**2,920**
Depreciation and amortisation	3,428	21,852	1,463	1,391	1,016	816
EBITDA	**-6,557**	**13,125**	**-14,686**	**-13,537**	**-5,469**	**3,736**
Contract liabilities & other	-5,662	1,259	-2,568	232	241	250
Share & warrant based payments	651	350	307	200	200	100
Changes in working capital	979	-2,144	2,271	-101	-76	-47
Cash interest net	-298	-647	-443	-560	-540	-540
Other adjustments	133	33	0	500	500	500
Operating cash flow	**-10,754**	**11,976**	**-15,119**	**-13,267**	**-5,144**	**3,999**
CapEx	-92	-1,005	-616	-160	-230	-380
Free cash flow	**-10,846**	**10,971**	**-15,735**	**-13,427**	**-5,374**	**3,619**
Other investments	4,118	-11,000	3,000	2,000	6,000	-4,000
Cash flow from investing	**4,026**	**-12,005**	**2,384**	**1,840**	**5,770**	**-4,380**
Debt Financing, net	0	0	0	0	0	0
Equity Financing, net	0	0	0	5,700	0	0
Other financing activities	-1,033	-282	-776	-461	-383	-191
Cash flow from financing	**-1,033**	**-282**	**-776**	**5,239**	**-383**	**-191**
Impact of exchange rates on cash	144	118	-39	0	0	0
Net cash flows	**-7,616**	**-193**	**-13,550**	**-6,188**	**243**	**-572**
Cash, start of the year	30,033	22,417	22,224	8,674	2,486	2,729
Cash, end of the year	**22,417**	**22,224**	**8,674**	**2,486**	**2,729**	**2,157**
Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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The production of this recommendation was completed on 16 January 2025 at 13:32

Person responsible for forwarding or distributing this financial analysis: Martin Bailey

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PRICE TARGET DATES

Unless otherwise indicated, current prices refer to the closing prices of the previous trading day.

AGREEMENT WITH THE ANALYSED COMPANY AND MAINTENANCE OF OBJECTIVITY

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First Berlin's system for asset valuation is divided into an asset recommendation and a risk assessment.

ASSET RECOMMENDATION

The recommendations determined in accordance with the share price trend anticipated by First Berlin in the respectively indicated investment period are as follows:

Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

Our recommendation system places each company into one of two market capitalisation categories. Category 1 companies have a market capitalisation of €0 – €2 billion, and Category 2 companies have a market capitalisation of > €2 billion. The expected return thresholds underlying our recommendation system are lower for Category 2 companies than for Category 1 companies. This reflects the generally lower level of risk associated with higher market capitalisation companies.

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RECOMMENDATION & PRICE TARGET HISTORY

Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	Today	€1.04	Buy	€3.80

INVESTMENT HORIZON

Unless otherwise stated in the financial analysis, the ratings refer to an investment period of twelve months.

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Legally required information regarding

- **key sources of information in the preparation of this research report**
- **valuation methods and principles**
- **sensitivity of valuation parameters**

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