

## **MediGene AG Reports First Nine Months of 2009: Increase in Revenue and Reduction of Loss**

- **Total revenue increased by 12% to 28.6 million EUR (9M 2008: 25.5 million EUR)**
- **EBITDA improved by 33% to -13.1 million EUR (9M 2008: -19.5 million EUR)**
- **Net loss reduced by 37% to 15.9 million EUR (9M 2008: 25.0 million EUR)**
- **Forecast for the full year clarified**
- **Analyst conference call with webcast (in English) at 2.30 pm (CET) today**

**Martinsried/Munich, November 13, 2009.** In the first nine months of 2009, the biotech company MediGene AG (Frankfurt: MDG, Prime Standard, TecDAX) improved its total revenue and EBITDA, and reduced its net loss compared to last year's reporting period. These results are reported in compliance with IFRS (International Financial Reporting Standards).

Total revenue, generated mainly from the commercialization of the drug Eligard<sup>®</sup> in Europe, amounted to 28.6 million EUR in the first nine months of 2009 (9M 2008: 25.5 million EUR) and to 8.6 million EUR in the third quarter 2009 (Q3 2008: 11.7 million EUR). The decrease in total revenue when comparing the third quarters is due to a one-time revenue item of 4.4 million EUR posted for the sale of the rights to Oracea<sup>®</sup> to Galderma in 2008. Adjusted for this one-time effect, revenue for the third quarter increased by 17 % compared to last year's reporting period.

The loss on an EBITDA basis in the third quarter of 2009 amounted to 6.3 million EUR compared to last year's reporting period (Q3 2008: 3.0 million EUR). Adjusted to the above-mentioned one-time item, the result was also significantly improved. In the first nine months of 2009, the loss on an EBITDA basis was reduced by 33 % to 13.1 million EUR (9M 2008: 19.5 million EUR).

The net loss was reduced by 37% to 15.9 million EUR in the first nine months of 2009 (9M 2008: 25.0 million EUR), and to 7.6 million EUR in the third quarter 2009 (Q3 2008: 8.4 million EUR). This decrease is primarily due to increased revenue, reduced R&D expenses, of which the mTCR technology spin-off contributed significantly, and to reduced selling, general, and administrative expenses during the first nine months of 2009. R&D expenses decreased by 37% to 13.6 million EUR in the first nine months of 2009 (9M 2008: 21.7 million EUR), and by 27% to 4.8 million EUR in the third quarter of 2009 (Q3 2008: 6.6 million EUR).

Cash used by operating activities decreased by 32% to -15.7 million EUR in the first nine months of 2009 (9M 2008: -23.0 million EUR), and by 45% to -4.3 million EUR in the third quarter of 2009 (Q3 2008: -7.8 million EUR). The average monthly net cash burn rate from operating activities in the first nine months of 2009 was 1.7 million EUR (9M 2008: 2.6 million EUR), and 1.4 million EUR in the third quarter of 2009 (Q3 2008: 2.6 million EUR).

As at closing date September 30, 2009, cash and cash equivalents totalled 9.7 million EUR. In addition MediGene has access to additional cash of up to 25 million EUR from an equity funding agreement signed with YA Global Investments L.P. in 2008. In October 2009 MediGene called two tranches from this SEDA program, and the proceeds collected against issue of 429,553 shares, which totalled 2 million EUR, are not included in the figures herein.

## Major events in the first nine months of 2009:

- **MediGene shares admitted to the TecDAX stock index**
- **Dr. Frank Mathias appointed new Chief Executive Officer of MediGene AG**
- **Reorganization initiated: shift of employees and financial resources to clinical development**
- **Start of sales promotion and active marketing of Veregen® in the USA through MediGene's partner Nycomed**
- **Positive assessment on market authorization for Veregen® in the first European countries, marketing authorization granted in Germany**
- **Marketing partnership agreements concluded for commercialization of Veregen® in Spain and Portugal, and in Germany, Austria, and Switzerland**
- **US regulatory authority grants orphan drug designation for EndoTAG™-1**

## Consolidated income statement (abbreviated)

In T€	Q3 2009 unaudited	Q3 2008 unaudited	Change	9M 2009 unaudited	9M 2008 unaudited	Change
Product sales	8,403	6,837	23%	26,988	19,706	37%
Other operating income	176	4,905	-96%	1,580	5,804	-73%
<b>Total revenue</b>	<b>8,579</b>	<b>11,742</b>	<b>-27%</b>	<b>28,568</b>	<b>25,510</b>	<b>12%</b>
Cost of sales	-7,321	-6,039	21%	-21,850	-16,012	36%
<b>Gross profit</b>	<b>1,258</b>	<b>5,703</b>	<b>-78%</b>	<b>6,718</b>	<b>9,498</b>	<b>-29%</b>
Selling, general, and administrative expenses	-2,971	-2,378	25%	-6,876	-8,180	-16%
Research and development expenses	-4,809	-6,559	-27%	-13,560	-21,684	-37%
Loss resulting from spin-off	0	-6,384	-%	0	-6,384	-%
<b>Operating result</b>	<b>-6,522</b>	<b>-9,618</b>	<b>-32%</b>	<b>-13,718</b>	<b>-26,750</b>	<b>-49%</b>
<b>Result before income tax</b>	<b>-7,522</b>	<b>-9,058</b>	<b>-17%</b>	<b>-15,838</b>	<b>-26,650</b>	<b>-41%</b>
<b>Net loss for the period</b>	<b>-7,550</b>	<b>-8,402</b>	<b>-10%</b>	<b>-15,866</b>	<b>-24,994</b>	<b>-37%</b>

**Dr. Thomas Klaue, Chief Financial Officer of MediGene AG**, commented: "During the first nine months of 2009 MediGene further increased revenue and significantly reduced loss. Moreover the equity funding agreement closed with YA Global Investments L.P. allows us to collect a total of 25 million euros additional cash. This enables us to stabilize MediGene's financial cushion, thus strengthening our negotiating position for the conclusion of a partnership for our cancer drug EndoTAG™-1. We drew the first tranches of cash in the fourth quarter of 2009. It remains our goal to reach the most favourable, and not necessarily the fastest achievable, partnership agreement for EndoTAG™-1."

## Forecast 2009:

Financial forecast: MediGene today clarifies its forecast for the full year 2009 as originally published in March 2009. MediGene expects to increase sales by approximately 13% to approximately 38 million EUR and to generate total revenue of approximately 40 million EUR (2008: total revenue 39.6 million EUR, sales revenue 33.5 million EUR). MediGene's previous forecast for 2009 was for increased total revenue compared to 2008, and this increase in total

revenue will not be achieved because certain milestone payments from existing Veregen<sup>®</sup> partnerships which were planned for 2009 will now be posted in 2010. However, MediGene confirms the forecast published in March 2009 which was to reduce the loss on EBITDA basis compared to last year. Depending on the date of allocation of a certain cost pool related to EndoTAG<sup>™</sup>-1, MediGene expects the result on an EBITDA basis to be in the range of -20 to -23 million EUR (2008: EBITDA -24.6 million EUR). This financial forecast does not take into account any proceeds from the intended partnership on EndoTAG<sup>™</sup>-1.

Eligard<sup>®</sup>: MediGene anticipates a continuous rise in the Eligard<sup>®</sup> market share, as well as a further increase in European sales revenues achieved with Eligard<sup>®</sup>, driven particularly by the six-month depot formulation of Eligard<sup>®</sup> (Eligard<sup>®</sup> 45 mg).

Veregen<sup>®</sup> (Polyphenon E<sup>®</sup>-Salbe): In February 2009, MediGene's marketing partner Nycomed started active marketing of the drug Veregen<sup>®</sup> in the USA. Therefore MediGene expects increasing sales revenues for the financial year 2009 from the commercialization of the ointment on the US market. The launch of the drug on the first European markets is expected in 2010.

EndoTAG<sup>™</sup>-1: The final evaluation of the ongoing clinical phase II trial of EndoTAG<sup>™</sup>-1 for the treatment of triple receptor-negative breast cancer is expected during the first half of 2010. In 2009 MediGene expects either the conclusion of a partnership or further progress in the partnering process.

RhuDex<sup>™</sup>: Since the UK regulatory authority MHRA consented in October 2009 to the continuation of the clinical development of the drug candidate in coordination with the authorities, MediGene is now preparing the further development plan..

oHSV and AAV: MediGene is not planning to continue development of oncolytic viruses, and intends to spin off or to sell a license for this technology, similar to that achieved in the successful mTCR spin-off. In addition MediGene is also planning to spin off the AAV research program into an independent company.

**Analyst conference call with webcast:** An analyst conference call in English will take place at 2.30 pm (CET) today, and will be webcast live. Access to the webcast including synchronized slides is possible at the MediGene website at [www.medigene.de](http://www.medigene.de). A replay will also be available.

**The detailed 9-months report** is available at:  
<http://www.medigene.de/englisch/quartalsberichte.php>

**Advance notice:** On December 15, 2009, MediGene's annual analyst conference will take place in Frankfurt. This event will also be webcast live. MediGene's management will report on its strategy, the status and design of the development programs, as well as the status of the partnering and spin-off processes. In addition MediGene will present its future business and finance plan. Time and agenda of the conference as well as the webcast link will be communicated in good time.

*This press release contains forward-looking statements representing the opinion of MediGene as of the date of this release. The actual results achieved by MediGene may differ significantly from the statements made herein. MediGene is not bound to update any of these forward-looking statements. MediGene<sup>®</sup>, EndoTAG<sup>™</sup>, EndoTAG<sup>™</sup>-1 and Veregen<sup>®</sup> are registered trademarks of MediGene AG. Eligard<sup>®</sup> is a registered trademark of QLT USA, Inc. RhuDex<sup>™</sup> is a trademark of MediGene Ltd. These trademarks may be owned or licensed in select locations only.*



**MediGene AG** is a publicly listed (Frankfurt: MDG, Prime Standard, TecDAX) biotechnology company located in Martinsried/Munich, Germany, with subsidiaries in Oxford, UK and San Diego, USA. MediGene is the first German biotech company to have drugs on the market, which are being distributed by partner companies and has several drug candidates in clinical development, two of which provide significant sales potential. In addition, the company has numerous projects in research and pre-clinical development and possesses innovative platform technologies. MediGene focuses on the research and development of novel drugs for the treatment of cancer and autoimmune diseases

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