



## PRESS RELEASE

### **Crucell Announces Record Revenues and Profits for Full Year 2009**

Total revenues and other operating income increased 26% to €358.0 million.

Operating profit increased more than four-fold to €39.0 million.

Net profit increased 68% to €23.9 million.

Undiluted EPS increased 55% to €0.34.

Year-end cash and short-term liquidities €428.0 million.

**2010 guidance:** Use continued strong operating cash flow to accelerate product development. R&D spending to increase by over one-third, while maintaining a healthy operating profit.

Revenues and other operating income<sup>1</sup> broadly in line with 2009.

**Leiden, the Netherlands (February 9, 2010)** – Dutch biopharmaceutical company Crucell N.V. (NYSE Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) today announced its financial results for the fourth quarter and full year of 2009, based on International Financial Reporting Standards (IFRS). These financial results are unaudited.

### **Business Highlights 2009:**

- Strategic agreement, worth over €1 billion, for revolutionary influenza antibody research signed with Johnson & Johnson (JNJ) in September 2009. Crucell's scientists discovered human monoclonal antibodies that cross-neutralize influenza viruses of different subtypes (including H5 and H1) and that provide immediate protection against the broadest range of flu strains in pre-clinical models.
- National Institutes of Health (NIH) awarded up to \$69.1 million for novel influenza antibody research in August 2009. Initial funding of up to \$40.7 million, with additional options that may be triggered at the discretion of the NIH worth a further \$28.4 million.
- Detailed positive results of the Phase II Philippines study of rabies monoclonal antibody combination were presented at the 20<sup>th</sup> Rabies in the Americas (RITA) Conference in Canada in October 2009.
- Promising preliminary results of the HIV vaccine Phase I study were presented in October 2009 at the AIDS Vaccine Conference 2009 in France, showing that this HIV candidate vaccine is safe and immunogenic.
- In July 2009 Crucell announced the collaboration with the PATH Malaria Vaccine Initiative (MVI) and the United States Agency for International Development (USAID) Malaria Vaccine Development Program (MVDP) to accelerate development of its malaria vaccine.
- In May 2009, Crucell announced that, following the success of Crucell's rabies and flu antibody programs, Crucell obtained an exclusive license

<sup>1</sup> In guidance currencies = EUR/USD rate of 1.41



from Stanford University for the development of an antibody combination against the hepatitis C virus.

- In August 2009 Crucell announced \$300 million worth of new awards from a large supranational organization for supplies of Quinvaxem<sup>®</sup>, the first portion of the new 3-year tender period (2010–2012). The new awards are in addition to the \$500 million obtained over the tender period 2007–2009.
- Construction of the new vaccine manufacturing facility in Incheon, Korea, has progressed in rapid pace and technical completion has been achieved in 13 months. First test runs are planned for the second quarter of 2010.
- Our partner Adimmune successfully started production of influenza vaccines in Taiwan and is a promising future supplier of flu antigens for us.
- In 2009 Crucell signed 12 new license/vendor agreements, including agreements with Centocor Inc., Momotaro-Gene Inc., Patrys Ltd., TapImmune Inc., Calmune Corporation, Cangene and Vivante GMP Solutions. Vendor Network Agreements were signed with Bioceros B.V. and KBI Biopharma Inc.

#### **Financial Highlights 2009:**

- Combined total revenues and other operating income were €358.0 million, compared to €283.3 million in 2008. The increase of 26% was mainly driven by strong sales of our paediatric vaccines. At guidance currency EUR/USD rate of 1.35, the total revenue growth was 29%. This is primarily due to the US dollar depreciating versus the Euro.
- Product sales were €304.4 million, a 35% increase compared to 2008, representing sales of paediatric vaccines (59%), travel and endemic vaccines (18%), respiratory vaccines (12%) and other products (11%).
- Gross margins of 42%, compared to 45% in 2008. Currency movements and the timing of milestones impacted margins.
- The Company achieved operating profit of €39.0 million for the full year, compared to €7.4 million operating profit in 2008.
- The consolidated effective income tax rate was 37% for 2009. Income taxes for the full year were €14.0 million. The effective tax rate is relatively high due to an operating loss in the Netherlands as a result of R&D expenses, for which no tax benefit is recognized.
- Crucell achieved a net profit of €23.9 million, compared to €14.3 million in 2008. Net profit per share of €0.34, compared to €0.22 in 2008.
- As part of the strategic collaboration with JNJ, the company issued 14.6 million new ordinary shares to JNJ for an aggregate purchase price of



€301.8 million. This included a premium of €69 million classified as deferred income.

- Operating cash flow of €76.9 million for the year, compared to minus €0.3 million in 2008.
- Cash used in investing activities amounted to €154.4 million, which includes a long term deposit of €100.0 million with a maturity of over 3 months, to take advantage of higher yields on longer term deposits.
- Net cash from financing activities for the full year was €231.5 million, compared to €16.6 million in 2008, driven by issuance of shares to JNJ.
- Cash and cash equivalents increased by €156.9 million during the year to €327.8 million at year-end 2009.

### Key Figures:

(€ million, except net result per share)

Fourth Quarter			Full Year			
2009 unaudited	2008 unaudited	Change		2009 unaudited	2008 unaudited	Change
111.3	93.7	19%	Total revenues and other operating income	358.0	283.3	26%
18.0	11.9	52%	Operating profit	39.0	7.4	425%
15.6	18.9	(18)%	Net profit	23.9	14.3	68%
0.19	0.29	(34)%	Net result per share (basic)	0.34	0.22	55%

Crucell's Chief Executive Officer Ronald Brus said:

"The key event of the year was the partnership agreement we signed with Johnson & Johnson (JNJ). This partnership, with a total deal value of over €1 billion, included a payment of over €300 million, mainly related to an equity investment of 18%. The partnership with JNJ provides us with additional R&D funding and enables us to further accelerate and expand our product development. In 2010 and onwards we have a responsibility to make the most of these opportunities.

"Our business is stronger than ever and in 2009 we achieved a solid overall revenue growth of 26%, driven by a 35% increase in vaccine sales. With a clear strategy for long-term growth and even more focus on research and



development, I am very proud that we significantly improved profitability in 2009 and together with a healthy balance sheet and a strong year-end cash position, we were able to end the year on a high.

"Our world-class vaccine production plant in Seoul, Korea, is being constructed at record pace. This allows us to efficiently produce high volumes of vaccines in Asia. Our partner Adimmune has also successfully started production of influenza vaccines in Taiwan and is a promising future supplier of flu antigens for us.

"Furthermore, in 2009 we made great progress in terms of global integration, improving performance and increasing accountability—all with the ultimate aim of increasing the impact CruCell has on human health. These achievements form a solid foundation on which to build our future."

#### **Product Sales Update:**

Product sales in the full year of 2009 increased 35% over the same quarter in 2008 to €304.4 million and represent sales of paediatric vaccines (59%), travel and endemic vaccines (18%), respiratory vaccines (12%) and other products (11%).

In September CruCell started its own dedicated marketing and sales organization in the United Kingdom by acquiring an experienced team, which will further strengthen its vaccine sales position in one of the largest vaccine markets in Europe. Distribution of the travel vaccines (Epaxal<sup>®</sup>, Vivotif<sup>®</sup> and Dukoral<sup>®</sup>) has started and is progressing well. Distribution of the influenza vaccine Inflexal<sup>®</sup> V will start in the flu season of 2010.

In November 2009 CruCell announced the launch of the global CruCell brand, a consistent identity for its worldwide activities and products. The rebranding is designed to promote recognition of the CruCell name and what it stands for: bringing meaningful innovation to global health, with a focus on combating infectious diseases. The establishment of a strong global brand will significantly support this mission.

#### **Research & Development:**

- **Flavimun<sup>®</sup> - Live Attenuated Yellow Fever Vaccine** (Phase III): Flavimun<sup>®</sup> was submitted for registration in Switzerland in March 2009. Submission in Germany is imminent.
- **Influenza - Seasonal Influenza Vaccine:** This seasonal influenza vaccine is being developed by Sanofi Pasteur, using CruCell's PER.C6<sup>®</sup> technology. In the third quarter of 2008, CruCell received a milestone payment from Sanofi Pasteur for progress of the Phase II trials involving healthy adult volunteers in the USA.
- **Influenza - Human Monoclonal Antibodies against a broad range of Influenza strains** (pre-clinical): CruCell's scientists discovered human monoclonal antibodies that cross-neutralize influenza viruses of different subtypes including H5 and H1 and that provide immediate protection against the broadest range of H5N1 and H1N1 strains in pre-clinical models. The most powerful of these antibodies, mAb CR6261 was shown



to prevent death and cure disease in pre-clinical models for prevention or treatment of a potentially lethal H5N1 and H1N1 infections and to strongly outperform the anti-influenza drug oseltamivir (Tamiflu) in terms of its value for flu prevention and treatment. The characterization of the antibody was described in the online journal PLoS ONE on December 16, 2008 and the journal Science on February 4, 2009.

In August 2009 Crucell received an award from the National Institute of Allergy and Infectious Diseases (NIAID)/National Institutes of Health (NIH) for the development of its Influenza monoclonal antibodies providing funding of up to \$40.7 million, with additional options worth a further \$28.4 million, bringing the potential total amount to \$69.1 million.

In September 2009 JNJ, through its subsidiary Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Crucell entered into a strategic collaboration for the development and commercialization of a universal monoclonal antibody product (flu-mAb) for the treatment and prevention of influenza. In addition the strategic collaboration involves three innovative discovery programs focusing on the development and commercialization of a universal influenza vaccine as well as vaccines directed against three other infectious and non-infectious disease targets.

- **Rabies Human Monoclonal Antibody Combination/CL184** (Phase II): Crucell's monoclonal antibody combination against rabies is being developed in collaboration with Sanofi Pasteur using Crucell's PER.C6<sup>®</sup> manufacturing technology. CL184 is designed for the post-exposure prophylaxis against rabies in combination with rabies vaccine. Under the terms of the collaboration agreement Crucell will be responsible for manufacturing the commercial product and has retained exclusive distribution rights in Europe, co-exclusive distribution rights in China and the rights to sell to supranational organizations such as UNICEF, while Sanofi Pasteur will have exclusive distribution rights for all other territories and co-exclusive distribution rights in China.

The completion of two Phase II studies in US and Philippines respectively has triggered milestone payments from Sanofi Pasteur as part of the total eligible amount of €66.5 million.

In June 2009, Crucell announced the results of the Philippines study, which showed that CL184 was safe and well tolerated. Neutralizing activity levels in subjects given the antibody product were similar to those in subjects given human immunoglobulin (HRIG), the current standard for inducing immediate, passive immunity. All study participants reached adequate immunity levels. This study in children further broadens the potential patient population for Crucell's rabies monoclonal antibody combination. Results of this study have been presented at the XX Rabies in the Americas RITA conference in Quebec, Canada on 20 October 2009.

Crucell is planning to start an additional Phase II study in India in the second quarter of 2010 to collect safety and neutralizing activity data of the CL184 antibody in combination with the vaccine in a simulated rabies post-exposure prophylaxis setting.



- **Tuberculosis Vaccine** (Phase II): Development of the candidate vaccine AERAS-402/CruceCell Ad35 is being carried out in collaboration with the Aeras Global TB Vaccine Foundation. Data from all AERAS-402/CruceCell Ad35 trials support the immunogenicity and acceptable safety profile of the TB candidate vaccine at all dose levels evaluated.

#### Phase II:

- The first Phase II study of AERAS-402/CruceCell Ad35, started in October 2008, is being conducted by the University of Cape Town Lung Institute, South Africa in conjunction with the South African Tuberculosis Vaccine Initiative. In this dose escalation study in adults who have had active TB, no evidence of an unacceptable safety issue has been found in the 72 subjects enrolled to date. Preliminary data indicate that the candidate vaccine induces CD8-cell immune responses in patients who have completed TB treatment.

#### Phase I:

- The US Phase I trial in healthy adults not previously immunized with the traditional TB vaccine, Bacille Calmette-Guérin (BCG), has been completed and demonstrated that the candidate vaccine is safe in this population.
- Results of a second study with the candidate vaccine in South Africa showed CD8 T cell immune responses that are much higher than those seen in humans in any previous TB vaccine study.
- Two Phase I studies in healthy adults in St. Louis, USA, focusing on the immunogenicity and safety of two boost doses administered at three to six month intervals after BCG priming in healthy adults have been completed. Data from these studies showed that two injections of the candidate vaccine are immunogenic, with an acceptable safety profile, when used in combination with a BCG-prime in healthy adults, regardless of the boosting interval. This immune response is greater than that detected in the absence of BCG prime, supporting the possible utility of AERAS-402/CruceCell Ad35 as a booster vaccine. BCG prime alone shows limited efficacy. A follow-up study conducted in the USA in healthy adults showed that injections with up to  $10^{11}$  vpu/ml of the candidate vaccine had an acceptable safety profile.
- In October 2008, a Phase I clinical trial to test the safety of the candidate vaccine in BCG-vaccinated adults with or without latent tuberculosis has been completed, with ongoing analysis and no safety issues identified. The study is being conducted by the KEMRI/Walter Reed Project-Kisumu at their Kombewa Clinical Trials Center near Kisumu, in western Kenya.
- In April 2009, a Phase I clinical trial was started in South Africa with the main objective to test the safety of the candidate vaccine in infants previously vaccinated with BCG vaccine, currently the only vaccine licensed to help prevent TB. This first clinical trial designed to test the candidate vaccine in infants is being conducted by the South African Tuberculosis Vaccine Initiative (SATVI) in the Western Cape region of South Africa. The study is fully enrolled and dosing is ongoing. No safety issues have been identified to date.



- In January 2010, a Phase I clinical trial was initiated in Portland, Oregon. This trial is using a known immunogenic regimen of BCG and the candidate vaccine in healthy adults, followed by collection of large numbers of immune cells, for more detailed analysis of the immune response to AERAS-402/Crucell Ad35.
- **Malaria Vaccine (Phase I):** Crucell and its collaborator, the US National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), are conducting a Phase I trial in the USA for a recombinant malaria vaccine, Ad35-CS, based on the company's AdVac<sup>®</sup> technology and PER.C6<sup>®</sup> manufacturing platform. In December 2009 boost vaccinations for the final group of volunteers have been completed. Ongoing safety monitoring has revealed no significant safety concerns to date. Preliminary examination of the blinded data from the first four cohorts indicated that the vaccine is immunogenic. Detailed analysis of the data is ongoing and unblinding is expected in the second quarter of 2010.

In July 2009 Crucell announced a new collaboration with US-based MVI and USAID MVDP to accelerate development of a promising new type of malaria vaccine. Through funding from the USAID MVDP, the partners will conduct studies to determine the effectiveness of Crucell's novel prime–boost vaccine approach against the malaria parasite *Plasmodium falciparum*. Using Crucell's AdVac<sup>®</sup> technology with two different adenovirus vectors -Ad35 and Ad26- as delivery mechanisms, this approach seeks to elicit a protective immune response obtained from delivering the circumsporozoite protein (CSP).

- **Multivalent Filovirus (Ebola & Marburg) Vaccine (Phase I):** In October 2008 Crucell announced that it has secured a NIAID/NIH award to advance the development of Ebola and Marburg vaccines, with the ultimate aim of developing a multivalent filovirus vaccine. The award provides funding of up to \$30 million, with additional options, worth a further \$40 million. The Phase I study of an adenovirus 5 (Ad5) and PER.C6<sup>®</sup> -based Ebola vaccine that Crucell is developing in partnership with the Vaccine Research Center (VRC) of the NIAID/NIH, showed safety and immunogenicity at the doses evaluated. Based on these results, a second Phase I study of an Ebola and/or Marburg vaccine is anticipated. This will use alternative multivalent adenovirus vectors that are able to bypass pre-existing immunity against Ad5.
- **HIV Vaccine (Phase I):** In October 2009 preliminary results of a Phase I study with a novel recombinant HIV vaccine, using adenovirus serotype 26 (rAd26) were presented at La Conférence AIDS Vaccine 2009 in Paris, France. The presentation was given by Dr Dan H. Barouch, MD, PhD, Associate Professor of Medicine, Division of Vaccine Research, Department of Medicine at the Beth Israel Deaconess Medical Center (BIDMC) in Boston, USA. The preliminary results of this study show that this HIV candidate vaccine is safe and immunogenic. The rAd26 vector, that Crucell is jointly developing with the Beth Israel Deaconess Medical Center, is specifically designed to avoid the pre-existing immunity to the more commonly used adenovirus serotype 5 (Ad5). The Phase I clinical



study is being conducted at the Brigham and Women's Hospital in Boston, USA and is focused on assessing the safety and immunogenicity of the vaccine.

- **Hepatitis C Human Monoclonal Antibodies** (Pre-clinical): In August 2009 Crucell obtained an exclusive license from Stanford University (Palo Alto, California) for the development of antibodies against the hepatitis C virus. A large panel of fully human monoclonal antibodies against the hepatitis C virus (HCV) is being evaluated by Crucell in a proof of concept phase.

#### **Building Development Capability:**

To strengthen Crucell's capabilities to deliver on its pipeline, the company hired over 120 new employees since January 2009. With these new employees Crucell strengthens its team with new leadership and process experts. Many of these new colleagues will be working in Switzerland, in the two buildings that have been reutilized to establish new process development laboratories. Crucell will use these laboratories to get FDA approval for Epaxal<sup>®</sup> in the US.

#### **Korean Production Facility:**

In October 2008 Crucell announced that an agreement was reached to relocate Crucell's Korean production facility from the Shingal site in Yongin City, Korea to the Incheon Free Economic Zone, Korea. Construction activities at the new site started in December 2008 and are progressing well. First test runs are planned for the second quarter of 2010. The new facility will enable the further growth and efficient production of Quinvaxem<sup>®</sup> and Hepavax-Gene<sup>®</sup>. The investments in the new facility are expected to total approximately €50 million, with the majority of spending having been made in 2009.

#### **The Crucell Ambition:**

In 2008, The Crucell Ambition program was rolled out throughout the Company, focusing on four priority areas. These areas are: Organization & People, Focus, Operational Excellence, and Deliver on Promises.

The Operational Excellence 'Healthy Ambition' part of the program was targeting savings of €30 million by the end of 2009 compared to the 2007 cost base (excluding R&D). This has been well achieved with the program ultimately delivering just over €30 million in run-rate savings at the end of 2009. Savings were predominantly achieved through improved yields, marketing and sales efficiency gain, and savings in overhead.

#### **Manufacturing & Licensing Agreements:**

- **Crucell** today announces an expansion of the PER.C6<sup>®</sup> research license agreement with Canada-based **Cangene** to include the development of additional antibodies by Cangene. Financial details of the agreement were not disclosed. [September 2009].



- **Crucell** today announces a patent license and a vendor network manufacturing service license agreement with US-based **Vivante GMP Solutions**. The patent license agreement grants Vivante a worldwide, non-exclusive license of intellectual property to conduct development and manufacture using Crucell's adenoviral-based patent portfolio. The vendor network manufacturing service license agreement grants Vivante a non-exclusive license to utilize Crucell's PER.C6<sup>®</sup> cell line in the manufacture of gene therapy and vaccine products for Vivante's clients through Phase 1 clinical trials. Financial details of the agreement were not disclosed. [October 2009].

#### **Patents:**

In Q4 2009 Crucell was granted a total of 93 patents, including patents for:

- Aspects of PER.C6<sup>®</sup> cell lines and recombinant adenovirus technology, in Europe
- Aspects of PER.C6<sup>®</sup> protein expression technology, in Europe and in the U.S.
- Aspects of AdVac<sup>®</sup> technology, in Europe and in Japan
- Improvements in influenza virus isolation using PER.C6<sup>®</sup> technology, in China
- Aspects of improved adenoviral AdVac<sup>®</sup> vectors, in Europe
- Elements of STARTM technology, in Australia
- Improved methods for quantifying influenza antigens, in New Zealand and in the U.S.
- Aspects of adenovirus manufacturing technology, in Europe

#### **Post Balance Sheet Events:**

- **Crucell** today announces a non-exclusive HER96 license agreement with France-based **Transgene** for use of this technology in the area of infectious diseases. Financial details of the agreement were not disclosed. [January 2010]
- **Crucell** today announces a non-exclusive, worldwide PER.C6<sup>®</sup> license agreement with the **Cancer Research UK Centre**, School of Cancer Sciences, University of Birmingham to manufacture, use and develop an adenovirus-based gene therapy product for the treatment and/or prophylaxis of prostate cancer, limited to performing Phase I clinical studies. Financial details of the agreement were not disclosed. [January 2010]



## **Financial Review Fourth Quarter 2009**

### **Total Revenues and Other Operating Income**

Total revenues and other operating income amounted to €111.3 million for the fourth quarter of 2009, an increase of 19% compared to the same quarter of 2008. The increase of 19% was driven by the strong sales of Quinvaxem<sup>®</sup> and contract manufacturing product sales.

Product sales in the fourth quarter of 2009 increased 19% over the same quarter in 2008 to €91.2 million and represent sales of paediatric vaccines (62%), travel and endemic vaccines (15%), respiratory vaccines (13%) and other products (10%).

License revenues were €11.3 million in the fourth quarter, an increase of €2.2 million compared to the fourth quarter of 2008.

Service fees for the quarter were €2.9 million, compared to €4.0 million in the same quarter of 2008. Service fees represent revenues for product development activities performed under contracts with partners and licensees.

Other operating income was €6.0 million for the quarter, compared to €4.1 million in the fourth quarter of 2008.

### **Cost of Goods Sold**

Cost of goods sold for the fourth quarter of 2009 amounted to €56.2 million. €54.1 million represents product costs; and €2.1 million the cost of service and license activities.

Gross margins were 47%, compared to 50% in the fourth quarter of 2008. We saw some pressure on margins as a result of exchange rates, which affected our product sales and cost of goods sold.

### **Expenses**

Total expenses consisted of research and development (R&D) expenses, marketing and sales (M&S) and general and administrative (G&A) expenses. Total expenses for the fourth quarter were €37.1 million, similar to the same period in 2008.

SG&A expenses for the quarter were €13.8 million compared to €17.7 million in the fourth quarter of 2008. This reduction was mainly due to lower selling expenses.

Operating profit was €18.0 million in the fourth quarter of 2009 compared to €11.9 million operating profit in the same quarter of 2008. Operating profit was positively affected by the increase of revenues and other operating income.

The company recorded a €4.8 million income tax charge in the fourth quarter of 2009, mainly due Korea. The consolidated effective income tax rate was 24% in the fourth quarter of 2009.



### **Net Result**

Net income of €15.6 million was reported in the fourth quarter of 2009 versus a net income of €18.9 million in the same quarter of 2008. Net result per share in the fourth quarter of 2009 is €0.19, compared to a net result per share of €0.29 in the fourth quarter of 2008.

### **Balance Sheet**

Tangible fixed assets amounted to €192.6 million on December 31, 2009. Intangible assets amounted to €75.4 million. This includes acquired in-process research and development, developed technology, patents and trademarks, and the value of customer and supplier relationships.

Investments in associates and joint ventures amounted to €11.4 million and mainly represent investments in AdImmune and the PERCIVIA PER.C6<sup>®</sup> Development Center. Crucell's investment in Galapagos NV is classified under available-for-sale investments.

Total equity on December 31, 2009 amounted to €738.3 million. A total of 81.4 million ordinary shares were issued and outstanding on December 31, 2009.

### **Cash Flow and Cash Position**

Cash and cash equivalents increased by €16.2 million in the fourth quarter to €327.8 million.

Net cash from operating activities in the fourth quarter was €31.7 million, down from €61.5 million in the same quarter of 2008. This decrease was a result of a higher accounts receivable balance resulting from higher revenues.

Cash used in investing activities amounted to €18.9 million, which includes the investment in the new production facility in Korea.

Net cash from financing activities in the fourth quarter was €1.3 million, compared to €9.4 million in the same quarter of 2008. In 2008 the amount included the flexible facility for the construction of the new site in Korea.

### **Change in accounting policy**

As of January 1, 2009, Crucell changed its accounting policy of recognizing actuarial gains and losses for its defined benefit pensions plans. The new policy requires that all actuarial gains and losses are recognized in 'other comprehensive income' in the period which they occur. Prior to this change all actuarial gains and losses arising from experience-based adjustments and changes in actuarial assumptions were accounted for in line with the 'corridor' method, which allowed deferral of these results. The new policy provides more relevant and timely information as all transactions and events of a defined benefit postretirement plan are recognized in the period in which they occur. Comparative amounts were adjusted as if the new accounting policy had always been applied.



## **Annual Report**

Crucell N.V. is currently finalizing the financial statements for the year ended December 31, 2009. We expect to be able to file our 2009 Annual Report on Form 20-F with the U.S. Securities and Exchange Commission as well as publish our Statutory Annual Accounts for the year 2009 before the end of April 2010. The consolidated balance sheet of Crucell N.V. as of December 31, 2009, the related consolidated statements of operations and consolidated statements of cash flows for the year ended December 31, 2009, and all quarterly information as presented in this press release are unaudited.

## **Forward-looking statements**

*This press release contains forward-looking statements that involve inherent risks and uncertainties. We have identified certain important factors that may cause actual results to differ materially from those contained in such forward-looking statements. For information relating to these factors please refer to our Form 20-F, as filed with the US Securities and Exchange Commission on April 22, 2009, in the section entitled 'Risk Factors'. The Company prepares its financial statements under International Financial Reporting Standards (IFRS).*

### **Conference Call and Webcast**

At 14:00 Central European Time (CET), Crucell's management will conduct a conference call, which will also be webcast. To participate in the conference call, please call one of the following telephone numbers 15 minutes prior to the event:

+44 203 003 2666 for the UK;  
+1 646 843 4608 for the US; and  
+3120 794 8426 for the Netherlands

Following a presentation of the results, the lines will be opened for a question and answer session.

The live audio webcast can be accessed via the homepage of Crucell's website at [www.crucell.com](http://www.crucell.com) and will be archived and available for replay following the event.

## **About Crucell**

Crucell N.V. (NYSE Euronext, NASDAQ: CRXL; Swiss Exchange: CRX) is a global biopharmaceutical company focused on research development, production and marketing of vaccines, proteins and antibodies that prevent and/or treat infectious diseases. Its vaccines are sold in public and private markets worldwide. Crucell's core portfolio includes a vaccine against hepatitis B, a fully-liquid vaccine against five important childhood diseases and a virosome-adjuvanted vaccine against influenza. Crucell also markets travel vaccines, such as the only oral anti-typhoid vaccine, an oral cholera vaccine and the only aluminum-free hepatitis A vaccine on the market. The Company has a broad development pipeline, with several product candidates based on its unique PER.C6<sup>®</sup> production technology. The Company licenses its PER.C6<sup>®</sup> technology and other technologies to the biopharmaceutical industry. Important partners and licensees include Johnson & Johnson, DSM Biologics, sanofi-aventis, Novartis, Wyeth, GSK, CSL and Merck & Co. Crucell is headquartered in Leiden, the Netherlands, with



subsidiaries in Argentina, China, Italy, Korea, Spain, Sweden, Switzerland, UK and the USA. The Company employs over 1200 people. For more information, please visit [www.cruCell.com](http://www.cruCell.com).

**Financial Calendar**

11 May 2010	Q1 Results 2010
4 June 2010	Annual General Meeting of Shareholders
17 August 2010	Q2 Results 2010
9 November 2010	Q3 Results 2010
15 February 2011	Q4/FY Results 2010

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**CONDENSED CONSOLIDATED STATEMENTS OF INCOME**
*in EUR '000 (except per share data)*

	12 months ended		Fourth Quarter	
	December 31,			
	2009	2008	2009	2008
	unaudited	unaudited	unaudited	unaudited
Product sales	304,439	226,055	91,178	76,539
License revenues	23,049	30,202	11,307	9,089
Service fees	10,675	10,900	2,883	3,965
<b>Total revenue</b>	<b>338,163</b>	<b>267,157</b>	<b>105,368</b>	<b>89,593</b>
Cost of product sales	-185,599	-138,790	-54,086	-42,567
Cost of service and license fees	-9,014	-6,965	-2,095	-2,199
<b>Total cost of goods sold</b>	<b>-194,613</b>	<b>-145,755</b>	<b>-56,181</b>	<b>-44,766</b>
<b>Gross margin</b>	<b>143,550</b>	<b>121,402</b>	<b>49,187</b>	<b>44,827</b>
Government grants	6,870	5,380	3,039	2,005
Other income	12,969	10,772	2,913	2,100
<b>Total other operating income</b>	<b>19,839</b>	<b>16,152</b>	<b>5,952</b>	<b>4,105</b>
Research and development	-70,176	-70,229	-22,411	-19,113
Selling, general and administrative	-61,400	-64,778	-13,822	-17,670
(Reversal of) impairment	7,199	4,888	-878	-266
<b>Total other operating expenses</b>	<b>-124,377</b>	<b>-130,119</b>	<b>-37,111</b>	<b>-37,049</b>
<b>Operating profit/(loss)</b>	<b>39,012</b>	<b>7,435</b>	<b>18,028</b>	<b>11,883</b>
Financial income & expenses	-3,193	-2,662	501	-1,973
Results investments in non-consolidated companies	2,147	1,442	1,836	431
Disposal of subsidiaries	0	-367	0	-367
<b>Profit/(loss) before tax</b>	<b>37,966</b>	<b>5,848</b>	<b>20,365</b>	<b>9,974</b>
Income tax	-14,028	8,402	-4,807	8,889
<b>Profit/(loss) for the period</b>	<b>23,938</b>	<b>14,250</b>	<b>15,558</b>	<b>18,863</b>
Net profit/(loss) per share - basic	0.34	0.22	0.19	0.29
Weighted average shares outstanding - basic	70,266	65,593	81,322	65,778
Net profit per share - diluted	0.33	0.21	0.19	0.28
Weighted average shares outstanding - diluted	71,686	66,315	83,742	66,315

**CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**
*in EUR '000*

	December 31	September 30	December 31
	2009	2009	2008
	unaudited	unaudited	unaudited
<b>ASSETS</b>			
<b>Non-current assets</b>			
Plant and equipment, net	192,615	178,329	151,206
Intangible assets	75,398	73,791	79,004
Goodwill	46,824	46,146	46,076
Investments in associates and joint ventures	11,433	9,296	9,239
Net pension asset	2,923	7,739	8,612
Available-for-sale investments	10,441	10,244	4,922
Other financial assets	16,426	16,187	14,920
	<u>356,060</u>	<u>341,732</u>	<u>313,979</u>
<b>Current assets</b>			
Cash and cash equivalents	327,837	311,640	170,969
Financial assets, short-term	100,286	100,256	1,761
Trade accounts receivables	87,031	67,848	40,108
Inventories	118,420	125,891	91,847
Other current assets	21,497	25,501	17,633
	<u>655,071</u>	<u>631,136</u>	<u>322,318</u>
<b>TOTAL ASSETS</b>	<b><u>1,011,131</u></b>	<b><u>972,868</u></b>	<b><u>636,297</u></b>
<b>LIABILITIES AND EQUITY</b>			
<b>Total equity attributable to equity holders of the parent</b>	<b>738,265</b>	<b>716,575</b>	<b>452,534</b>
<b>Non-current liabilities</b>			
Long-term financial liabilities	33,533	34,206	35,297
Long-term provisions	6,853	6,663	5,876
Deferred tax liabilities	18,830	16,522	16,644
Other non-current liabilities and deferred income	55,484	56,666	7,645
	<u>114,700</u>	<u>114,057</u>	<u>65,462</u>
<b>Current liabilities</b>			
Accounts payable	79,099	56,822	59,205
Short-term financial liabilities	18,767	17,874	25,454
Other current liabilities and deferred income	47,512	55,516	29,284
Tax payable	12,049	11,154	2,777
Short-term provisions	739	870	1,581
	<u>158,166</u>	<u>142,236</u>	<u>118,301</u>
<b>Total liabilities</b>	<b>272,866</b>	<b>256,293</b>	<b>183,763</b>
<b>TOTAL LIABILITIES AND SHAREHOLDER'S EQUITY</b>	<b><u>1,011,131</u></b>	<b><u>972,868</u></b>	<b><u>636,297</u></b>

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
*in EUR '000*

	12 months ended		Fourth Quarter	
	December 31,		2009 unaudited	2008 unaudited
	2009 unaudited	2008 unaudited		
<b>Cash flows from/(used in) operating activities</b>				
Profit/(loss) for the period	23,938	14,250	15,558	18,863
Reversal of non-cash items				
Tax	14,028	-8,402	4,807	-8,889
Results investments non-consolidated companies	-2,147	128	-1,836	-431
Unrealized financial income and expenses	-814	3,963	-678	3,346
Depreciation	20,393	16,629	4,610	4,670
Amortization	11,107	11,674	2,475	2,951
(Reversal of) Impairment	-7,199	-4,888	878	266
Fair value write-down on Inventory	132	1,165	0	229
Change in long-term liabilities, receivables and provisions	-10,064	-4,881	-8,651	-2,511
Gain on disposal of non-current assets	-47	-1,304	-11	445
Stock based compensation	7,732	5,053	1,635	1,460
	<b>57,059</b>	<b>33,387</b>	<b>18,787</b>	<b>20,399</b>
Change in net working capital				
Trade accounts receivable	-42,933	-912	-15,632	16,223
Inventories	-21,475	-37,121	10,296	3,565
Other current assets	-1,594	5,103	3,911	7,489
Trade accounts payable	18,838	15,978	20,007	20,884
Other current liabilities and advance payments	19,033	-14,080	-8,137	-6,912
Short-term provisions	382	1,218	201	647
Receipts from / (payments of) long-term liabilities, receivables and provisions	54,167	-567	3,740	85
Interest paid	-2,934	-2,684	-346	-898
Income taxes paid	-3,677	-576	-1,116	65
<b>Net cash from/(used in) operating activities</b>	<b>76,866</b>	<b>-254</b>	<b>31,711</b>	<b>61,547</b>
<b>Cash flows from/(used in) investing activities</b>				
Purchase of property, plant and equipment	-51,035	-15,787	-17,187	-3,287
Proceeds from sale of equipment	371	0	212	0
Investments in intangible assets (including goodwill)	-5,925	-237	-2,562	-237
Proceeds from/(investments in) financial assets	-100,052	2,722	-145	-2,521
Interest received	2,254	4,395	820	1,561
<b>Net cash from/(used in) investing activities</b>	<b>-154,387</b>	<b>-8,907</b>	<b>-18,862</b>	<b>-4,484</b>
<b>Cash flows from/(used in) financing activities</b>				
Proceeds from issue of share capital	241,265	3,230	1,934	1,171
Proceeds from financial liabilities	3,316	35,732	266	10,569
Repayment of financial liabilities	-13,069	-22,336	-872	-2,376
<b>Net cash from (used in) financing activities</b>	<b>231,512</b>	<b>16,626</b>	<b>1,328</b>	<b>9,364</b>
<b>Total cash flow</b>	<b>153,991</b>	<b>7,465</b>	<b>14,177</b>	<b>66,427</b>
Effects of exchange rate on cash and cash equivalents	2,877	256	2,020	619
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>156,868</b>	<b>7,721</b>	<b>16,197</b>	<b>67,046</b>
Cash and cash equivalents at beginning of period	170,969	163,248	311,640	103,923
<b>Cash and cash equivalents at end of period</b>	<b>327,837</b>	<b>170,969</b>	<b>327,837</b>	<b>170,969</b>

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**
*in EUR '000*

	12 months ended December 31,		Fourth Quarter	
	2009 unaudited	2008 unaudited	2009 unaudited	2008 unaudited
Profit/(loss) for the period	23,938	14,250	15,558	18,863
Foreign currency translation	13,424	-4,957	9,134	3,888
Unrealized result on available for sale securities	5,219	-5,086	187	-345
Actuarial gains / losses on pensions	-6,589	-184	-6,589	-184
Result unrealized cash flow hedges	742	-685	-171	-685
Other comprehensive income for the period	12,796	-10,912	2,561	2,674
Total comprehensive income for the period	36,734	3,338	18,119	21,537

**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**
*in EUR '000*

	Issued capital	Share premium	Net unrealized gains reserve	Hedging reserve	Actuarial gains / losses	Translation reserve	Accumulated deficit	Total
<b>At January 1, 2008</b>	15,685	735,578	8,340	0	1,792	-28,289	-292,193	440,913
Issue of shares	115	3,115	0	0	0	0	0	3,230
Costs share based payment transactions	0	5,053	0	0	0	0	0	5,053
Total comprehensive income for the period	0	0	-5,086	-685	-184	-4,957	14,250	3,338
<b>At December 31, 2008</b>	<b>15,800</b>	<b>743,746</b>	<b>3,254</b>	<b>-685</b>	<b>1,608</b>	<b>-33,246</b>	<b>-277,943</b>	<b>452,534</b>
<b>At January 1, 2009</b>	15,800	743,746	3,254	-685	1,608	-33,246	-277,943	452,534
Issue of shares	3,747	237,518	0	0	0	0	0	241,265
Costs share based payment transactions	0	7,732	0	0	0	0	0	7,732
Total comprehensive income for the period	0	0	5,219	742	-6,589	13,424	23,938	36,734
<b>At December 31, 2009</b>	<b>19,547</b>	<b>988,996</b>	<b>8,473</b>	<b>57</b>	<b>-4,981</b>	<b>-19,822</b>	<b>-254,005</b>	<b>738,265</b>