



PRESS RELEASE

Crucell Announces Third Quarter 2009 Results

Total revenues and other operating income increased by 15% to €94.3 million.

Operating profit of €15.5 million versus €9.6 million in Q3 2008.

Quarter-end cash and short-term liquidities of €411.9 million.

Undiluted EPS of €0.15 for the quarter.

2009 full year guidance reiterated: total revenues and other operating income expected to grow 20% in constant currencies¹; operating profit for 2009 expected to improve significantly compared to 2008; strong cash position.

Leiden, the Netherlands (November 3, 2009) – Dutch biopharmaceutical company Crucell N.V. (Euronext, Nasdaq: CRXL; Swiss Exchange: CRX) today announced its financial results for the third quarter of 2009, based on International Financial Reporting Standards (IFRS). These financial results are unaudited.

Highlights:

- In the third quarter of 2009 total revenues and other operating income increased by 15% to €94.3 million, compared to €82.1 million in the same quarter of 2008. The increase was driven by a robust 28% growth in product sales and in particular growth of our paediatric and respiratory vaccines.
- In December 2008, Crucell announced the discovery of a new class of human monoclonal antibodies (mAbs) with the unprecedented ability to combat a broad range of influenza virus strains². This breadth of protection opens up the new possibility of developing a universal means of influenza control, solving the key challenge in influenza prevention and treatment: the ease with which influenza viruses mutate, leading to new seasonal strains every year, periodic outbreaks of pandemic strains, and the emergence of drug-resistant viruses.
- The exciting therapeutic potential of this discovery attracted the attention of global leaders in healthcare innovation, which, in September 2009, resulted in a strategic collaboration between Crucell and Johnson & Johnson (JNJ). This collaboration focuses on the discovery, development and commercialization of monoclonal antibodies and vaccines for the treatment and prevention of influenza and other infectious and non-infectious diseases.

¹ Constant currencies = EUR/USD rate of 1.35

² The discovery and characterization of this unique class of human influenza antibodies was reported in the online journal *PloS ONE* on 16 December 2008. An imaging study published in the prestigious journal *Science* on 26 February 2009 described the mechanism explaining their broad-spectrum protection by showing that the antibody binds to a part of the influenza virus that is conserved (invariable) from one viral strain to the next. Antibodies produced by the body in response to influenza infection or vaccination bind to a part of the virus that tends to mutate.



- The agreement with JNJ, with a potential deal value of over €1 billion, also includes an 18% equity investment in Crucell at a premium of 30% as well as significant milestones over the development period of the innovation programs. JNJ will hold commercialization rights for products resulting from the collaborations in all countries throughout the world with the exception of the European Union, certain additional European countries and supranational organizations, where Crucell will retain commercialization rights. Additionally Crucell holds all bulk manufacturing rights.
- The strategic collaboration with JNJ follows the announcement in August 2009 of an award to Crucell from the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). The award was designed to support early development of Crucell's mAbs for the treatment of seasonal and pandemic influenza. The award provides 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, bringing the potential total amount to \$69.1 million.
- Crucell announced \$300 million worth of new awards from a large supranational organization for supplies of Quinvaxem[®], the first portion of the new 3-year tender period. The new awards are the largest ever received by Crucell and cover the period 2010–2012. With only half of the original tender volume awarded to date the initial amount of \$300 million is expected to grow further over the three year period. The new awards are in addition to the \$500 million obtained over the tender period 2007–2009. During the first tender round in 2006, Crucell initially received an award of \$230 million (Dec 2006) and received additional incremental awards of \$130 million and \$140 million in May and September, 2008, respectively.
- In line with Crucell's strategy to increase its market share and cost efficiency, the company announced the start of its own dedicated marketing and sales organization in the United Kingdom. The acquisition of an experienced team further strengthens Crucell's vaccine sales position in one of the largest vaccine markets in Europe.
- Detailed positive results of the Phase II Philippines study of Crucell's rabies monoclonal antibody combination (CL 184) were presented at the XX Rabies in the Americas (RITA) Conference in Quebec, Canada. The start of the third phase II clinical study in India is imminent.
- Promising preliminary results of the Phase I study of Crucell's HIV vaccine were presented at La Conférence AIDS Vaccine 2009 in Paris, France, showing that this HIV candidate vaccine is safe and immunogenic.
- Crucell announced that the PANFLUVAC consortium consisting of eight European research partners, which includes Crucell, completed the first stage of their phase I clinical trial in healthy volunteers, using a virosomal vaccine against A/H5N1 influenza.



- Crucell signed three new license agreements, which includes agreements with Australia-based Patrys Ltd., US-based TapImmune Inc. and US-based Calmune Corporation.
- Construction of the new vaccine manufacturing facility in Korea, which started in December 2008, is progressing well. First test runs are planned for the first half of 2010.

Financial Highlights:

- Combined total revenues and other operating income for the third quarter were €94.3 million, compared to €82.1 million in the same quarter of 2008. The increase of 15% was mainly driven by strong sales of paediatric and respiratory vaccines. Travel and endemic vaccines also showed solid growth due strong sales of Epaxal[®], despite the impact of reduced travel from the economic crisis.
- In line with expectations, gross margins were 39% in the quarter, compared to 50% in the same period in the prior year. The timing of development milestone payments from partners significantly influence margins and profitability in the period in which they are recognized. The third quarter of 2008 included €6.0 million milestone payments. The remaining drop in margins is due to unfavorable movement of the US Dollar versus the Euro.
- The Company achieved operating profit of €15.5 million in the third quarter of 2009 compared to €9.6 million operating profit in the same quarter of 2008. Operating profits were positively affected by a €8.1 million impairment reversal of two state-of-the-art buildings in Bern (Switzerland). The buildings were impaired in the fourth quarter of 2006 as there was no direct use for them. The buildings are now being used as development production sites for Epaxal[®] (hepatitis A) and tuberculosis vaccines. The buildings have been adapted to the specific needs of the development programs, which will avoid major spending in the construction of new development facilities.
- As part of the strategic collaboration with JNJ, the company sold 14.6 million newly issued ordinary shares to JNJ for an aggregate purchase price of €301.8 million. This included a premium of €69.5 million classified as deferred income, which will be amortized in the coming years.
- Income taxes were €4.6 million in the third quarter, mainly due in Switzerland, Spain and Korea. The consolidated effective income tax rate was 32% in the third quarter of 2009. The consolidated profit before tax was reduced by a significant operating loss in the Netherlands as a result of R&D expenses for which no tax benefit is recognized.
- Net cash from operating activities in the third quarter improved significantly to €72.1 million, up from minus €9.9 million in the same quarter of 2008. This was driven by the upfront payment of JNJ for participation in Crucell's development programs.



- Cash used in investing activities amounted to €118.0 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 in the third quarter was €235.0 million, compared to €11.3 million in the same quarter of 2008. This increase reflects the cash proceeds from the issuance of shares to JNJ.
- Cash and cash equivalents at the end of the third quarter of €311.6 million, versus €171.0 million at year-end 2008.

Key Figures:

(€ million, except net result per share)

Third Quarter			Nine months ended September 30			
2009 unaudited	2008 unaudited	Change		2009 Unaudited	2008 unaudited	Change
94.3	82.1	15%	Total revenues and other operating income	246.7	189.6	30%
15.5	9.6	62%	Operating profit/(loss)	21.0	(2.5)	–
10.0	12.8	(22)%	Net profit/(loss)	8.4	(3.1)	–
0.15	0.19	(21)%	Net result per share (basic)	0.13	(0.05)	–

CruCell's Chief Executive Officer Ronald Brus said:

"The recently announced collaboration with Johnson & Johnson - the world's largest healthcare company – has a potential deal value of over €1 billion and reflects the innovative strength of our company. It represents an important validation of the promise of our new class of broadly protective anti-influenza antibodies. The immediate focus of this exciting collaboration will be the development and commercialization of a universal monoclonal antibody product (flu-mAb) for the prevention and treatment of any type of influenza strain. In addition, we will receive a significant amount of potential milestones throughout the development period as well as royalty payments upon commercialization of the products, whilst retaining commercialization rights for the European Union, certain additional European countries and supranational organizations.

"Over the past few years we have made great strides in building on our innovation and excellence in the global fight against infectious diseases. We have been able to accelerate our product sales significantly and expand our promising R&D programs. Our researchers focus on the discovery and development of



much-needed solutions for major threats to human health, resulting in a strong pipeline of candidate products with the potential to revolutionize the fight against diseases such as influenza, rabies, malaria and tuberculosis.

“Crucell is becoming stronger and more effective as a global force in healthcare. Our goal has been, and remains, to strengthen our ability to bring meaningful innovation to global health by actively investing in our pipeline and by building on our existing knowledge of the vaccine and antibody markets in infectious disease.”

Product Sales Update:

Product sales in the third quarter of 2009 increased 28% over the same quarter in 2008 to €83.7 million and represent sales of paediatric vaccines (46%), travel and endemic vaccines (14%), respiratory vaccines (31%) and other products (9%).

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. The UK team will market and sell Epaxal[®], Vivotif[®], Dukoral[®] and Inflexal[®] V. Distribution of the travel vaccines has started, distribution of the influenza vaccine will start in 2010.

Paediatric

Sales of our paediatric vaccines, continued to show good growth in the third quarter 2009, particularly driven by Quinvaxem[®].

- **Quinvaxem[®]**: Fully liquid pentavalent vaccine against five important childhood diseases.
- **Hepavax-Gene[®]**: Recombinant vaccine against hepatitis B.
- **Epaxal[®] Junior**: Paediatric dose (0.25mL) of Epaxal[®], the only aluminum-free vaccine against hepatitis A for use in children.
- **MoRu-Viraten[®]**: Vaccine for protection against measles and rubella (for all age groups).

Travel and Endemic

In the third quarter of 2009, sales of our travel and endemic portfolio showed solid growth. Our travel portfolio has seen limited impact from the economic crisis as we were able to compensate sales declines with good uptake of our hepatitis A vaccine Epaxal[®] in new territories.

- **Epaxal[®]**: Aluminum-free vaccine against hepatitis A.
- **Vivotif[®]**: Oral vaccine against typhoid fever.
- **Dukoral[®]**: Oral vaccine against cholera and diarrhea caused by ETEC (enterotoxigenic E. coli).



Respiratory

The third quarter of 2009 showed solid growth, compared to the same quarter of 2008 of our flu vaccine Inflexal[®] V. Sales of Inflexal[®] V were particularly strong, due to the global strong demand for flu products. Shipments of Inflexal[®] V were mainly phased into the third quarter and thus earlier than sales in 2008.

- **Inflexal[®] V:** A virosomal adjuvanted vaccine against influenza (for all age groups). Due to the seasonality of the product, we build inventory in the first half of the year to sell flu vaccines in the second half of the year.

Research & Development:

- **Flavimun[®] - Live Attenuated Yellow Fever Vaccine** (Phase III): Flavimun[®] was submitted for registration in Switzerland in March 2009. Submission in Germany is expected within the next few months.
- **Influenza - Seasonal Flu Vaccine** (Phase II; FluCell collaboration with Sanofi Pasteur): This seasonal influenza vaccine is being developed by Sanofi Pasteur, using Crucell's PER.C6[®] technology. Phase II testing of the cell-based influenza vaccine was initiated in the USA in November 2007. 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. The trials focus on the safety profile and immunogenicity of the cell-based vaccine. All data collected so far confirm that the PER.C6[®] cell line supports the growth of all flu virus strains in high quantities. The cell line has also been found to be commercially scalable to any desired scale and no problems related to the PER.C6[®] cell line have been encountered to date.
- **Human Monoclonal Antibodies against a broad range of Influenza strains** (Preclinical): Crucell's scientists discovered a set of human monoclonal antibodies that provide immediate protection and neutralize the broadest range of H5N1 strains in preclinical models. When the most powerful of these antibodies was tested in preclinical models for prevention or treatment of a potentially lethal H5N1 infection, it was shown to prevent death and cure the disease.

In a preclinical study, Crucell's mAb CR6261 was compared with the anti-influenza drug oseltamivir (Tamiflu) in terms of its value for flu prevention and treatment. In December 2008, Crucell announced that its monoclonal antibody strongly outperformed the anti-influenza drug in these tests. The results were presented at IBC's 19th Annual International Conference on Antibody Engineering in San Diego, USA.

The flu strains tested included the 'bird flu' strain H5N1, which experts fear has the potential to cause a pandemic, and H1N1, which is similar to a descendant of the flu virus that caused the devastating pandemic in 1918. Importantly, the study showed that CR6261 provides immediate protection against the influenza virus, suggesting that it will be able to prevent disease spread. In contrast, oseltamivir was less efficacious and in



some cases not effective at all. The characterization of the antibody was described in the online journal PLoS ONE on December 16, 2008.

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 monoclonal antibodies for the treatment of seasonal and pandemic influenza. The award provides 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, bringing the potential total amount to \$69.1 million.

In September JNJ, through its subsidiary Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Crucell entered into a strategic collaboration focusing on the discovery, development and commercialization of monoclonal antibodies and vaccines for the treatment and prevention of influenza and other infectious and non-infectious diseases.

The immediate focus of the collaboration will be the development and commercialization of a universal monoclonal antibody product (flu-mAb) for the treatment and prevention of influenza. The focus of the long-term innovation collaboration will be on new discovery programs leading to the development and commercialization of a universal influenza vaccine as well as the development of monoclonal antibodies and/or vaccines directed against up to 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 close collaboration with Sanofi Pasteur using Crucell's PER.C6[®] manufacturing technology. In 2008, Crucell initiated two Phase II studies in the USA and the Philippines. Promising Phase I data in 2007 showed no serious adverse effects and demonstrated the expected rabies neutralizing activity upon administration. The rabies human monoclonal antibody combination was granted a Fast Track designation by the FDA Department of Health and Human Services, ensuring priority handling of the regulatory dossier. Under the terms of the collaboration agreement with Sanofi Pasteur, 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. This antibody combination is designed to be used in combination with a rabies vaccine for post-exposure prophylaxis (PEP) against this fatal disease.
 - Positive preliminary results of the Phase II US study were presented to rabies experts at the 19th annual RITA meeting in Atlanta on October 1, 2008. These results triggered another milestone payment from Sanofi Pasteur at the end of September, as part of the total eligible amount of €66.5 million.
 - A second Phase II clinical study evaluating the monoclonal antibody combination together with a rabies vaccine in healthy children and adolescents was conducted in the Philippines from May to October



2008. The completion of this study triggered another milestone payment from Sanofi Pasteur, at the end of October. In June 2009, Crucell announced the results of the Philippines study, which showed that the antibody combination 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. Detailed results of this study have been presented at the XX Rabies in the Americas RITA conference in Quebec, Canada on 20 October 2009.

- Plans to start an additional Phase II clinical study are progressing well after recent approval received from the Drug Controller General of India. This third Phase II study will be carried out at Lotus Laboratories in Bangalore, India and is planned to start within the next six months. The rationale for this study is to collect safety and neutralizing activity data of the CL184 antibody in combination with the vaccine in a simulated rabies post-exposure prophylaxis setting to be used in Phase III.
- **Tuberculosis Vaccine** (AdVac[®]/PER.C6[®] Technology based; Phase II): Development of the candidate vaccine AERAS-402/Crucell Ad35 is being carried out in collaboration with the Aeras Global TB Vaccine Foundation. Data from all AERAS-402/Crucell Ad35 trials support the immunogenicity and acceptable safety profile of the TB candidate vaccine at all dose levels evaluated.

Phase II:

- In October 2008 enrollment for the first Phase II study of AERAS-402/Crucell Ad35 in Cape Town, South Africa was started. The study is being conducted by the University of Cape Town Lung Institute in conjunction with the South African Tuberculosis Vaccine Initiative. The candidate vaccine is being tested in 116 adults who have had active TB. This study is currently enrolling. No evidence of an unacceptable safety issue has been found in its dose escalation design after enrollment and vaccination of 60 subjects to date.

Phase I:

- The US Phase I trial in healthy adults not previously immunized with Bacille Calmette-Guérin (BCG), the traditional TB vaccine, has been completed and has demonstrated that AERAS-402/Crucell Ad35 is safe in this population.
- Results of a second study in South Africa showed encouraging results, notably CD8-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 AERAS-402/Crucell Ad35 boost doses administered at three to six month intervals after BCG priming in healthy adults have been completed. Data from these studies specifically indicate that two injections of AERAS-402/Crucell Ad35 are



immunogenic, with an acceptable safety profile, when used with a BCG-prime in combination with the AERAS-402/Crucell Ad35 candidate vaccine in BCG vaccinated 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/Crucell Ad35 as a booster vaccine. BCG prime alone shows limited efficacy.

- In October 2008, a Phase I clinical trial of the jointly developed TB vaccine was started in Kenya. The study is being conducted by the KEMRI/Walter Reed Project-Kisumu at their Kombewa Clinical Trials Center near Kisumu, in Western Kenya. Its main objective will be to test the safety of the candidate vaccine in BCG-vaccinated adults with or without latent tuberculosis. This study has been completed, with ongoing analysis and no safety issues identified.
- In April 2009, a Phase I clinical trial in infants of the jointly developed TB candidate vaccine AERAS-402/Crucell Ad35 was started in South Africa. This is the first clinical trial designed to test this candidate vaccine in infants. The Phase I study of AERAS-402/Crucell Ad35 is being conducted by the South African Tuberculosis Vaccine Initiative (SATVI) in the Western Cape region of South Africa. The main objective of the study is to test the safety of the TB candidate vaccine in infants previously vaccinated with BCG vaccine, which is currently the only vaccine, licensed to help prevent TB. This study is fully enrolled and dosing is ongoing. No safety issues have been identified.
- **Malaria Vaccine** (AdVac[®]/PER.C6[®] Technology based; 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[®] technology and PER.C6[®] manufacturing platform. The candidate vaccine is made by inserting the gene for the circumsporozoite protein (CSP) from the *Plasmodium falciparum* malaria parasite into adenoviral vectors, which act as a 'vehicle' for vaccination delivery. The study is being carried out at two sites, Vanderbilt University in Nashville, Tennessee and Stanford University in Palo Alto, California. All four cohorts have been enrolled, and ongoing safety monitoring has revealed no significant safety concerns to date. Boost vaccinations for the fourth and final group of volunteers is underway. Preliminary examination of the blinded data from the first four cohorts indicates that the vaccine is immunogenic. Detailed analysis of the data awaits completion of the fourth cohort and unblinding of the data.

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 *P. falciparum*. This approach uses Crucell's proprietary recombinant adenoviruses (a type of virus associated with the common cold and other mild respiratory infections), to deliver a malaria antigen to the immune system. Using Crucell's AdVac[®] 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** (AdVac®/PER.C6® Technology based; 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, which may be triggered at the discretion of the NIH, worth a further \$40 million. The Phase I study of an adenovirus 5 (Ad5)-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** (AdVac®/PER.C6® Technology based; Phase I): The Investigational New Drug Application (IND) for Phase I of the trial with Harvard Medical School (supported by the NIH) was approved by the FDA in January 2008. In April 2008, Crucell announced the start of a Phase I clinical study of the novel recombinant HIV vaccine, using adenovirus serotype 26 (rAd26) as vector, that Crucell is jointly developing with the Beth Israel Deaconess Medical Center. The rAd26 vector 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. Enrollment is ongoing and involves 48 healthy volunteers. Dose escalation has proceeded without difficulty and the third cohort has been fully enrolled. Boost vaccinations are ongoing. On 21 October 2009 preliminary results of the Phase I study 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.
- **Alternative Adenovirus Serotype Technologies:** In November 2008, the leading scientific journal *Nature* published a study that demonstrated the value of Crucell's alternative adenovirus serotype technologies. Using Crucell's AdVac® vaccine technology and PER.C6® manufacturing technology, scientists engineered the rare adenovirus serotypes Ad26 and Ad35 to express a protein of SIV, the non-human primate equivalent of HIV. Rare serotype adenoviral vectors—such as rAd26 and rAd35 vectors—have been developed by Crucell to provide more potent prime–boost vaccine regimens. The study, which investigated the immunogenicity and protective efficacy of different vaccination regimes using rAd26, rAd35 or rAd5 as a prime, followed by a boost with rAd5, showed that in particular the rAd26/rAd5 combination elicits a strong T-cell immune response and



provides protection against the HIV-like virus in non-human primate models. Crucell has several vaccines in development using alternative rAd26 and rAd35 vectors, including vaccines against malaria and tuberculosis.

- **Hepatitis C Antibody Combination** (Preclinical): In August 2009 Crucell obtained an exclusive license from Stanford University (Palo Alto, California) for the development of an antibody combination 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. The monoclonal antibodies have been found to neutralize HCV across all genotypes tested and each recognizes a different part of the HCV surface protein.
- **Blood Coagulation Factor V^{L/C}** (Research): Preclinical work on this program continues but conclusive proof of concept is not expected in the near future.

Building Development Capability:

To strengthen Crucell's capabilities to deliver on its pipeline, the company hired 110 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[®] in the USA.

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 first half of 2010. The new facility will enable the further growth and efficient production of Quinvaxem[®] and Hepavax-Gene[®]. The investments in the new facility are expected to total approximately €50 million, with the majority of spending 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 is targeting savings of €30 million by the end of 2009 compared to the 2007 cost base (excluding R&D). In the first nine months of 2009, a total of €15 million of net cost savings were achieved (Q1 2009 €6 million; Q2 2009 €4 million; Q3 2009



€5 million). Savings were predominantly achieved through improved yields, marketing and sales efficiency gain, and savings in overhead.

Manufacturing & Licensing Agreements:

- **Crucell** announced a non-exclusive PER.C6[®] research license agreement with Australia-based **Patrys Ltd.** for the production of several undisclosed antibodies. Financial details of the agreement were not disclosed. [July 2009]
- Crucell today announces a non-exclusive PER.C6[®] research license agreement with US-based **TapImmune Inc.** for use in its vaccine development programs. Financial details of the agreement were not disclosed. [September 2009]
- Crucell today announces an agreement with US-based **Calmune Corporation**, including an exclusive license on an undisclosed antibody based on Calmune's technology and a co-development for the discovery of new antibodies against the same target. Financial details of the agreement were not disclosed. [September 2009].

Patents:

In Q3 2009 Crucell was granted a total of 22 patents, including patents for:

- Monoclonal antibodies against rabies, in the U.S. and Singapore
- AdVac[®] based malaria vaccines, in Australia
- Production of antibody fragments using PER.C6[®] expression technology, in Australia
- Elements of STAR[®] technology, in India
- Improvements in PER.C6[®] expression technology, in New Zealand
- Purification of AdVac[®] vectors, in Europe and New Zealand



Financial Review Third Quarter 2009

Total Revenues and Other Operating Income

Total revenues and other operating income amounted to €94.3 million for the third quarter of 2009, an increase of 15% compared to the same quarter of 2008. The increase of 15% was mainly driven by strong sales of paediatric and respiratory vaccines. Travel and endemic vaccines also showed solid growth due to the growth of Epaxal[®], despite the impact of reduced travel from the economic crisis.

Product sales in the third quarter of 2009 increased 28% over the same quarter in 2008 to €83.7 million and represent sales of paediatric vaccines (46%), travel and endemic vaccines (14%), respiratory vaccines (31%) and other products (9%).

License revenues were €3.8 million in the third quarter, a decrease of €6.6 million compared to the third quarter of 2008 (which included milestone payments of €6.0 million for the Phase II results of the rabies monoclonal antibody combination and for Sanofi Pasteur's seasonal influenza vaccine (FluCell)).

Service fees for the quarter were €2.4 million, compared to €2.6 million last year. Service fees represent revenues for product development activities performed under contracts with partners and licensees.

Other operating income was €4.4 million for the quarter, compared to €3.5 million in the third quarter of 2008.

Cost of Goods Sold

Cost of goods sold for the third quarter of 2009 amounted to €55.1 million, €53.1 million of which represents product costs and €2.0 million the cost of service and license activities.

In line with expectations, gross margins were 39% in the quarter, compared to 50% in the same period in the prior year. The timing of development milestone payments from partners significantly influence margins and profitability in the period in which they are recognized. The third quarter of 2008 included €6.0 million milestone payments. The remaining drop in margins is due to unfavorable movement of the US Dollar versus the Euro.

We expect continued pressure on margins in the last quarter of the year as a result of exchange rates, which affects our reported product sales and cost of goods sold.

Expenses

Total expenses consist of research and development (R&D) expenses, marketing and sales (M&S) and general and administrative (G&A) expenses. Total expenses for the third quarter were €23.7 million, representing a €9.2 million decrease compared to the same period in 2008. The decrease was mainly due to the reversal of impairment of two buildings in Switzerland, which were selected as development production sites for Epaxal[®] (hepatitis A) and tuberculosis vaccines.



SG&A (M&S+G&A) expenses for the quarter were €15.2 million compared to €15.2 million in the third quarter of 2008.

Operating profit was €15.5 million in the third quarter of 2009 compared to €9.6 million operating profit in the same quarter of 2008. Operating profit was positively affected by a €8.1 million impairment reversal of two state-of-the-art buildings in Bern (Switzerland). The buildings were impaired in the fourth quarter of 2006 as there was no direct use for the buildings. In 2009 alternative use of the buildings arose as additional development facilities were required for two strategic development programs and the buildings proved to be suitable. The buildings are currently being adapted to the specific needs of the development programs, which will avoid major spending in the construction of new development facilities. The initial impairment that was already partially reversed in the first quarter of 2008 for an amount of €5.2 million has now fully been reversed.

Financial Expenses and Taxes

Net financial expenses in the third quarter were €0.9 million. This was mainly the result of interest expenses and currency losses on the US Dollar.

The company recorded a €4.6 million income tax charge in the third quarter of 2009, mainly due in Switzerland, Spain and Korea. The consolidated effective income tax rate was 32% in the third quarter of 2009. The consolidated profit before tax was reduced by a significant operating loss in the Netherlands as a result of R&D expenses for which no tax benefit is recognized. This led to a relatively high effective tax rate. A further tax charge was due to the reversal of impairment.

Net Result

Net income of €10.0 million was reported in the third quarter of 2009 versus a net income of €12.8 million in the same quarter of 2008. Net result per share in the third quarter of 2009 is €0.15, compared to a net result per share of €0.19 in the third quarter of 2008.

Balance Sheet

Tangible fixed assets amounted to €178.3 million on September 30, 2009. Intangible assets amounted to €73.8 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 €9.3 million and mainly represent investments in AdImmune and the PERCIVIA PER.C6[®] Development Center. CruCell's investment in Galapagos NV is classified under available-for-sale investments.

As part of the strategic collaboration with JNJ, the company sold 14.6 million newly issued ordinary shares to JNJ for an aggregate purchase price of € 301.8 million, which included a premium of €69.5 million classified as deferred income, which will be amortized over the development period of flu-mAbs.



Total equity on September 30, 2009 amounted to €717.5 million. A total of 81.3 million ordinary shares were issued and outstanding on September 30, 2009.

Cash Flow and Cash Position

Cash and cash equivalents increased by €190.0 million in the third quarter to €311.6 million.

Net cash from operating activities in the third quarter improved significantly to €72.1 million, up from minus €9.9 million in the same quarter of 2008. This was driven by the upfront payments of JNJ for participation in Crucell's development programs.

Cash used in investing activities amounted to €118.0 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 in the third quarter was €235.0 million, compared to €11.3 million in the same quarter of 2008. This increase reflects the cash proceeds from the issuance of shares to JNJ.

Outlook 2009 reiterated³

- Crucell expects its combined full-year 2009 total revenues and other operating income to grow 20% in constant currencies.
- Operating profit for 2009 is expected to improve significantly compared to 2008.
- Maintain current strong cash position.
- Crucell does not expect its results to be materially affected by the global recession.

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).

³ Constant currencies = EUR/USD rate of 1.35



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 and will be archived and available for replay following the event.

About Crucell

Crucell N.V. (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[®] production technology. The Company licenses its PER.C6[®] technology and other technologies to the biopharmaceutical industry. Important partners and licensees include 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.

Financial Calendar

9 February 2010	Q4 Results 2009
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 Results 2010

For further information please contact:

Crucell N.V.
Oya Yavuz
Vice President
Corporate Communications & Investor Relations
Tel. +31 (0)71 519 7064
ir@crucell.com
www.crucell.com



CONDENSED CONSOLIDATED STATEMENTS OF INCOME

in EUR '000 (except per share data)

	9 months ended September 30,		Third Quarter	
	2009	2008	2009	2008
	unaudited	unaudited	unaudited	unaudited
Product sales	213,262	149,516	83,696	65,606
License revenues	11,742	21,112	3,763	10,357
Service fees	7,791	6,937	2,429	2,634
Total revenue	232,795	177,565	89,888	78,597
Cost of product sales	-131,514	-96,222	-53,120	-37,462
Cost of service and license fees	-6,919	-4,767	-2,027	-2,164
Total cost of goods sold	-138,433	-100,989	-55,147	-39,626
Gross margin	94,362	76,576	34,741	38,971
Government grants	3,831	3,374	1,805	1,271
Other income	10,056	8,672	2,574	2,215
Total other operating income	13,887	12,046	4,379	3,486
Research and development	-47,796	-51,116	-16,527	-17,661
Selling, general and administrative	-47,576	-45,182	-15,239	-15,226
(Reversal of) impairment	8,107	5,153	8,107	0
Total other operating expenses	-87,265	-91,145	-23,659	-32,887
Operating profit/(loss)	20,984	-2,523	15,461	9,570
Financial income & expenses	-3,694	-689	-879	1,403
Results investments in non-consolidated companies	311	1,012	86	1,195
Profit/(loss) before tax	17,601	-2,200	14,668	12,168
Income tax	-9,220	-901	-4,647	614
Profit/(loss) for the period	8,381	-3,101	10,021	12,782
Net profit/(loss) per share - basic	0.13	-0.05	0.15	0.19
Weighted average shares outstanding - basic	66,540	65,549	66,938	65,688
Net profit per share - diluted	0.12	-0.05	0.15	0.19
Weighted average shares outstanding - diluted	68,129	65,549	68,527	66,452



CONDENSED CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

in EUR '000

	September 30	June 30	December 31
	2009	2009	2008
	unaudited	unaudited	audited
ASSETS			
Non-current assets			
Plant and equipment, net	178,329	156,859	151,206
Intangible assets	73,791	72,936	79,004
Goodwill	46,146	45,445	46,076
Investments in associates and joint ventures	9,296	9,442	9,239
Net pension asset	7,739	7,668	8,612
Available-for-sale investments	10,244	9,350	4,922
Other financial assets	16,187	16,061	14,920
	<u>341,732</u>	<u>317,761</u>	<u>313,979</u>
Current assets			
Cash and cash equivalents	311,640	121,591	170,969
Financial assets, short-term	100,256	602	1,761
Trade accounts receivables	67,848	46,816	40,108
Inventories	125,891	124,805	91,847
Other current assets	25,501	20,463	17,633
	<u>631,136</u>	<u>314,277</u>	<u>322,318</u>
TOTAL ASSETS	<u>972,868</u>	<u>632,038</u>	<u>636,297</u>
LIABILITIES AND EQUITY			
Total equity attributable to equity holders of the parent	717,533	463,155	453,492
Non-current liabilities			
Long-term financial liabilities	34,206	32,168	35,297
Long-term provisions	5,364	5,000	4,577
Deferred tax liabilities	16,522	15,372	16,985
Other non-current liabilities and deferred income	57,007	6,058	7,645
	<u>113,099</u>	<u>58,598</u>	<u>64,504</u>
Current liabilities			
Accounts payable	56,822	53,488	59,205
Short-term financial liabilities	17,874	17,446	25,454
Other current liabilities and deferred income	55,516	31,691	29,284
Tax payable	11,154	6,975	2,777
Short-term provisions	870	685	1,581
	<u>142,236</u>	<u>110,285</u>	<u>118,301</u>
Total liabilities	255,335	168,883	182,805
TOTAL LIABILITIES AND SHAREHOLDER'S EQUITY	<u>972,868</u>	<u>632,038</u>	<u>636,297</u>



CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

in EUR '000

	9 months ended September 30,		Third Quarter	
	2009 unaudited	2008 unaudited	2009 unaudited	2008 unaudited
Cash flows from/(used in) operating activities				
Profit/(loss) for the period	8,381	-3,101	10,021	12,782
Reversal of non-cash items				
Tax	9,220	901	4,647	-614
Results investments non-consolidated companies	-311	564	-86	373
Unrealized financial income and expenses	-137	611	372	-1,482
Depreciation	15,783	11,959	5,338	4,584
Amortization	8,632	8,723	2,927	2,877
(Reversal of) Impairment	-8,107	-5,153	-8,112	0
Fair value write-down on Inventory	130	936	1	351
Change in long-term liabilities, receivables and provisions	-1,399	-4,296	-252	-838
Gain on disposal of non-current assets	-23	-1,749	-37	-1,666
Stock based compensation	6,095	3,593	1,898	1,190
	38,264	12,988	16,717	17,557
Change in net working capital				
Trade accounts receivable	-27,300	-17,136	-20,244	-20,172
Inventories	-31,771	-40,685	3,088	-12,199
Other current assets	-5,505	-2,386	-4,663	787
Trade accounts payable	-1,170	-4,906	3,647	1,536
Other current liabilities and advance payments	27,172	-7,167	23,154	3,815
Short-term provisions	181	7	179	190
Receipts from / (payments of) long-term liabilities, receivables and provisions	50,425	-88	51,353	245
Interest paid	-2,587	-1,787	-744	-1,225
Income taxes paid	-2,562	-641	-408	-391
Net cash from/(used in) operating activities	45,147	-61,801	72,079	-9,857
Cash flows from/(used in) investing activities				
Purchase of property, plant and equipment	-33,849	-12,501	-16,169	-6,210
Proceeds from sale of equipment	159	0	101	0
Investments in intangible assets (including goodwill)	-3,364	0	-2,095	0
Proceeds from/(investments in) financial assets	-99,904	5,244	-100,137	1,308
Interest received	1,436	2,834	269	531
Net cash from/(used in) investing activities	-135,522	-4,423	-118,031	-4,371
Cash flows from/(used in) financing activities				
Proceeds from issue of share capital	239,330	2,059	232,864	152
Proceeds from financial liabilities	3,056	25,163	2,947	11,861
Repayment of financial liabilities	-12,196	-19,960	-857	-681
Net cash from (used in) financing activities	230,190	7,262	234,954	11,332
Total cash flow	139,815	-58,962	189,002	-2,896
Effects of exchange rate on cash and cash equivalents	856	-363	1,047	-64
Net increase/(decrease) in cash and cash equivalents	140,671	-59,325	190,049	-2,960
Cash and cash equivalents at beginning of period	170,969	163,248	121,591	106,883
Cash and cash equivalents at end of period	311,640	103,923	311,640	103,923



CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

in EUR '000

	9 months ended September 30,		Third Quarter	
	2009 unaudited	2008 unaudited	2009 unaudited	2008 unaudited
Profit/(loss) for the period	8,381	-3,101	10,021	12,782
Foreign currency translation	4,290	-9,412	9,144	-1,668
Unrealized result on available for sale securities	5,032	-4,742	881	-960
Result unrealized cash flow hedges	913	0	-423	0
Other comprehensive income for the period	10,235	-14,154	9,602	-2,628
Total comprehensive income for the period	18,616	-17,255	19,623	10,154



CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

in EUR '000

	Issued capital	Share premium	Net unrealized gains reserve	Hedging reserve	Translation reserve	Accumulated deficit	Total
At January 1, 2008	15,685	735,578	8,340	0	-28,317	-290,183	441,103
Issue of shares	83	1,992	0	0	0	0	2,075
Costs share based payment transactions	0	3,807	0	0	0	0	3,807
Total comprehensive income for the period	0	0	-4,742	0	-9,412	-3,101	-17,255
At September 30, 2008	15,768	741,377	3,598	0	-37,729	-293,284	429,730
At January 1, 2009	15,800	743,746	3,254	-685	-33,026	-275,597	453,492
Issue of shares	3,704	235,626	0	0	0	0	239,330
Costs share based payment transactions	0	6,095	0	0	0	0	6,095
Total comprehensive income for the period	0	0	5,032	913	4,290	8,381	18,616
At September 30, 2009	19,504	985,467	8,286	228	-28,736	-267,216	717,533